ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

DOTTORATO DI RICERCA IN

LAW, SCIENCE AND TECHNOLOGY

Ciclo XXXVI

Settore Concorsuale: 12/H3 – FILOSOFIA DEL DIRITTO

Settore Scientifico Disciplinare: IUS/20 – FILOSOFIA DEL DIRITTO

COLLECTION OF HUMAN BIOLOGICAL SAMPLES AND PERSONAL DATA FOR BIOBANKING PURPOSES: A LEGAL STUDY FOR A TRUSTWORTHY BIOBANK GOVERNANCE

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Esame finale anno 2024

ABSTRACT

Research biobanks are collections of human biological samples and personal data on a long-term basis for future scientific research purposes and, therefore, fundamental infrastructure for the conduction of scientific research and the advancement of society, especially in the medical field. However, the matter is not specifically regulated, either at the supranational or the national level, and therefore the applicable provisions should be found in the sectorial regulations that govern biobanking activities. Among the various controversial issues that arise in this field, that of the models for the collection of human biological samples and the personal data to be stored in the biobank is particularly controversial. The aim of this study is, therefore, to provide a comprehensive analysis of these models from a regulatory perspective, at both the supranational and national level. After having provided general definitions of the main concepts used in biobanking and an overview of the hard and soft law instruments applicable to the field, the study is devoted to describing the available lawful methods for collecting biological samples and personal data first as a primary and then as a secondary use. In order to choose the appropriate method, the biobank should evaluate its impact on the participant's right to data protection in its actual conceptualisation, and strike a balance between the latter and the interest of society in the advancement of scientific research. Moreover, the study proposes a subsidiary test to conduct to this end, i.e. a trust test to evaluate the impact of the choice on participant's trust in biobanking. Finally, an overview of the issue of anonymity in the context of biobanking is provided, usually referred to as the technical measure to solve data protection issues, but which is rendered increasingly more challenging to achieve by technological advancements.

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INTRODUCTION

In the last decades, biobanks have acquired an increasingly important role in the conduction and advancement of scientific research, especially in the medical field. In their simplest definition, biobanks are collections of human biological samples and personal data, mostly genetic and health-related data, stored in order to be processed for future scientific research projects. Therefore, because of their existence, researchers might have (relatively) easy access to large quantities of data.

Their importance for society was particularly evident during the COVID-19 pandemic, because of their fundamental role in ensuring the availability of biological samples and personal data for scientific research aimed at discovering possible strategies for treating and curing the disease and making the stored samples and data available transnationally through cooperation.[1]

Because of the importance of scientific research for changes and advancements in society,[2] biobanks might be said to play an essential public function,[3] because they represent fundamental infrastructures for scientific research.[4]. In order to adequately fulfil such function, they need to adopt a governance system in which all the emerging issues are solved via a careful balancing exercise among the various rights and interests possibly affected and involved in their activities. In particular, biobanks shall ensure the protection of the privacy and fundamental rights of the participants, while at the same time guaranteeing fair access to the stored resources for public good purposes and the advancement of society in the medical field.[5]

Varied are the issues that arise in biobanking, among which are worth mentioning those of "consent, especially for secondary research purposes; feedback to participants; benefit sharing the public interest; participation in decision making; protecting privacy; access;

[1] Annaratone, Laura, et al. "Basic Principles of Biobanking: from Biological Samples to Precision Medicine for Patients"; Juozapaitė, Dovilė, et al. "The COVID-19 Pandemic Reveals the Wide-ranging Role of Biobanks." *Frontiers in Public Health,* vol. 11, 2023, pp. 1-7.

[2] Guarda, Paolo, *Il Regime Giuridico dei Dati della Ricerca Scientifica,* Editoriale scientifica, 2021.

[3] Rapisarda, Ilenia "Brevi Note sullo Statuto Giuridico del Materiale Biologico Umano." *Europa e Diritto Privato,* vol. 2, 2017, pp. 625-666.

[4] *Ibid*

[5] Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: il Possibile Ruolo delle Biobanche." *Jus Civile,* vol. 3, 2014, pp. 65-10.

ownership and intellectual property rights".[6] Among these, the following study intends to study the possible methods available for the collection of human biological samples and personal data for biobanking purposes, with the aim of suggesting for biobank governance purposes a solution that not only is the result of a fair balance between the various interests at stake but also adequately preserves and enhances participants' trust in the biobanking activities.

In particular, the biobanking field is highly heterogenous and, in the lack of a common and harmonised legal framework, requires a careful analysis of its various aspects in order to evaluate which specific sectorial legislation is applicable, as well as soft-law instruments and more generally ethical guidelines, and how to concretely apply the provisions established thereby. Therefore, problems for the interpreter arise at the very beginning of the discussion, both in the attempt to define its object and in collecting the pieces of the regulatory patchwork applicable to biobanks. The coexistence of hard and soft law instruments at various levels of enforceability hinders harmonisation on the matter, and that of supranational and national norms renders any attempt at collaborating among biobanks in different Member States extremely difficult. To the analysis of this complicated framework is devoted Chapter I of this work, where I provide a description of the main characteristics of research biobank, which will be the focus of the entire analysis, and an overview of the hard and soft law instruments applicable to the various elements of the biobanking implementation, and in particular to the collection of the human biological samples and personal data to be subsequently used for research purposes.

Indeed, precisely on the ability to collect and retain personal data and making these available for future specific scientific research projects depends the very existence of the biobank. Therefore, in general, this work will be devoted to presenting the possible lawful scenarios according to the regulations applicable to the processing of personal (and sensitive) data available for biobanks at both the supranational and national levels.

The decision in this regard has direct consequences on the level of participants' trust in the biobank and its activities, which, as I will extensively discuss in Chapter II, is of fundamental importance for existence and appropriate functioning of the collection. To

[6] Kaye, Jane "Do We Need a Uniform Regulatory System for Biobank across Europe?", *European Journal of Human Genetics*, vol. 15, 2005, pp. 245-248.

emphasise such importance and attempt at protecting and enhancing trust throughout the biobank lifecycle, but particularly at the moment of the collection of its content, I will provide an example of *trust test* that may be conducted when choosing the method for collecting samples and data to be implemented in the biobank governance. In this regard, I believe that after having established which are the possible lawful methods available to adopt in a concrete situation and having carefully balanced the various contrasting rights and interests at stake (namely those of the participants and of society at large in the advancement of research), it may be beneficial for the biobank to address the issue of trust and to finally choose the option that better protects it.

Chapter III is then devoted to the detailed analysis of the alternative models for the collection of the content of the biobank, namely biological samples and personal data. On the one hand, in Part A I will analyse the issues related to human biological samples, which in particular are connected to and derived from their dual nature, i.e. their existence as material samples and at the same time sources of important genetic data on the person. This characteristic of the samples, as well as their intrinsic and ontological link with the human body, complicates their legal qualification. The issue in this regard relates to the possibility of considering them as objects possibly transferable from the patient to the biobank for scientific research purposes by simply providing consent (*rectius*, *interventional biobank consent*, as I will be referring to) or as equivalent to personal data. As I will attempt to demonstrate, I believe that the last solution should be preferred, given that the value of the samples for research nowadays mainly derives from their informational nature.

Part B is then dedicated to the study of the possible alternative models for the collection of personal data, both "ordinary" and sensitive data, at the supranational and national level. As it will become apparent throughout the discussion, the GDPR provides for various alternative models, both for the primary use of the personal data and their further processing. In particular, the data controller (*rectius*, the biobank in my analysis) is left with a choice to be made (usually from the outset) between a regime that directly involves the data subject, considered as factual controller of the use of her data (*consent-based model*), and using the provisions available for maximising the processing of the personal data by reducing the concrete involvement of the data subject in the decision-making

process with the aim of fostering the conduction and development of scientific research (*necessity-based model*).

At the national level, the Italian legislator opted for asking for the informed consent of the data subject (which I will refer to as *informational consent*) in almost the totality of the cases, thus both for the processing of the personal data for biobanking or for scientific research purposes, and as a primary or secondary purpose.

The last part of Chapter III is therefore dedicated to providing biobanks with a method for choosing between the various alternatives at her disposal. Indeed, as mentioned, I believe that any choice related to the choice of the biobank governance should be first of all made according to the balance of the various rights and interests at stake. In this regard, one of the rights possibly affected by the biobanking activities is the participant's fundamental right to data protection, which should therefore be carefully analysed for its significance, content and value. Subsequently, the result of such a balance is evaluated in terms of impact on participant's trust by conducting the trust test, whose core elements were identified in Chapter II. The same test is applied in case none of the contrasting interests should concretely prevail.

Finally, I will evaluate the applicability of two newly introduced regulations, the Data Governance Act and the Proposal for a European Health Data Space, to biobanking and their impact on the decision-making process previously highlighted.

The final Chapter IV is then devoted to the study of anonymisation. Indeed, the latter is frequently suggested as the technical solution to the data protection issues posed by the processing of personal data for scientific research purposes, but rendered increasingly difficult by the collection of large amounts of data and by the very activity conducted by the biobank.

Overall, in its various parts the analysis is devoted to demonstrating that under a regulatory point of view and because of the absence of a comprehensive and specific regulation, biobanking does not entail the mere application of fixed norms but is frequently the result of a balancing exercise between various contrasting interests all worth of (constitutional) protection. In this regard, assuming the role of intermediate impartial entity might help making the mentioned choice, while at the same time preserving participants' trust in the biobanking activities and, more generally, society at large.

CHAPTER I – DEFINITIONS, LEGAL FRAMEWORK AND STRUCTURE OF THE WORK

Summary: 1 Introduction; 2 Definitions; 2.1 Biobank; 2.1.1 An umbrella term – Identifying its core elements; 2.1.2 Research biobanks and their classification; 2.1.3 The content of research biobanks; 2.1.3.1 Human biological samples; 2.1.3.2 Data for biobanks – Their importance for precision medicine; 2.1.3 Research purposes and precision medicine; 2.2 A categorisation of the different purposes of the collection and use of biological samples and data; 2.3 Other important terminologies; 3 The applicable legal framework; 3.1 The supranational Level; 3.1.1 Soft law instruments; 3.1.1.1 The Declaration of Helsinki and the Declaration of Taipei; 3.1.1.2 The CIOMS International Ethical Guidelines; 3.1.1.3 The OECD Recommendations; 3.1.1.4 The UNESCO Declarations; 3.1.1.6 The Recommendation R(2016)6; 3.1.2 Hard law instruments; 3.1.3 The Oviedo Convention; 3.2 (binding and non-binding) instruments at the national level; 4 Structure of the work

1 INTRODUCTION

The field of biobanking is governed by highly heterogeneous norms from various disciplines, established by hard and soft instruments enacted at all levels of enforceability and at the interception among law, ethics and technology. Therefore, reconstructing the applicable framework is a complex theoretical and practical task because of the difficulties that the interpreter encounters in finding the applicable norms of this "fragmented landscape"[7] and harmonising them in order to have a viable framework.

Consequently, it is first of all important to define the perimeter of the discussion and the fundamental terms to be used, especially because of the absence of sector-specific definitions. Setting the foundations[8] of the specific analysis is paramount to avoid possible confusion and differences in interpretations.

[7] Tzortatou, Olga, et al. "Biobanking Across Europe Post-GDPR: A Deliberately Fragmented Landscape." *GDPR and Biobanking*, edited by Slokenberga, Santa, Springer, 2021, pp. 397-420.

[8] Slokenberga, Santa "Setting the Foundations: Individual Rights, Public Interest, Scientific Research and Biobanking." *GDPR and biobanking*, edited by Slokenberga, Santa, Springer, 2021, pp. 11-30.

As a consequence, in the following paragraphs, I will first of all provide the definitions of the fundamental concepts to be used throughout the whole discussion, while other terms more specific to other Parts or Chapters of this work will be defined or identified later on. I will then provide an overview of the legal "fragmented landscape"[9] applicable to biobanks. Indeed, in the absence of a universal, European or national general regulation of the matter, systematising the constellation of sectorial regulations and norms, soft law instruments and guidelines relevant to the biobanking fields would help navigate the matter. To this end, the discussion will be divided between the supranational and the national level, taking into consideration both soft law and hard law documents. Indeed, the field of biobanking is primarily regulated via non-binding instruments, mainly because of its high heterogeneity, while the binding ones deal primarily with topics (such as data protection, for instance) that are not specific to biobanking but are nonetheless applicable to it.

Finally, I will provide a general overview of the structure of the work of the following chapters.

2 DEFINITIONS

First and foremost, it is necessary to define the general concepts further used in the discussion. Indeed, given the absence of a specific unique regulation applicable to biobanking, any analysis of the issues on the matter usually lacks anchor points[10], and setting the boundaries of the concepts used is of paramount importance.

Indeed, it has been pointed out that providing definitions would help increase uniformity and ease communication among the different stakeholders involved,[11] as well as their (translational) collaborations, and is also valuable to anchor the following discussion to concepts with a definite meaning and specifically designed for the biobanking field.

Moreover, the multifaceted nature of biobanking brings along a wide variety of ethical and legal issues and defining the concepts to be used will also help delimit the horizon of the discussion in the following pages.

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[9] Tzortatou, Olga, et al. "Biobanking Across Europe Post-GDPR: A Deliberately Fragmented Landscape."

[10] Macilotti, Matteo, *Le biobanche di ricerca, Studio comparato sulla "zona grigia" tra privacy e proprietà,* Università di Trento, 2013.

[11] Gray, Stacy W., et al. "Social and Behavioral Research in Genomic Sequencing: Approaches from the Clinical Sequencing Exploratory Research Consortium Outcomes and Measures Working Group." *Genetics in medicine: official journal of the American College of Medical Genetics*, vol. 16, n. 10, 2014, pp. 727-35.

2.1 BIOBANK

There are multiple definitions of the term *biobank*, both at the national and supranational level, given the absence of a universally agreed one[12] and because such a concept usually applies to a wide variety of organisations and facilities.[13]

Indeed, also because of the lack of a precise definition, the term "biobank" is sometimes confused or interchanged with others, such as "biorepositories" or "biological resource centres", and drawing the exact dividing line among these concepts is not always easy.[14] It derives from this difficulty, for instance, the decision taken in the Declaration of Taipei to provide the same principles for both biobanks and health databases because they "both give rise to similar concerns about dignity, autonomy, privacy, confidentiality and discrimination".[15]

As notorious, the term biobank first appeared in 1996[16] and was initially used to describe human population-based biobanks.[17] Indeed, an example of this initial approach is provided in 2006 by the Organisation for Economic Co-operation and Development (OECD) in the report entitled "Creation and Governance of Human Genetic Research Databases" where biobanks were defined as "a collection of biological material and the associated data and information stored in an organised system, for a population or a large subset of a population." Later on, in 2009, in its Recommendation on Human Biobanks and Genetic Research Database, the OECD described biobanks in general as "structured resources that can be used for genetic research and which include: (a) human biological material and information generated from the analysis of the same; and (b) extensive

[12] Slokenberga, Santa "Setting the Foundations: Individual Rights, Public Interest, Scientific Research and Biobanking"; Hewitt, Robert, and Peter, Watson "Defining Biobank." *Biopreservation and Biobanking*, vol. 11, n. 5, 2013, pp. 309-315; Gaspari, Francesco "La Circolazione dei Dati Genetici e delle Biobanche: Limiti e Prospettive *de iure condendo." federalismi.it,* vol. 5, 2021, pp. 129-173.

[13] For a comprehensive analysis of the topic, see Hewitt, Robert, and Peter, Watson "Defining Biobank."

[14] Slokenberga, Santa "Setting the Foundations: Individual Rights, Public Interest, Scientific Research and Biobanking."

[15] Preamble paragraph 4). On the topic, Chassang, Gauthier, and Emmanuelle, Real-Sebbag "Research Biobanks and Health Databases: The WMA Declaration of Taipei, Added Value to European Legislation (Soft and Hard Law)." *European Journal of Health Law*, vol. 25, n. 5, 2018, pp. 501-516.

[16] European, Middle Eastern and African Society for Biopreservation and Biobanking, Aix-en-Provence, France.

[17] Hewitt, Robert, and Peter, Watson "Defining Biobank."

associated information".[18] The latter definition clearly moved away from defining population-based biobanks exclusively to adopt a more comprehensive approach.[19]

At the European level, an official definition can be extrapolated by the provisions of Recommendation R(1994)1, where biobanks are qualified as "non-profit-making institutions which are officially licensed by national health administrations, or recognised by the competent authorities"[20] responsible for the collection, storage and distribution of human tissues. However, Recommendation R(1994)1 is not decisive on the matter, because it substantially builds upon the norms for such licensing or recognition and therefore upon the definitions included therein, transferring to national legislators the task of defining, and the responsibilities that come with it.

Moreover, on the specific topic of *population-based biobanks*, Recommendation R(2006)4 gives the following definition: "a collection of biological materials that (…) i. has a population basis; ii. it is established, or has been converted, to supply biological materials or data derived therefrom for multiple future research projects; iii. it contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated; iv. it receives and supplies materials in an organised manner".[21]

Definitions at the national level vary considerably among Member States as well. For instance, the Spanish regulation on the matter establishes that a biobank is "a public or private, non-profit establishment that houses a collection of biological samples conceived for diagnostic or biomedical research purposes and organised as a technical unit with criteria of quality, order and destination"[22] with a strong focus on its non-profitable character and its organised structure.

Somewhat differently and more generally, the new Swedish Biobank Act of 2023 defined biobanks very broadly as "one or more sample collections held by one and the same

[18] Organisation for Economic Co-Operation and Development, Recommendation on Human Biobanks and Genetic Research Database, 2009.
[19] Slokenberga, Santa "Setting the Foundations: Individual Rights, Public Interest, Scientific Research and Biobanking."
[20] Council of Europe, Recommendation R(1994)1 of the Committee of Ministers to Member States on Human Tissue Banks, 1994.
[21] Council of Europe, Recommendation R(2006)4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin, 2006.
[22] Act on Biomedical Research—Ley de Investigación Biomédica, LIB-, Article 3 (d).

principal", that in turn is the "legal entity responsible for a biobank" and that established it.[23]

In Italy, given the absence of a specific national regulation on biobanks and on biobanking research, definitions can be found in various documents, such as non-legislative acts adopted by administrative authorities or other soft law documents, but never in officially binding laws on biobanking. Indeed, as a matter of example, in the agreement between the Italian government and the Italian regions signed in 2009 biobanks are defined as service units without a direct profitable character built within public or private healthcare facilities, whose aim is to collect, process, store and distribute human biological samples for diagnosis, research or therapeutical purposes.[24] Moreover, the Guidelines for certification of biobanks drawn up by the National Committee for Biosecurity and Biotechnologies in 2006 defines biobanks as "service units, not for direct profit, aimed at collecting and preserving human biological material used for diagnosis, biodiversity studies and research".[25]

It appears thus clear that there is no general supranational consensus on a definition for biobank, nor can it be inferred from the national provisions. However, this high terminology heterogeneity may cause a problem of nomenclature, but more importantly, is an obstacle to harmonisation and transnational cooperation among biobanks,[26] and may cause regulatory uncertainty because of possible doubts that may emerge on whether a certain repository should be qualified as a biobank, with the related consequences in terms of specific national or supranational rules to be complied with.[27]

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[23] Biobank Sweden's translation of the Biobank Act (2023:38), Chapter 1 Section 2.

[24] The original version is the following "unità di servizio situate all'interno di strutture sanitarie pubbliche o private, senza fini di lucro diretto, finalizzare alla raccolta, alla lavorazione, alla conservazione, allo stoccaggio e alla distribuzione di materiale biologico umano, a scopo di indagine diagnostica, ricerca e uso terapeutico." Accordo tra il Governo, le Regioni e le Province autonome di Trento e Bolzano sulle linee progettuali per l'utilizzo da parte delle Regioni delle risorse vincolate, ai sensi dell'articolo 1, commi 34 e 34bis, della legge 23 dicembre 1996, n. 662, per la realizzazione degli obiettivi di carattere prioritario e di rilievo nazionale per l'anno 2009, stipulato in sede di Conferenza permanente per i rapporti tra lo Stato, le Regioni e le Province autonome di Trento e Bolzano, in data 25 marzo 2009.

[25] Comitato Nazionale per la Biosicurezza e le Biotecnologie, Linee Guida per la certificazione delle biobanche, Rapporto del gruppo di lavoro, 2006.

[26] Beier, Katharina, and Christian, Lenk "Biobanking Strategies and Regulative Approaches in the Eu: Recent Perspectives." *Journal of Biorepository Science for Applied Medicine*, vol. 3, 2015, pp. 69-81; Shaw, David M et al. "What is a biobank? Differing definitions among biobank stakeholders." *Clinical genetics* vol. 85, n. 3, 2014, pp. 223-227.

[27] On the topic, see Shaw, David M et al. "What is a biobank? Differing Definitions among Biobank Stakeholders"; Kaye, Jane and Susan M. C., Gibbons "Mapping the Regulatory Space for Genetic Databases and Biobanks in England and Wales." *Medical Law International,* vol. 9, 2008, pp. 111-130.

Indeed, it has been pointed out that a comprehensive definition of the term biobank is difficult to reach because of its nature as "umbrella term" used to describe a wide variety of collections of samples and data devoted to supporting scientific research at large.[28] Moreover, precisely because of the high heterogeneity and dynamic nature of biobanks,[29] strongly intertwined with, and somehow dependent on the advancement of technology and science, finding a static definition might not be the ideal solution.[30]

Instead, Heeney proposed identifying only the core characteristics of what constitutes a biobank,[31] and along the same line of reasoning I will now try to identify the general and common traits of a collection that qualifies as a biobank.

2.1.1 AN UMBRELLA TERM – IDENTIFYING ITS CORE ELEMENTS

Acknowledging the difficulty in providing an omnicomprehensive and clear definition of the term biobank, Hewitt et al. proposed the following general definition "A biobank is a facility for the collection, preservation, storage and supply of biological samples and associated data, which follows standardised operating procedures and provides material for scientific and clinical use", and at the same time underlined the importance of linking the term with additional specifications, such as population-based, disease-oriented, hospital-integrated, etc., in order to circumscribe the focus of every analysis or discussion.[32]

In line with these approaches, the German National Ethics Council already in 2010 set a list of criteria to help assess whether a collection of samples and data should be considered a biobank. Starting from the assumption that biobanks have a dual nature because they

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[28] Hallinan, Dara *Protecting Genetic Privacy in Biobanking through Data Protection Law,* OUP Oxford, 2021; Hewitt, Robert, and Peter, Watson "Defining Biobank."

[29] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici." *federalismi.it,* vol. 12, 2023, pp. 231-249; Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona*, PhD Thesis, Università degli Studi di Napoli Federico II, Anno Accademico 2013-2014; Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea,* PhD thesis, Università degli Studi di Cagliari - Universidad de Sevilla, Anno Accademico 2018-2019; Bovenberg, Jasper A. "Property Rights in Blood Genes and Data: Naturally Yours?" *Nijhoff Law Specials*, 2005.

[30] Guerra, Luca, et al. "Orientamenti per 'linee guida' in materia di biobanche." *Biobanche. Aspetti Scientifici ed Etico-Giuridici*, edited by Eusebi, Luciano, Vita e Pensiero, 2014.

[31] Kaye, Jane "Embedding Biobanks in a Changing Context." *Governing Biobanks. Understanding the Interplay between Law and Practice*, edited by Kaye, Jane, et al. Bloomsbury, 2012, pp. 30-51. On the importance of focusing on the characteristics of the collection, instead of providing a static definition, also Minssen, Timo, and Jens Schovsbo "Legal Aspects of Biobanking as Key Issues for Personalised Medicine and Translational Exploitation." *Personalised medicine*, vol. 11, n. 5, 2014, pp. 497-508.

[32] Hewitt, Robert, and Peter, Watson "Defining Biobank."

are collections of both human samples and data, the Council listed the three following criteria:

1 A biobank shall contain genetic material of human origin and related data;
2 Samples shall be electronically linked to personal information and other further information, in particular, related to health;
3 Those samples and data are collected, preserved or used for scientific research purposes.[33]

Subsequently, these criteria have been further elaborated by the European Commission in the Report "Biobanks for Europe: A Challenge for Governance", where it is suggested that biobanks:

a. "collect and store biological materials that are annotated not only with medical but also epidemiological data (e.g. environmental exposures, lifestyle/occupational information);
b. are not static "projects" since biological materials and data are usually collected on a continuous or long-term basis;
c. are associated with current (defined) and future (not yet specified) research projects at the time of biospecimen collection;
d. apply coding or anonymisation to assure donor privacy but have, under specific conditions, provisions that participants remain re-identifiable to provide clinically relevant information back to the donor; and
e. include established governance structures (e.g. ethics review committees) and procedures (e.g. consent) that serve to protect donors' rights and stakeholder interests".[34]

It is worth noticing that both the mentioned documents include the *purpose* of the collection among the elements to be focused on in order to identify a collection that constitutes a biobank.

However, I agree with those scholars who consider the purpose more a classification element than a substantial one.[35] As a consequence, I suggest not including it among the

[33] German National Ethics Council, Human biobanks for research – Opinion. 2010.
[34] Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research, Biobanks for Europe. a challenge for governance, 2012.
[35] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona*. the author divides among research biobanks, disease biobanks, forensic biobanks, etc.

general defining elements, and I will consider it for classifying biobanks in the following paragraph.[36] I therefore propose limiting the notion of biobanks to collections meeting the following criteria related to:

- *the content* – samples of human origin and data, also linked to one another and stored respecting the donors' rights, collected on a continuous basis.[37] According to the new Declaration of Taipei, the dual nature of the content (samples and data) is what distinguishes biobanks from health databases.[38] Indeed, according to the Declaration the latter are collections of data only, without any biological sample being included;
- *the structure/organisation* – a specific governance system is in place to collect samples and data for a given purpose, for providing access to the content, etc.[39]

Finally, I also propose not to include the non-profitable character as a determinant factor for identifying what constitutes a research biobank. Indeed, some legislative acts include it, such as for example the Spanish legislation, in order to establish a more relaxed regulatory regime for the collections that meet specific requirements, usually related to pursue public interests rather than private individual ones. As a consequence, the exclusion of the element of profit from the definition is most of the time the result of a balancing operation already conducted by the legislator between private and public

[36] On the contrary, on the importance of including the research purpose among the criteria used to identify when a collection is a biobank, see Gray, Stacy W., et al. "Social and Behavioral Research in Genomic Sequencing: Approaches from the Clinical Sequencing Exploratory Research Consortium Outcomes and Measures Working Group."

[37] On the importance of the content aspect of biobanks, see Annaratone, Laura, et al. "Basic Principles of Biobanking: from Biological Samples to Precision Medicine for Patients.".

[38] Gaspari, Francesco "La Circolazione dei Dati Genetici e delle Biobanche: Limiti e Prospettive *de iure condendo"*; Novelli, Giuseppe, and Ilenia Pietrangeli, "I Campioni Biologici." *Trattato di Biodiritto. Il governo del corpo Tomo I*, edited by Canestrari, Stefano, et al. Giuffrè, 2011, pp. 1027-1062; Macilotti, Matteo "Le Biobanche: Disciplina e Diritti della Persona." *Il Governo del Corpo Tomo I*, edited by Canestrari, Stefano et al. Giuffrè, 2011, pp. 1195-1215; Ducato, Rossana "Database Genetici, Biobanche e "Health Information Technologies" *Il Diritto dell'Era Digitale,* edited by Pascuzzi, Giovanni, Il Mulino, 2016, pp. 305-320.

[39] On the importance of the organisational aspect, Macilotti, Matteo, *Le biobanche di ricerca, Studio comparato sulla "zona grigia" tra privacy e proprietà*, and also the guidelines on recognition and accreditation of biobanks by the Comitato Nazionale per la Biosicurezza e le Biotecnologie e le Scienze della Vita - Linee Guida per il riconoscimento/accreditamento delle Biobanche, 2008. Moreover, on the same topic, Gottweis, Herbert, and Alan, Petersen *Biobanks Governance in Comparative Perspective*, Routledge, Taylor & Francis Group, 2008; Müller, Heimo, et al. "Biobanks for Life Sciences and Personalized Medicine: Importance of Standardization, Biosafety, Biosecurity, and Data Management." *Current Opinion in Biotechnology*, vol. 65, 2020, pp. 45-51.

interests.[40] Therefore, the elements used to abstractly identify a research biobank for the purposes of this analysis do not include the hypothetical profit that the collection may make out of the use of the samples and data stored therein.

2.1.2 RESEARCH BIOBANKS AND THEIR CLASSIFICATION

As previously mentioned, different types of biobanks exist,[41] as well as different classification methods.[42] As for the latter, classifications are based on tissue type, purpose, ownership, group of participants, or size.[43]

In particular, as far as the purpose is concerned, some of the documents mentioned in the previous paragraph provide a list of characteristics that are fundamental for the identification of a biobank and include conducting research among them (i.e. the purpose of the biobank). However, the term biobank may also be used for collections of samples and data for other purposes, such as in a clinical context (*clinical biobanks*) or for forensic purposes (*forensic biobanks*),[44] and therefore, as mentioned, I suggested not to include conducting scientific research among the identifying elements, but to consider it as a classifying element and in particular to distinguish among research biobanks, clinical biobanks, forensic biobanks, etc.

Stemming from the belief that any legal evaluation shall be context-dependent, I chose to focus this work only on *research biobanks*, i.e. biobanks established for the purposes of providing human biological samples and data for research projects. This choice originates from the belief that research biobanks have a peculiar impact on individuals and society at large, different from those of other biobanks with different purposes, while at the same time they are tools to pursue public health and the public good more generally. Indeed,

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[40] Moreover, the non-profitable character is usually more an obligation to be complied with than an actual defining element.

[41] Olson, Josephine E., et al. "Biobanks and Personalized Medicine." *Clinical Genetics* vol. 86, n. 1, 2014, pp. 50-55.

[42] Annaratone, Laura, et al. "Basic Principles of Biobanking: from Biological Samples to Precision Medicine for Patients"; Kinkorová, Judita "Biobanks in the Era of Personalized Medicine: Objectives, Challenges, and Innovation: Overview." *the EPMA Journal*, vol. 7, n. 4, 2016, pp. 1-9; Gottweis, Herbert, and Kurt, Zatloukal "Biobank Governance: Trends and Perspectives." *Pathobiology*, vol. 74, n. 4, 2007, pp. 206–211; Rebulla, Paolo, et al. "Biobanking in the year 2007." *Transfusion Medicine and Hemotherapy*, vol. 34, 2007, pp. 286–92.

[43] Arampatzis, Asterios, et al. "A Classification and Comparative Study of European Biobanks: an Analysis of Biobanking Activity and its Contribution to Scientific Progress." *Archives of Medicine*, vol. 8, n. 3, 2016, pp. 1-10; Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*.

[44] Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea.*

the structure, governance and balance between the different interests at stake for building a research biobank are drastically different from those considered for biobanks with other purposes.[45]

In this regard, two specifications are of particular importance, a practical and a conceptual one.

On the one hand, as it stems also from the definition of the term provided above, biobanks are collections of samples and data on a long-term basis. Therefore, when their purpose is conducting scientific research, their aim is to provide samples and data for a possible undefined or unlimited number of scientific research projects, provided that the applicable ethical, legal and governance principles are complied with. This specific aspect of biobanks has peculiar consequences on the way human biological samples and data are collected, because of the impossibility of providing in advance to the participant a clear and detailed overview of every scientific project for which the collected material will be used.

On the other hand, as stated by BBMRI research biobanks are expected to act as an "intermediary" between donors/participants, scientists, patients, hospitals, etc.[46] Consequently, research biobanks are not research projects *per se*, but are ontologically built to provide human biological samples and data for research.[47] In this regard, in the vast majority of cases, biobanks provide a service for researchers in the sense that they collect the samples and data, store them in a manner suitable for preserving their quality,

[45] Tomasi, Marta "Il Modello Italiano di Regolamentazione Giuridica delle Biobanche: alla Ricerca di una Sintesi per una Materia Poliedrica." *Biobanche: importanza, implicazioni e opportunità per la società. Risvolti scientifici, etico-giuridici e sociologici*, edited by Caenazzo, Luciana, *libreriauniversitaria.it*, 2010, pp. 21-48; Iannuzzi, Antonio, and Francesca, Filosa "Il trattamento dei dati genetici e biometrici." *Il Nuovo Codice in Materia di Protezione Dei Dati Personali: La Normativa Italiana Dopo il D. Lgs. 101/2018*, edited by Midiri, Mario, et al. Giappichelli, n. 2, 2019, pp. 113-131.

[46] Argudo-Portal, Violeta, and Miquel Domènech "The Reconfiguration of Biobanks in Europe under the BBMRI-ERIC Framework: towards Global Sharing Nodes?" *Life Sciences, Society and Policy*, vol. 16, n. 1, 2020, pp. 1-15; Melham, Karen, et al. "The Evolution of Withdrawal: Negotiating Research Relationships in Biobanking." *Life Sciences, Society and Policy*, vol. 10, n. 16, 2014, pp. 1-13; Chassang, Gauthier, and Emmanuelle, Real-Sebbag "Research Biobanks and Health Databases: The WMA Declaration of Taipei, Added Value to European Legislation (Soft and Hard Law)."

[47] Melham, Karen, et al. "The Evolution of Withdrawal: Negotiating Research Relationships in Biobanking"; Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*; Macilotti, Matteo "Le Biobanche: Disciplina e Diritti della Persona."

grant the researchers' requests to access the content for their own research projects, and so on.[48]

To reach their purpose, research biobanks can be implemented in various settings and environments, in particular hospitals (hospital-based biobanks which receive samples and data from the organisation they are built-in), research centers (for instance as part of clinical trials or case-control biobanks), pharmaceutical companies and patient advocacy organisations.[49]

At the same time, different classifications of research biobanks exist,[50] which include for instance population-based biobanks, disease-oriented biobanks, case-control biobanks, tissue biobanks and biobanks within the context of clinical trials.[51] A general classification of research biobanks identifies *population-based* biobanks on the one hand and *disease-oriented* biobanks on the other.[52]

In the first case, as previously mentioned, the biobank collects samples and data from a vast group of people or a large percentage of a given population and aims at studying common and complex diseases[53] by linking data with environmental factors and other information related to a patient's health status and lifestyle.[54] Therefore, data and samples

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[48] In a limited number of instances, the biobank may also be the entity which collects and stores the biological samples and data, while at the same time conducting some or all the research projects. While I will make reference to this scenario whenever relevant, it will not be specifically addressed in the present work, because of the substantially different characteristics and issues of the eventuality in which the biobank is open to external researchers or not.

[49] Annaratone, Laura, et al. "Basic Principles of Biobanking: from Biological Samples to Precision Medicine for Patients"; Ducato, Rossana *Lo Statuto Giuridico della Bioinformazione tra Biobanche di Ricerca e Fascicolo Sanitario Elettronico*, PhD Thesis, University of Trento, Anno Accademico 2012-2013.

[50] Gaspari, Francesco "La Circolazione dei Dati Genetici e delle Biobanche: Limiti e Prospettive *de iure condendo"*; Paris, Chiara "Biobanche di Ricerca e Banca Dati Nazionale del DNA: un Difficile Bilanciamento tra Interessi Contrapposti." *BioLaw Journal*, vol. 1, 2022, pp. 83-107.

[51] Minssen, Timo, and Jens Schovsbo "Legal Aspects of Biobanking as Key Issues for Personalised Medicine and Translational Exploitation."

[52] On the topic, among others, Macilotti, Matteo, *Le biobanche di ricerca, Studio comparato sulla "zona grigia" tra privacy e proprietà*; Guerra, Luca, et al. "Orientamenti per 'linee guida' in materia di biobanche"; Gaspari, Francesco "La Circolazione dei Dati Genetici e delle Biobanche: Limiti e Prospettive *de iure condendo."*

[53] Kinkorová, Judita "Biobanks in the Era of Personalized Medicine: Objectives, Challenges, and Innovation: Overview"; Coppola, Luigi, et al. "Biobanking in Health Care: Evolution and Future Directions." *Journal of Translational Medicine*, vol. 17, n. 172, 2018, pp. 1-18; Ducato, Rossana *Lo Statuto Giuridico della Bioinformazione tra Biobanche di Ricerca e Fascicolo Sanitario Elettronico*; Pontisso, Patrizia "Aspetti Giuridici delle Biobanche." *Biobanche: importanza, implicazioni e opportunità per la società. Risvolti scientifici, etico-giuridici e sociologici*, edited by Caenazzo, Luciana, *libreriauniversitaria.it*, 2010.

[54] Gaspari, Francesco "La Circolazione dei Dati Genetici e delle Biobanche: Limiti e Prospettive *de iure condendo."*

to be stored in this kind of biobank are usually collected from healthy representative donors for a given region, country or specific ethnic group.[55] A popular example of this kind of biobank is the UK Biobank.

On the contrary, a disease-oriented biobank focuses on storing (and conducting scientific research on) samples and data related to a specific condition to identify possible therapeutic strategies.[56] Riegman further divides disease-oriented biobanks into *disease-oriented biobanks for epidemiology*, where samples from both healthy and diseased subjects are stored, and *disease-oriented general* biobanks, where the samples and data stored are collected from patients with a specific disease throughout the life-cycle of disease progression and treatment.[57] For disease-oriented biobanks, biological materials are usually collected in the context of clinical care.[58]

2.1.3 THE CONTENT OF RESEARCH BIOBANKS

As previously mentioned, the dual nature of research biobanks derives from the fact that their content comprises both human biological samples and related data of participants, collected from various sources which are possibly of a different nature.

Therefore, one of the most important aspects to consider when developing and building a research biobank is the standardisation of the processes for the collection, storage and quality control of human biological samples and data.[59] Indeed, standardised processes would help not only to ensure high quality of the biobank content, but also improve exchanges and cooperation between different biobanks and various researchers. In this regard, the ISO 20387:2020 was released in 2020,[60] concerning the general requirements for the competence, impartiality and consistent operation of biobanks for research and development (thus excluding clinical and therapeutic diagnostic biobanks), including

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[55] Minssen, Timo, and Jens, Schovsbo "Legal Aspects of Biobanking as Key Issues for Personalised Medicine and Translational Exploitation."

[56] Coppola, Luigi, et al. "Biobanking in Health Care: Evolution and Future Directions"; Ducato, Rossana *Lo Statuto Giuridico della Bioinformazione tra Biobanche di Ricerca e Fascicolo Sanitario Elettronico.*

[57] Riegman, Peter H. J., et al. "Biobanking for Better Healthcare." *Molecular Oncology* vol. 2, n. 3, 2008, pp. 213-222. On the topic, see also Pontisso, Patrizia "Aspetti Giuridici delle Biobanche"; Gaspari, Francesco "La Circolazione dei Dati Genetici e delle Biobanche: Limiti e Prospettive *de iure condendo."* Further on classifying biobanks, see Annaratone, Laura, et al. "Basic Principles of Biobanking: from Biological Samples to Precision Medicine for Patients."

[58] Minssen, Timo, and Jens, Schovsbo "Legal Aspects of Biobanking as Key Issues for Personalised Medicine and Translational Exploitation."

[59] Annaratone, Laura, et al. "Basic Principles of Biobanking: from Biological Samples to Precision Medicine for Patients."

[60] As an update of the previous version ISO 20387:2018.

quality control requirements for their content. However, more broadly than the focus of this work, ISO 20387 is applicable to biobanks that store biological material derived from humans, but also animals, plants, microorganisms or multicellular organisms.[61]

Moreover, biobanks shall include in their governance also processes to ensure the traceability of their content, as well as procedures for their destruction (i.e. destruction of the human biological samples and deletion of the data), should it be necessary or required. All the mentioned aspects shall be addressed in the biobank governance, to ensure transparency and consistency in their application.

In this context, Bledsoe and Grizzle identified three governance models that biobanks may adopt to provide samples and related data for research purposes: the tissue procurement model, the classic biobanking model and the population based/epidemiological bioresource.[62]

In the first model, biological samples and data are collected to meet the specific requirements of individual researchers or individual research projects and to this end the samples are distributed soon after collection.[63]

According to the classic biobanking model, the biobank decides autonomously what samples and data to collect and according to which criteria and procedures. This model is particularly useful for studies that require an extensive number of clinical data and samples.[64]

Finally, as for the third model, the content of a biobank is collected to address a specific healthy population or subpopulation or from patients with a specific disease.[65]

For the purposes of our analysis, what can be inferred from this categorisation is a confirmation of the above-mentioned idea that biobanks provide a service for research and cannot be qualified as research projects per se or are not generally involved directly in the conduction of the research projects that use their content.

I will now provide a general overview of the types and sources of each content of a biobank, highlighting their respective characteristics.

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[61] As it stems from the definition of *biological material* provided for in paragraph 3.7 of ISO 20387:2020.
[62] Bledsoe, Marianna J., and William E., Grizzle "The Use of Human Tissues for Research: What Investigators Need to Know." *Alternatives to Laboratory Animals: ATLA*, vol. 50, n. 4, 2022, pp. 265-174.
[63] Bledsoe, Marianna J., and William E., Grizzle "The Use of Human Tissues for Research: What Investigators Need to Know."
[64] Bledsoe, Marianna J., and William E., Grizzle "The Use of Human Tissues for Research: What Investigators Need to Know."
[65] *Ibid*

2.1.3.1 HUMAN BIOLOGICAL SAMPLES (HBSs)

There are various types of biological samples that may be stored in a biobank. Among the others, tissues, blood, cells and stem cell lines, DNA, RNA are worth mentioning.[66] At the same time, possible new sources of human biological samples (HBSs) are imagine techniques such as structural and functional magnetic resonance imaging, positron emission tomography, magnetoencephalography, etc.[67]

However, the following analysis and this work will not take into consideration samples that may be stored and subsequently used only for reproductive purposes, such as for instance cryopreserved embryos for undergoing an assistive reproductive practice, even though they are included in the category of the HBS on abstract terms. The reason for this choice stems from the assumption, as mentioned earlier, that my research project focuses on research biobanks only, and therefore biobanks whose samples and data are stored and used for future research purposes. In this regard, the possibility of conducting scientific research with and on these biological materials (if it is at all possible to include embryos in this category) is in itself controversial and possibly banned under national or international law. As a consequence, the analysis of the legal issues that such possibility arises are radically different to, and not compatible with the ones that will be the focus of my research question.[68]

Moreover, I strongly agree with those who believe that also the discussion on the issues that arose in the context of human biological samples should be context-dependent and therefore shall take into consideration the specificities of the case under consideration. In particular, for the purpose of this analysis, as it will be further elaborated in Chapter III, Part A, these core elements of the discussion are the following: (1) the samples under consideration are human biological samples (focus on the *type* of sample), (2) these

[66] Olson, Josephine E., et al. "Biobanks and Personalized Medicine"; Kinkorová, Judita "Biobanks in the Era of Personalized Medicine: Objectives, Challenges, and Innovation: Overview."

[67] Kinkorová, Judita, and Ondřej Topolčan "Biobanks in the Era of Big Data: Objectives, Challenges, Perspectives, and Innovations for Predictive, Preventive, and Personalised Medicine." *the EPMA Journal* vol. 11, n. 3, 2020, pp. 333-341.

[68] The same approach is adopted by the Recommendation R(2016)6 when in Art. 2 it excludes from its material scope of application "embryonic or foetal biological materials." More generally on the importance to differentiate the analysis according to the type of biological sample and the purposes for which these samples are used, see Sartea, Claudio "Verso uno Statuto Giuridico dei Campioni Biologici Umani. Premesse Teoriche." *Lo Statuto Etico-giuridico dei Campioni Biologici Umani*, edited by Farace, Dario, Diritto, Mercato e Tecnologia, 2016, pp. 113-142.

samples are stored in a biobank specifically and only for research purposes (focus on the *final purpose* of the use of the samples).[69]

Furthermore, varied are also the ways possibly used to collect samples,[70] which may be mirrored in the following major categorisation: *left-over samples*, *donated samples* and *samples from deceased persons*.[71]

As far as *left-over samples* are concerned, those are all the human samples collected during the provision of clinical care, such as for instance the biological material that remains after a surgical operation.[72] This specific type of sample was initially considered a "waste" not worth saving or storing, but through time their value as sources of fundamental information and data about participants/patients has been recognised. Today, samples of this kind are usually stored in disease-oriented biobanks. However, precisely because they are initially collected in the context and for the purposes of providing clinical care, problems and difficulties arise with the quality of the samples, the registration of related information and the provision of informed consent.[73] In this category, it is possible to include also biological samples donated for transplants and subsequently not used or considered not fit for the purpose.

In particular, from a national point of view, pathologists are under the obligation to retain tissues collected during healthcare activities in diagnostic archives for care and prevention purposes.[74] To this end, the Italian Superior Council of Health adopted a set

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[69] Deplano, Stefano "Il Campione Biologico di Unidentified Person. Profili di Sistema." *BioLaw Journal*, vol. 1, 2022, pp. 45-56; Zatti, Paolo "Il Corpo e la Nebulosa dell'Appartenenza." per *uno Statuto del Corpo*, edited by Mazzoni, Cosimo Marco, Giuffrè Editore, 2008, pp. 69-110; Calderai, Valentina, "A Pound of man's Flesh. Consenso alla Ricerca sui Tessuti Biologici Umani e Teoria dei Beni." *La Ricerca sui Materiali Biologici di Origine Umana: Giuristi e Scienziati a Confronto*, edited by Gambino, Alberto M., Nuova Editrice Universitaria, 2018, pp. 76-77.

[70] On more technical aspects related to the processing of collected biological samples, see Coppola, Luigi, et al. "Biobanking in Health Care: Evolution and Future Directions."

[71] On this categorisation, see Bledsoe, Marianna J., and William E., Grizzle "The Use of Human Tissues for Research: What Investigators Need to Know"; Ducato, Rossana *Lo Statuto Giuridico della Bioinformazione tra Biobanche di Ricerca e Fascicolo Sanitario Elettronico*. Also more generally, Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi." *Comparazione e Diritto Civile*, vo. 1, 2018, pp. 1-22; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: il Possibile Ruolo delle Biobanche."

[72] Barbosa, Carla, and De Costa Andrade, Andreia, "Secondary use (Part I)." *GDPR requirements for biobanking activities across Europe*, edited by Colcelli, Valentina, et al. Springer, pp. 383-388.

[73] Pontisso, Patrizia "Aspetti Giuridici delle Biobanche"; Annaratone, Laura, et al. "Basic Principles of Biobanking: from Biological Samples to Precision Medicine for Patients."

[74] Stefanelli, Stefania, "Italy." *GDPR requirements for biobanking activities across Europe*, edited by Colcelli, Valentina, et al. Springer, pp. 531-541.

of Guidelines containing provisions on the term for the duration of the retention obligation and more generally on its implementation.[75]

Donated samples are those collected specifically for biobanking purposes from participants recruited to this end. In this case, participants are voluntarily providing their samples to the biobank. Donated samples are mostly stored in population biobanks, but they are also frequent in research biobanks as well.

Finally, *samples from deceased persons* are those obtained after an autopsy.

The analysis in the following pages will only consider the first two categories of human biological samples, because of the substantial differences that exist between these and samples from deceased persons. Indeed, precisely because of the characteristics of a research biobank as highlighted above, collecting, storing and processing biological samples (and also personal data, as it will be extensively discussed) for future and undefined research projects pose questions related to the necessity for the participants to be aware of the purposes of the processing, and the way in which her samples/data are generally stored and used, throughout the life of the biobank. In this scenario, substantially different issues emerge between the case of samples from deceased persons on the one hand, and that of left-over and donated samples on the other. Indeed, for instance, in the first scenario, the rights of the specific person who provided the samples (or the data) are not relevant for the discussion anymore, while the different interests of the descendants of such a person should be considered. However, the same is not true for left-over and donated samples (or at least not in the same way).

Such a distinction is particularly relevant for the analysis of the models for the collection of HBSs, included in Chapter III.

Usually, biological samples collected are linked to health information and data about the participant/patient and precisely this linkage and connection is an important part of the value of the content of a biobank for research,[76] especially for the advancement of

[75] Ministry of Health, Italian Superior Council of Health (2015) Guidelines on traceability, collection, transport, storage and archiving of cells and tissues for pathological anatomy diagnostic investigations. https://www.salute.gov.it/imgs/C_17_pubblicazioni_2369_allegato.pdf; Stefanelli, Stefania, "Italy."

[76] Giesbertz, Noor A. A. et al. "Inclusion of Residual Tissue in Biobanks: Opt-in or Opt-out?" *PLoS biology*, vol. 10, n. 8, 2012, pp. 1-6; Kinkorová, Judita, and Ondřej Topolčan "Biobanks in the Era of Big Data: Objectives, Challenges, Perspectives, and Innovations for Predictive, Preventive, and Personalised Medicine"; Azzini, Sara, "Biobanche, Consenso e Fonti del Diritto: un Caso di Eccezionale Disordine?" *Forum Biodiritto 2020. La Disciplina delle Biobanche a Fini Terapeutici e di Ricerca,* edited by Casonato, Carlo, et al. Quaderni del Dipartimento di Scienze Giuridiche, 2012, pp. 117-150; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: il Possibile Ruolo delle Biobanche."

precision medicine as it will be highlighted in the following paragraph. As will be extensively analysed in Chapter III, biological samples are most valuable for research biobanks precisely because of the potential information and (health and genetic) data that can be extracted from them.

2.1.3.2 DATA FOR BIOBANKS - THEIR IMPORTANCE FOR PRECISION MEDICINE

The data stored in research biobanks are of different types and collected from various sources as well (for the sake of clarity, all the data stored in the biobank will be referred to collectively as *biobank data*). Indeed, biobank data include for instance clinical data (demographics, death/survival data, questionnaires), imaging (ultrasound, magnetic resonance), biosamples, data (values from blood, urine, saliva), molecular data (genomics, proteomics), digital pathology data, "omics" data, possibly data from wearable devices, and much more.[77]

It appears clear already from this non-comprehensive list of sources of data to be collected that the amount of data possibly stored in a biobank is astonishing.[78] Moreover, new sources of data are generated continuously by the digitalisation of patient-level data, which are stored in electronic health records and health information exchanges, and by imaging and test results, medical and prescription claims and personal health devices.[79]

All these data stored in biobanks usually show the characteristics of big data,[80] or big health data.[81] Through time, Big data have been said to possess multiple characteristics, starting from the notorious 3 Vs (Volume, Variety and Velocity) and arriving at 10 Vs (including Value, Validity, Vagueness, etc).[82] As far as biobanking is concerned, it

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[77] Leff, Daniel R., and Guang-Zhong, Yang "Big-data for Precision Medicine." *Engineering,* vol. 1, n. 3, 2015, pp. 277-279; Hulsen, Tim, et al. "From Big Data to Precision Medicine." *Frontiers in medicine* vol. 6, n. 34, 2019, pp. 1-14;

[78] Kinkorová, Judita, and Ondřej Topolčan "Biobanks in the Era of Big Data: Objectives, Challenges, Perspectives, and Innovations for Predictive, Preventive, and Personalised Medicine."

[79] Minelli, Michael, et al. *Big Data, Big Analytics: Emerging Business Intelligence and Analytic Trends for Today´s Business*, Wiley & Sons, 2013.

[80] Kinkorová, Judita, and Ondřej Topolčan "Biobanks in the Era of Big Data: Objectives, Challenges, Perspectives, and Innovations for Predictive, Preventive, and Personalised Medicine."; Guarda, Paolo, *Il Regime Giuridico dei Dati della Ricerca Scientifica,* Editoriale scientifica, 2021.

[81] Tzanou, Maria, *Health data privacy under the GDPR: Big Data Challenges and Regulatory Responses*, Routledge, 2021.

[82] On the characteristics of big data, see extensively Luo, Jake et al. "Big Data Application in Biomedical Research and Health Care: a Literature Review." *Biomedical informatics insights* vol. 8, 2016, pp. 1-10; Craven, Mark, and David, Page "Big Data in Healthcare: Opportunities and Challenges." *Big data,* vol. 3, n. 4, 2015, pp. 209-210; Chen, Philip C. L., and Chun-Yang, Zhang "Data-Intensive Applications,

suffices to underline that Big data are generated faster than normal data, because of the variety of possible sources[83] and the fact that they are sometimes collected on a continuous basis.[84] Moreover, Big data are usually of a huge volume, because they are collected from a large patient group or from a portion of the population in a given geographical area (while data collected from a single patient are not big data).[85] As a consequence, biobanks may sometimes need to work with both "normal" data and Big data, causing difficulties in their management, processing and storing.

Because of their characteristics, Big data make patient stratification possible, which in turn is the foundation of precision medicine (also called personalised medicine, individualised medicine, etc).[86] Indeed, precision medicine intends to develop personalised care for each specific patient, in particular causing a paradigmatic shift from treatment to prevention.[87] Such a shift, and the very possibility of providing personalised care, is only possible if large quantities of biological samples and data are available.[88] In particular, personalised medicine is characterised by four different features and thus it is:

- *predictive*, i.e. aims at discovering predictive factors for certain diseases;
- *preventive*, i.e. intends to elevate prognosis values of early symptoms and connect them with genetic data, to increase physicians' chances of discovering diseases on time and provide the most adequate treatment to patients;

Challenges, Techniques and Technologies: a Survey on Big Data." *Information Sciences*, vol. 275, 2014, pp. 314–47 for their 3Vs characterisation; Ibnouhsein, Issam, et al. "The Big Data Revolution for Breast Cancer Patients." *European journal of breast health* vol. 14, n. 2, 2018, pp. 61-62, for their 5Vs characterisation; Andreu-Perez, Javier, et al. "Big data for Health." *IEEE Journal of Biomedical and Health Informatics*, vol. 19, n. 4, 2015, pp. 1193-1208, for their 6Vs characterisation; the 7 V´s of Big Data. impact. blog post. 2016, for their 7Vs characterisation; Borne, Kirk "Top 10 Big Data Challenges – a Serious Look at 10 big Data V´s." *MapR*, 2014, for their 10Vs characterisation.

[83] Tzanou, Maria, *Health data privacy under the GDPR: Big Data Challenges and Regulatory Responses*.

[84] Iacomussi, Sofia "Regulating Biobanks: an Ethical Analysis of the Spanish Law and the New Challenges of the Bigdata-driven Biomedical Research." *Revista de Bioética y Derecho*, vol. 53, 2021, pp. 215-233.

[85] Kinkorová, Judita, and Ondřej Topolčan "Biobanks in the Era of Big Data: Objectives, Challenges, Perspectives, and Innovations for Predictive, Preventive, and Personalised Medicine."

[86] Minssen, Timo, and Jens, Schovsbo "Legal Aspects of Biobanking as Key Issues for Personalised Medicine and Translational Exploitation"; Kinkorová, Judita, and Ondřej Topolčan "Biobanks in the Era of Big Data: Objectives, Challenges, Perspectives, and Innovations for Predictive, Preventive, and Personalised Medicine." Extensively on precision medicine, also from a technical point of view, see Hays, Prya *Advancing Healthcare through personalised medicine*, Springer, 2021; Iacomussi, Sofia "Regulating Biobanks: an Ethical Analysis of the Spanish Law and the New Challenges of the Bigdata-driven Biomedical Research."

[87] Kinkorová, Judita, and Ondřej Topolčan "Biobanks in the Era of Big Data: Objectives, Challenges, Perspectives, and Innovations for Predictive, Preventive, and Personalised Medicine."

[88] Iacomussi, Sofia "Regulating Biobanks: an Ethical Analysis of the Spanish Law and the New Challenges of the Bigdata-driven Biomedical Research"; Pontisso, Patrizia "Aspetti Giuridici delle Biobanche."

- *personalised*, i.e. featured to provide specific treatments according to the genotypic and phenotypic differences in the human population;
- *participatory*, i.e. developed for increasing communication between patients and physicians.[89]

At the same time, biobanks also have a primary role in, and possibly are, the foundation of, the development of precision medicine[90] because of the structural link between biological samples and related data collected from participants.[91] Indeed, biobanks may possibly "enable investigators in the field of genomics to search, record and analyse phenotypic information pertaining to large numbers of patients in a 'real world' context".[92] For these reasons, biobanks have been included among the pillars for precision medicine.[93] Indeed, by storing both normal data and Big data, maintaining the mentioned link with the participants' biological samples, and being able to provide large quantities of samples and data,[94] biobanks would be and currently are a fundamental resource for identifying risks associated with disease and thus developing personalised treatments, the final goal of precision medicine. Moreover, given that precision medicine aims at being preventive and personalised for a specific target patient, in supporting its development biobanks are at the same time infrastructures for the common good and the benefits of society at large.[95]

It contributes to reinforcing the importance of research biobanks for precision and personalised medicine the fact that they store also genetic data, alongside other types of

[89] More extensively on the characteristics of personalised medicine, see Paskal, Wiktor, et al. "Aspects of Modern Biobank Activity - Comprehensive Review." *Pathology oncology research: POR* vol. 24, n. 4, 2018, pp. 771-785.

[90] Liu, Angen, and Kai, Pollard "Biobanking for Personalized Medicine." *Biobanking in the 21st Century*, edited by Karimi-Busheri, Feridoun, Springer International Publishing, 2015, pp. 55-68; Montanari Vergallo, Gianluca "Campioni Biologici da Vivente Capace e Biobanche di Ricerca: Raccolta, Utilizzo e Circolazione." *European Journal of Privacy Law and Technologies*, vol. 1, 2021, pp. 180-198; Hewitt, Robert E. "Biobanking: The foundation of Personalized Medicine." *Current Opinion in Oncology* vol. 23, n. 1, 2011, pp. 112-119.

[91] Scott, Christopher Thomas, et al. "Personal Medicine – the New Biobank Crisis." *Nature Biotechnologies*, vol. 30, n. 2, 2012, pp. 141–147.

[92] Minssen, Timo, and Jens Schovsbo "Legal Aspects of Biobanking as Key Issues for Personalised Medicine and Translational Exploitation."

[93] Kinkorová, Judita "Biobanks in the Era of Personalized Medicine: Objectives, Challenges, and Innovation: Overview."

[94] Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*; Marsano, Annalisa *Il Ruolo dei Material Transfer Agreements nel Rapporto tra Biobanche ed Enti di Ricerca: Comparazione tra Diritto Italiano e Statunitense*, PhD thesis, Università Luiss Guido Carli, Anno Accademico 2014-2015.

[95] Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*.

personal and non-personal data. Indeed, from the discovery of the structure of the DNA in 1953,[96] the discoveries about the human genome that followed brought about new insights on the human body and the developments of diseases, which are nowadays another foundation of a personalised therapeutic response, and thus personalised medicine.[97]

Among the main consequences of the link between biobanks, Big data and precision medicine,[98] two are of particular importance, which will be extensively analysed in the following Chapters, but that I believe are worth mentioning already here.

On the one hand, because of the advancement of precision medicine and the gradual shift in focus in healthcare that it brings with it, biobanks need to start moving towards a patient-centered approach,[99] which in turn requires a stronger focus on participants' trust and greater involvement of patients.[100]

On the other hand, given that the data stored in research biobanks usually qualify as Big data, to successfully anonymise samples and data is becoming increasingly difficult, if not impossible.[101]

As for the HBSs, it is possible to categorise the types of data collected to be stored in a biobank as well. In particular, the ways in which the collection and the processing for biobanking purposes may occur permit the following classification:

- Data collected specifically for biobanking purposes, i.e. to be stored in a biobank for future research purposes. This category is somewhat conceptually similar to that of donated samples because in both cases the participant is generally involved for the sole purposes of the biobank (*donated data*);

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[96] Dagna Bricarelli, Francesca, "I test genetici." *Trattato di Biodiritto. Il governo del corpo. Tomo I,* edited by Canestrari, Stefano, et al. Giuffrè, 2011, pp. 371-388.

[97] Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*. Moreover, the UNESCO International Declaration on Human Genetic Data addresses the importance and specificities of genetic data for medical research.

[98] Minssen, Timo, and Jens Schovsbo "Legal Aspects of Biobanking as Key Issues for Personalised Medicine and Translational Exploitation"; Scott, Christopher Thomas, et al. "Personal medicine--the new banking crisis." *Nature biotechnology* vol. 30, n. 2, 2012, pp. 141-7.

[99] Annaratone, Laura, et al. "Basic Principles of Biobanking: from Biological Samples to Precision Medicine for Patients"; Mitchell, Derick, et al. "Biobanking from the patient perspective." *Research involvement and engagement,* vol. 1, n. 4, 2015, pp. 1-17.

[100] Iacomussi, Sofia "Regulating Biobanks: an Ethical Analysis of the Spanish Law and the New Challenges of the Bigdata-driven Biomedical Research."

[101] The analysis of the issue is provided for in Chapter IV.

- Data primarily used for other purposes, for instance for providing medical care or conducting specific scientific research project, and subsequently stored in the biobank. This category is somewhat conceptually similar to that of left-over samples because for both the primary purpose of the collection was not the inclusion in a biobank (*left-over data*);
- Data extracted from a HBS. This category is conceptually separated from the others because technically data are not collected directly from the person herself, but only indirectly, because they are extracted from a sample collected from the person (*HBS data*).

2.2 A CATEGORISATION OF THE DIFFERENT PRACTICAL SCENARIOS FOR THE COLLECTION AND USE OF THE CONTENT OF RESEARCH BIOBANKS

Samples and data to be stored in a biobank may be collected in various ways. As a matter of example, a biobank may be implemented within a more extensive scientific research activity, such as before and in view of the conduction of a clinical trial, or in the course of clinical care, with left-over samples and related data being stored in a biobank and subsequently made available for research.[102] In the latter case, samples and tissues are usually linked to information about the person.[103] As underlined above, such a link, established either before or after the implementation of the biobank, is an important element for qualifying a collection as a biobank.

The existence of different practical modes of collecting samples and data and of implementing the biobank itself may cause some difficulties. In particular, a clear distinction between the primary and secondary uses of what is stored therein is difficult to conceptualise, as well as a homogeneous handling of the different possible situations in this regard. However, untangling the yarn of this issue is of utmost importance for the lawful use and processing of the content of a biobank, in particular when it comes to the legal requirements to be complied with when collecting biological samples and data.[104]

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[102] Nordberg, Ana "Biobank and Biomedical Research: Responsibilities of Controllers and Processors Under the EU General Data Protection Regulation." *GDPR and Biobanking*, edited by Slokenberga, Santa, Springer, 2021, pp. 61-90.

[103] Giesbertz, Noor A. A. et al. "Inclusion of Residual Tissue in Biobanks: Opt-in or Opt-out?"

[104] In particular, when it comes to the selection of the legal basis for the processing of personal data according to the GDPR. This aspect will be further analysed in the following Chapter.

To help categorise the matter, I believe that a fundamental distinction is possible between the following scenarios:

(a) when samples and data are collected specifically to be stored in a biobank. In this case, being stored in a biobank is the primary use of the samples and data (*Scenario 1: collection for biobanking purposes).* Participants are thus recruited for this specific purpose or, more generally, they are asked to undergo some kind of procedure (to hand over the data, to undergo a medical procedure in order to obtain the biological samples, etc) only in order to create, or increase the content of, the biobank. These samples and data will be subsequently used for one or multiple scientific research projects by researchers that are separated from the biobank itself and ask the biobank to get access to the samples and data;

(b) when the implementation of a biobank is ancillary to a broader scientific research activity performed on or with samples and data to be subsequently stored in the biobank itself for future use.[105] Indeed, the samples and data are collected for a specific research purpose in the first place, and at the same time they are stored in a biobank for future undefined research projects to be conducted by different researchers. Here, the primary use of the collection is to be used in the first scientific research project (*Scenario 2: collection for scientific research purposes*). In this eventuality, the entity that creates the biobank and conducts the first scientific research project is the same one, while the future research projects will be carried on by other researchers. This is for example the case of a biobank created in the context of a clinical trial;

(c) when the content of a biobank consists of left-over samples and data collected or more generally used for other purposes, for instance in order to provide health care, which represents their primary use. In this scenario, to be stored in a biobank is the secondary purpose of the samples and data, because participants are asked to provide a sample or hand over the data for a different

[105] The present work will not consider the case of a biobank built specifically in the context of a research project and exclusively for that purpose, without keeping the collection in place for future use. the reason for this choice relates to acknowledging that biobanks of this kind pose substantially different (and somewhat easier) legal and ethical issues than biobanks that store samples and data (also) for future use.

primary purpose, such as for instance undergoing a surgical procedure (*Scenario 3: collection for other purposes*).[106]

In the first scenario (a), samples and data are collected from patients or general donors specifically for the purpose of creating a biobank. Once the biobank is implemented, samples and data stored therein are made available for various research projects, either foreseeable or foreseen at the time of collection or not.

In the second (b), it is decided to organise and store in biobanks samples and data collected throughout a clinical trial or a different scientific research project. The biobank will be kept in place even after the end of the clinical trial, for future, undefined research projects possibly different from the first one.

Finally, scenario (c) concerns the hypothesis of the collection and processing of biological samples and data for various purposes that are different from the previous two, such as for instance for the provision of medical care or healthcare treatment, etc. In this case, left-over samples or already processed data are then stored in a biobank for future use.

As it will become apparent in the following pages, Scenarios 2 and 3 usually entail the same legal and regulatory issues.

I believe this distinction has fundamental consequences for the analysis that follows. In particular, most of the documents applicable to research biobanks, both soft law and hard law instruments, include the "primary-secondary purpose" distinction at the basis of their provisions. Therefore, to exemplify what constitutes a primary and a secondary purpose of the collection of samples and data for biobanking is essential to understand which norms are applicable.

It is now possible to provide an overview of the categorisations discussed above for the modes of collection HBSs and biobank data in Figure 1.

[106] A similar categorisation is also included in the Commentary on Guideline 11 of the CIOMS International Ethical Guidelines.

Modes of collection	HBSs	Biobank data
Scenario 1 - collection for biobanking purposes	Donated HBSs	Donated data HBSs data
Scenario 2 - collection for scientific research purposes	Left-over HBSs	Left-over data HBSs data
Scenario 3 - collection for other purposes	Left-over HBSs	Left-over data HBSs data

Figure 1

2.3 OTHER IMPORTANT TERMINOLOGIES

Other terms frequently used in the field and for the purposes of this analysis are worth being defined.[107]

First of all, widely used in this work will also be the term *biobanking*. It identifies the new field of biobank research and covers all the aspects of the biobank functioning, as well as the social, legal and ethical problems raised by it.[108] Therefore, while the term *biobank* refers to the collection itself in its materiality, the term *biobanking* is related to the field more generally and everything surrounding the activity of a biobank. In particular, *biobanking* refers to the process of acquisition and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as related information and data.[109]

Moreover, the term *governance* will be used in the context of biobanking according to the definition provided in this regard by the European Commission in its study "Biobanking for Europe – A challenge for governance". Here, governance is defined as "formally-constituted regulatory bodies, statute and other legal instruments, as well as informal mechanisms such as advisory boards, professional guidance, biobank policies and professional values and culture that help to guide decision-making" and the creation

[107] Throughout the work, it will be sometimes necessary to define other sectorial concepts related to specific topics or fields of inquiry. These terms will be defined in the related sections.
[108] Malsagova, Kristina, et al. "Biobanks-A Platform for Scientific and Biomedical Research." *Diagnostics (Basel, Switzerland)*, vol. 10, n. 7, pp. 1-21.
[109] Definition of *biobanking* given by ISO 20387:2020.

of sound governance for biobanks as one of the challenges for the European innovation system.[110] The governance of a biobank is especially complicated by technological innovations and the increased necessity for data sharing, both of which raise extremely diverse expectations from and obligations of the different stakeholders involved. Indeed, in the absence of a specific common regulation on the matter, a fixed governance mechanism is necessary for biobanks to guarantee the necessary quality of samples and data, a fair distribution of resources[111] and ensure participants' trust.[112]

Furthermore, the individuals providing samples and data to be stored in the biobank and used for the specific purposes of its existence will be addressed as *participants*, either when they actively consent to the storage of their samples and data or in case such activity is performed without their explicit consent.[113] *Participants* provide samples and data, which therefore become the *content* of the biobank itself.

As for the *content*, as mentioned biobanks store both biological samples and data. For the purpose of this analysis, it does not matter the specific type of biological samples to be stored in the biobank, as long as they are of human origin.

3 THE APPLICABLE LEGAL FRAMEWORK

As previously mentioned, there is no general applicable regulation to research biobanks (nor to biobanks in general, for that matter).[114] Therefore, the normative landscape is composed of a constellation of different sectorial regulations or legislative acts applicable to, among others, a specific biobank activity[115] or a specific content of the research biobank, either HBSs or biobank data.

Indeed, the applicable regulatory framework derives not only from the specificities of biobanking itself but also from the various fields somewhat involved and the normative interventions that occurred at multiple levels.[116] As a consequence, both hard-law and

[110] Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research, Biobanks for Europe. a challenge for governance, 2012.
[111] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona*.
[112] CIOMS International Ethical Guidelines. The aspect is further analysed in Chapter II.
[113] The specific cases in which this might happen will be explored below.
[114] Gaspari, Francesco "La Circolazione dei Dati Genetici e delle Biobanche: Limiti e Prospettive *de iure condendo"*; Macilotti, Matteo "Le Biobanche: Disciplina e Diritti della Persona"; Ducato, Rossana "Database Genetici, Biobanche e "Health Information Technologies."
[115] Gaspari, Francesco "La Circolazione dei Dati Genetici e delle Biobanche: Limiti e Prospettive *de iure condendo."*
[116] On the framework applicable to biobanks, through time, Tomasi, Marta "Il Modello Italiano di Regolamentazione Giuridica delle Biobanche: alla Ricerca di una Sintesi per una Materia Poliedrica";

soft-law instruments, as well as guidelines, non-binding self-regulation, soft rules of bioethics and soft modes of governance are included in the following paragraphs.[117]

The result is a fragmented regulatory landscape[118] composed of documents and rules from various sources and issuing bodies, with multiple levels of enforceability, not always clear at first glance.[119] This heterogeneity of applicable instruments mirrors the ontological complexity and fluidity of biobanks themselves,[120] which I partly described in the previous paragraphs.

This approach, i.e. the adoption of soft-law instruments instead of hard-law treaties, is usually criticised because of its lack of stability and enforceability, and consequently global governance on biobanks has been frequently called for.[121]

However, a soft-regulation approach on the matter is sometimes welcomed. For instance, as underlined by Fanni, the adoption of mainly soft-law instruments better responds to the necessities of bioethics and biolaw. Indeed, the matter is generally characterised on the one hand by fast development and therefore the necessity of a similar fast protection of the rights and interests possibly involved, and on the other hand by a plurality of different national views, which renders it particularly difficult to adopt a strong normative harmonised approach.[122]

In attempting to provide a comprehensive and clear view on the matter, I will divide the analysis between supranational instruments/acts, virtually applicable to any research

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Gaspari, Francesco "La Circolazione dei Dati Genetici e delle Biobanche: Limiti e Prospettive *de iure condendo"*; Vivas-Tesòn, Inmaculada "Bioresearch, Biobanks and Informed Consent from Vulnerable Donors in Spanish Law." *Europa e Diritto Privato,* vol. 4, 2013, pp. 1069-1095; Scaffardi, Lucia "Legal Protection and Ethical Management of Genetic Databases: Challenges of the European Process of Harmonization." *Jean Monnet Working Paper,* vol. 19, 2008, pp. 1-41; Godard, Béatrice, et al. "Data Storage and DNA Banking for Biomedical Research: Informed Consent, Confidentiality, Quality Issues, Ownership, Return of Benefits. a Professional Perspective." *European journal of human genetics: EJHG,* vol. 11, n. 2, 2003, pp. 88-122.

[117] Mayrhofer, Michaela and Barbara, Prainsack, "Being a Member of the Club: The Transnational (Self-)Governance of Networks of Biobanks." *International Journal of Risk Assessment and Management*, vol. 12, n. 1, 2009, pp. 64–79.

[118] Tzortatou, Olga, et al. "Biobanking Across Europe Post-GDPR: A Deliberately Fragmented Landscape":

[119] Indeed, the variety of applicable soft and hard law instruments applicable to biobanking has been defined as a patchwork by Maestri, Enrico "Biobanche e Consenso Informato tra Finzioni Scientifiche e Finzioni Giuridiche." *Filosofia del Diritto e Nuove Tecnologie. Prospettive di Ricerca tra Teoria e Pratica*, edited by Brighi, Raffaella, and Silvia, Zullo, Aracne Editrice, 2015, pp. 511-524.

[120] Tomasi, Marta "Il Modello Italiano di Regolamentazione Giuridica delle Biobanche: alla Ricerca di una Sintesi per una Materia Poliedrica."

[121] Chen, Haidan, and Pang, Tikki "A Call for Global Governance of Biobanks." *Bulletin of the World Health Organization*, vol. 93, n. 2, 2015, pp. 113-7.

[122] Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*.

biobank (at least if implemented in Europe), and national ones, therefore mainly relevant for Italian research biobanks.

The analysis of the international legal documents is relevant not only because of the necessity for biobanks to cooperate among them regardless of their location in order to promote the advancement of scientific research and precision medicine, but also because of the inherent transnationality of any field in which law, science and technology are intertwined,[123] such as biobanking.

The following paragraphs will therefore present analytically the different sources of obligations, prescriptions or requirements for biobanking, addressing in particular the issue of their theoretical applicability to the field and their enforceability. The aim is to provide a clear overview of the regulatory (albeit fragmented) landscape.

An extensive analysis of the relevant norms or prescriptions of each instrument in the parts relevant to this work will be conducted in Chapter III.

3.1 SUPRANATIONAL LEVEL

At the supranational level, there are soft law and hard law instruments relevant to research biobanks. In the following paragraphs, I will provide an overview of both.

3.1.1 SOFT LAW INSTRUMENTS

First of all, there are international soft law instruments devoted to addressing some of the issues of research biobanks, in particular those adopted by Intergovernmental bodies. These instruments establish the principles that should be respected in conducting scientific research, even though they lack legal enforceability, and are primarily enacted by the following bodies or organisations: the World Medical Association (WMA), the Organisation for Economic Co-operation and Development (OECD), the UNESCO and the Council of Europe.

The OECD Recommendations and the UNESCO Declarations intend to provide general principles and a shared basis at the international level for future hard laws regulating the matter. While being non-binding instruments, their relevance to the discourse derives in particular from the fact that they are often cited or more generally considered by hard

[123] Santosuosso, Amedeo and Sara, Azzini "Scienza, Tecnologia e gli Attuali Flussi Giuridici Trasnazionali." *Trattato di Biodiritto. Ambito e Fonti del Biodiritto,* edited by Tallachini, Mariachiara and Stefano, Rodotà, Giuffrè editore, 2010, pp. 731-770; Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona*.

laws relevant for biobanking or scientific research[124] and by the European Court of Human Rights in its judgments.[125]

The high influence and prevalence of soft law instruments to provide principles and guidance to the field of biobanking have at least the following three reasons, which in turn derive from some characteristics of research biobanks.

First of all, soft law instruments regularly emerge to provide guidance principles for biobanking because of the absence of a binding regulation on the matter and given the need for biobanks to have protocols and guidelines to ethically conduct their activities. As affirmed by Mayrhofer and Prainsack this "can be seen as a pragmatic way of self-governance from the side of biobankers for the sake of both their scientific objectives and the reputation of their careers and institutions".[126]

Moreover, such an approach to biobanking, i.e. the adoption of principles or best practices approach instead of specific treaties or hard law instruments, supports the open-endedness of the possible scientific purposes of research biobanks.

Finally, this tendency also resembles the more general one adopted for regulating matters related to technology and science, such as biolaw in particular. One of the reasons for such an approach is the so-called law lag, i.e. the (ontological) difficulty of law to keep up with technoscientific advances.[127]

3.1.1.1 THE DECLARATION OF HELSINKI AND THE DECLARATION OF TAIPEI

The WMA is an international confederation of medical associations whose aim is to protect human rights and values in clinical or research activities.[128] The main international

[124] Kaye, Jane, and Organisation for Economic Co-operation and Development "Building a Foundation for Biobanking: The 2009 OECD Guidelines on Human Biobanks and Genetic Research Databases (HBGRDs)." *European Journal of Health Law*, vol. 17, n. 2, 2010, pp. 187-190; Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona*.

[125] On the issue, more extensively, Glas, Lize R. "The European Court of Human Rights' Use of Non-Binding and Standard Setting Council of Europe Documents." *Human Rights Law Review*, vol. 17, n. 1, 2017, pp. 97–125.

[126] Mayrhofer, Michaela and Barbara, Prainsack, "Being a Member of the Club: The Transnational (Self-)Governance of Networks of Biobanks."

[127] Tallacchini, Mariachiara "To Bind or Not Bind? European Ethics as Soft Law." *Science and Democracy. Making Knowledge and Making Power in the Biosciences and Beyond*, edited by Hilgartner, Stephen, et al. Routledge, 2015, pp. 156- 175.

[128] World Medical Association, Who we are, 2017 available at https://www.wma.net/who-we-are/; Chassang, Gauthier, and Emmanuelle, Real-Sebbag "Research Biobanks and Health Databases: The WMA Declaration of Taipei, Added Value to European Legislation (Soft and Hard Law)."

documents adopted by the WMA and relevant for biobanking are the Declaration of Helsinki and the Declaration of Taipei.

On the one hand, the Declaration of Helsinki – Ethical principles for medical research involving human subjects was enacted in 1964 and last revised in 2013. It focuses exclusively on scientific research and provides a set of ethical principles for medical research involving human subjects, including research on identifiable human material and data involving biobanks. Moreover, some general provisions specifically address the matter of biobanks.[129]

Therefore, such a Declaration is relevant in the present work not only because of the specific purpose of the type of biobanks under scrutiny here but also because of the Declaration's general importance in the field. Indeed, it has been defined as a cornerstone[130] guideline, the most influential[131] and the most significant[132] on the ethics of biomedical research and it is frequently cited in legally binding instruments, such as the Clinical Trial Regulation (Regulation (EU) 2014/536) in §43,[133] or by other soft-law instruments, such as the UNESCO Universal Declaration on Bioethics and Human Rights in its introduction. Therefore, it is a "basic reference point in the ethics of biomedical research".[134] In its last revision, the updates mainly focused on prioritizing the rights and interests of the research subjects.

On the other hand, the new Declaration on the Ethical Considerations regarding Health Databases and Biobanks (Declaration of Taipei) was adopted in 2016 during the WMA's 67th General Assembly in Taipei (Taiwan) as an update of the Declaration previously adopted in 2022. Its aim is to establish ethical principles for scientific research activities

[129] See for example paragraph 32 on informed consent, which will be analysed in Chapter II.
[130] Carlson, Robert V., et al. "The Revision of the Declaration of Helsinki: Past, Present and Future." *British Journal of Clinical Pharmacology,* vol. 57, n. 6, 2004, pp. 695-713.
[131] Ashcroft, Richard "The Declaration of Helsinki." *the Oxford textbook of clinical research ethics*, edited by Emanuel, Ezekiel J., Oxford University Press, 2008, pp. 141–148; Goodyear, Michael D. E., et al. "The Declaration of Helsinki." *BMJ (Clinical research ed.),* vol. 335, n. 7621, 2007, pp. 624–625.
[132] Griffin, John P., et al. "Appendix 1: Declaration of Helsinki." *the Textbook of Pharmaceutical Medicine*, edited by Griffin, John P. and John, O'Grady, Blackwell Publishing Ltd, 2005, pp. 723-726.
[133] In which it is established that "The members of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) have agreed on a detailed set of guidelines on good clinical practice which is an internationally accepted standard for designing, conducting, recording and reporting clinical trials, consistent with principles that have their origin in the World Medical Association's Declaration of Helsinki."
[134] Ehni, Hans-Joerg and Urban, Wiesing "Illegitimate Authorship and Flawed Procedures: Fundamental Formal Criticisms of the Declaration of Helsinki." *Bioethics*, vol. 33, n. 3, 2018, pp. 319-325.

involving human participants[135], in addition to those included in the Declaration of Helsinki.

When compared to other soft instruments on the matter, the innovation of the Declaration of Taipei rests on its entire focus on regulating biobanks and health databases, contrary to other acts that address scientific research more generally while including certain provisions applicable to biobanks.[136] This approach mirrors the one usually adopted at the national level when a specific biobank legislation is adopted,[137] and is coherent with the very nature of biobanks, as highlighted before.

Indeed, as mentioned, biobanks are not research projects per se, but they provide samples and data used for research purposes. When the creation of a biobank is a step in a research project, it is usually a tool to support the latter as well as future projects. Addressing biobanking activities enables the recognition of its specificity. The Declaration of Taipei then ensures the respect of the principles applicable to scientific research by establishing its complementarity with the Declaration of Helsinki.

Unlike the Declaration of Helsinki, the Declaration of Taipei adopts an innovative approach and aims to provide principles for a wide range of uses of the content of biobanks (and health databases) other than individual use, thus including non-health-related purposes or commercial purposes and envisioning the possibility of using HBS and data for purposes different from those identified at the time of collection.[138]

More generally, the Declarations establish that the biobank governance shall be based on the principles of protection of individuals, transparency, participation and inclusion, and accountability.[139]

3.1.1.2 THE CIOMS INTERNATIONAL ETHICAL GUIDELINES

Lastly revised in 2016, the International Ethical Guidelines for Health-related Research Involving Humans (CIOMS International Ethical Guidelines) was adopted by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the

[135] Paragraph 1 of the Preamble.
[136] Chassang, Gauthier, and Emmanuelle, Real-Sebbag "Research Biobanks and Health Databases: The WMA Declaration of Taipei, Added Value to European Legislation (Soft and Hard Law)."
[137] See as a matter of example Finland and Sweden.
[138] On the issue, see Iacomussi, Sofia "Regulating Biobanks: an Ethical Analysis of the Spanish Law and the New Challenges of the Bigdata-driven Biomedical Research."
[139] Chassang, Gauthier, and Emmanuelle, Real-Sebbag "Research Biobanks and Health Databases: The WMA Declaration of Taipei, Added Value to European Legislation (Soft and Hard Law)."

World Health Organization (WHO) and has been defined as the most comprehensive set of ethical guidelines.[140]

The CIOMS International Ethical Guidelines contain principles applicable to biobanks in Guideline 11 and 12, which establish that biobanks shall have a governance system in place and require informed consent for almost every use for research purposes of the biological samples and health data, with a general strong focus on consent and individual control as the primary ethical values to guide scientific research.[141]

The International Ethical Guidelines are relevant for research biobanks, independently of the concrete practical scenario for the collection of its content (*Scenario 1 - collection for biobanking purposes; Scenario 2 - collection for scientific research purposes; Scenario 3 - collection for other purposes*).

Indeed, in the Preamble it is clearly affirmed that "the term 'health-related research' in the Guidelines refers to activities designed to develop or contribute to generalizable health knowledge within the more classic realm of research with humans, such as observational research, clinical trials, biobanking and epidemiological studies". By doing so, the document broadens the meaning of "human subject research" by including also scientific research without the direct involvement of an individual, such as when it is conducted with already available biological samples or health data.[142]

3.1.1.3 THE OECD RECOMMENDATIONS

Furthermore, two Recommendations from the OECD are particularly relevant for biobanks. First of all, in October 2009 the OECD Council adopted the Recommendation on Human Biobanks and Genetic Research Databases (OECD Recommendation 2009), whose aim is to provide guidelines for the establishment, management, governance, operation, access, use and discontinuation of Human Biobanks and Genetic Research Databases, being research biobanks the focus of the entire document. The document recognises that the primary purpose of these databases is to foster scientific research and aims at improving advancements in research, through access to the biobanks' content,

[140] For instance, the Pan American Health Association has described the CIOMS International Ethical Guidelines as "the most comprehensive, up-to-date and detailed international consensus guidelines for human research." Report from Pan American Health Association. January 30, 2018.

[141] Ballantyne, Angela "Adjust the Focus: a Public Health Ethics Approach to Data Research." *Bioethics*, vol. 33, n. 3, 2019, pp. 357-366.

[142] Pormeister, Kärt "Genetic Research and Consent: on the Crossroads of Human and data research." *Bioethics* vol. 33, n. 3, 2019, pp. 347-356.

while at the same time enduring respect for participants, their human dignity, fundamental freedoms and human rights.[143]

Secondly, in 2017 the Recommendation on Health Data Governance (OECD Recommendation 2017) was adopted, which includes conditions for encouraging greater availability and processing of health data within countries and across borders for health-related public policy objectives while minimizing or managing risks to privacy and security. Therefore, it applies to the access to and processing of personal health data for health-related public interest purposes, such as improving health care quality, safety and responsiveness; reducing public health risks; discovering and evaluating new diagnostic tools and treatments to improve health outcomes, etc.

3.1.1.4 THE UNESCO DECLARATIONS

Moreover, in 1997 UNESCO unanimously adopted[144] the Universal Declaration on the Human Genome and Human Rights (UNESCO Universal Declaration on Human Genome), which in its very first article proclaims the value of the human genome, "fundamental unity of all members of the human family", "recognition of their inherent dignity and diversity" and thus "heritage of humanity". The Declaration further recognises the importance of freedom of research, especially on the human genome, and the necessity of conducting it to improve public health (art. 12).

Subsequently, UNESCO adopted the International Declaration on Human Genetic Data (UNESCO International Declaration) and the Universal Declaration on Bioethics and Human Rights (UNESCO Universal Declaration on Bioethics) in 2003 and 2005 respectively. As for the first one, the International Declaration aims to ensure in the context of the collection and processing of genetic data and biological samples the protection of human dignity, personal data, and fundamental freedoms, as well as freedom of expression and advancement of scientific research.[145] On the other hand, the second has a more general scope, providing that it aims at addressing the ethical issues related to

[143] Kaye, Jane, and Organisation for Economic Co-operation and Development "Building a Foundation for Biobanking: The 2009 OECD Guidelines on Human Biobanks and Genetic Research Databases (HBGRDs)."

[144] Macillotti, Matteo, et al. "La Disciplina Giuridica delle Biobanche." *Pathologica*, vol. 100, 2008, pp. 86-101.

[145] *Ibid*

medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.[146]

All three Declarations include a strong focus on informed consent and the information to be provided to participants, as well as the necessity to preserve the right to self-determination of the person whose data and samples are used for research purposes, within a more general balancing of the different public and private interests at stake.[147] Moreover, the International Declaration from 2003 also includes an article referred to biobanks stating that "The persons and entities responsible for the processing of human genetic data, human proteomic data and biological samples should take the necessary measures to ensure the accuracy, reliability, quality and security of these data and the processing of biological samples. They should exercise rigour, caution, honesty and integrity in the processing and interpretation of human genetic data, human proteomic data or biological samples, in view of their ethical, legal and social implications" (art. 15).

3.1.1.5 THE RECOMMENDATION R(2016)6

Finally, among the soft law instruments, in 2016 the Council of Europe adopted Recommendation R(2016)6 on research on biological materials of human origin[148], which builds on and supersedes the previous Recommendation R(2006)4.[149] In the Recommendation of 2016, the Council of Europe stems from the assumption that new developments in biobanking and biomedical research bring along the necessity of a higher level of protection of the dignity and the fundamental rights of the individuals whose biological materials are stored and used for research, while at the same time recognising the freedom of scientific research.[150] These difficulties are primarily related to the increasingly diverse origins of biological materials to be stored and used, the difficulty in

[146] Art. 1 para. 1

[147] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona.*

[148] Recommendation R(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin.

[149] As clearly stated in the Explanatory Memorandum, Recommendation R(2016)6 is the outcome of the re-examination of Recommendation R(2006)4. https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016805c204c. See also on this point Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*.

[150] Explanatory memorandum.

guaranteeing their non-identifiability, and the increasing amount of multicentre research projects using these samples.[151]

At the same time, the Recommendation recognises the importance of scientific research conducted on and with biological samples and the related information that may be extracted from them. While the Recommendation never explicitly mentions biobanks, its Art. 2 establishes that it applies to specific activities, which include the obtaining and storage of biological materials of human origin and eventually associated data for storage for future research purposes, and the use in a research project of the biological material either already stored or obtained for another purpose. As previously analysed, these activities are those qualifying a research biobank.[152]

Moreover, the specific applicability of the Recommendation to research biobanks and not research projects more generally is further specified in Art. 2, where "the use in a specific research project of biological materials of human origin removed for the sole purpose of that project" is explicitly excluded from the material scope of application of the document.

As a matter of ethical principles, the Recommendation aims at ensuring that biobanking activities (1) respect the dignity, autonomy, privacy and confidentiality of individuals, and (2) have a public health end and contribute to the benefit of society. The first goal is reached by giving individuals control over the use of their data and biological material, in particular by asking for their consent and providing certain information on the functioning of the biobank itself.

Finally, the Recommendation lists the 4 guiding principles for the development of a trustworthy biobank governance, namely Protection of Individuals, Transparency, Participation and Inclusion, Accountability, and the main governance issues to address.

Differently from the previous Recommendation R(2006)4,[153] in the new document, the Council of Europe extensively elaborates on the level and type of information to be provided to participants and the provisions surrounding informed consent.

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[151] *Ibid*

[152] Moreover, paragraph 2 of the Recommendation R(2016)6 explicitly excludes from its application "the use in a specific research project of biological materials of human origin removed for the sole purpose of that project)."

[153] Recommendation R(2006)4.

3.1.2 HARD LAW INSTRUMENTS

Apart from the multiple soft law instruments listed above, there are specific hard law ones devoted to either an activity of the biobank or the processing of its content. Differently from above, all the instruments listed in this paragraph are legally binding in all Member States.

All the following documents do not specifically regulate biobanks, but some of the core activities characterising biobanks, such as the processing of personal information, the use of human biological material, and some of the prerequisites for research involving humans. This is because following the Subsidiarity Principle only Member States have the competence to issue regulations and legislations on health matters, which include biobanking.[154]

First of all, the Human rights framework applicable to biobanking is composed of the EU Charter of Fundamental Rights and Freedoms of the European Union (EU Charter), the European Convention on Human Rights (ECHR) and the International Convention on Economic, Social and Cultural Rights.

In particular, concerning the first one, the EU Charter was formally proclaimed in Nice in December 2000 by the European Parliament, the Council of the European Union and the Commission and became legally binding in all Member States with the entry into force of the Treaty of Lisbon in 2009. From that moment onwards, the EU Charter has the same legal value as the EU treaties (art. 6 TUE).

More generally, the Charter is considered to contain "several principles which can be relevant in the context of research"[155] and establishes multiple rights to be protected.

Both the EU Charter and the ECHR do not address specifically biobanking or scientific research involving biological samples or data, but they provide a number of provisions that shall be respected in performing these activities.[156]

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[154] Mayrhofer, Michaela and Barbara, Prainsack, "Being a Member of the Club: The Transnational (Self-)Governance of Networks of Biobanks." Critical on this, Slokenberga, Santa "Setting the Foundations: Individual Rights, Public Interest, Scientific Research and Biobanking."

[155] European Commission. (2013). Ethics for researchers. Facilitating Research Excellence in FP7: 5. Retrieved March 2, 2018, from https://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf; Pormeister, Kärt "Genetic Research and Consent: on the Crossroads of Human and data research."

[156] Pormeister, Kärt "Genetic Research and Consent: on the Crossroads of Human and data research."

As for the relationship between these two human rights instruments, art. 52 para. 3 of the EU Charter establishes that "in so far as this Charter contains rights which correspond to rights guaranteed by the Convention for the Protection of Human Rights and Fundamental Freedoms, the meaning and scope of those rights shall be the same as those laid down by the said Convention", thus referring not only to the Charter itself and its Protocols but also to the by the case-law of the European Court of Human Rights and by the Court of Justice of the European Union.[157]

Furthermore, and when it comes to the regulation applicable to specific activities or content of the biobank, the General Data Protection Regulation (EU) 2016/679 (GDPR)[158] shall be referred to and is applicable to any processing of personal data within the geographical scope of application of the Regulation. Indeed, in Recital 157 the GDPR specifically refers to research based on data registries,[159] whose potential for the advancement of research and society as a whole is underlined.

Moreover, in the context of data protection, two other hard law instruments will be relevant for our analysis and have (or will have) an impact on biobanking: Regulation 2022/868 (Data Governance Act - DGA) and Proposal for a Regulation on the European Health Data Space (EHDS).

On the one hand, the DGA is a horizontal regulatory framework entered into force on 23rd June 2022 and is fully applicable in all Member States from September 2023. It is a key pillar of the European strategy for data, whose aim is to create a single market for data in Europe, placing at first the interests of the individual whose data are used for data-

[157] See the Explanation to the EU Charter provided by the European Union Agency for Fundamental Rights at https://fra.europa.eu/en/eu-charter/article/52-scope-and-interpretation-rights-and-principles?page=1#explanations.

[158] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation).

[159] Recital 157 GDPR "By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer and depression.

On the basis of registries, research results can be enhanced, as they draw on a larger population. Within social science, research on the basis of registries enables researchers to obtain essential knowledge about the long-term correlation of a number of social conditions such as unemployment and education with other life conditions. Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people and improve the efficiency of social services. In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law."

driven innovations that will benefit society as a whole.[160] The regulation lays down a horizontal set of rules and conditions relevant to developing all the Common European data spaces as envisioned in the European Data Strategy.[161]

On the other hand, the EHDS is a health-sector specific regulatory proposal. Indeed, within the European Strategy for data, different Common European data spaces will be developed "in strategic economic sectors and domain of public interest", within which is listed a Common European health data space. As a sector-specific legislation, it builds upon other horizontal relevant regulations such as the GDPR and the DGA.[162] In particular, the "scientific research regime 2.0" derived from the joint application of the GDPR and the EHDS might become "a data research standard within the EU".[163]

The EHDS aims to regulate primary and secondary uses of health data, support health research and innovation, personalised medicine, as well as the implementation of some of the data subjects' rights in the context of health data sharing.[164] Provisions of Chapter IV EHDS related to the secondary use of health data are particularly relevant for biobanks and will be further discussed.

Finally, two binding instruments relevant in the context of scientific research are worth mentioning, which however do not apply to research biobanks: Regulation 536/2014 (Clinical Trial Regulation) and Directive 2004/23/EC.

Indeed, on the one hand, the Clinical Trial Regulation establishes the applicable legal framework for clinical trials, i.e. clinical studies in which a particular therapeutic strategy that does not fall within normal clinical practice is applied to a subject.[165] Therefore, this

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[160] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – a European strategy for data, 2020.

[161] Baloup, Julie, et al. *White Paper on the Data Governance Act*, CiTiP Working Paper, 2021.

[162] Shabani, Masha and Sami, Yilmaz "Lawfulness in Secondary Use of Health Data – Interplay Between Three Regulatory Frameworks of GDPR, DGA EHDS." *Technology and Regulation*, vol. 2022, 2022, pp. 128–134; EDPS, Preliminary Opinion 08/2020 on the European Health Data Space, 2020.

[163] Slokenberga, Santa "Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject that the Proposed EHDS Regulation Promises to Bring Along." *Technology and Regulation*, vol. 2020, 2022, pp. 135–147.

[164] Shabani, Masha and Sami, Yilmaz "Lawfulness in Secondary Use of Health Data – Interplay Between Three Regulatory Frameworks of GDPR, DGA EHDS"; Slokenberga, Santa "Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject that the Proposed EHDS Regulation Promises to Bring Along"; Lalova-Spinks, Teodora, et al. "The Application of Data Altruism in Clinical Research Through Empirical and Legal Analysis Lenses." *Frontiers in Medicine*, 2023, pp. 1-14.

[165] See Art. 1 Clinical Trials Regulation for the definition of the purpose and art. 2 for the definition of "clinical trial."

Regulation is not directly applicable to biobanks, independently of the concrete mode for collection adopted, because biobanks are not research projects per se, as mentioned.
Indeed, it appears evident that on the one hand the collection of HBSs and data for future and undefined research purposes (i.e. biobanking as defined previously in this paragraph) is not a "clinical trial" for the purposes of Regulation 536/2014 and therefore is outside of the scope of its provisions. On the other hand, the biobank or the entity that runs it does not usually directly intervene or participate in the scientific research project identified from time to time (which however may well be regulated by the Clinical Trial Directive, under given circumstances).
On the other, Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells specifies in Art. 1 and Art. 2 that it applies to "the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications and of manufactured products derived from human tissues and cells i*ntended for human applications*".[166]
However, while theoretically its norms might apply to the biobanking field,[167] Art. 2 restricts the scope of the Directive to the donation, procurement, testing, etc of human tissues and cells, but only if intended for human applications. Considering that Art. 3 lett. (l) defines "human application" as "the use of tissues or cells on or in a human recipient and extracorporeal application." it appears clear that Directive 2004/23/EC cannot be applied to research biobanks, as previously defined.[168] Indeed, the biological samples and tissues are stored in the biobank not for future human application, but to be subsequently used for research projects.[169]
Moreover, Recital 11 of the Directive clearly specifies that "this Directive does not cover research using human tissues and cells, such as when used for purposes other than application to the human body".

[166] Emphasis added.
[167] So much so that Art. 3 lett. (o) defined the "tissue establishment" as "a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken." thus potentially resembling the general definition of a *biobank.*
[168] However, it would apply to different typed of biobanks. On the topic, Tomasi, Marta "Il Modello Italiano di Regolamentazione Giuridica delle Biobanche: alla Ricerca di una Sintesi per una Materia Poliedrica."
[169] As a consequence, the corresponding national legislative acts will not be analysed in the paragraph devoted to the discussion of the national legal framework.

3.1.3 THE OVIEDO CONVENTION

A separate analysis is now devoted to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention) and its Additional Protocols. The Convention entered into force in 1999 and is generally recognised as the first international document in bioethics and the only one binding for the 29 Member States of the Council of Europe that ratified it.[170]
The Convention aims to establish norms for the protection of human beings in the context of scientific research. Indeed, it builds on the assumption that innovations in biology and medicine might at least theoretically violate human dignity and fundamental rights and freedoms of human beings, being thus necessary to preserve the latter, while at the same time ensuring proper use of scientific innovations for present and future generations.[171]
To this end, Art. 2[172] of the Convention intends to protect human beings on three different levels:

- *individual level*, by establishing fundamental rights and interests of the individual;
- *social level*, by including the possibility of balancing private and public interests under specific circumstances, including whenever restricting one's individual rights is necessary for protecting those of others or other collective interests;[173]
- *universal level*, by explicitly protecting the human genome.[174]

As mentioned, the Convention establishes multiple principles to be followed in the context of the application of biology and medicine (Art. 1). In order to determine whether the Oviedo Convention applies to research biobank, it is first of all necessary to evaluate whether Convention itself and its Additional Protocols are legally binding for Italy.
Indeed, in Italy the law authorising the ratification of the Convention was enacted in 2001 (Law n. 145/2001). However, Italy never completed the ratification process,[175] because

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[170] Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea.*
[171] In these terms, see the Preamble of the Convention.
[172] Art.2 of the Oviedo Convention: "The interests and welfare of the human being shall prevail over the sole interest of society or science."
[173] Art. 26 of the Oviedo Convention. "(1) No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others."
[174] Campiglio, Cristina "Le Fonti Internazionali ed Europee in Materia di Biomedicina." *Le Scienze Biomediche e il Diritto,* edited by Santosuosso, Amedeo, et al. Ibis, 2010, pp. 61-74.
[175] The lack of completion of the ratification process has been defined as "unlikely unintentional." Casonato, Carlo *Introduzione al Biodiritto,* Giappichelli Editore, 2012.

the instrument of ratification was never deposited, an essential and conditioning constitutive element of the ratification process according to the provisions of the Vienna Convention.[176] Consequently, neither the Oviedo Convention nor its Additional Protocols entered into force in the Italian legal framework.

Therefore, it remains to be established whether these norms may be considered legally binding for Italy for other reasons, and the following two are particularly relevant.

First of all, on a general level, the Italian Corte di Cassazione established that the Oviedo Convention is to be used to interpret national norms in order to provide an interpretation of the latter in line with the provisions of the Convention, as much as possible. However, in case of contrast between the two, i.e. between national norms and provisions of the Oviedo Convention, the former shall prevail.[177]

Indeed, the Oviedo Convention cannot benefit from the special regime and legal value applicable to European legal instruments (art. 117 Italian Constitution, but also Art. 10 and 11), because such a Convention pertains to the broader group of international treaties. Nor is it possible to equate it to the ECHR and thus apply its special regime.[178] As a consequence, the Convention cannot directly prevail over national provisions.

However, some of its provisions might also be eventually considered either included among the fundamental principles of Art. 2 TUE, binding for the European Union, or the expression of already existing international principles. Both theories are advanced by De Angelis for the requirement of informed consent.[179]

Therefore, while not being directly binding in Italy per se, the Oviedo Convention might still influence the interpretation or application of national norms (as well as their conceptualisation from the outset) because of its value as interpretative instrument or carrier of international principles.

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[176] Art. 11 and in particular art. 16 of the Vienna Convention on the Law of Treaties "Unless the treaty otherwise provides, instruments of ratification, acceptance, approval or accession establish the consent of a State to be bound by a treaty upon: (a) their exchange between the contracting States; (b) their deposit with the depositary; or (c) their notification to the contracting States or to the depositary, if so agreed." On the importance of the deposit of the instrument of ratification, see also Italian Constitutional Court order n. 282/1983 and sentence n. 379/2004. More extensively on this point, Casonato, Carlo *Introduzione al Biodiritto*; Penasa, Simone "Alla Ricerca dell'Anello Mancante: il Deposito dello Strumento di Ratifica della Convenzione di Oviedo." Forum di Quaderni Costituzionali, 2007, pp. 1-10.

[177] Corte di Cassazione sentence of the 16th of October 2007, n. 21748, para.7.2.

[178] De Angelis, Fernando "Consenso Libero ed Informato: la Convenzione di Oviedo nell'Articolato Contesto Storico e Giuridico delle Fonti." *Medicina e Morale*, vol. 65, n. 1, 2016, pp. 57-67.

[179] De Angelis, Fernando "Consenso Libero ed Informato: la Convenzione di Oviedo nell'Articolato Contesto Storico e Giuridico delle Fonti."

3.2 (BINDING AND NON-BINDING) INSTRUMENTS AT THE NATIONAL LEVEL

Mirroring the situation at the supranational level, biobanks lack an ad hoc regulation in the Italian national context as well.[180] Therefore, the applicable provisions shall be derived from different level sources, both binding and non-binding instruments, in particular those adopted by administrative authorities upon delegation by the legislator. For this reason, the Italian framework has been defined as a "hybrid model".[181]

Indeed, at the national level three main regulatory models may be identified when it comes to biobanks: 1) adoption of a specific regulation, which is the model adopted for instance by Spain and Belgium; 2) adoption of a hybrid model,[182] i.e. both hard and soft law domestic instruments applicable; 3) reliance on the international guidelines and instruments.[183] Indeed, Italy pertains to the second model.

As for the legally binding instruments, it is worth mentioning first of all the Legislative Decree n. 101/2018 whose aim is the alignment of the already existing domestic legislation (in particular Legislative Decree n. 196/2003) to the GDPR.[184] In this regard, an important point of reference[185] is the General Authorisations issued by the Italian Data Protection Authority (DPA) n. 8/2016 on the processing of genetic data and n. 9/2016 on the processing of personal data for scientific research purposes, as confirmed and modified by Provvedimento n. 146/2019 issued by the Garante according to Art. 21(1) of the Legislative Decree 101/2018.[186]

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[180] Penasa, Simona and Marta, Tomasi "The Italian Way for Research Biobanks After GDPR: Hybrid Normative Solutions to Balance the Protection of Individuals and Freedom of Research." *GDPR and biobanking,* edited by Slokenberga, Santa, Springer, 2021, pp. 309-322; Stefanelli, Stefania, "Italy."

[181] See Italian DPA, Decision n. 389, 6 October 2016; Tribunal of Cagliari, Sez. I, decision n. 1569/2017; Italian DPA, Decision n. 561, 21 December 2017. On the topic, Penasa, Simona and Marta, Tomasi "The Italian Way for Research Biobanks After GDPR: Hybrid Normative Solutions to Balance the Protection of Individuals and Freedom of Research."

[182] Penasa, Simona and Marta, Tomasi "The Italian Way for Research Biobanks After GDPR: Hybrid Normative Solutions to Balance the Protection of Individuals and Freedom of Research."

[183] Provvedimento recante le prescrizioni relative al trattamento di categorie particolari di dati, ai sensi dell'art. 21, comma 1 del d.lgs. 10 agosto 2018, n. 101 del 5 giugno 2019, published in G.U. n. 176 of the 29th of July 2019, available at https://www.garanteprivacy.it/home/docweb/-/docwebdisplay/docweb/9124510.

[184] Throughout the thesis, the Legislative Decree 196/2003 as subsequently modified, in particular by the Legislative Decree 101/2018 will be referred to as the Italian Privacy Code.

[185] Penasa, Simona and Marta, Tomasi "The Italian Way for Research Biobanks After GDPR: Hybrid Normative Solutions to Balance the Protection of Individuals and Freedom of Research."

[186] Under the previous regime and in particular according to Art. 26 of the old version of the Legislative Decree 196/2003 the processing of particularly sensitive categories of data was possible only upon consent of the data subject and after having obtained a specific authorisation to the processing by the Italian DPA.

Moreover, a recent Italian Law n. 3/2018 charged the Italian Government with the task of enacting various Legislative Decrees containing provisions on clinical trials on medicinal products for human use, in particular with the aim of simplifying the processing for research purposes of biological samples previously collected in Scenarios 2 or 3, under the condition of obtaining the patient's informed consent beforehand.[187] Subsequently, the Higher Institute of Healthcare was assigned the task of defining the criteria for such a collection.[188]

Furthermore, the Italian DPA adopted the "Deontological rules for processing for statistical or scientific purposes) on December 19th, 2018. According to Art. 2 paragraph 1 the Deontological rules refer to "all processing operations carried out for statistical and scientific purposes - in accordance with the methodological standards of the relevant subject area - which are carried out by universities, other research bodies or institutes and scientific societies, as well as by researchers working within such universities, research bodies, research institutes and members of such scientific societies".

Finally, as far as the Human rights framework is concerned, the Italian Constitution shall be referred to as well.

As for the non-binding instruments, it is worth mentioning the Guidelines for the institution and the certification of biobanks issued by the National Committee for Biosecurity and Biotechnology in 2006, which provides principles and guidelines to implement a biobank.[189]

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to this end, Art. 40 of the old version of the Legislative Decree 196/2003 established that the Italian DPA had the duty to issue the so-called *General Authorisations,* i.e. administrative provisions which established a set of rules applicable to these types of processing activities. Through time, therefore, the Italian DPA has issued various General Authorisations, including the numbers 8/2016 and 9/2016. However, with the advent of the GDPR, these Authorisations should have been considered abolished. In order for this not to happen, the Italian legislator introduced in Art. 21 of the Legislative Decree 101/2018 the possibility of the Italian DPA to identify with an ad hoc normative act those provisions included in the General Authorisations and referred to processing related to Art. 6(1)(c) and (e), as well as Art. 9(2)(b) and (4) GDPR that were deemed compatible with the GDPR and there that would have continued to be applicable. All the other General Authorisations, as well as the provisions included therein, would have ceased to have any effect under the Italian legal framework. to this end, the Italian DPA adopted the Provvedimento n. 146 of the 5th of June 2019, according to which only the General Authorisations 1/2016, 3/2016, 6/2017, 8/2016 and 9/2016 remained in force. On this, see Penasa, Simona and Marta, Tomasi "The Italian Way for Research Biobanks After GDPR: Hybrid Normative Solutions to Balance the Protection of Individuals and Freedom of Research."

[187] Cannovo, Nunzia, et al. "Regulation of Biobanks in Italy." *Frontiers in pediatrics* vol. 8 n. 415, 2020, pp. 1-5.

[188] Italian Legislative Decree n. 52/2019.

[189] For a more comprehensive analysis of the non-binding national instruments, see Calzolari, Alessia, et al. "Review of the Italian Current Legislation on Research Biobanking Activities on the Eve of the

4 STRUCTURE OF THE WORK

After having clarified some of the fundamental definitions to be used in the following analysis and the applicable fragmented regulatory landscape, the aim of the present work will be to establish how a biobank may lawfully conceptualise its governance to collect for future research purposes human biological samples and personal data.

To this end, various methods are possible, both under a supranational and a national level. Establishing the method for the collection of the content of a biobank is one of the first decisions to be made for the biobanking governance and shapes most of the others to follow. Moreover, as it will be apparent throughout the discussion, it influences to a great extent the relationship between researchers and participants and the impact of scientific research more generally.

The choice between the models available should be made first of all by conducting a balancing test of the various rights and interests at stake, and secondly by evaluating the consequences of each option on participants' trust, in order to preserve it and enhancing it in the future. Indeed, the very existence of biobanks rests on the willingness of participants to provide samples and data and not to subsequently withdraw them.

The elements for such an evaluation (trust test) will be provided in Chapter II, while Chapter III will be devoted to the extensive analysis of the legal requirements that compose the various possible models for the collection of HBSs and data among which the biobank may choose (namely the necessity-based model and the consent-based model). I will then evaluate the impact and consequences of each identified method of collection firstly on the private and public interest at stake in biobanking, trying to find the balance between them, and then on participants' trust.

Finally, in Chapter IV I will analyse the issue of the anonymisation of personal (health and genetic) data, usually considered as the technical means to be used to escape regulatory conundrum, but in reality more difficult to be applied than what appears at first glance.

Participation of National Biobanks' Network in the Legal Consortium BBMRI-ERIC." *Biopreservation and Biobanking*, vol. 11, n. 2, 2013, pp. 124-128.

CHAPTER II – TRUST IN BIOBANKING

Summary: 1 Introduction; 2 The importance of trust in biobanking – (A) Practical examples; 3 ... (B) Theoretical analysis: (B1) Hard and soft law instruments; 3.1 ... (B2) Scholars; 4 Trust as a dynamic concept – Relevant factors for the biobank governance; 5 Conclusion

1 INTRODUCTION

Biobanks rely greatly on public participation and trust,[190] so much so that the latter has been defined as a "vital component for biobanking".[191] This is particularly due to the fact that biobanks always depend to a certain extent on the willingness of participants to provide HBSs or personal data and control their use for research purposes, or to not ask for their erasure or destruction.[192]

[190] Brand, Angela, et al. "Biobanking for Public Health." *Trust in Biobanking: Dealing with Ethical, Legal and Social Issues in an Emerging Field of Biotechnology*, edited by Dabrock, Peter, et al. Springer, 2012, pp. 3-20.

[191] Samuel, Gabrielle, et al. "Public Trust and Trustworthiness in biobanking. the Need for More Reflexivity." *Biopreservation and Biobanking*, vol. 20, n. 3, 2022, pp 291-296. Similarly, Petersen, Alan "Biobanks "Engagements": Engendering Trust or Engineering Consent?" *Genomics, Society and Policy*, vol. 3, n. 1, 2007, pp. 31-43; Chalmers, Don, et al. "Has the Biobank Bubble Burst? Withstanding the Challenges for Sustainable Biobanking in the Digital Era." *BMC Medical Ethics*, vol. 17, n. 1, 2016, pp. 1-14; Gille, Felix, and Caroline, Brall "Can We Know if Donor Trust Expires? About Trust Relationships and Time in the Context of Open Consent for Future Data Use." *Journal of Medical Ethics*, vol. 48, 2022, pp. 184-188; Gille, Felix, et al. "Evidence-Based Guiding Principles to Build Public Trust in Personal Data Use in Health System." *Digital Health*, 2022, pp. 1-11; Locock, Louise, and Anne-Marie R., Boylan "Biosamples as Gifts? How Participants in Biobanking Projects Talk about Donation." *Health Expectations: an International Journal of Public Participation in Health Care and Health Policy*, vol. 19, n. 4, 2016, pp. 805-816; van Staa, Tjeerd-Pieter, et al. "Big Health Data: The Need to Earn Public Trust." *BMJ*, vol. 354, 2016, pp. 1-3; Gille, Felix, and Caroline, Brall "Public Trust: Caught Between Hype and Need." *International Journal of Public Health*, vol 65, 2020, pp. 233-234.

[192] Hansson, Mats G., "Building on Relationships of Trust in Biobank Research." *Journal of Medical Ethics*, vol. 31, n. 7, 2005, pp. 415-418.

Indeed, trust has been defined as "the main determinant of participants' willingness to cooperate with biobanking"[193] and more generally one of the key factors in deciding to share personal data for research purposes.[194]

Indeed, low levels of public and participants' trust in biobanking activities may decrease their participation rate or encourage "privacy protecting behaviours", which include providing inaccurate or incomplete information or continuously changing one's health care provider[195] and consequently hinder the sustainability of the biobanking system as a whole.[196]

In recent years, a growing number of studies focused on the importance of trust not only in the specific context of biobanking[197] but also in the more general one of scientific research, especially if data-driven[198] and involving Big data. In particular, studies highlighted a positive general attitude of people in sharing their data for research

[193] Lipworth, Wendy, et al. "An Empirical Reappraisal of Public Trust in Biobanking Research: Rethinking Restrictive Consent Requirements." *Journal of Law and Medicine,* vol. 17, n.1, 2009, pp. 119-138; Beskow, Laura M., and Elizabeth, Dean "Informed Consent for Biorepositories: Assessing Prospective Participants' Understanding and Opinions." *Cancer Epidemiology, Biomarkers & Prevention: a Publication of the American Association for Cancer Research, Cosponsored By the American Society of Preventive Oncology*, vol. 17, n. 6, 2008, pp. 1440-1451.

[194] Bak, Marieke A. R., et al. "Health Data Research on Sudden Cardiac Arrest: Perspectives of Survivors and Their Next-Of-Kin." *BMC Medical Ethics*, vol. 22, n. 7, 2021, pp. 1-15; Bak, Marieke A. R., et al. "Towards Trust-Based Governance of Health Data Research." *Medicine, Health Care and Philosophy*, vol. 26, 2023, pp. 185-200; Brand, Angela, et al. "Biobanking for Public Health"; Kerasidou, Angeliki "Trust Me, I'm a Researcher! the Role of Trust in Biomedical Research." *Medicine, Health Care, and Philosophy*, vol. 20, n. 1, 2017, pp. 43-50.

[195] Williams, Gemma A., and Nick, Fahy "Building and Maintaining Public Trust to Support the Secondary Use of Personal Health Data." *Eurohealth*, vol. 25, n. 2, 2019, pp. 7-11; El Emam, Khaled, et al. "Anonymising and Sharing Individual Patient Data." *BMJ (Clinical Research ed.)*, vol. 350, 2015, pp. 1-6; Walker, Daniel M., et al. "Trust Me, I'm a Doctor: Examining Changes in How Privacy Concerns Affect Patient Withholding Behavior." *Journal of Medical Internet Research*, vol. 19, n. 1, 2017.

[196] Samuel, Gabrielle, et al. "Public Trust and Trustworthiness in Biobanking. the Need for More Reflexivity"; Petersen, Alan, "Biobanks "Engagements": Engendering Trust or Engineering Consent?"

[197] Hawkins, A. K, and Kieran, O'Doherty "Biobank Governance: a Lesson in Trust." *New Genetics and Society*, vol. 29, n. 3, 2010, pp. 311-327; Sanchini, Virginia, et al. "A Trust-Based Pact in Research Biobanks. From Theory to Practice." *Bioethics*, vol. 30, n. 4, 2016, pp. 260-271; Dabrock, Peter, et al. *Trust in Biobanking: Dealing with Ethical, Legal and Social Issues in an Emerging Field of Biotechnology*, Springer, 2012.

[198] Gille, Felix, and Caroline, Brall "Limits of Data Anonymity: Lack of Public Awareness Risks Trust in Health System Activities." *Life Sciences, Society and Policy*, vol. 17, n. 7, 2021, pp. 1-8; Lawler, Mark, et al. "A Roadmap for Restoring Trust in Big Data." *the Lancet. Oncology*, vol. 19, n. 8, 2018, pp. 1014-1015.

purposes[199] if they perceive they can trust researchers in handling their data.[200] It is precisely this particular trust that should be preserved and enhanced by biobanks.

Examples of successful biobanks or data-drive projects based on a solid trust relationship are the electronic health records built to improve health management and quality of care,[201] and the collection of data to curb the coronavirus pandemic in 2019,[202] while at the same time examples exist of the failure of analogous projects in case of low level of public trust (as analysed below).

Indeed, confirmation of the value of trust for biobanking stems also from the development of the *charitable biotrust* as a possible governance model for biobanks by David Winickoff,[203] which is increasingly mentioned in the literature about data governance for research, especially in common law systems.[204] More in detail, this model replicates the general structure of a *charitable trust*:

- Participants identify as *settlors* and would donate their data to the biobank, usually by providing consent to their processing;
- The biobank assumes the role of the *trustee* (called *Biotrust foundation*), which is the independent structure with the duty to share the data in a fair, safe and equitable way[205] and it is thus invested with a *legal fiduciary duty*;
- The biobank would share the data with researchers in the interest of the *beneficiary*, i.e. society as a whole, for purposes identified in the *trust charter*, which also includes provisions related to the ethical principles guiding its

[199] Skovgaard, Lea L., et al. "A Review of Attitudes Towards the Reuse of Health Data Among People in the European Union: The Primacy of Purpose and the Common Good." *Health policy (Amsterdam, Netherlands)*, vol. 123, n. 6, 2019, pp. 564-571.

[200] TEHDAS, *Healthy Data, an online citizen consultation about health data reuse – intermediate report*, 2022; TEHDAS, *Qualitative study to assess citizens' perception of sharing health data for secondary use and recommendations on how to engage citizens in the EHDS*, 2023.

[201] Hays, Rebecca, and Gavin, Daker-white "The Care.Data Consensus? a Qualitative Analysis of Opinions Expressed on Twitter." *BMC Public Health*, vol. 15, n. 838, 2015, pp. 1-13.

[202] Ienca, Marcello, and Effy, Vayena "On the Responsible Use of Digital Data to Tackle the COVID-19 Pandemic." *Nature Medicine*, vol. 26, n. 4, 2020, pp. 463-464.

[203] Winickoff, David E, and Richard N., Winickoff "The Charitable Trust as a Model for Genomic Biobanks." *the New England Journal of Medicine*, vol. 349, n. 12, 2003, pp. 1180-1184; Winickoff, David E. "From Benefit Sharing to Power Sharing: Partnership Governance in Population Genomics Research." *Principles and Practice in Biobank Governance*, edited by Kaye, Jane, and Stranger, Mark, Routledge, 2009; Milne, Richard, et al. "What Can Data Trusts for Health Research Learn from Participatory Governance in Biobanks?" *Journal of Medical Ethics*, vol. 48, n. 5, 2022, pp. 323-328.

[204] Milne, Richard, et al. "What Can Data Trusts for Health Research Learn from Participatory Governance in Biobanks?"

[205] Hall, Dame Wendy, and Jérome, Pesenti "Growing the Artificial Intelligence Industry in the UK." London Department for Digital, Culture, Media & Sport and Department for Business, Energy & Industrial Strategy, 2017.

activities, the rights and duties of the parties involved, the consequences of withdrawing from the trust, etc.[206]

For the mentioned activities, the *Biotrust foundation* collaborates with

- the *Ethical Review Committee* (ERC), responsible for evaluating the research project that could get access to the content of the biobank, according to ethical parameters, and in which participants' representatives participate,
- and the *Donor Advisory Committee* (DAC), composed exclusively of participants' representatives and whose primary aim is to maximise the use of the content of the biobank for the public good.[207]

The applicability of the biotrust model to European biobanks is controversial, because of the difficulties of implementing in civil law systems the model of *trust*, traditionally developed in common law environments[208] and possible issues related to the risks of diminishing the collective and solidarity dimension of biobanking.[209]

However, what can be inferred from the theories that claim the applicability of this model to biobank governance is the at least theoretical possibility of building the biobank-participant relationship as a fiduciary relationship[210] based on trust.[211]

Therefore, it is fundamental in general for the well-functioning of a biobank to understand which biobank activities broadly considered, or elements of the biobank governance, may somehow impact on participants' trust, either positively or negatively, and consequently identify various practices (defined as vital components of biobanking success)[212] that may be included in the biobank governance itself to help protect or enhance participants' trust.

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[206] Extensively on the topic, Winickoff, David E, and Richard N., Winickoff "The Charitable Trust as a Model for Genomic Biobanks"; Milne, Richard, et al. "What Can Data Trusts for Health Research Learn from Participatory Governance in Biobanks?"; Ducato, Rossana, *La Disciplina Giuridica delle Biobanche di Ricerca,* PhD thesis, Università Trento, Anno Accademico 2009-2010; Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona*.

[207] Ducato, Rossana, *La Disciplina Giuridica delle Biobanche di Ricerca*.

[208] Gaspari, Francesco "La Circolazione dei Dati Genetici e delle Biobanche: Limiti e Prospettive *de iure condendo"*; Ducato, Rossana, *La Disciplina Giuridica delle Biobanche di Ricerca*; Piciocchi, Cinzia, et al. "Legal Issues in Governing Genetic Biobanks: The Italian Framework as a Case Study for the Implications for Citizen's Health Through Public-Private Initiatives." *Journal of Community Genetics*, vol. 9, n. 2, 2018, pp. 177-190.

[209] Marilotti, Lorenzo "Ipotesi per una Gestione Partecipata delle Biobanche Genetiche Concepite Come Beni Comuni." *BioLaw Journal*, vol. 2, 2023, pp. 383-410.

[210] Winickoff, David E., and Laeissa B., Neumann "Towards a Social Contract for Genomics: Property and the Public in the "Biotrust" Model." *Genomics, Society and Policy*, vol 1, n. 8, 2005, pp. 8-32.

[211] Milne, Richard, et al. "What Can Data Trusts for Health Research Learn from Participatory Governance in Biobanks?"

[212] Samuel, Gabrielle, et al. "Public Trust and Trustworthiness in Biobanking. the Need for More Reflexivity."

Indeed, despite there being various trust mechanisms, i.e. reasons behind the decision to trust someone or an institution,[213] as well as moral components, through time studies have been conducted to identify various factors that may influence the level of participants' trust in the biobanking activities.

The focus of my analysis in this context will be restricted to those elements of participants' trust that may be influenced directly by biobank's governance choices related to the models for the collection of HBSs and personal data for their future use.[214] Moreover, the aim is thus to develop an additional tool for the choice of the governance measures to be adopted in the biobank when choosing the model for the collection of its content in order to be (also) trustworthy.[215] He mentioned analysis would be conducted keeping in mind that an appropriate biobank governance is already considered as a "trustworthy framework" *per se*, especially when it addresses issues such as unforeseeable consequences of biobanks, controlling vested interests, managing the

[213] To this end, Spencer et al. speak about deterrence-based trust, calculus-based trust, relational trust, and institution-based trust. Spencer, Kare, et al. "Patient Perspectives on Sharing Anonymized Personal Health Data Using a Digital System for Dynamic Consent and Research Feedback: a Qualitative Study." *Journal of Medical Internet Research,* vol. 18, n. 4, pp. 1-11. On the same topic, Samuel et al. speak about "rational decision making, knowledge-based trust rooted in previous experience and/or identification-based trust that relates to emotional ties, shared values." Samuel, Gabrielle, et al. "Public Trust and Trustworthiness in biobanking. the Need for More Reflexivity."

[214] An example may help clarify the issue. The DGA for instance establishes in Recital 46 that "[i]n order to assist data subjects and data holders to easily identify, and thereby increase their trust in data intermediation services providers recognised in the Union, a common logo recognisable throughout the Union should be established." It can thus be inferred from this provision the European legislator believes in the value of recognisable logos to increase data subjects' trust over data intermediations services providers. The same line of reasoning could in principle be applied to biobanking, by recommending the adoption of a logo to enhance participants' trust in the biobanking activities. However, such a recommendation and the recommended activity itself do not have anything specifically to do with the collection of the content of the biobank, or with the provisions to include in the biobank governance in this regard. As a consequence, their analysis and their inclusion in the trust test is outside of the scope of this work, given its exclusive focus on the models for collection of the content of the biobank and its consequences for the biobank governance.

[215] Milne, Richard, et al. "Demonstrating Trustworthiness When Collecting and Sharing Genomic Data: Public Views Across 22 Countries." *Genome Medicine,* vol. 13, n. 92, 2021, pp. 1-12. Moreover, Samuel, Gabrielle, et al. "Public Trust and Trustworthiness in Biobanking. the Need for More Reflexivity" speak about "the formalization of trustworthiness as a set of governance structures" and stress on the importance of avoiding reducing trustworthiness only to a series of governance mechanisms, without concretely acting according to them. On the need to act in a trustworthy manner, see also Richter, Cornelia "Biobanking. Trust as Basis for Responsibility." *Trust in Biobanking: Dealing with Ethical, Legal and Social Issues in an Emerging Field of Biotechnology,* edited by Dabrock, Peter, et al. Springer, 2012, pp. 43-68. Moreover, in Milne, Richard, et al. "Demonstrating Trustworthiness When Collecting and Sharing Genomic Data: Public Views Across 22 Countries." The authors highlighted that placing blind trust on persons or institutions that do not act in a trustworthy manner may be detrimental for both the trustor and the trustee.

potential public benefits of biobanks, the potential misuse of the data, results and technology, and jurisdiction and boundaries of biobanks.[216]

Indeed, similarly to the provision of health care, where it has been proven that trust increases with the duration of the physician-patient relationship,[217] I believe it is possible to identify some specific elements that should be considered while conducting when weighing possible alternatives for specific issues of the biobank governance model to be adopted, in particular the issue of collecting the samples and data for future research use.[218] The evaluation of these elements in the described context will be used to develop what I will call the *trust test.*

To this end, simply applying the results of the studies conducted on trust in health care to the context of biobanks is not possible, because of the differences in the relationship that binds the various entities,[219] and therefore because of the necessity to valorise the characteristics of biobanking as opposed to more traditional forms of scientific research. Indeed, while the doctor-patient relationship is direct and personal and usually built via in-person encounters, the one among participants, the biobank and researchers is usually anonymous, conducted via rare physical encounters and communications, established via electronic means, which is also a more general characteristic of data-driven research.[220]

Therefore, this Chapter is devoted to trying to understand which elements should be considered when addressing the issue of participants' trust in biobanking activities. These elements will be included in a trust test to be conducted whenever the applicable legal framework leaves to the biobank the choice among various equally lawful possibilities on a specific governance element (for the purposes of this work, among various models for the collection of HBSs and personal data). Indeed, the trust test will make it possible to consider and address the possible impact of a governance decision on the model for collecting the biobank content on participants' trust and consequently choose the option that either preserves trust the most or does not excessively impact on it.

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[216] Hawkins, A. K, and Kieran, O'Doherty "Biobank Governance: a Lesson in Trust."

[217] Stepanikova, Irena, et al. "Trust in Managed Care Settings." *Whom Can We Trust? How Groups, Networks, and Institutions Make Trust Possible*, edited by Cook, Karen S., et al. Russell Sage Foundation, 2009; Bak, Marieke A. R., et al. "Towards Trust-Based Governance of Health Data Research."

[218] Other issues might be related to other aspects, such as the return of results.

[219] Bak, Marieke A. R., et al. "Towards Trust-Based Governance of Health Data Research."

[220] *Ibid*

However, this test should and will not prevail over the careful balancing exercise of the various rights and interests at stake in the concrete scenario under consideration (balancing test) which should always be the first and preferred method for the mentioned choice. Therefore, the trust test may be used in two cases with different aims. Whenever the balancing test does not reach a decisive conclusion because there is no prevailing right or interest in the concrete situation under consideration, the trust test may help choose one of the options. On the contrary, if the balancing test provides for a definite answer, conducting the trust test may help assess whether such a conclusion might negatively impact participants' trust. This in turn would entail the necessity for the biobank to implement other governance mechanisms or measures for enhancing it.[221]

As a consequence, throughout this work, whenever a choice between various lawful alternatives is possible, both criteria will be applied, i.e. the balancing of fundamental rights on the one hand (*balancing test*) and evaluating the impact on trust on the other (*trust test*). Even though in case of contrast between the results of the two tests, the balancing test should and will prevail, I believe that adding the trust test to the analysis will provide an additional criterion for structuring complex decisions and preserving the existence of biobanks, as well as their role for the development of scientific research.

This approach is justified by considering that, as mentioned, biobanks are fundamental infrastructures for the development of science, medicine and ultimately society, and their very existence depends on the willingness of participants to be involved in research, which in turn depends on their level of trust in the system. Striving to improve public trust in their activities is "unquestionably important for biobanks",[222] but restoring trust is considerably more challenging than preserving it from the beginning.[223] Therefore, it is important to include an evaluation of the impact on trust in the procedure for deciding on the specific model for collection to be included in the governance model.

[221] The same can be done whenever the choice is made *ab origine* by the legislator, because there is no room left for biobanks to choose between alternatives.

[222] Samuel, Gabrielle, et al. "Public Trust and Trustworthiness in biobanking. the Need for More Reflexivity."

[223] Spencer, Kare, et al. "Patient Perspectives on Sharing Anonymized Personal Health Data Using a Digital System for Dynamic Consent and Research Feedback: a Qualitative Study."

Indeed, the idea of implementing trust as a fifth principle in clinical research[224] or as a priority-setting value[225] is not new and has been extensively studied. In particular, Resnik conducted research on trust in research on human subjects, and I agree with Bak on the possibility of applying the same logic also in non-interventional research,[226] and particularly in the biobank field, which may be considered a peculiar type of non-interventional, data-driven research.

From a methodological point of view, the elements included in the trust test are chosen by combining 1) the identified reasons for the failure of some biobanking projects, mentioned above, 2) the analysis of the relevant literature on the matter, as well as studies/projects conducted specifically to this end, and 3) the solutions to the issue of trust identified by the European legislator in selected fields relevant to biobanking, and therefore in the applicable regulations and/or documents, as identified in Chapter I. Even though some differences may exist between European countries on how trust is perceived, established and enhanced,[227] I believe in the possibility of finding some general common traits to be included in the analysis.

The Chapter will therefore be structured as follows. I will begin by providing two concrete examples of the importance of trust for biobanks, i.e. two projects that failed because of a lack of public trust, and also trying to identify the reasons behind it.

I will then proceed to identify the core elements of participants' trust, which will include not only those responsible for the failure of the mentioned projects but also an analysis of the soft and hard legal instruments applicable to biobanks that include preserving trust among their objectives, and the norms and requirements provided for therein to this end. Finally, I will include the results of sociological studies on the matter and influential scholars' opinions, especially on the reasons for participating in or withdrawing from biobanking activities.

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[224] Resnik, David B., the *Ethics of Research with Human Subjects. International Library of Ethics, Law, and the New Medicine*, Springer, 2018.

[225] Bak, Marieke A. R., et al. "Towards Trust-Based Governance of Health Data Research."

[226] *Ibid*

[227] *Ibid.* In particular, see the work of Bekker et al. that demonstrated how a trust-based governance approach is more likely to succeed in countries like the Netherlands instead of the United Kingdom. Bekker, Marleen P. M., et al. "Comparative Institutional Analysis for Public Health: Governing Voluntary Collaborative Agreements for Public Health in England and the Netherlands." *European Journal of Public Health*, vol. 28, 2018, pp. 19–25.

The last paragraph aims at collecting the most shared elements with a possible impact on participants' trust, in order to establish the content and functioning of the trust test for the mentioned use.

2 THE IMPORTANCE OF TRUST IN BIOBANKING – (A) PRACTICAL EXAMPLES

At least the following two examples may be provided to prove the importance of participants' trust for the existence and functioning of biobanks: the UK Care.data project and the Digital Data Grab project.

First of all, the Care.Data project was a project carried out by England's National Health Service (NHS) in 2013, which aimed to collect patients' data from general practitioners through the General Practice Extraction Service and store them in a central database. Those data were then to be used in anonymised form by healthcare researchers outside the (NHS), including commercial companies. In this project, the collection of data was based on an opt-out system, and therefore patients' data registered with a general practitioner were to be uploaded in the database unless the person concerned had objected to such a processing.

On their website, the NHS stated that the project aimed at ensuring that the best possible evidence was available to improve the quality of healthcare for all, by providing data for identifying patterns in diseases and discovering possible treatments.[228] Thus, the project was developed for the public good, at least theoretically.

However, from the beginning, it faced a lot of opposition, both from general practitioners and patients, who started opting out. According to commentators on the matter, the project "failed to win the public's trust and lost the battle for doctors' support",[229] and was thus abandoned.[230]

Indeed, among the critical elements of the initiative was the implementation of an opt-out system and the "toxic possibility"[231] of data being accessed by private commercial

[228] Sterckx, Sigrid, et al. "You Hoped We Would Sleepwalk into Accepting the Collection of Our Data": Controversies Surrounding the UK care.data Scheme and Their Wider Relevance for Biomedical Research." *Medicine, Health Care and Philosophy*, vol. 19, 2016, pp. 177–190.

[229] Godlee, Fiona "What Can We Salvage from care.data?" *BMJ*, vol. 354, 2016; van Staa, Tjeerd-Pieter, et al. "Big Health Data: The Need to Earn Public Trust."

[230] Melham, Karen, et al. "The Evolution of Withdrawal: Negotiating Research Relationships in Biobanking."

[231] Godlee, Fiona "What Can We Salvage from care.data?"

companies, which were characteristics of the project that made patients and participants lose trust in the transparency of the activity of the biobank and in particular in its aim of processing the data for public food purposes. This substantial decrease in participants' trust has been identified as the main cause of the failure of the project.[232]

This belief was partially caused and reinforced by the failure of those in charge of the project to engage in communication with the public to ensure the trustworthiness of the database and the project more generally and explain the benefits of its implementation.[233]

According to commentators, a substantial decrease in public trust derived from concerns about informed consent, data security and privacy risks, lack of communication and involvement of private companies with commercial interests.[234] As it has been affirmed by commentators, "The program aimed at securing the bare minimum of trust while maximising potential returns on investment. It thus quickly dismissed privacy and respect for individual autonomy as individualistic rights opposing wider prosperity, rather than seeing them as principles of social trust and public engagement".[235]

More recently, a different UK project was put on hold for reasons related to lack of trust. Indeed, the NHS Digital Data Grab project envisioned the collection of patient data, at least partially anonymised, to develop health and social care policies, and enable research and other services. The system established an opt-out system, which was activated by over a million people in one month,[236] mainly because of the fear of their data being shared with private companies,[237] and thus mainly for problems of transparency and communication.

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[232] Spencer, Kare, et al. "Patient Perspectives on Sharing Anonymized Personal Health Data Using a Digital System for Dynamic Consent and Research Feedback: a Qualitative Study"; Carter, Pam et al. "The Social Licence for Research: Why care.data Ran into Trouble." *Journal of Medical Ethics,* vol. 41, n. 5, 2015, pp. 404-409.

[233] Melham, Karen, et al. "The Evolution of Withdrawal: Negotiating Research Relationships in Biobanking."

[234] Nwebonyi, Ngozi, et al. "Public Views About Involvement in Decision-Making on Health Data Sharing, Access, Use and Reuse: The Importance of Trust in Science and Other Institutions." *Frontiers in Public Health,* vol. 10, 2022, pp. 1-11; Skovgaard, Lea L., et al. "A Review of Attitudes Towards the Reuse of Health Data Among People in the European Union: The Primacy of Purpose and the Common Good"; Carter, Pam et al. "The Social Licence for Research: Why care.data Ran into Trouble."

[235] Vezyridis, Paraskevas, and Timmons, Stephen "Resisting Big Data Exploitations in Public Healthcare: Free Riding or Distributive Justice?" *Sociology of Health & Illness,* vol. 41, n. 8, 2019, pp. 1585-1599.

[236] Jayanetti, Chaminda "NHS Data Grab on Hold as Millions Opt Out." *the Guardian*, 2021. https://www.theguardian.com/society/2021/ aug/22/nhs-data-grab-on-hold-as-millions-opt-out. (accessed 16 January August 2024)

[237] Tibbitt, Alastair "Millions Opt Out of England's Health Data-Sharing Plan." *Open Democracy*, 2021. https://www.opendemocracy. net/en/ournhs/millions-opt-out-of-englands-health-datasharing-plan/. (accessed 16 January August 2024)

2.1 ... (B) THEORETICAL ANALYSIS: (B1) HARD AND SOFT LAW INSTRUMENTS

As mentioned, the importance of the preservation of trust in the biobanking activities is also frequently underlined in the applicable hard and soft law instruments, listed in Chapter I.

Among the soft law instruments analysed, the notion of trust is mentioned by the Declaration of Taipei, the CIOMS International Ethical Guidelines, and Recommendation R(2016)6.

As for the first one, the Declaration of Taipei explicitly establishes four guiding principles that should govern biobanking in order to foster the trustworthiness of the system:

- *protection of individuals* – the biobanking governance should always prioritise the interests of participants over those of science or the other stakeholders;
- *transparency* – any relevant information on the biobank should be made available to the public;
- *participation and inclusion* – individuals and their communities should be consulted and engaged in the biobanking decisions and activities;
- *accountability* – those responsible for the biobank should also be accessible and responsive to all the stakeholders involved.

The matter is also extensively addressed by the CIOMS International Ethical Guidelines. In particular, the Guidelines focus on the importance of public engagement and community involvement to build trust between the participants and researchers, as specifically addressed in Guideline 7.[238]

Furthermore, Recommendation R(2016)6 underlines already in the preamble that it is important for biobanks to earn trust and consequently it stresses on the role of "good and transparent governance" of the HBSs and data stored to this end.

Taking into account the hard law instruments, trust is often cited as a value to be preserved by regulations on data protection or the processing of health data. In particular, in the European strategy for data, the European Commission first of all underlines that citizens' trust in data-driven innovations rests on their trust in compliance with general data

[238] CIOMS International Ethical Guidelines - Guideline 7 "Researchers, sponsors, health authorities and relevant institutions should engage potential participants and communities in a meaningful participatory process that involves them in an early and sustained manner in the design, development, implementation, design of the informed consent process and monitoring of research, and in the dissemination of its results."

protection rules, and to this end, the GDPR constitutes "a solid framework for digital trust".[239]

Indeed, in this regard, data protection and security are also essential for maintaining trust, because individuals' decision to share their data is directly influenced by the level of safety and protection of their data.[240]

Moreover, both the DGA and the EHDS aim to preserve trust in the sharing and processing of data. On the one hand, the DGA aims to "develop further the borderless digital internal market and a human-centric, *trustworthy* and secure data society and economy",[241] and is based on the assumption that transparency may increase trust and encourage data subjects to share personal data for altruistic purposes, which is indeed as a form of data collection. On the other, the EHDS aims at creating "a common space where natural persons can easily control their electronic health data" and "researchers, innovators and policy makers [may use] electronic health data in a trusted and secure way that preserves privacy", by "enhancing security and trust in the technical framework designed to facilitate the exchange of electronic health data for both primary and secondary use".

In particular, in Recital 5 the DGA expressly underlined the necessity to increase trust in data sharing "by establishing appropriate mechanisms for control by data subjects (...) over the data that relates to them" and affirmed that "[a] Union-wide governance framework should have the objective of building trust among individuals and undertakings in relation to data access, control, sharing, use and re-use, in particular by establishing appropriate mechanisms for data subjects to know and meaningfully exercise their rights, as well as with regard to the re-use of certain types of data held by the public sector bodies, the provision of services by data intermediation services providers to data subjects, data holders and data users, as well as the collection and processing of data made available for altruistic purposes by natural and legal persons" and that "[i]n particular, more transparency regarding the purpose of data use and conditions under which data is stored by undertakings can help increase trust".

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[239] European Commission, a *European strategy for data*, Brussels, 2020.

[240] EDPB-EDPS, Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, 2022; European Commission, Assessment of the EU Member States' rules on health data in the light of GDPR, 2021.

[241] Emphasis added.

More generally, for what is relevant in our analysis, the DGA's framework as a whole is built in order for people and stakeholders to trust the data altruism organisations and to this end, the DGA includes numerous requirements that these organisations should comply with. Such compliance should "bring trust that the data made available for altruistic purposes is serving an objective of general interest" and that "trust should result in particular from having a place of establishment or a legal representative within the Union, as well as from the requirement that recognised data altruism organisations are not-for-profit organisations, from transparency requirements and from specific safeguards in place to protect rights and interests of data subjects and undertakings".[242]

It appears thus clear that the DGA not only considers trust a fundamental element in the processing and sharing of data but also establishes that trust is enhanced and preserved by a) providing adequate information to the data subjects on the processing and use of their data, especially if made available for altruistic purposes, b) establishing adequate mechanisms for control that may be used by the data subject, c) preserving and/or increasing the overall transparency of the processing, and d) having adequate measures in place to protect the data subjects. As mentioned, the focus on the control of the data subject over the processing of the data and on the protection of her rights and interests is also included in the EHDS.

Finally, the importance of transparency, accountability and communication to ensure public trust and trustworthiness "in the responsible and effective stewardship of patient data" by the NHS in the UK has also been underlined by an Academic of Medical Sciences report in 2018.[243]

2.2 ... (B2) SCHOLARS

Various studies have been conducted on participants' trust in the field of scientific research, personalised medicine, data-driven research and biobanking. Specifically for biobanking, BBMRI affirmed that trust should be not only referred to and placed in the characteristics and arrangements of a given project but also in "the broader organisational framework into which a given biobank project is embedded".[244]

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[242] Recital 46 DGA.

[243] Sheehan, Mark, et al. "Trust, Trustworthiness and Sharing Patient Data for Research." *Journal of Medical Ethics*, vol. 0, 2020, pp. 1-4.

[244] BBMRI "*Biobanks and the Public. Governing Biomedical Research Resources in Europe. a* Report from the BBMRI Project." 2013.

Studies specifically focused on trust in biobanking and biobank research frequently highlight the existence of a strong link between public trust, transparency and the level of information provided to participants.[245] In particular, providing adequate information to participants may help foster "acceptance of the ways a biobank is developed and used"[246] and addressing participants' concerns focus on the conditions for sharing their data with third parties, the possible purposes of processing activities by the latter, and in general,[247] and on privacy and data security.[248] Precisely concerns about privacy and confidentiality have been identified as being related to lower participation rates.[249]

Indeed, as affirmed by Gille et al. "[c]onveying relevant information about a given organisation is considered a basic principle of good governance; it contributes to accountability and it is associated with increased public and donor trust in biobanks", so much so that a truthful and honest communication has been defined as "key" and "central" to build-up the participants-biobank trust relationship,[250] or the "lifeblood of public

[245] Hansson, Mats G., "Building on Relationships of Trust in Biobank Research"; Gille, Felix, et al. "Transparency About Governance Contributes to Biobanks' Trustworthiness: Call for Action." *Biopreservation and biobanking*, vol. 19, n.1, 2021, pp. 83-85; Yuille, Martin, et al. "Biobanking for Europe." *Briefings in Bioinformatics*, vol. 9, n. 1, 2008, pp. 14-24; Ursin, Lars et al. "«If You Give Them Your Little Finger, They'll Tear Off Your Entire Arm»: Losing Trust in Biobank Research." *Medicine, Health Care, and Philosophy*, vol. 23, n. 4, 2020, pp. 565-576; Mitchell, Derick, et al. "Biobanking from the Patient Perspective."

[246] Mitchell, Derick, et al. "Biobanking from the Patient Perspective."

[247] Milne, Richard, et al. "Demonstrating Trustworthiness When Collecting and Sharing Genomic Data: Public Views Across 22 Countries"; Hansson, Mats G., "Building on Relationships of Trust in Biobank Research"; Gille, Felix, et al. "Transparency About Governance Contributes to Biobanks' Trustworthiness: Call for Action"; Gille, Felix, et al. "Evidence-Based Guiding Principles to Build Public Trust in Personal Data Use in Health System."

[248] Gaskell, George, et al. "Publics and Biobanks: Pan-European Diversity and the Challenge of Responsible Innovation." *European Journal of Human Genetics: EJHG* vol. 21, n. 1, 2013, pp. 14-20; Gille, Felix, et al. "Evidence-Based Guiding Principles to Build Public Trust in Personal Data Use in Health System"; Lipworth, Wendy, et al. "An Empirical Reappraisal of Public Trust in Biobanking Research: Rethinking Restrictive Consent Requirements."

[249] Broekstra, Reinder, et al. "Motives for Withdrawal of Participation in Biobanking and Participants' Willingness to Allow Linkages of Their Data." *European Journal of Human Genetics*, vol. 30, 2022, pp. 367–377; Kaufman, David J., et al. "Public Opinion About the Importance of Privacy in Biobank Research." *American Journal of Human Genetics*, vol. 85, n. 5, 2009, pp. 643-54.

[250] Gille, Felix, et al. "Towards a broader conceptualization of "public trust" in the health care system." *Social Theory & Health*, vol. 15, 2017, pp. 25-43; Gille, Felix, et al. "Transparency About Governance Contributes to Biobanks' Trustworthiness: Call for Action"; Gille, Felix, *Theory and conceptualisation of public trust in the health care system: Three English case studies: care.data, biobanks and 100,000 Genomes Project*, PhD thesis, London School of Hygiene & Tropical Medicine, 2017. the importance of providing information to participants and the public is frequently underlined by soft law instruments, especially those listed in Chapter I. See, for instance, the Declaration of Taipei and the Declaration of Helsinki.

trust".[251] Ideally, such communication, and therefore the format with which information is provided, is tailored to the participants and the other relevant stakeholders to which they should be communicated.[252] Participants' trust is usually not directly affected by the communication of risks or uncertainties, which have been proven to only have a minor impact on trust.[253]

Moreover, providing information and more generally implementing measures and conducting activities to ensure transparency are not only important for biobanks at the moment of asking for consent or at the first encounter between participants and the biobank itself but should also be constantly present throughout the entire duration of the participants-biobank relationship.[254]

However, it has been highlighted that transparency alone is not enough to ensure trust, if not coupled with "adequate oversight mechanisms holding organisations accountable for their operations".[255]

At the same time, engaging with participants and the donor community more generally is another element frequently mentioned, as well as granting donors' autonomy, maintaining donors' privacy and an active regulatory system.[256]

Finally, and coherently with the studies and authors already taken into consideration, BBMRI established that to build trust the biobank should provide participants "with sufficient transparency and accountability, while also offering a certain degree of participation", not only at the moment of recruiting them, but also throughout the entire

[251] Gille, Felix, et al. "Evidence-Based Guiding Principles to Build Public Trust in Personal Data Use in Health System."
[252] Gille, Felix, et al. "Transparency About Governance Contributes to Biobanks' Trustworthiness: Call for Action."
[253] van der Bles, Anne Marthe, et al. "The effects of communicating uncertainty on public trust in facts and numbers. Proceedings of the National Academy of Sciences." vol. 117, n. 14, 2020, pp. 7672–7683; Bak, Marieke A. R., et al. "Towards Trust-Based Governance of Health Data Research."
[254] Kraft, Stephanie, et al. "Beyond consent: Building trusting relationships with diverse populations in precision medicine research." *American journal of bioethics*, vol. 18, n. 4, 2018, pp. 3-20; Spencer, Kare, et al. "Patient Perspectives on Sharing Anonymized Personal Health Data Using a Digital System for Dynamic Consent and Research Feedback: a Qualitative Study."
[255] Gille, Felix, et al. "Transparency About Governance Contributes to Biobanks' Trustworthiness: Call for Action."
[256] BBMRI *Biobanks and the Public. Governing Biomedical Research Resources in Europe. a Report from the BBMRI Project.* 2013; Gille, Felix, et al. "What is public trust in the healthcare system? a new conceptual framework developed from qualitative data in England." *Social Theory & Health*, vol. 19, 2021, pp. 1-20; Gille, Felix et al. "Transparency About Governance Contributes to Biobanks' Trustworthiness: Call for Action."

lifecycle of the biobank, via ongoing communication and constant dialogue.[257] BBMRI goes on to clarify that "the governance principle for biobanks is not so much "informed consent", but rather "informed trust" – a long-term relationship of trust between biobanks and donors that is based on, and motivated by, a continuous stream of information about the activities of a biobank project and, in some cases, ways for donors to, at least, partly influence the governance and directions of a biobank effort".[258] To this end, biobanks should find "innovative ways to interact with, and engage their donors and even consult with donors on such questions and issues as "governance", "access" to biobank resources, or the "benefits" created by biobank research".[259] Along the same line, it has also been suggested that the biobank may develop a more patient-centred governance, involving patients as active participants in biobanking, to help address the needs of personalised medicine and move towards greater public involvement in research.[260]

Coherently with this approach, Hawkins and Doherty affirmed that building a biobank governance that addresses the specific concerns of participants represents "a way to achieve public trust through accountability, transparency and control",[261] thus indirectly underlying how these are measures to be adopted to preserve participants' trust.

Finally, it has been shown that biobank participation is correlated with institutional trust.[262] However, while it is possibly a determinant factor, there is little or nothing that the biobank could implement at the level of its governance for the collection of HBSs and personal data to influence the general level of participants' institutional trust.

Studies focusing on sharing data for scientific research purposes highlighted the importance of transparency and patient involvement for maintaining participants' trust as

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[257] Raivola, Vera, et al. "Attitudes of blood donors to their sample and data donation for biobanking." *European journal of human genetics*, vol. 27, 2019, pp. 1659-166.

[258] BBMRI "*Biobanks and the Public. Governing Biomedical Research Resources in Europe. a* Report from the BBMRI Project." 2013.

[259] *Ibid*

[260] Mitchell, Derick, et al. "Biobanking from the patient perspective." The authors here also provide insights on patient-led and patient-run biobanks, by focusing especially on three case studies, such as the Chordoma Foundation Biobank in the U.S.A., the Patients' Tumor Bank of Hope in Germany and the Italian Biobank AHC in Italy.

[261] Hawkins, A. K, and Kieran, O'Doherty "Biobank Governance: a Lesson in Trust." The authors underline how this approach is consistent with political science literature on how to ensure public trust within society more broadly. Indeed, they affirm that "governance is seen as the solution to concerns raised by biobanks" and that this "reflects the notion that governance mechanisms mediate relationships of trust in modern democratic societies."

[262] Raivola, Vera, et al. "Attitudes of blood donors to their sample and data donation for biobanking." *European journal of human genetics*, vol. 27, 2019, pp. 1659-1667.

well. In particular, Spencer et al. in their study confirmed a general positive attitude of patients towards sharing their data for scientific research purposes, and that a major role in taking this decision is played by social responsibility and trust.[263] In order to maintain the latter, important prerequisites have been identified in transparency and engagement.[264] These findings are confirmed by Milne et al. in their survey "Your DNA, Your say", where it is also established that participants value the possibility of being able to communicate directly with the gatekeepers of genomic and health data collections.[265]

Furthermore, the possibility of exercising personal autonomy via retaining a certain degree of control over one's data is affirmed as a further element of maintaining participants' trust in scientific research.[266]

Moreover, studies are almost unanimous in highlighting that participants are usually concerned about the sharing of their data with private entities or for-profit organisations and that this may also diminish their general trust in the system.[267]

3 TRUST AS A DYNAMIC CONCEPT – RELEVANT FACTORS FOR THE BIOBANK GOVERNANCE

Trust is a dynamic concept possibly affected by multiple factors, as previously described. Indeed, it has been defined as "multifaced and contextual", because it may differ

[263] Spencer, Kare, et al. "Patient Perspectives on Sharing Anonymized Personal Health Data Using a Digital System for Dynamic Consent and Research Feedback: a Qualitative Study."

[264] *Ibid.* The same conclusion is also confirmed by Taylor, Mark J, and Taylor, Natasha, "Health research access to personal confidential data in England and Wales: assessing any gap in public attitude between preferable and acceptable models of consent." *Life sciences, society and policy*, vol. 10, n. 15, 2014, pp. 1-24; van Staa, Tjeerd-Pieter, et al. "Big Health Data: The Need to Earn Public Trust."

[265] Milne, Richard, et al. "Demonstrating Trustworthiness When Collecting and Sharing Genomic Data: Public Views Across 22 Countries."

[266] Gille, Felix, et al. "Evidence-Based Guiding Principles to Build Public Trust in Personal Data Use in Health System."

[267] Critchley, Christine, et al. "The impact of commercialisation and genetic data sharing arrangements on public trust and the intention to participate in biobank research." *Public health genomics*, vol. 18, n. 3, 2015, pp. 160-72; Gaskell, George, et al. "Publics and biobanks: Pan-European diversity and the challenge of responsible innovation"; Williams, Gemma A., and Nick, Fahy "Building and Maintaining Public Trust to Support the Secondary Use of Personal Health Data"; Milne, Richard, et al. "Demonstrating Trustworthiness When Collecting and Sharing Genomic Data: Public Views Across 22 Countries"; Ursin, Lars et al. "«If You Give Them Your Little Finger, They'll Tear Off Your Entire Arm»: Losing Trust in Biobank Research"; Lipworth, Wendy, et al. "An Empirical Reappraisal of Public Trust in Biobanking Research: Rethinking Restrictive Consent Requirements."

according to the situation or discipline in which it is considered,[268] and requires constant "effort and responsiveness to changes".[269]

However, some common traits may be identified from the analyses provided above.

In particular, systemic elements or personality or psychological traits may influence the people's willingness to exhibit trusting attitudes.[270] These, however, cannot be taken into consideration here because are not directly related to the biobank governance and are inherently subjective.

It can be inferred from the analysis conducted above that participants' trust seems to be preserved and/or enhanced by (1) *transparency aspects,* and (2) *participation aspects* of the biobank governance.

(1) As for the *transparency aspects,* it seems that trust appears to be influenced and thus may possibly be preserved and enhanced by maintaining or implementing an adequate level of transparency in the biobank governance and providing participants with information on the biobank activities and functioning. In particular, both transparency and the provision of information should address the issues mentioned above that are sources of concern for participants. In particular, they should be related to (a) the functioning of the biobank, (b) the characteristics of the processing of the HBSs and data stored therein, as well as the purposes of the processing activities, (c) the safeguards adopted to protect the rights and interests of participants, as well as the security of the content of the biobank, and (d) accountability. This in turn entails that the biobank should have implemented concrete measures to protect the fundamental rights of participants, be compliant with the applicable framework, have in place oversight and accountability mechanisms, etc, about which subsequently provide transparent information to participants. Moreover, it stems from this that the model for the collection of HBSs and personal data should preserve such transparency, or enable it.

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[268] Samuel, Gabrielle, et al. "Public Trust and Trustworthiness in biobanking. the Need for More Reflexivity"; Milne, Richard, et al. "Demonstrating Trustworthiness When Collecting and Sharing Genomic Data: Public Views Across 22 Countries."

[269] Bak, Marieke A. R., et al. "Towards Trust-Based Governance of Health Data Research"; van der Burg, Wibren, "Dynamic Ethics." *Journal of Value Inquiry*, vol. 37, 2003, pp. 13–34.

[270] Platt, Jodyn E., et al. "Public Trust in Health Information Sharing: a Measure of System Trust." *Health Research and Educational Trust,* vol. 53, n. 2, pp. 824-845.

As frequently mentioned in the previous paragraphs, the information should preferably be provided with ongoing communication between the biobank and the participants tailored to the characteristics of at least the general group of participants considered.

(2) Moreover, participants should be involved in the functioning of the biobank. As mentioned earlier, in order for their trust to be maintained it is important to provide participants with a certain degree of control over the use of their biological samples and personal data for research purposes, and this level of control should not be fictional or purely theoretical. Therefore, it appears that on a general level, measures to ensure public involvement in the biobank activities should also be included in the governance mechanism, and on a more specific one that the governance model for the collection of the biobank's content should be designed as to ensure or preserve the mentioned trust. This does not necessarily mean that the biobank should choose the model for collection that guarantees the highest level of participants' control, but that the chosen model should not either completely eliminate such control or disproportionately restrict it.

Finally, it is worth mentioning O'Neill's concerns about the soundness of the opinion according to which the implementation of the principles of accountability, openness and transparency is actually a method to "reduce uncertainty, lower the risk of harm and maintain control", thus in turn preserving trust.[271] Indeed, the author claims that this approach may prevent trust instead of preserving and enhancing it because it "removes the conditions required for trust" itself.[272] This objection may be broadened up to include any biobank governance measure adopted to enhance or preserve trust, because by doing so it automatically eliminates the very conditions for trusting.

While recognising the value of O'Neill's approach, I agree with Sheehan et al. in believing that any of the mentioned measures may and should still be adopted to demonstrate trustworthiness and reliability.[273] Being trustworthy does not guarantee trust by participants, nor is the opposite true (i.e. that trust is only placed on trustworthy entities

[271] O'Neill, O., a *Question of Trust: BBC Reith lectures*, Cambridge: Cambridge University Press, 2002.
[272] *Ibid*
[273] Sheehan, Mark, et al. "Trust, Trustworthiness and Sharing Patient Data for Research." It is important to stress here that I agree with Holland et al. that in public health literature, the "distinction between trust and reliance (...) is entirely lost" and that the terms trust, reliance, confidence, etc. are used interchangeably. On this Holland, Stephen, et al, "Trust and the Acquisition and Use of Public Health Information." *Health Care Analysis,* vol. 30, 2022, pp. 1-17.

or people), but it may well be considered a first valuable step in this direction and, therefore, a valid reason for adopting the approach described above.

4 CONCLUSION

In this Chapter I have analysed the issue of trust in biobanking, focusing in particular on the elements of the biobank governance that are more likely to have an impact on participants' trust in the biobank activities and the processing of HBSs and personal data for future research purposes. The examples provided attempt to demonstrate such importance.

Therefore, and considering that preserving trust is generally easier than restoring it, I suggested including a trust test in the decision-making process for the choice of the model to be adopted for the collection and subsequent use of the content of the biobank for concrete future research purposes.

Such a test will take into consideration the elements highlighted and in particular the transparency aspect and the participatory aspect of the biobank governance, developed through the analysis not only of the concrete examples of failure of biobank projects because of decreased or not sufficient level of participants' trust, but also of the relevant literature and applicable framework on the matter.

As a consequence, the trust test will be used alongside the balancing test whenever the applicable legal framework leaves the biobank with the choice between various alternatives for collecting HBSs and personal data for future research purposes, other requirements being equal, and always letting the balancing test prevail over the trust one. However, even if conceptualised as subordinated to the formed, I believe the trust test might provide a valuable tool for the decision-making process for addressing complex issues of the biobank governance, in particular that of the chosen model for the collection of its content.

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CHAPTER III – PROPOSED MODELS FOR THE COLLECTION OF HUMAN BIOLOGICAL SAMPLES AND BIOBANK DATA

Summary: Structure of Chapter III – General introduction; **Part A – Human Biological Samples** 1. Introduction; 2. Relevant conceptual distinctions and scope of the analysis; 3 The framework applicable to the collection of HBSs for biobanking purposes – Consent at the supranational level; 3.1 ...and the national level; 4 The Dual nature of HBSs – (A) The material nature, or Human biological samples as detached parts of the human body; 4. Informational nature – Human biological samples as sources of personal data and parts of; 4.1 ... (B) The informational nature, or Human biological samples as sources of personal data and parts of the identity of the person; 5. Developing a framework for HBSs – On the unitarian consideration of their dual nature; 5.1 Assessing the applicability of the relational-control model to the unitarian consideration of HBSs; 6 Conclusion; **Part B – Biobank Data** 1 Introduction; 2 Types of biobank data; 3 Preliminary considerations – (A) The actor classification system applied to biobanking; 3.1 ...(B) Biobanking purposes v. Scientific research purposes; 4 Collecting biobank data – (I) The legal framework at the supranational level; 4.1 Consent-based model – 4.1.1 Withdrawal of consent; 4.2 ... and the Necessity-based model; 4.2.1 The legal bases of Art. 6(1) GDPR; 4.2.2 The exemptions of Art. 9(2) GDPR; 4.2.2.1 Art. 9(2)(i) Public interest in the area of public health; 4.2.2.2 Art. 9(2)(j) Scientific research; 4.2.3 Possible consequences of the Necessity-based model; 4.2.3.1 (A) Derogations derived from provisions of the GDPR; 4.2.3.2 (B) Derogations derived from enacted Union or Member States law; 5 ...(II) The legal framework at the national level; 6 The secondary use of personal data in biobanking; 6.1 The supranational level – Art. 5(1)(b) and 6(4) GDPR; 6.2 The national level – Art. 110 and 110-bis Italian Privacy Code and the General Authorisations; 6.3 The duty to provide information according to Art. 14(4) GDPR in case of further processing of personal data; 7 Assessing the framework for the biobank choice; 7.1 The participants' right to data protection; 7.2 The choice at the supranational level – Between the necessity-based model and the consent-based model; 7.3 The choice at the national level – Alternative models for collecting informational consent; 7.3.1 Broad consent model; 7.3.2 Dynamic consent model; 7.3.3 Choosing an alternative model for collecting informational consent for biobanking; 7.3.4 An alternative solution . Specific informational consent for biobanking; 8 The DGA and the EHDS; 8.1 Data Governance Act; 8.1.1 Specificities of the DGA system for data altruism; 8.1.2 Applying the DGA's data altruism mechanism to biobanks; 8.2 The European Health Data Space; 8.2.1 Applying the EHDS to biobanks; 8.2.2 The proposed amendments to the EHDS Proposal

STRUCTURE OF CHAPTER III – GENERAL INTRODUCTION

After having provided a general overview of the legal documents applicable, having circumscribed the matter of the analysis, and having identified the foundations of the trust test to be included in the following pages, I will now describe the possible legal approaches for the collection and storage of HBSs on the one hand and biobank data on the other for biobanking purpose, i.e. for future undefined research purposes.

The choice of the concrete modalities and the general approach to be adopted, within the limits provided for by law, for collecting both samples and data highly influences the very existence of the biobank and the scientific research that may be conducted thanks to it, and should be made carefully balancing the various rights and interests at stake and with the aim of protecting and enhancing the trust of participants in the biobanking activities and in scientific research more generally.

The traditional approach to scientific research and to the mentioned balancing exercise in this field is constantly changing both because of the peculiar characteristics of biobanks and because of the advancement in research that constantly modifies the legal approach to its content.

On the one hand, biological samples are nowadays not only used for scientific research because of their nature as parts of the original human body but also because of the valuable genetic information that may be extracted therefrom. As it will be further explained, this raises new instances of protection that should however be balanced against the interest of society in conducting research on this limited and perishable resource.[274]

In this regard, Part A will be devoted to the description of the two theoretically applicable frameworks, namely one that protects and concerns the material nature of HBSs and the other focused on their informational nature, to attempt to determine whether is sufficient to consider either one of them or it is compulsory a unitarian consideration of both natures. It is worth anticipating that the conclusion will be on the prevalence of the informational nature, given the fact that HBSs are mostly collected and processed for the genetic data they may provide, and because the only instances of protection of fundamental rights that may arise from their processing relate to their informational nature.

[274] Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*.

Consequently, this generates the duty to process the HBSs as genetic data, raising some issues related to the interplay between the data protection legal framework and some soft law instruments applicable to HBSs.

Part B will be thus devoted to the analysis of the various provisions at the supranational and national levels to be complied with in order to collect and store personal data for biobanking purposes, including health-related data and genetic data. As mentioned, the analysis will be conducted taking into consideration the supranational level first, and the national one subsequently. A comparison between the two will be conducted whenever relevant.

The aim of the analysis in Part B will therefore be to provide an overview of the possible models for the collection of the biobank data, when applied to the peculiar processing activity of biobanking, and establish a method for choosing among various alternatives whenever the biobank might be left with different possible equivalent governance pathways.

In particular, the choice should be made first of all by balancing the public and private interests at stake in the given situation, and afterwards in case equal alternatives still exist by including the trust test, i.e. the evaluation of the choice that better protects participants' trust in biobanking. Indeed, in the various regulations and documents currently under development or last issued there is a clear tendency towards increasing the sharing of data among stakeholders and their re-use for purposes of general public interests, among which scientific research is frequently included, while at the same time carefully protecting the rights of the data subjects.

As for the concrete analysis of Part B, I will first of all extensively analyse the two possible approaches envisioned by the GDPR, namely the consent-based model (i.e. collecting and processing personal data with the *consent* of the data subject) and the necessity-based model (i.e. collecting and processing personal data based on the *necessity* of the processing), and the possible consequences of choosing one or the other. Afterward, I will conduct the same analysis under the national data protection regime, in order to present the choice of the Italian legislator, focused on acquiring the informational consent especially when data are processed for scientific research purposes, I will then provide an overview of the legal framework for the *secondary use* of personal data, i.e. the processing of the latter for purposes different from the original one. Indeed, the matter is

relevant for biobanking, where personal data are stored to be processed multiple times for different purposes, and is subject to specific legal provisions, which are often difficult to interpret and apply. Finally, I will analyse how the processing of personal data for biobanking purposes is influenced by two further regulations: the DGA, which is already fully applicable but only hypothetically relevant for biobanks, and the EHDS, which is currently under development but will be of compulsory application in the biobanking field once enacted.

A preliminary general consideration is necessary for the sake of clarity and in order to better proceed in the discussion. Both Part A and Part B will extensively discuss consent as the main requirement for the collection and storage of HBSs (Part A) or as one of the models for the collection and storage of personal data (Part B). However, these two types of consent are substantially different from one another and also compared to the type of consent usually required specifically for scientific research in general.

On the one hand, the participants' consent to the processing of personal data according to the GDPR will be hereinafter referred to as *informational consent,* adopting the nomenclature of Gefenas et al..[275] This consent is one of the legal bases available according to the GDPR and aims at ensuring the protection of the right to data protection and informational self-determination of the data subject.

On the other, the collection of HBSs is usually allowed after having acquired the informed consent of the patient to the medical procedure, which will be addressed as *interventional consent*.[276] Interventional consent is the participant's consent to an intervention that affects her physical integrity, which cannot lawfully be undergone otherwise unless in exceptional circumstances. As will be extensively discussed in the following pages, interventional consent is a basic principle and requirement of any medical intervention, even if not associated with scientific research, i.e when the medical intervention is necessary to safeguard or restore the health of the person concerned. Each type of consent highlighted above protects different rights and interests of the participant, from physical integrity (interventional consent) to information self-determination (informational consent).

[275] Gefenas, Eugenijus "Controversies Between Regulations of Research Ethics and Protection of Personal Data: Informed Consent at a Cross-Road." *Medicine, health care and philosophy,* vol. 25, 2022, pp. 23-30.
[276] Nomenclature of Gefenas, Eugenijus *ibid*

In the context of research with biological samples, whether traditional or biobank research, this consent is somehow coupled with the decision of the participant on how to use the sample:

- If the sample is collected for a specific research project, I will refer to this as *interventional research consent;*
- If the sample is to be stored in a biobank for future research uses, I will refer to this as *interventional biobank consent*.

As a consequence, what is traditionally referred to as "informed consent" for scientific research is somehow composed of two distinct parts: (a) consent to the medical intervention itself and (b) consent to the processing of the detached sample for a given purpose.[277] This purpose may be (b1) a specific research project (interventional research consent) or (b2) to be stored in a biobank for future use (interventional biobank consent). These two parts of consent ((a) to the detachment and (b) to the processing of the HBS) may be collected from the participants simultaneously or at different times. This may happen in two different cases in biobanking. For instance, in Scenario 1, participants undergo a medical procedure for the sole purpose of donating the biological sample to be collected and presumably the two parts of consent will be asked simultaneously. Differently, in Scenarios 2 and 3 where the intervention is conducted for purposes other than storing the sample in a biobank, and left-over samples are only subsequently stored in the biobank, the participants' consent on the use of these samples, when relevant, is usually asked on a later stage and by a different entity. The same may be said for left-over data or HBSs data.

Here, it suffices to highlight that the interventional consent asked in the context of biobanking and for biobanking purposes was built by applying by way of analogy the same requirements of and *ratio* behind the interventional consent asked in the more general context of the traditional scientific research. However, biobanking research is characterised by distinctive features, which in turn raise instances of protection different

[277] This dual nature of the participants consent asked in the context of scientific research that involves biological samples is highlighted by Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi"; Caredda, Valeria, "Campioni Biologici e Big Data: l'Evoluzione del Consenso." *Diritto di Famiglia e delle Persone,* vol. 2, n. 3, 2022, pp. 1061-1095; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: il Possibile Ruolo delle Biobanche."

from traditional scientific research. From, and because of, this some of the issues around the consent to be asked in biobanking arise.
Figure 2 will help clarify these distinctions.

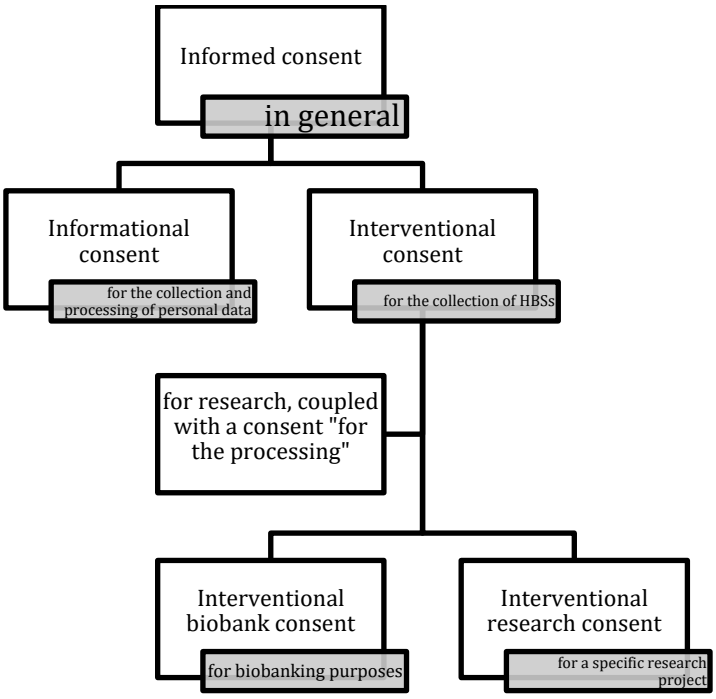

Figure 2

The consequences of this categorisation will be addressed whenever relevant throughout the discussion.

PART A – HUMAN BIOLOGICAL SAMPLES

Summary of Part A: 1. Introduction; 2. Relevant conceptual distinctions and scope of the analysis; 3 The framework applicable to the collection of HBSs for biobanking purposes – Consent at the supranational level; 3.1 ...and the national level; 4 The Dual nature of HBSs – (A) The material nature, or Human biological samples as detached parts of the human body; 4.1 ... (B) The informational nature, or Human biological samples as sources of personal data and parts of the identity of the person; 5. Developing a framework for HBSs – On the unitarian consideration of their dual nature; 5.1 Assessing the applicability of the relational-control model to the unitarian consideration of HBSs

1 INTRODUCTION

Advancements in science and technology enabled researchers to understand the importance of biological samples, previously ignored or considered merely organic waste especially in the case of left-over samples.[278]

Indeed, contrary to the past, the importance of HBSs for the advancement of scientific research is nowadays clearly recognised by most soft law instruments, such as Recommendation R(2016)6 when it acknowledged in the Preamble "the value of biomedical research for the advancement of health care and for the improvement of the quality of life and the potential of collections of biological materials of human origin to facilitate the realisation of these benefits".

The reason for such gained importance in research is mainly due to the discovery of the possibility of extracting personal data out of HBSs, which therefore became fundamental sources of valuable genetic data about the person they belong to, her health and lifestyle in general.[279] Indeed, these data may be used to study the origin of various genetic diseases or to develop new diagnostic methods. In particular, genetic data extracted from

[278] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici"; Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*.

[279] Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: il Possibile Ruolo delle Biobanche."

biological materials may be used for the development of -omic sciences[280] and personalised medicine,[281] which includes pharmacogenetics, somatic genetic therapies, etc,[282] because of the special relationship that bonds the HBS, the genetic data and the donor. For these reasons, HBSs are nowadays said to be at the centre of a new gold rush.[283] Precisely because of their newly discovered value (and nature) as sources of genetic data, HBSs are now considered not only in their *material nature* as detached parts of one's body, but also for the information they may provide about the person, and thus in their *immaterial*[284] or *informational nature*.[285] The analogy is frequently built by comparing the biological samples to a document with information on a specific person written on it,[286] or to vessels of the data included therein.[287]

This dual nature of HBSs and the link between them, the data possibly extracted therefrom and the donor contributed to the development of new instances of protection. Indeed, originally, research and biobank research processed samples only considered in their material nature. In this case, the detachment from the participants' body creates the HBS as an autonomous object and destroys the ontological and material connection between the HBS and the participant's body. As a consequence, any processing or intervention on the HBS does not have any direct consequences on the physical integrity of the person, and the remaining issues to resolve are those related to the legal nature and qualification of the samples and the limits and conditions for their sharing, circulation and processing.

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[280] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici."

[281] Ferrando, Gilda, "Il Principio di Gratuità, Biotecnologie e Atti di Disposizione del Proprio Corpo." *Europea e Diritto Privato*, 2002, pp. 771-780.

[282] Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*.

[283] Nelkin, Dorothy, and Lory, Andrews "Il Mercato del Corpo." *Il Commercio dei Tessuti Umani nell'Era Biotecnologica*, edited by Marcano, Maria Michela and Luca, Parisoli, Giuffrè 2002; Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona;* Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*.

[284] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici."

[285] Among many others Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: il Possibile Ruolo delle Biobanche"; Zullo, Silvia "Corpo e Property Rights: Limiti Criticità nel Bilanciamento tra Interessi Individuali e Collettivi." *Revista de Bioética y Derecho,* vol. 42, 2018, pp. 143-161.

[286] Tamponi, Michele "Campioni Biologici e Atti di Disposizione del Corpo." *Lo Statuto Etico-Giuridico dei Campioni Biologici Umani,* edited by Farace, Dario, Diritto, Mercato e Tecnologia, 2016, pp. 207-223; Nicolussi, Andrea "Campioni Biologici tra Bioetica E Biodiritto." *Lo Statuto Etico-Giuridico dei Campioni Biologici Umani,* edited by Farace, Dario, Diritto, Mercato e Tecnologia, 2016, pp. 145-158.

[287] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona*.

In particular, the question in this regard is whether it is possible to apply the rules governing property, with the necessary limits and adaptation.[288]

On the other hand, however, precisely from the moment of collection and the detachment of the sample from the participant's body, a new *informational* connection is built, one that did not exist before. Indeed, HBSs contain genetic data and information of the participant, which are ontologically linked to the donor's genetic identity for possibly an undefined period of time.

It is precisely this two-faced nature[289] that complicates the definition of the legal nature and qualification of a HBS, and consequently the possibility of it being shared and circulating in biobanking.

Indeed, as it has been pointed out, differently from the biological characteristics, the genetic traits of a person transcend the individual under both a spatial and a temporal dimension, because they are shared among all the people that pertain to a specific group or family and are inherited by the descendants.[290] The *informational nature* of HBSs contributes then to the development of what has been authoritatively defined as the *electronic body*,[291] which raises instances of protection that are different from those concerning the *physical body*.

As mentioned, the possible future application for research of HBSs considered now in this dual dimension raised new concerns that are related to the need to protect the person as a functional unit in which the body in its integrity and the samples that may be obtained from it are considered as a unicum worth of protection independently of their spatial location,[292] and of their nature as samples (materiality) or data (information).

In this context, only the protection of the person in her entirety allows a full exercise of her fundamental right of self-determination.[293] It is precisely the existence of this new permanent link between the samples (in their dual nature) and the person that calls into

[288] Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: il Possibile Ruolo delle Biobanche."

[289] Macilotti, Matteo "Proprietà, Informazione ed Interessi nella Disciplina delle Biobanche a Fini di Ricerca." *Nuova Giurisprudenza Civile Commentata,* vol. 7-8, 2008, pp. 222-235.

[290] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona.*

[291] Rodotà, Stefano "Il Corpo "Giuridificato." *Trattato di Biodiritto. Il Governo del Corpo. Tomo I,* edited by Canestrari, Stefano, et al. Giuffrè, 2011, pp. 51-76.

[292] Rodotà, Stefano, *La Vita e le Regole. Tra Diritto e non Diritto,* Feltrinelli, 2018.

[293] *Ibid*

question the possibility of granting participants extended control not only over their body but also over any parts separated from it and their possible future use in research.

From the dual nature of the HBS (material and informational), a double need for the protection of the human dignity of the person concerned arises. On the one hand, dignity declined as physical integrity, whenever the material dimension of the HBS is under scrutiny, and on the other as personal identity, if the processing concerns the personal (genetic) data extracted from the HBS.[294]

However, at the same time, HBSs and the related data are incredibly valuable resources for scientific research and as such the instances of individual protection should be balanced against the interests of society as a whole in the advancement of research, and ultimately -omic sciences and precision medicine. Indeed, granting participants full control would limit the possibility of researchers to freely use the HBSs for the research projects they consider valuable the most and fundamental for protecting and advancing collective health.

Therefore, the difficulties in finding a fair balance among the various instances at stake originate from the complexity of defining the legal qualification of HBSs and consequently the regime applicable to their collection and processing.

Both aspects, the legal qualification of HBSs and the regime applicable to their collection, influence the governance choice of the way of collecting them for biobank purposes. Indeed, the biobank should carefully evaluate the alternatives and balance the various and possibly contrasting interests and rights of participants on the one hand and society as a whole and scientific research on the other for lawfully conducting its activities and protecting participants' trust.[295]

On the one hand in order to protect the individual rights possibly affected by the processing of the *material part* of the HBS, soft law instruments generally establish the duty to ask for the informed consent of the participant (interventional biobank or research consent). On the other hand, the informational nature of the HBS requires the interpreter

[294] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici"; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: Il Possibile Ruolo delle Biobanche."

[295] It is worth anticipating here that the protection of participants' trust in the handling of HBSs is also included in Recommendation R(2016)6 in the Preamble: "Emphasising the importance of earning trust and stressing the role of good and transparent governance of biological materials of human origin stored for research purposes, including the establishment of an appropriate feedback policy."

to consider the HBS also as personal data and comply with the norms provided for by the relevant national and supranational legislation on data protection. Therefore, it will be paramount to understand whether these requirements are cumulative or alternative.

To this end, in the following paragraphs, after having deeply analysed the requirements provided for by the applicable soft law instruments for the processing of biological samples, I will describe separately and in detail both the *material* and the *informational nature*. I will then present the issue to be addressed when deciding the model for collecting HBSs, namely whether the two natures of the samples should be addressed alternatively or cumulatively when choosing how to collect HBSs to be stored in a biobank and what is the relationship between the biobank and the participant in this regard. The answer to the question may be found only by considering the different rights and interests at stake in this type of collection.

2 RELEVANT CONCEPTUAL DISTINCTIONS AND SCOPE OF THE ANALYSIS

First of all, to delimit the scope of the analysis it is of paramount importance here to clarify a preliminary distinction. Indeed, one of the main characteristics of biobanks has been identified in the fact that these are collections of HBSs and data to be used for future research purposes (the *purpose* element of biobank, as described in Chapter I). In this regard, the biobank usually stands somewhat in between participants and researchers and provides various services, which include preserving a certain quality of the samples and data and regulating access by researchers.[296]

As a consequence, I believe in the necessity to separate the various purposes of the processing of the HBSs when it comes to identifying the requirements for their collection. Indeed, the collection and storage of the content of the biobank is an activity ontologically different from that of using the HBSs and data for research purposes and, to this end, should be subject to autonomous requirements, tailored on the selected rights and interests to be protected in a given scenario, and therefore on the specificities of the activity under consideration. Proceeding otherwise, and thus imposing on the sole biobanking activity (i.e. collection and storage of samples and data) the same requirements provided for

[296] In a more limited number of cases, the biobank may also be the entity that directly conducts the future research projects, but as mentioned this scenario will not be directly taken into consideration.

research would mean duplicating the duties and responsibilities, even in cases where this would not be necessary for the protection of a specific fundamental right or interest, and possibly at the (unjustified) expenses of freedom of scientific research at large and thus society.

Therefore, the following analysis of the requirements for the collection of HBSs provided for by hard and soft law instruments will focus only on those related to the storage of the samples in the biobank for future research purposes and, for instance, I will not include any provision of hard or soft law instruments that requires consent for the use in a research project of the HBS or establishes specific requirements for scientific research,[297] unless otherwise provided by hard law instruments or case law.

Another distinction should be kept in mind for the purposes of this Part A.

Samples are divided among left-over samples, donated samples and samples from deceased persons, with only the first two being relevant to the present work. As previously mentioned in Chapter I, the difference between the two rests on the fact that in the first case (*left-over samples*) the participant originally agreed to undergo a medical procedure or asked for medical assistance more generally, which resulted in the collection of one or more biological samples. Here, storing these HBSs in a biobank constitutes secondary use, i.e. a processing of the samples different from the one for which they were originally collected and, possibly, of which the participant was originally informed. The sample is then considered valuable for research and therefore qualifies for being stored in a biobank for future research use. In the second (*donated samples*), the participant consents to undergo a medical intervention with the sole purpose of collecting a biological sample to be stored in a research biobank.

As already mentioned and also extensively described in the following pages, collecting and storing biological samples in a biobank for future research purposes usually requires the consent of the participant, which in the biobanking context I have identified as *interventional biobank consent.* As previously highlighted, this consent is different from

- on the one hand, *informational consent*, which is relevant in the context of the collection, storage and use of personal data according to the GDPR (and further elaborated in Part B);

[297] This approach will also be the one adopted for biobank data, in Part B.

- on the other, *interventional research consent,* which is usually asked for specific research projects. However, for both interventional consents (*research* and *biobank*) the participants had to previously consent to the medical procedure for collecting the biological sample (i.e. interventional consent).

Interventional consent was first introduced by the Nuremberg Code in 1947,[298] and subsequently by most hard and soft law instruments at the supranational level,[299] which provide for the duty of physicians and researchers to acquire specific informed consent to the medical procedure and for participating in the research project. Asking for the interventional consent of the participant represented the first step away from a paternalistic consideration of patients, according to which physicians were considered to know what was in the best medical interest of patients, and towards a more active role and participation of patients in the protection of their health.[300]

At the national level, providing interventional consent qualifies as a right according to articles 2, 13 and 32 paragraph 2 of the Italian Constitution, and it is provided for by other sectorial regulations such as Law No. 219/2017 entitled "Provisions for informed consent and advance treatment directives".

Interventional consent has thus become an act both of legal and ethical-deontological relevance, at the national and supranational level, and "one of the primary principles on which the framework of protections for human subjects in research is built".[301]

Similarly, the original aim of asking for interventional research consent is to respect the autonomy and physical integrity of the patient,[302] in her decision on whether to undergo a medical procedure and participate in a research project that had a direct impact on her

[298] Granados Moreno, Palmira, and Yann, Joly "Informed Consent in International Normative Texts and Biobanking Policies: Seeking the Boundaries of Broad Consent." *Medical Law Journal,* vol. 15, n. 4, 2015, pp. 216-245. For a deeper analysis of the origin of this consent, see Weindling, Paul, et al. "The Origins of Informed Consent: The International Scientific Commission on Medical War Crimes, and the Nuremberg Code." *Bulletin of the History of Medicine*, vol. 75, no. 1, 2001, pp. 37-71; Dankar, Fida K., et al. "Informed Consent in Biomedical Research." *Computational and Structural Biotechnology Journal,* vol. 17, 2019, pp. 463-474; Manson, Neil C., and Onora, O'Neil *Rethinking Informed Consent in Bioethics*, Cambridge University Press, 2007.

[299] Among others, the Oviedo Convention; Declaration of Helsinki; CIOMS International Ethical Guidelines; UNESCO International Declaration; EU Charter of Fundamental Rights.

[300] Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea.*

[301] Bazzano, Lydia A, et al. "A Modern History of Informed Consent and the Role of Key Information." *Ochsner Journal,* vol. 21, 2021, pp. 81–85.

[302] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici."

physical integrity and possibly health. For these reasons, the requirements applicable to this type of consent were particularly stringent especially as for the information to provide to the participant in order to ensure that her decision was really informed, based on a careful evaluation of all the characteristics of the concrete procedure or project and of the risks and benefits of her participation. Almost the same requirements are also applicable to research conducted on biological samples, even though no direct physical harm or risk to the person is envisioned.

However, as mentioned, this consent does not refer to the storage of the samples (both left-over and donated) in a biobank or their subsequent use for future research.[303] Indeed, this decision requires a different manifestation of consent, i.e. the *interventional biobank consent* in the context of biobanking.[304]

Biobanking is a peculiar way of conducting research, understood in a broader sense, with different characteristics and risks if compared to the more traditional way of conducting research. Indeed, as will be further explained, on the one hand, biobanks process HBSs (and also data) for the purpose of making them available for future undefined research projects (and not for directly conducting one). Moreover, and also consequently, there is little or no harm possible to the physical integrity of the person, and the risks related specifically to biobanking activities are relatively low. Most of the risks, possibly to the self-determination of the participant, her genetic identity or right to data protection and privacy, are related to the future use of the HBSs by researchers, to whom the biobank granted access to the data but that are separated from it.

As a consequence, the *interventional biobank consent*, i.e. consent to the collection of the samples in order to store them in a biobank for future use, usually required by the soft law instruments analysed in detail in Chapter I and referred to in the next paragraphs, is conceptually different from the traditional *interventional research consent*, also and in particular because of the different risks posed by the two activities (research and biobanking).

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[303] Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context." *European Journal of Health Law,* vol. 19, 2012, pp. 271-288.

[304] Indeed, in this regard, Calderai affirms that this "second" consent is the one that confers value to a biological sample that would otherwise be discarded, and therefore would not be the object of any right, proprietary or otherwise. Calderai, Valentina, "A Pound of Man's Flesh. Consenso alla Ricerca sui Tessuti Biologici Umani e Teoria dei Beni."

However, through time *interventional biobank consent* has been conceptually developed from the traditional version of *interventional research consent,* i.e. the consent to participate in research on human subjects, also attempting to apply the same requirements. Only in limited cases the norms relevant on the matter have acknowledged the mentioned difference, especially in terms of the information to be provided to the subject when sking for consent.

In this specific context and referring to the various ways of collecting HBSs and data, it is important to underline that in Scenario 1 (where donated samples are collected), interventional biobank consent is the only type of consent required for the collection and storage in a biobank of HBSs. Such consent, as mentioned, includes not only the interventional consent necessary to authorise the medical procedure for the detachment of the sample but also that for further processing it for biobanking purposes. Both elements of the interventional biobank consent will probably be collected at the same time.

In Scenarios 2 and 3 (where for our purposes, left-over samples are collected), processing the HBSs for biobanking purposes is a secondary processing of samples previously collected for different purposes (and gain such collection had been authorised by the participant via the provision of the interventional consent). Consequently, in both Scenarios the consent to the medical procedure and for storing HBSs in the biobank might be asked separately, possibly after a long time and almost always by separate entities.

3 THE FRAMEWORK APPLICABLE TO THE COLLECTION OF HBSs FOR BIOBANKING PURPOSES – CONSENT AT THE SUPRANATIONAL LEVEL

I will now analyse the specific requirements for the collection of HBSs in the biobanking context, as provided in the applicable framework described in Chapter I, and thus in the various hard and soft law instruments applicable to biobanking.

First of all, at the supranational level, the participant's informational biobank consent is asked as a requirement by the Declaration of Taipei,[305] which lists the information to be

[305] When it comes to informed consent, paragraphs 11-19 of the Declaration of Taipei are relevant. as for the Declaration of Helsinki, consent is usually required for scientific research involving humans, and research with biological samples is only addressed in Paragraph 32 "For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional

provided in order for this consent to be *informed*. In particular, paragraph 11 of the Declaration of Taipei clearly affirms that the specific, voluntary, free and informed consent of the participant shall be provided for the *collection, storage and use* of biological material.

In order for consent to be informed when biological materials are stored in the biobank for future undefined research uses, the participant should be adequately provided with the specific information listed in paragraph 12. Therefore, in this case, the Declaration of Taipei seems to acknowledge the specific characteristics of the biobanking field, as opposed to the more classical way of conducting scientific research, and thus in particular the fact that HBSs may be stored for future research purposes, which are undefined at the time of the collection and subsequently.[306]

In order to adequately protect the right to be informed of the participant, in this case, the Declaration adapts the information that the Declaration of Helsinki requires to be provided when asking for specific consent (*rectius* interventional research consent). Indeed, the information on the research project is substituted with corresponding information on the functioning or governance of the biobank. For instance, the risks and burdens to be informed about will be those of the process of collection and storage of the HBSs and not those associated with the research project. Moreover, the duty to inform about sources of funding and any possible conflicts of interest related to the project is substituted by information about the possible commercial use and benefit sharing, as well as intellectual property issues.

Finally, participants shall receive information about how their privacy is protected, their fundamental rights, and the consequences of their samples being made non-identifiable,

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situations where consent would be impossible or impracticable to obtain for such research. In such situations, the research may be done only after consideration and approval of a research ethics committee." However, as explained at the beginning of this Chapter, asking for consent to the research project (interventional research consent) is not the same as asking for biobanking purposes, i.e. to include the samples in the biobank for future use (interventional biobank consent). Indeed, the same Declaration of Taipei highlights such a difference when in paragraph 11 it establishes that "[t]he collection, storage and use of data and biological material from individuals capable of giving consent must be voluntary" but that "[i]f the data and biological material are collected *for a given research project*, the specific, free and informed consent of the participants must be obtained in accordance with the Declaration of Helsinki." Emphasis added.

[306] Chassang, Gauthier, and Emmanuelle, Real-Sebbag "Research Biobanks and Health Databases: The WMA Declaration of Taipei, Added Value to European Legislation (Soft and Hard Law)"; Hallinan, Dara "Broad Consent Under the GDPR: an Optimistic Perspective on a Bright Future." *Life Sciences, Society and Policy*, vol. 16, n. 1, 2020.

in particular the fact that they might not be able to be aware of the various uses of their materials and to withdraw the provided consent.

Such consent may be withdrawn at any time, and therefore, the participant might ask for her samples not to be stored "for future use" anymore.[307] This last specification, i.e. that withdrawing consent is only valid *pro futuro* and therefore *ex nunc,* enables researchers to complete ongoing research projects and avoid negative consequences on them.

Finally, the requirement of consent may be waived in exceptional circumstances, such as when "a clearly identified, serious and immediate threat" is identified and "anonymous data will not suffice".[308] Processing the samples for biobanking purposes in these circumstances would require a careful evaluation conducted by an independent ethics committee.[309]

Moreover, informational biobank consent is specifically required by the CIOMS International Ethical Guidelines, and may be waived by the research ethics committee if (1) the research would not be feasible or practicable to carry out without the waiver; (2) the research has important social value; and (3) the research poses no more than minimal risks to participants or to the group to which the participant belongs. Here, the Guidelines seem to acknowledge the possibility of balancing the rights of the participant and the interests of research and society at large. Indeed, a third impartial entity, the ethics committee, may evaluate whether the value of research for society is high enough to accept a certain degree of risk for the rights of participants at risk, which however shall be minimal. The Guidelines, however, further explain that such an option should not be feasible, among others, when controversial or high-impact techniques are used, when research is conducted on certain tissue types, for example gametes.

Moreover, OECD Recommendation 2009 establishes in principle 4.B the necessity for the operators of the biobank to acquire prior, free and informed consent. The information to be provided in this regard is related to the risks and benefits of the participation, and should interestingly cover not only the biological sample, but also the intended use and storage of the "data to be collected, *data anticipated to be derived from the analysis of*

[307] Paragraph 15 of the Declaration of Taipei.
[308] Paragraph 16 of the Declaration of Taipei.
[309] in these terms, paragraph 32 of the Declaration of Helsinki and paragraph 16 of the Declaration of Taipei. In particular, according to paragraph 32 of the Declaration of Helsinki, this may be done when asking for consent is impractical. On the possible meanings of this term, see Laurijssen, Sara JM, et al. "When is it impractical to ask informed consent? a systematic review." *Clinial trials*, vol. 19, n. 5, 2022, pp. 545-560.

samples, and the health and other records to be accessed" (emphasis added).[310] Therefore, the consent requested by the OECD Recommendation 2009 intends to cover not only the actual collection of samples and data, but also those data that might be possibly derived from the samples.

Differently from other instruments, OECD Recommendation 2009 addresses specifically the collection and processing for biobanking of left-over HBSs, and in this case if subsequent use of the HBSs was not envisaged at the time of the provision of the first interventional consent, the OECD Recommendation 2009 recommends asking for new consent, unless authorised otherwise by a research ethics committee or an appropriate authority, provided that adequate protection of the participant's rights is ensured.[311] In order to understand if re-consenting is necessary, it should be evaluated whether the new scopes and purposes are consistent with the original one and only in case of a negative answer re-contacting participants is required.[312]

For the consent to be *informed,* participants should in particular be aware of the possibility of withdrawing consent,[313] how their samples and data will be protected,[314] and be provided with extensive information on the functioning of the biobank and possible uses of their materials.[315] In this case as well, information should be provided on the functioning of the biobank and not on the specific research project, thus tailoring the requirements applicable to interventional biobank consent to the specific context.

As far as the right to withdraw consent is concerned, paragraph 42 of the Annotations to the OECD Recommendation 2009 provides for the possibility of exercising it gradually. Indeed, the participant may decide not to be further contacted, but (a) to permit the continued retention and use of the already collected and stored samples and data, (b) to ask for the destruction or anonymisation of the samples and data, or (c) to ask specifically for their destruction (complete withdrawal). Finally, information should be provided to participants on possible limitations of such a right, i.e. when withdrawing is not possible,

[310] Best practice 4.4 OECD Recommendation 2009.
[311] Best practice 4.5 OECD Recommendation 2009.
[312] Paragraph 33 of the Annotations to the OECD Recommendation 2009.
[313] Best practice 4.13 OECD Recommendation 2009.
[314] Principle 6.C OECD Recommendation 2009.
[315] Paragraph 35 and 36 of the Annotations to the OECD Recommendation 2009.

for instance because samples have been anonymised and/or distributed, or results are in the public domain or have been published, complete withdrawal may not be possible.[316]

When it comes to the UNESCO Declarations, similarly to the OECD Recommendation 2009, prior, free, informed and expressed consent to use samples is required by the UNESCO International Declaration,[317] which establishes that consent is necessary for undergoing the procedure for collecting the samples, and processing, using and storing them for research, i.e. processing them for biobanking purposes, unless "prescribed for compelling reasons by domestic law consistent with the international law of human rights".

Indeed, according to Art. 16, HBSs may be used for a purpose incompatible with the one specified at the time of consent only with a new consent. Interestingly, and differently from most of the other instruments, re-consent may be waived if the processing "corresponds to an important public interest reason and is consistent with international law of human rights" or more generally "in accordance with domestic law".

The International Declaration grants the participant the possibility of withdrawing a previously provided consent,[318] and establishes the consequences of such withdrawal, namely the duty to not use them for any future research project, unless fully anonymised. Therefore, similarly to the Declaration of Taipei, also the UNESCO International Declaration clarifies the *ex nunc* effect of the withdrawal.

Finally, under exceptional circumstances, the requirement of consent may be waived "for compelling reasons established by domestic law" and guaranteeing the respect of fundamental human rights.[319]

Similarly, after having recognised the importance of the willingness to participate in, and contribute to biomedical research,[320] Recommendation R(2016)6 in Art. 11 addresses specifically interventional informed consent, i.e. "for storage for future research". It is also the only document that addresses the different modalities for the collection of

[316] Paragraph 43 of the Annotations to the OECD Recommendation 2009.

[317] See Art. 8 "(a) Prior, free, informed and express consent, without inducement by financial or other personal gain, should be obtained for the collection of human genetic data, human proteomic data or biological samples, whether through invasive or non-invasive procedures, and for their subsequent processing, use and storage, whether carried out by public or private institutions. Limitations on this principle of consent should only be prescribed for compelling reasons by domestic law consistent with the international law of human rights."

[318] Art. 9 of the UNESCO International Declaration.

[319] Art. 8 of the UNESCO International Declaration.

[320] See the Preamble of the Recommendation R(2016)6.

biological samples and specifies the requirements for interventional biobank consent accordingly. Indeed, the first paragraph refers to *donated samples,* i.e., those samples collected in the course of a medical treatment undergone specifically for that purpose, and asks for prior, free, expressed, and documented interventional consent. In contrast, paragraph 2 addresses the conditions to be complied with when it comes to interventional biobank consent for *left-over samples,* by establishing that "[b]iological materials previously removed for another purpose should only be stored for future research with the consent of the person concerned, as provided for by law. Whenever possible, consent should be requested before biological materials are removed". The third paragraph then concerns the case in which left-over samples are anonymised and stored for future research, by establishing the possibility of waiving the requirement of consent under the condition of being authorised by law.

When it comes to donated samples, Art. 11 paragraph 1 specifies that in order to be adequately informed consent should be "i) specific to the intervention carried out to remove the materials and ii) as precise as possible with regard to the envisaged research use". It seems reasonable to consider that the same could be said for left-over samples.

Finally, Art. 13 establishes the right to withdraw such consent, which entails the possibility of asking for the samples and associated data to be either destroyed or rendered non-identifiable.

It is finally necessary to analyse whether there are provisions established by the Oviedo Convention that prescribe the necessity to ask for the consent of the participant for the processing of her HBSs in the biobanking context. Two provisions might be relevant in this regard.[321]

On the one hand, Art. 5 prescribes the necessity of acquiring informed consent (interventional consent according to the above-mentioned categorisation) in any human intervention in the health field, that is to say, according to the Explanatory Report, any

[321] It is important here to remind that the Oviedo Convention has not been ratified by Italy and therefore it is not legally binding per se. However, it has been argued that some of its provision, and in particular those related to informed consent, may qualify as the expression of already existing international principles. On this, De Angelis, Fernando "Consenso Libero ed Informato: la Convenzione di Oviedo nell'Articolato Contesto Storico e Giuridico delle Fonti." For this reason, I will include its provisions in the analysis. For an extended analysis on this, see Chapter I.

medical act and in particular those performed for the purpose of preventive care, diagnosis, treatment, rehabilitation or research.[322]

On the other, Art. 22 establishes the same duty to ask for consent and provide information for storing and subsequently using left-over samples for research.[323]

Indeed, the Explanatory Report clarifies that "parts of the human body are often removed in the course of interventions, for example surgery" and Art. 22 aims at protecting individuals in this eventuality, by establishing "a rule consistent with the general principle in Article 5 on consent, i.e. that parts of the body which have been removed during an intervention for a specified purpose must not be stored or used for a different purpose unless the relevant conditions governing information and consent have been observed". In this regard, it also establishes that the choice of the type of consent to be adopted depends on the circumstances and "express consent of an individual to the use of parts of his body is not systematically needed". Indeed, if specific consent is impossible or particularly difficult because of the circumstances, *presumed* consent may be sufficient, provided that appropriate information is provided to the participant.

Moreover, theoretically relevant for biobanking is also the Additional Protocol to the Convention on Human Rights and Biomedicine[324] that aims to "protect the dignity and identity of all human being (…) with regard to any research involving interventions on human beings in the field of biomedicine" (Art. 1).

Art. 2 clarifies that the Protocol applies to a wide range of research activities, including not only (a) those that directly involve physical interventions on human beings but also (b) any other intervention that may involve a risk to the psychological health of the person concerned (Art. 2). In this regard, similarly to what stated in the Explanatory Report to the Convention itself, in the Explanatory Report to the Additional Protocol it is clearly stated that "insofar as a human being is involved in research, this protocol applies",[325]

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[322] The Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine in particular establishes that the term should be interpreted in the "widest sense." On the topic, also Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*.

[323] Art. 22 Oviedo Convention "When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures."

[324] Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research. Strasbourg, 2005.

[325] Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, art. 2 para. 15.

and that “the term ‘intervention’ covers physical interventions” and is to "be understood here in a broad sense”. Moreover, “the Protocol does not address established medical interventions independent of a research project, even if they result in biological materials or personal data that might later be used in biomedical research. However, research interventions designed to procure biological materials or data are covered under this Protocol”.[326]

Therefore, it appears that in the biobanking context the applicability of the Oviedo Convention and its Protocols may be controversial. Indeed, while the applicability of Art. 22 in Scenarios 2 and 3, and thus to left-over samples is relatively straightforward, applying Art. 5 in Scenario 1 (donated data) depends on whether collecting HBSs for biobanking purposes qualifies as a “human intervention in the health field”, and in particular as a medical act performed for the purpose of research. According to what has been previously underlined concerning the diversity of biobanking when compared to traditional scientific research, it seems that Art. 5 does not apply in Scenario 1, because collecting and storing samples in a biobank does not constitute in itself either “scientific research” or “intervention”, within the meaning of the Oviedo Convention or its Additional Protocol.[327]

Finally, if samples are collected in Scenario 2 – collection for scientific research purposes in the context of a clinical trial, the EU Clinical Trials Expert Group issued the document “Compliance with Member State applicable rules for the collection, storage and future use of human biological samples (Article 7.1h)”, required by the Clinical Trial Regulation and not mandatory, in which section 4 acknowledges the possibility of storing for future use the samples and data collected for a specific research project. It appears safe to imagine that this storage may also happen in a biobank. In filling in this section, account should be taken to the requirements underlined above.

It is worth noticing here that another important general requirement to be complied with when it comes to the processing of samples is the prohibition of financial gain from the processing of HBSs.[328] This principle has been interpreted in two distinct ways. The first

[326] Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, art. 2 para. 15.

[327] On this interpretation, see *mutadis mutandis* Pormeister, Kärt “Genetic Research and Consent: on the Crossroads of Human and data research.”

[328] Art. 21 of the Oviedo Convention “The human body and its parts shall not, as such, give rise to financial gain”; Art. 3 EU Charter of Fundamental Rights “2. In the fields of medicine and biology, the following

interpretation claims that there is absolutely no possibility to claim property rights on the body and its parts, even after the collection of biological samples, while the second one interprets the provision in a narrow sense, as implying only a ban on marketing the HBSs as any other good.[329] However, this prohibition is mainly relevant to the possibility of patenting biological samples or any invention derived from their processing, which will not be discussed in the present work.

3.1 ...AND THE NATIONAL LEVEL

At the national level, Art. 2 of the Law n. 3/2018 establishes that the Italian Government should issue various legislative decrees on the general field of clinical trials, among which is included one on the provisions to be complied with for the use for scientific research purposes of left-over samples (Art. 2 lett. f). While Art. 1 leaves considerable room for manoeuvre on the choice of the requirements, it establishes that the interventional research consent of the participant should always be collected. However, the mentioned legislative decrees have not been issued yet.

Various other soft-law instruments require the collection of the interventional biobank consent of the participant before storing the samples in the biobank and using them for research purposes. For instance, relevant in this context is the Rapporto ISS Covid-19 n. 13/2020 issued by the Istituto Superiore di Sanità on Recommendations for the collection, transport and storage of COVID-19 biological samples of April 2020 provides for the duty to collect the interventional biobank consent of the participant/patient as soon as possible for the collection of COVID-19 samples for research on the disease. The document, which is not legally binding, clearly affirms that in the context of biobanks, a pact is made between the biobank itself and participants, in which the interventional biobank consent should be understood as a dynamic process to conduct scientific research and protect the interests of participants.

Acquiring the participant's interventional biobank consent is also prescribed by the General Authorisation n. 8/2016, which refers to the processing of genetic data, but contains some provisions applicable to HBSs or that have direct consequences on their

must be respected in particular: (c) the prohibition on making the human body and its parts as such a source of financial gain"; Art. 3(2)(c) of the EU Charter.

[329] On this possible dual interpretation, see Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: il Possibile Ruolo delle Biobanche."

legal regime. First of all, paragraph 4.2 of the General Authorisation n. 8/2016 establishes some general provisions for the storage and safety of genetic data and HBSs, which include the duty to pseudonymise or otherwise protect them and their quality, integrity, traceability and availability.

Particularly significant is the provision that establishes that whenever the participant withdraws the previously provided informed consent to the use of genetic data and samples for scientific research purposes (and therefore not to include those in the biobank), the biological samples should be destroyed, unless the person is not identified or identifiable from the samples (therefore unless rendered anonymous) (paragraph 4.5). As it will be addressed later on, these provisions expressly link the material to the informational nature of HBSs.

Moreover, paragraph 4.11 establishes the conditions for processing HBSs for scientific research purposes. In particular, a first general condition is that such processing is lawful only if it aims at protecting the health of the data subject, of third parties or of society as a whole in the medical or biomedical field. However, the subsequent paragraphs require the processing to be based on a project drawn up in compliance with relevant standards, thus rendering these provisions hardly applicable to biobanking because of the peculiarities of the field, as highlighted above.

Differently from the others, paragraph 4.11.3 establishes the provisions to be complied with for left-over samples in Scenario 3 and 2. Indeed, as for the first one, it provides that the storage (and subsequent use) for scientific research purposes of the genetic data collected for the provision of healthcare and left-over samples (Scenario 3) is possible in general if (a) interventional biobank consent is acquired or (b) as an exemption without it

> (b1) for scientific research projects provided by law; or
>
> (b2) for scientific research purposes directly related or linked to those for which a previous consent was already collected (i.e. interventional research consent or interventional consent).

Furthermore, as for the second (Scenario 2), paragraph 4.11.3 provides the requirements for the storage for future use for scientific research purposes of left-over samples and genetic data processed in a previous research project. The norm affirms that the use of these HBSs in research projects different from the original ones is legitimate either (a) with the interventional biobank consent of the participant or (b) without such consent if

it is impossible to inform her, and any reasonable effort has been put in an attempt to this end, and the project cannot be conducted with other samples or data for which consent may be collected. Two further alternative conditions should be respected in the latter case: (b1) the samples and data should not enable the identification of the participant (i.e. are anonymous or have been anonymised) and the participant never opposed the use of the samples and data; (b2) the scientific program has been approved by the competent ethics committee and art. 36 of the GDPR have been complied with.[330]

4 THE DUAL NATURE OF HBSS – (A) THE MATERIAL NATURE, OR HUMAN BIOLOGICAL SAMPLES AS DETACHED PARTS OF THE HUMAN BODY

As mentioned, HBSs come into existence and acquire conceptual and functional autonomy in their material nature with the action of collection and therefore detachment from the body of the person they belonged to.[331] Such collection should respect the applicable national provisions, and in particular the limits of Art. 5 of the Italian Civil Code read and interpreted together with Art. 2, 13 and 32 of the Italian Constitution related to the protection of the physical integrity of the participant and her right to self-determination in relation to her health,[332] as well as Law n. 219/2017. As a consequence,

[330] The translation is mine. The original version of this paragraph is the following "In assenza del consenso degli interessati, i campioni biologici prelevati e i dati genetici raccolti per scopi di tutela della salute possono essere conservati e utilizzati per finalità di ricerca scientifica o statistica nei seguenti casi: a) indagini statistiche o ricerche scientifiche previste dal diritto dell'Unione europea, dalla legge o, nei casi previsti dalla legge, da regolamento; b) limitatamente al perseguimento di ulteriori scopi scientifici e statistici direttamente collegati con quelli per i quali è stato originariamente acquisito il consenso informato degli interessati. Quando a causa di particolari ragioni non è possibile informare gli interessati malgrado sia stato compiuto ogni ragionevole sforzo per raggiungerli, la conservazione e l'ulteriore utilizzo di campioni biologici e di dati genetici raccolti per la realizzazione di progetti di ricerca e indagini statistiche, diversi da quelli originari, sono consentiti se una ricerca di analoga finalità non può essere realizzata mediante il trattamento di dati riferiti a persone dalle quali può essere o è stato acquisito il consenso informato e: aa) il programma di ricerca comporta l'utilizzo di campioni biologici e di dati genetici che in origine non consentono di identificare gli interessati, ovvero che, a seguito di trattamento, non consentono di identificare i medesimi interessati e non risulta che questi ultimi abbiano in precedenza fornito indicazioni contrarie; bb) ovvero il programma di ricerca, preventivamente oggetto di motivato parere favorevole del competente comitato etico a livello territoriale, è sottoposto a preventiva consultazione del Garante ai sensi dell'art. 36 del Regolamento (UE) 2016/679."

[331] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona;* Deplano, Stefano "Il Campione Biologico di Unidentified Person. Profili di Sistema."

[332] Cordiano, Alessandra "Biobanche di ricerca e modelli regolativi"; Gambaro, Antonio, *La Proprietà. Beni, Proprietà, Comunione*, Giuffrè, 1990; Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici"; Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context."; Soro, Antonello "Autodeterminatione Terapeutica ed Autodeterminatione Informativa: I Nuovi Aspetti della Dignità." *Intervento al Convegno "La Smaterializzazione dei Documenti e il Suo Impatto sul Sistema Salute,* Roma, 2016.

collecting the HBS is possible only with and after the participant has provided what has been referred to as *interventional consent* (i.e. consent to the medical procedure).

Indeed, up to the collection, the sample functionally and ontologically pertains to the participant's body and could not be the object of any autonomous right, interest, or action (where "autonomous" should be interpreted as "separated from the body in its integrity and entirety). Moreover, in order to store these samples in a biobank and subsequently use them for future research purposes, informational biobank consent should be provided as well, as required by the soft law instruments cited above, except for in exceptional circumstances.[333]

This has two main consequences. On the one hand, the HBS is created in its material nature by the act of collection and from this moment onwards it may be the direct object of legal considerations and actions.[334] In particular, the HBS can be physically and legally transferred from the participant to the biobanks and subsequently to researchers. On the other hand, and because of the first consequence, the material link and connection between the sample and the body is destroyed and therefore any operation performed on the sample will not have any direct effect on the physical integrity and health of the person they belonged to.

Consequently, questions arise about how to conceptualise and regulate the new relationship between the person and the biological sample. Indeed, it is not possible to directly extend over the samples the liberties and powers that a person can exercise over her body, precisely because of the physical autonomy that characterises HBSs after collection.[335] In particular, the relationship between the sample and the person cannot be solved on the grounds of the right to health and the protection of a person's physical integrity, because any intervention on the sample does not directly affect the body of the donor. Indeed, genetic research and more generally research on biological samples or with data do not raise instances of protection of the physical integrity of the participant.[336]

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[333] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici."

[334] Eusebi, Luciano "Diritti fondamentali, Biobanche e Gestione dei Materiali Biologici Umani." *Lo Statuto Etico-Giuridico dei Campioni Biologici Umani*, edited by Farace, Dario, Diritto, Mercato e Tecnologia, 2016, pp. 59-72; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: Il Possibile Ruolo delle Biobanche."

[335] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona*.

[336] Rapisarda, Ilenia "Brevi Note sullo Statuto Giuridico del Materiale Biologico Umano.".

The solution to this question is influenced and influences the issue of the qualification and consequences of providing interventional biobank consent to the biobank processing of HBS. As mentioned, this consent relates to the decision on the use of the collected sample.

The European approach in the early discussion on the matter focused exclusively on the material nature of the samples and pivoted around the question of whether it was possible to exercise property rights over them.[337] In this regard, consent would have the consequence of transferring the property of (and the power to control) the HBS.

Indeed, as underlined by Macilotti, the material nature of HBSs generates questions related to (a) the possibility of qualifying HBSs as objects capable of being owned (b) identifying who eventually may be the owner of the samples and (c) if the participants own the HBSs, what legal effect might have to provide consent in the biobanking field.[338]

(a) Indeed, at the very early stages, at a time when their informational nature had not been discovered or did not have the importance recognised today,[339] the majority of Italian scholars agreed on framing the issue within the dimension of property and on the applicability of property rights to HBS.[340]

Indeed, according to them, upon the moment of collection HBSs acquired ontological and material autonomy from the body of the participant and should have been qualified as *disposable personal goods* according to Art. 810 of the Italian Civil Code.[341] As a consequence, their property could be transferred from the participant, who was the original owner, to another person or entity in the same way as any other good.[342]

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[337] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici."

[338] Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context."

[339] Deplano, Stefano "Il Campione Biologico di Unidentified Person. Profili di Sistema."

[340] Paris, Chiara "Biobanche di Ricerca e Banca Dati Nazionale del DNA: un Difficile Bilanciamento tra Interessi Contrapposti." For instance, among others, Mantovani, Ferrando, *I trapianti e la sperimentazione umana nel diritto Italiano e straniero*, Cedam, 1974.

[341] De Cupis, Adriano *I Diritti della Personalità*, Giuffrè, 1982.

[342] Ravà, Adolfo "I Diritti sulla Propria Persona nella Scienza e nella Filosofia del Diritto." *Rivista Italiana per le Scienze Giuridiche*, vol. XXXI, 1901, pp. 289–313; Santoro Passarelli, Francesco *Dottrine Generali del Diritto Civile*, Jovene editore, 1964; De Cupis, Adriano *I Diritti della Personalità*; Resta, Eligio "Corpo." *Diritto Vivente*, edited by Resta, Eligio, Laterza, 2008, pp. 37-80; Le Breton, David "L'Appartenence du Corps." *Trattato di Biodiritto. Il Governo del Corpo Tomo I*, edited by Canestrari, Stefano, et al. Giuffrè, 2011, pp. 77-98.fisp

Here, questions arose as to the mode of acquisition of such property,[343] keeping in mind that the basic principles of the matter are that of the gratuity of the disposal of the samples and of the necessity of informed consent,[344] as confirmed by the applicable instruments above.

First of all, it was affirmed that the property of HBSs pertains directly and immediately to the person from whom the samples were collected (*ius in re ipsum*).[345] This approach stemmed from the assumption that everyone may exercise a property right over her body, and consequently also over any detached part of it, such as the biological samples.[346]

Against the theory of the *ius in re ipsum,* there were authors who believed that upon collection HBSs acquired the legal status of *res nullius,* i.e. objects whose property does not pertain to anybody,[347] but the property over these samples was of the person who physically took them and had an interest in using them.[348] However, this theory has been disproved by Judicial authorities.[349]

Particularly known in this regard is the work of De Cupis, who clearly affirmed that the collection represents the act because of, and from which the HBS ceases to be part of the body and thus be governed by personality rights, and acquires the legal status of objects on which the participants exercise their property rights and whose property may be transferred like any other object.[350] According to the author, there is no intermediate status as *res nullius,* namely that of a good without an owner, because there is no discontinuity between the HBS being part of the person and it being her property. As mentioned, the dividing line between, and the cause of this change of, the HBSs legal statuses is represented by the act of collection, which substantially becomes a new mode for

[343] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici"; Tuccillo, Clara "La Natura del Rapporto Giuridico che Lega i Donatori ai Materiali Biologici Staccati dal Proprio Corpo." *Gruppo di Pisa,* vol. 2, 2022, pp. 109-124; Rapisarda, Ilenia "Brevi Note sullo Statuto Giuridico del Materiale Biologico Umano."

[344] Rapisarda, Ilenia "Brevi Note sullo Statuto Giuridico del Materiale Biologico Umano."

[345] Deplano, Stefano "Il Campione Biologico di Unidentified Person. Profili di Sistema."

[346] Carnelutti, Francesco "Problema Giuridico della Trasfusione di Sangue." *Il Foro Italiano,* vol. 63, n. 4, 1938, pp. 80-103.

[347] Bianca, Cesare, Massimo *Diritto Civile. Volume I: la Norma Giuridica, i Soggetti,* Giuffrè, 1978; Dogliotti, Massimo "Atti di Disposizione sul Proprio Corpo e Teoria Contrattuale." *Rassegna di Diritto Civile,* vol. 2, 1990, pp. 1-22.

[348] Romboli, Robert *La Libertà di Disporre del Proprio Corpo. Sub art. 5,* Zanichelli, 1988; Bianca, Cesare, Massimo *Diritto Civile. Volume I: la Norma Giuridica, i Soggetti*; Dogliotti, Massimo "Atti di Disposizione sul Proprio Corpo e Teoria Contrattuale."

[349] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona*.

[350] De Cupis, Adriano *I Diritti della Personalità*.

acquiring the property of objects. The most important critique to this theory is precisely the fact that the Italian Civil Code does not admit the creation of new modes of acquisition of property, apart from those identified by the Code itself.[351]

Another theory is worth mentioning, the one that considered HBSs as *intellectual works,* on which the inventor (i.e. the physician) could exercise property rights according to Art. 2576 of the Italian Civil Code.[352] Indeed, upon collection, the sample automatically became the property of the physician/researcher, who was the person responsible for its creation, i.e. its existence as an autonomous entity.[353] In this regard, the participant could not claim any interest in owing the samples or controlling their use.[354]

(b) However, the main issue in applying the proprietary model to biobanks is the allocation of property itself. Indeed, the choice of whether to allocate full property powers and rights to the participant or to the biobank/researchers is heavily influenced by the balancing exercise of the various rights and interests at stake in this context[355] and (c) has important consequences on the value of interventional biobank consent[356] and consequently biobank governance.

In a first scenario, the participant might have property rights on the detached biological sample, adopting one of the various alternatives underlined above, and consequently may freely decide whether and how to process the samples for research or biobanking purposes. In this case, providing interventional biobank consent would transfer the ownership of the samples from the participant to the biobank.[357] Various reasons may be provided for ruling out this scenario.

First of all, physicians have the duty to destroy left-over samples, if not used otherwise and consent is not provided to any alternative use.[358] This duty proves that participants

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[351] Fanni, Simona "Le Biobanche di Popolazione al Vaglio della Suprema Corte di Cassazione: Alcune Note Critiche sull'Ordinanza n. 27325 del 7 ottobre 2021." *BioLaw Journal*, vol. 4, 2022, pp. 277-300.

[352] Santoro Passarelli, Francesco *Dottrine Generali del Diritto Civile*.

[353] Mantovani reaches the same conclusion in Mantovani, Ferrando *I Trapianti e la Sperimentazione Umana nel Diritto Italiano e Straniero,* Cedam, 1974.

[354] Santoro Passarelli, Francesco *Dottrine Generali del Diritto Civile*.

[355] Zullo, Silvia "Corpo e Property Rights: Limiti Criticità nel Bilanciamento tra Interessi Individuali e Collettivi."

[356] Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context."

[357] *Ibid*

[358] Calderai, Valentina, "A Pound of man's Flesh. Consenso alla Ricerca sui Tessuti Biologici Umani e Teoria dei Beni." The matter is regulated by Directive 2008/98/EC as lastly modified by Directive (EU) 2018/851 at the supranational level and by Legislative Decree 152/2006 and D.P.R. 254/2003 at the national level.

cannot qualify as owners of the detached samples.[359] It appears thus evident that the final decision on the use or destruction of the samples would have otherwise been that of the participant, who might have had the right to decide to simply keep the biological sample. Moreover, in the absence of any substantial risk or harm possibly caused by research on the (already detached) sample, giving participants full control over the possible use of the biological samples, especially left-over samples, may have detrimental consequences for research, which would depend on any (rational or irrational) decision of the participant.[360] Finally, in this scenario the participants' consent to process the samples for biobanking purposes would transfer the property to the biobank, with no possibility of retaining any degree of control over their subsequent use. Indeed, the bundle of property rights cannot be shared among various entities but is entirely transferred from one subject to the other. On the other hand, allocating full property rights on the biobank from the beginning entails different problems related to the impossibility of having any control over their use on the part of the participant, independently of the HBS nature under consideration, and the degree of responsibility on the biobank on the choice of the research projects where the samples might be used. [361]

To solve the mentioned issues, recently, scholars have started debating over the possibility of applying the category of *commons* to HBSs, i.e. that of goods that may be shared and used by multiple individuals in a given community.[362] Within this context, researchers could freely use the samples, under the condition of processing them for the benefit of society as a whole.[363] Here, by providing consent the participant would

[359] Tuccillo, Clara "La Natura del Rapporto Giuridico che Lega i Donatori ai Materiali Biologici Staccati dal Proprio Corpo"; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: Il Possibile Ruolo delle Biobanche."

[360] Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi."

[361] Rapisarda, Ilenia "Brevi Note sullo Statuto Giuridico del Materiale Biologico Umano"; Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi"; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: Il Possibile Ruolo delle Biobanche."

[362] Macilotti, Matteo, et al. "La Disciplina Giuridica delle Biobanche"; De Robbio, Antonella "Biobanche e Proprietà Intellettuale: Commons o Caveau?" *Bibliotime*, vol. 3, 2010; Tuccillo, Clara "La Natura del Rapporto Giuridico che Lega i Donatori ai Materiali Biologici Staccati dal Proprio Corpo." On a similar line of reasoning, also applying the category of *semi-commons* has been proposed. Differently from these approaches, Pacia stresses the importance of refer to the social function of property according to Art. 42 of the Italian Constitution, instead of recurring to new categories of goods for HBSs. Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: Il Possibile Ruolo delle Biobanche."

[363] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici."

authorise the biobank and possibly researchers to process her samples, without transferring any property rights.[364]

As it has been authoritatively suggested, [365] apart from issues related to the legal qualification of HBSs as goods, and possibly the object of property rights,[366] the traditional proprietary paradigm is problematic for biobanking (or scientific research more generally) for various reasons.[367]

First of all, qualifying human biological samples as goods within the meaning of the Italian Civil Code may violate the human dignity of the participant.[368]

Moreover, the proprietary paradigm cannot be reconciled with the right of the participant to withdraw consent, provided for by the soft instruments mentioned above.[369] This is because, as mentioned, transferring property is the transfer of exclusive powers and control over the use of what is transferred. Indeed, according to this approach, either the participant or the biobank would have full control over the use of the samples. In the biobanking context, as mentioned, there is a need to constantly balance the various rights and interests at stake, and in particular those of science and society in processing samples and data for scientific advancements and those of participants in retaining a certain degree of control over the samples and data related to them, because of the possible impact of the processing for research purposes on their fundamental rights.

In particular, such an impact is the possible consequence of the informational nature of HBSs. Indeed, the approaches mentioned so far were developed (and therefore justifiable) when biological samples were mainly considered surgical waste or were not attributed any value, because their informational nature, and thus the possibility of extracting genetic data from them, had not been discovered or sufficiently developed.[370]

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[364] Marilotti, Lorenzo "Ipotesi per una Gestione Partecipata delle Biobanche Genetiche Concepite Come Beni Comuni"; Macilotti, Matteo, et al. "La Disciplina giuridica delle biobanche." *Pathologica*, vol. 100, 2008, pp. 86-101; Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici."

[365] Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi."

[366] In this regard, Rapisarda affirmed that it is almost impossible to conceptualise biological samples a good within the meaning of the Italian Civil Code. Rapisarda, Ilenia "Brevi Note sullo Statuto Giuridico del Materiale Biologico Umano."

[367] Generally on the topic, Zullo, Silvia "Corpo e Property Rights: Limiti Criticità nel Bilanciamento tra Interessi Individuali e Collettivi."

[368] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici."

[369] *Ibid*

[370] Deplano, Stefano "Il Campione Biologico di Unidentified Person. Profili di Sistema."

Consequently, HBSs were considered exclusively in their possible economic value as disposable goods,[371] also because no direct impact on participants' rights and interests might have been the consequence of the future processing of the samples, given that no direct connection between the sample and the person exists after the collection. In this context, the absence of any control on the part of participants over the use of the samples could have been justified.

The discovery of the nature of HBSs as sources of genetic data on the one hand increased their value for research, but at the same time raises new instances of protection. Indeed, the long-lasting (genetic) link between the sample in its informational nature and the genetic identity of the participant, even after collection, makes it necessary to protect the rights and interests of the latter, possibly affected by the processing of the samples for research.[372]

Consequently, any attempt at identifying the legal nature and qualification of HBSs should take into consideration both aspects of the sample, the material and the informational.[373] Indeed, this need is also confirmed by various applicable soft law instruments on the matter.

First of all, the definition of biological material provided for by the UNESCO International Declaration links the samples to the genetic data on the person included therein.[374] Moreover, Art. 6 lett. d) of the latter Declaration establishes a duty to provide information to the participant on the genetic data being derived from the samples, and stored in the biobank.[375]

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[371] Bianca, Cesare, Massimo *Diritto Civile. Volume I: la Norma Giuridica, i Soggetti.*

[372] On the need to provide participants with a certain degree of control over the use of the samples, especially because of their informational nature, Rapisarda, Ilenia "Brevi Note sullo Statuto Giuridico del Materiale Biologico Umano."

[373] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici"; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: il Possibile Ruolo delle Biobanche"; Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi"; Macilotti, Matteo "Lo Statuto Giuridico della Corporeità e le Biobanche di Ricerca." *Forum Biodiritto 2010. La Disciplina delle Biobanche a Fini Terapeutici e di Ricerca,* edited by Casonato, Carlo, et al. Quaderni del Dipartimento di Scienze Giuridiche, 2012, pp. 205-224.

[374] UNESCO International Declaration art. 2 para. IV

[375] Art. 6 lett. d) UNESCO International Declaration "It is ethically imperative that clear, balanced, adequate and appropriate information shall be provided to the person whose prior, free, informed and express consent is sought. Such information shall, alongside with providing other necessary details, specify the purpose for which human genetic data and human proteomic data are being derived from biological samples, and are used and stored. This information should indicate, if necessary, risks and consequences. This information should also indicate that the person concerned can withdraw his or her consent, without coercion, and this should entail neither a disadvantage nor a penalty for the person concerned."

Moreover, concerning the data protection framework art. 4 para. 13 GDPR defines genetic data as "personal data relating to the inherited or acquired genetic characteristics of a natural person (...) *which result, in particular, from an analysis of a biological sample* from the natural person in question".[376] Therefore, the mentioned article binds together the biological sample and the genetic information of a person when it comes to the provisions on the protection of the genetic identity to be complied with. Such an approach is further confirmed in Italy by the General Authorisation n. 8/2016 which defines biological samples as "any biological sample *from which genetic data* related to the person that provided the sample itself *may be extracted*",[377] and establishes that whenever previously provided consent to the processing of (genetic) data is withdrawn, the biological sample from which the data were extracted shall be destroyed as well, unless anonymised.[378] As a consequence, while the definition of genetic data conceptually links the HBS and the genetic data that may be extracted therefrom, the provision related to the withdrawal of consent links the two when it comes to their material destiny.

As a consequence, I will now provide an overview of the informational nature of HBSs, before proceeding with the analyses of possible models for the collection and processing of HBSs in biobanking that take into consideration both natures and the consequent instances of protection.

4.1 ... (B) THE INFORMATIONAL NATURE, OR HUMAN BIOLOGICAL SAMPLES AS SOURCES OF PERSONAL DATA AND PARTS OF THE IDENTITY OF THE PERSON

The *informational nature* of HBSs is twofold because the data possibly associated with them are of two different types. As underlined by Guarino, on the one hand, there are (1) the data related to the sample itself, and that describe its physical characteristics, while on the other there are (2) the data possibly extracted from the samples, that are health data related to the person and her (genetic) identity.[379] Indeed, as mentioned, from the analysis

[376] Emphasis added.
[377] Emphasis added.
[378] General Authorisation, paragraph 6). On this, Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici."
[379] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona;* Macilotti, Matteo "La Natura dei Campioni Biologici Utilizzati a Scopo di Ricerca Medica: Un Difficile Equilibrio tra la Tutela della Persona e il Mercato." *Biobanche e Informazioni Genetiche: Problemi Etici e Giuridici*, edited by Faralli, Claudia, and Matteo, Galletti, Aracne editrice, 2011, pp. 13-34.

of the samples, it is possible to extract genetic data, which is information on the participant, and develop her genetic profile, containing details on her health, medical history, and lifestyle.[380] Frequently, the value of a biological sample depends directly on the quantity and quality of information on the participant that may be extracted.[381]

The possibility of storing in the biobank data related to the HBSs has also been acknowledged by Recommendation R(2016)6 first of all in Art. 2 which establishes that "[w]hen obtained, stored or used, biological materials of human origin may be accompanied by associated personal data", and secondly in Art. 3 which includes in the category of the *identifiable biological samples* those HBSs that may be associated with a natural person also thanks to data.[382]

Differently from what happens concerning the material nature between the biological sample and the person, the informational nature of HBSs does not end with the act of collection of the sample and thus its detachment from the body, but begins with it, because of the essence of the biological samples as a source of information.[383] The act of collection only enables the circulation of the HBS in its materiality[384] and (potential) informational nature but does not separate the information from the person, contrary to what happens when the material nature is under scrutiny.[385] Indeed, the genetic data that pertains to the information nature of HBSs are permanently connected to the person, and possibly her descendants and family, because they are part of her genetic heritage.[386] Moreover, these are data particularly sensitive and deserve a special degree of protection because of their characteristics, identified by the UNESCO International Declaration in Art. 4 as

- Predictive of genetic predispositions concerning individuals;

[380] See the definition of *biological sample* provided by BBMRI on its website, available here https://www.bbmri.it/nodo-nazionale/biobanche/faq/#:~:text=Si%20definisce%20campione%20biologico%20umano,sani%20o%20affetti%20da%20malattia.

[381] Maestri, Enrico "Biobanche e Consenso Informato tra Finzioni Scientifiche e Finzioni Giuridiche."

[382] On the same point, see also the UNESCO International Declaration.

[383] Eusebi, Luciano "Diritti fondamentali, Biobanche e Gestione dei Materiali Biologici Umani."

[384] Macilotti, Matteo "La Natura dei Campioni Biologici Utilizzati a Scopo di Ricerca Medica: Un Difficile Equilibrio tra la Tutela della Persona e il Mercato."

[385] Paris, Chiara "Biobanche di Ricerca e Banca Dati Nazionale del DNA: Un Difficile Bilanciamento tra Interessi Contrapposti"; Macilotti, Matteo "Proprietà, Informazione ed Interessi nella Disciplina delle Biobanche a Fini di Ricerca"; Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona*.

[386] Sartea, Claudio "Verso uno Statuto Giuridico dei Campioni Biologici Umani. Premesse Teoriche"; D'Avack, Lorenzo, *Il Potere sul Corpo. Limiti Etici e Giuridici*, Giappichelli, 2015.

- Possibly impacting on the relatives of the person from whom they are been extracted;
- Possibly containing information, the significance of which is not necessarily known at the time of the collection of the sample from which they are extracted.

Finally, the importance of the human genome and the information that may be derived therefrom is notorious, so much so that the Universal Declaration on the Human Genome established in Art. 1 qualifies the human genome as the heritage of humanity in a symbolic sense and as the "fundamental unity of all members of the human family".

Moreover, the informational nature of HBSs enables the development of a new dimension of the person, who is now considered not only as *physical body* but also as the sum of data (personal, genetic, related to health, etc) that pertain to her.[387] In the context of our analysis, these data may also be extracted from HBSs and are those that constitute their informational nature.

In this regard, the informational nature of HBSs may on the one hand influence the future processing of both the sample and the data, and on the other impact the fundamental rights and interests of the person, given that the biological samples maintain a permanent relationship with the identity of the person from whom they derive, especially the genetic identity.[388] As a consequence, while providing consent in the framework of property rights would mean transferring the property of the object under consideration, providing consent in that of personality rights is an expression of that person's self-determination.[389]

In order to protect this new dimension of the person, the informational nature of HBSs raises questions about the protection of privacy and personal identity,[390] as well as personality rights more generally,[391] in the same way as their material dimension possibly implies issues on the protection of property.[392] A main difference here that should be

[387] Eusebi, Luciano "Diritti Fondamentali, Biobanche e Gestione dei Materiali Biologici Umani."
[388] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona. In* this regard, HBSs have been also defined as "instruments of biological identity." Salaris, Giuseppina *Corpo Umano e Diritto Civile,* Giuffrè, 2007; Macilotti, Matteo "La Natura dei Campioni Biologici Utilizzati a Scopo di Ricerca Medica: Un Difficile Equilibrio tra la Tutela della Persona e il Mercato."
[389] Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context."
[390] Paris, Chiara "Biobanche di Ricerca e Banca Dati Nazionale del DNA: un Difficile Bilanciamento tra Interessi Contrapposti."
[391] Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context."
[392] Paris, Chiara "Biobanche di Ricerca e Banca Dati Nazionale del DNA: un Difficile Bilanciamento tra Interessi Contrapposti"; Macilotti, Matteo "La Natura dei Campioni Biologici Utilizzati a Scopo di Ricerca Medica: Un Difficile Equilibrio tra la Tutela della Persona e il Mercato"; Macilotti, Matteo "Le Biobanche: Disciplina e Diritti della Persona."

highlighted is that, unlike property rights, personality rights are "inextricably linked to the person, inalienable, not descendible and not limited in time".[393]

As a consequence, the processing of these data (taken alone) should be regulated by the legislative framework applicable to *personal data* and extensively elaborated in Part B,[394] which therefore should be referred to in order to understand how to lawfully collect HBSs for biobanking purposes.

5 DEVELOPING A FRAMEWORK FOR HBSs – ON THE UNITARIAN CONSIDERATION OF THEIR DUAL NATURE

The dual nature of HBSs involves different rights of the person from whom they were derived. On the one hand, as mentioned, the material nature of HBSs raises possible questions of property,[395] which however is an unsuitable framework for HBSs, as mentioned. On the other, the informational nature relates to the identity of the person and thus involves her personality rights, such as the right to informational self-determination, the right to privacy, etc.[396]

Considered separately, according to the instruments mentioned above, handling the material dimension of donated HBSs would mean asking for the consent provided for as a requirement by the instruments mentioned above, unless in case of exceptional circumstances. The same is usually established for left-over samples. Differently, the processing of genetic data alone should comply with the provisions of the GDPR and more generally the regulations applicable to the protection of personal data, as extensively discussed in Part B.

However, the peculiarity of HBSs rests on the fact that their processing requires at the same time the processing of the sample in their material nature and of the data that may be extracted therefrom.

It is precisely this dual nature and dual need for protection that complicates the definition of the legal nature of HBSs.[397] In particular, it should be established whether one aspect

[393] Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context."
[394] The qualification of the informational nature of HBSs and *personal data* will be discussed in Part B.
[395] Tuccillo, Clara "La Natura del Rapporto Giuridico che Lega i Donatori ai Materiali Biologici Staccati dal Proprio Corpo."
[396] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona.*
[397] The debate started in the United States already at the end of the last century. See for instance Gold, Richard *Body Parts: Property Rights and the Ownership of Human Biological Materials*, Georgetown University Press, 1998; Hartman, Rhonda "Beyond Moore: Issues of Law and Policy Impacting Human

of the HBS should prevail over the other, or on the contrary, whether the material nature and the informational one pertain to different moments of the processing of the samples. The question has not only theoretical value but profound practical consequences. In particular, if the two natures should be considered cumulatively, in order to process HBSs a unique and comprehensive legal regime for their storage in a biobank should be identified[398] and therefore the norms applicable to the material nature (i.e. acquiring *interventional biobank consent*) and those applicable to the informational nature (described in Part B, and mostly included in the GDPR) should be both complied with, either at the same time or in different moment of the biological sample "life cycle" or for different processing purposes.

Differently, one nature might be considered to prevail over the other, and in this case only the legal regime applicable to the prevailing one should be complied with.

The choice in this regard should follow the specific balance of the various and contrasting rights and interests at stake in biobanking, keeping in particular under consideration that in research biobanks and genetic research more generally there is no physical direct effect or impact on the participant's physical integrity, differently from other research activities, such as clinical trials conducted on human subjects.[399] The only risks in this regard are related to possible misuse of the information related to the HBSs (of the dual types described above), such as possible violation of the legal provisions related to their processing, or the issue of the returning of results, that may cause discrimination of mental health problems.[400]

5.1 THE PREVALENCE OF THE INFORMATIONAL NATURE – THE RELATIONAL-CONTROL MODEL

Usually, scholars favour considering the informational nature as prevalent,[401] thus reducing the sample in its materiality as a mere vessel of the information that may be

Cell and Genetic Research in the Age of the Biotechnology." *Journal of Legal Medicine,* vol. 14, 1993, pp. 463-477.

[398] Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: il Possibile Ruolo delle Biobanche."

[399] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona.*

[400] *Ibid*

[401] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici"; Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi"; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: Il Possibile Ruolo delle Biobanche"; Macilotti, Matteo "Proprietà, Informazione ed Interessi nella Disciplina delle Biobanche a Fini di Ricerca";

extracted therefrom.[402] This approach stems from the consideration that the only risks that may arise from the processing of the sample are those related to the information that it carries,[403] and in this regard, the participant retains a long-lasting interest in controlling their use for biobanking purposes. On the contrary, no interest can be claimed in relation to its material nature, because any processing of the sample in its materiality cannot have direct possible consequences on the participant.

Moreover, the prevalence of the informational nature of HBSs stems not only from the fact that the only binding regulation that explicitly refers to HBSs is that applicable to genetic data, in particular the General Authorisation n. 8/2016,[404] but also from the link established by the latter between the withdrawal of the informational consent by the participant and the duty to either destroy or anonymise the sample.[405]

To explain the relationship that exists between the biobank and participants over the use of the samples it is useful to make reference to the participatory-controlled model theorised by Cordiano based on the regulatory model usually established for the processing of personal data.[406] According to the author, the participant's consent at the

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Macilotti, Matteo, *Le biobanche di ricerca, Studio comparato sulla "zona grigia" tra privacy e proprietà*; Nicolussi, Andrea "Campioni Biologici tra Bioetica E Biodiritto"; Macilotti speaks about the material nature being *absorbed* by the informational one Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context."

[402] Macilotti, Matteo "Proprietà, Informazione ed Interessi nella Disciplina delle Biobanche a Fini di Ricerca"; Macilotti, Matteo, *Le biobanche di ricerca, Studio comparato sulla "zona grigia" tra privacy e proprietà*; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: Il Possibile Ruolo delle Biobanche"; Bravo, Elena "Organizzazione delle Biobanche e Strumenti di Controllo." *La Ricerca su Materiali Biologici di Origine Umana: Giuristi e Scienziati a Confronto*, edited by Gambino, Alberto M., et al. Nuova editrice Universitaria, 2016, pp. 29-40; Morresi, Assuntina "L'Accesso al Materiale Biologico. Il Consenso: Requisiti e Divieto di Corrispettivo." *La Ricerca su Materiali Biologici di Origine Umana: Giuristi e Scienziati a Confronto,* edited by Gambino, Alberto M., et al. Nuova editrice Universitaria, 2016, pp. 93-106.

[403] Indeed, the Explanatory Report to the Oviedo Convention justified the duty of Art. 22 to ask for consent for the subsequent storage and use for research purposes of left-over samples by explaining that "[p]arts of the human body are often removed in the course of interventions, for example surgery. the aim of this article is to ensure the protection of individuals with regard to parts of their body which are thus removed and then stored or used for a purpose different from that for which they have been removed. *Such a provision is necessary in particular, because much information on the individual may be derived from any part of the body*, however small (for example blood, hair, bone, skin, organ). Even when the sample is anonymous the analysis may yield information about identity."

[404] Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: Il Possibile Ruolo delle Biobanche."

[405] the same is established by Recommendation R(2016)6, that provides that after withdrawing consent, the participant might ask to have her biological sample destroyed or anonymised.

[406] Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi." The author proposed another model as an alternative to applying the proprietary regime, i.e. the solidaristic model. In this scenario, providing interventional biobank consent, the participant would transfer to the biobank any right to use the collected sample and, at the same time, lose any right to control the processing of the latter. Consequently, the biobank (and researchers) might freely use the donated sample under the sole condition of pursuing

same time authorises the intervention on the physical integrity of the person (interventional consent) and transfers to the biobank the right to use the collected sample. However, the participant retains the right to withdraw the consent if the biobanking intends to process the HBS for purposes different from those known and accepted by the participant or, more generally, as an exercise of her right to self-determination.[407] This model is justified by the fact that participants always maintain an interest in controlling some aspects of the processing of their samples because of their right to withdraw consent, particularly in case of illegitimate processing activities, and also a right to access the biobank, to ask for the rectification of some of their personal data, etc.[408] Therefore, the collection of the sample and the subsequent decision on the use of the samples for biobanking purposes creates an ongoing relationship among the participant, the biobank and the researchers that process the HBS.[409]

According to scholars, this model is appropriate for biobanking because it considers providing consent as a means to transfer a right to use the HBSs,[410] thus abandoning a full proprietary regime, while at the same time enabling the expression of the participant's self-determination, which in turn enables the participant to withdraw it at any time.[411] In this regard, the interventional biobank consent provided by the participant includes, as mentioned, both the interventional consent and the consent to store and process for future research use the sample, but only considered the genetic data that may be extracted therefrom.

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solidaristic purposes with its processing. Participants might thus withdraw the previously provided consent if the biobank authorises processing activities without a solidaristic aim. This approach is therefore based on solidarity and gratuity as fundamental principles. However, the solidaristic model is of difficult and controversial adoption because it contrasts with the normative framework highlighted above that entitles the participant with the right to withdraw consent at any time and without providing specific reasons.

[407] Here, the author further proposes *de iure condendo* to normatively establish a limit on the participant's right to withdraw consent, i.e. only *ex nunc* effects and no possibility of affecting the processing for scientific research purposes already conducted and concluded. See also Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici."

[408] De Robbio, Antonella "Biobanche e Proprietà Intellettuale: Commons o Caveau?"; Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi."

[409] Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi"; De Robbio, Antonella "Biobanche e Proprietà Intellettuale: Commons o Caveau?"

[410] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: il Nodo dei Campioni Biologici"; Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi"; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: Il Possibile Ruolo delle Biobanche."

[411] Macilotti, Matteo "Proprietà, Informazione ed Interessi nella Disciplina delle Biobanche a Fini di Ricerca"; Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi."

However, the HBS is subject to the provisions applicable to personal data and its use by the biobank and researchers may be explained according to the relational-control model only in so far as it is identifiable. Indeed, if the sample is anonymised, its material nature is the only one that remains and therefore it can be freely processed, because of the absence of any need for protection of the participant's interests in this regard,[412] as highlighted above. The specific issue of the anonymisation of HBSs will be addressed in Chapter IV.

To summarise, according to the framework described in this paragraph, the act of the collection of the sample needs to be "authorised" by the participant providing interventional consent, either for the specific purpose of biobanking (Scenario 1) or for different ones (such as a scientific research project – Scenario 2, or a medical procedure that entails the collection of a sample – Scenario 3). This consent, however, does not specifically cover the use of the sample for any purposes.

Given that the only fundamental rights and interests to be protected in the processing of HBSs are those related to the use of the genetic data extracted therefrom, i.e. right to data protection and right to genetic identity, because of the permanent link between these data and the participant's genetic identity, the informational nature of HBSs should prevail over the material one.[413] As a consequence, the processing of HBSs for biobanking purposes should follow the provisions established for the processing of genetic data for the same purpose, as described in Part B.[414]

5.2 ASSESSING THE APPLICABILITY OF THE RELATIONAL-CONTROL MODEL TO THE UNITARIAN CONSIDERATION OF HBSS

After having theoretically presented a possible model for the collection of HBSs, it is now necessary to verify its concrete applicability. In particular, this paragraph will concentrate

[412] Pacia, Romana "Ricerca Genetica, Biobanche e Consenso Informato." *Famiglia e Diritto,* vol. 8-9, 2012, pp. 838-852; Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi"; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: Il Possibile Ruolo delle Biobanche."

[413] Moreover, in the vast majority of cases research projects intend to process only the genetic data that may be extracted therefrom and not the HBS *per se*.

[414] Guarda, Paolo, and Giorgia, Bincoletto "Scientific Research and the Biomedical Sector. Requirements and Methods for Planning and Managing a "Data Protection By Design" Project." *GDPR Requirements for Biobanking Activities Across Europe,* edited by Colcelli, Valentina, et al. Springer, pp. 371-382; Barbosa, Carla, and Andreia, De Costa Andrade "Secondary Use (Part I)."; Penasa, Simona and Marta, Tomasi "The Italian Way for Research Biobanks After GDPR: Hybrid Normative Solutions to Balance the Protection of Individuals and Freedom of Research"; Taylor, Mark *Genetic Data and the Law. a Critical Perspective on Privacy Protection*, Cambridge University Press, 2012.

on (1) verifying whether it is actually possible to apply the legal framework provided for genetic data also to HBSs; (2) addressing the issue of the possible contrast between the ethical framework established by the instruments mentioned above and the legal framework for the processing of personal data; (3) evaluating the consequences of the proposed model on trust, if necessary.

(1) In order to establish whether the informational nature can prevail in the legal regime applicable to HBSs, it should first be verified whether it is possible to consider HBSs (also) as personal data according to the GDPR. Indeed, in case of a negative answer, the GDPR would apply only to the genetic data once extracted from the HBS, but not for handling the sample itself. The matter is usually disputed among scholars, in the absence of a clear provision in the GDPR or other relevant documents and guidelines, and in particular taking into consideration that the Article 29 Working Party in Opinion 4/2007 seemingly conclusively affirmed that "human tissue samples (...) are themselves sources out of which data is extracted, but *they are not data themselves"*.[415]

Contrary to this statement, I agree with those who believe in the possibility of applying the GDPR to HBSs.[416] Three arguments have been elaborated by Hallinan in favour of this opinion: (a) teleological legitimacy, (b) legal-technical legitimacy, and (c) jurisprudential support.

(a) From a teleological point of view, most of the time biological samples are stored and processed in biobanks because of the genetic data that may be extracted therefrom,[417] and therefore "it is increasingly difficult, in practice, to distinguish between data/information and their biological carriers...there is frequently an intimate link between biological samples and the information they generate".[418] However, I believe this argument cannot be conclusive, since biological samples are also sometimes used because of and for their materiality.

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[415] Emphasis added. Article 29 Working Party, Opinion 4/2007 on the concept of personal data 2007.

[416] Amon many others Hallinan, Dara, and Raphael, Gellert "The Concept of 'Information': an Invisible Problem in the GDPR." *SCRIPTed: a Journal of Law, Technology and Society*, vol. 17, n. 2, 2020, pp. 269-319; Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona;* Hallinan, Dara *Protecting Genetic Privacy in Biobanking through Data Protection Law*; Guarda, Paolo, *Il Regime Giuridico dei Dati della Ricerca Scientifica*.

[417] Hallinan, Dara, and Raphael, Gellert "The Concept of 'Information': an Invisible Problem in the GDPR."

[418] Bygrave, Lee A. "The Body as Data? Biobank Regulation via the 'Back Door' of Data Protection Law." *Law, Innovation and Technology*, vol. 2, n. 1, 2010, pp. 1-25.

Moreover, the author provides two further arguments, namely that (b) there are no "clear legal-technical obstructions" possibly raised to this position and that (c) the ECHR in her judgements frequently recognised that "cellular samples constitute personal data",[419] and that "DNA material is personal data".[420] Indeed, in all these cases, the ECHR founded her reasoning on the violation of the applicants' right to respect of private life under Art. 8 ECHR.

Finally, the approach of the Italian DPA, as well as other national provisions on the matter, especially concerning the processing of genetic data, supports this conclusion. In particular, confirm this approach to the issue, among other documents,

- the General Authorisation n. 8/2016, which clearly establishes a strong link as for the processing of the HBSs and the genetic data to be extracted therefrom;
- the Provvedimento n. 389/2016 issued by the Italian DPA, that establishes provisions for the processing and transferring of both samples and genetic data stored in a genetic biobank in Ogliastra, as well as the subsequent Order of the Italian Court of Cassation[421] and the Decision of the Italian DPA n.170 of April 27th, 2023.

[419] ECHR *Marper case,* Case of S. and Marper v. the United Kingdom, Apps. N. 30562/04 and 30566/04. See on the same conclusion the ECHR *Gaughran case,* Case of Gaughran v. the United Kingdom, App. N. 45245/15, and *Trajkovsi case,* Case Trajkovski and Chipovski v. North Macedonia, Apps. N. 53205/13 and 63320/13. In particular, in the *Marper case,* the Court stated that "the Court notes at the outset that all three categories of the personal information retained by the authorities in the present case, namely fingerprints, DNA profiles and cellular samples, constitute personal data within the meaning of the Data Protection Convention as they relate to identified or identifiable individuals."

[420] ECHR *Gaughran case,* Case of Gaughran v. the United Kingdom, App. N. 45245/15, and *Trajkovsi case,* Case Trajkovski and Chipovski v. North Macedonia, Apps. N. 53205/13 and 63320/13.

[421] Italian Corte di Cassazione, Order n. 27325/2021. the facts of the case concerned are the following. In the early 2000 the company Shr.Dna found a genetic biobank in Ogliastra, a province in the Italian region of Sardinia, with the aim of conducting genetic studies on the longevity of a consistent part of the population in this area. the biobank included both samples and genetic data. In 2016, the company Shr.Dna that was the data controller of the personal data stored therein went bankrupt. Consequently, the company sold its branch, which included the genetic biobank, to a different company Tiziana Life Sciences PLC, with registered office in the UK. In 2016, the Italian DPA issued an injunction against the company Tiziana Life Sciences for preventing the latter from keeping on processing the data included in the biobank. Only the safe storage of such data was allowed. the Italian DPA established in such the injunction n.389/2016 that the company Tiziana had to previously inform the data subjects of the transferring of their data and of the subsequent possible processing that the company intended to perform on them, as well as to ask their prior and informed consent, necessary in order to process the data for scientific research purposes according to the Italian legislative framework at the time (prior to the GDPR). the company appealed the injunction, but finally the Italian Corte di Cassazione decided in favour of the Injunction issued by the Italian DPA and confirmed what established therein. For a comment on the issue, Fanni, Simona "Le Biobanche di Popolazione al Vaglio della Suprema Corte di Cassazione: Alcune Note Critiche sull'Ordinanza n. 27325 del 7 ottobre 2021."

Indeed, both the General Authorisation and the Proveddimento take into consideration HBSs in deciding an issue that, at least theoretically, could concern personal data exclusively and, therefore, apply to the biological samples, the framework, and the relative conclusion for data.

Consequently, I believe it is possible for the mentioned reasons to consider the processing of HBSs in their informational nature as subject to data protection provisions.

(2) A second issue to address is the contrast possibly generated by the ethical framework built by the mentioned soft law instruments and the legal provisions applicable in general to the processing of personal data.

Indeed, the soft law instruments applicable to HBSs require the interventional biobank consent of the participant in order to process the sample unless exceptional circumstances are applicable. Such consent, as mentioned, is the consent to the use of the sample for biobanking purposes and is different from the consent to the collection of the sample. If the informational nature of the samples should prevail, processing of the sample itself should follow the legal framework applicable to personal data. As it will be explained in detail in Part B, this framework does not always require the informational consent of the data subject for the lawful processing of the personal data, or sensitive data (among which genetic data are included), because other legal bases are listed in Art. 6 GDPR, as well as exceptions in Art. 9 GDPR. Consequently, it is possible and lawful under the GDPR to process personal sensitive data without the informational consent of the data subject. In this case, it is not even required by the mentioned regulation to prove that asking for informational consent was impossible, but it is a free choice of the data processor.

While a detailed description of the legal framework applicable to the processing of personal data will be provided for in Part B, it suffices here to highlight that there might be cases in which the participant provides interventional consent to the procedure, but the processing of the sample collected (*rectius*, the genetic data) is based on a different legal basis.[422]

Admittedly, in the Italian legal framework applicable to the processing of genetic data the mentioned possible contrast is avoided, because asking for the informational consent of the participant is the general rule as provided for by the General Authorisation n. 8/2016,

[422] Caredda, Valeria, "Campioni Biologici e Big Data: l'Evoluzione del Consenso." highlights the problema as well.

for HBSs, as mentioned, and genetic data, as described in Part B. However, this approach was an Italian legislative choice. Therefore, while the possible contrast highlighted above will probably not occur for Italian biobanks, this might well be the case for other Member States, whenever the data controller is left with the choice of processing genetic data asking for consent or applying a different legal basis and exemption. This differentiation might also be problematic whenever biobanks need to cooperate or exchange samples and data.

It appears that the provisions established for the processing of personal data should prevail over those included in the mentioned soft law instruments, not only because the informational nature of HBSs should prevail over the material one, but especially because the norms applicable to the processing of personal data and analysed in Part B are established by binding legal instruments.

Possible alternatives may be (1) to ask for informational biobank consent as an additional safeguard according to Art. 89 GDPR for the processing of genetic data and HBSs for biobanking purposes, or (2) to consider that because of the mentioned soft law instruments the legal exemption of Art. 9 to be preferred when processing HBSs and the genetic data extracted therefrom should be consent. The first hypothesis is coherent with the EDPB's Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR), where the same reasoning now provided for interventional biobank consent is applied to the consent required by the CTR. Moreover, the second hypothesis is inconsistent with the intention of the European legislator, as explained in Part B, and with Art. 8 of the Charter of Fundamental Rights, where it is established in paragraph 2 that the processing of personal data is allowed "for specific purposes and on the basis of the consent of the person concerned *or some other legitimate basis laid down by law".*

In any case, as previously mentioned, interventional consent for authorising the collection of the HBS is always required.

(3) Finally, as mentioned, the consequences on participants of the model identified above should be addressed. However, I believe that the decision to apply the legal framework for the processing of personal data *per se* could not have direct consequences on participants' trust, provided that the mentioned impact is evaluated when choosing the

governance approach for complying with the data protection framework, and in particular as for the model for collecting personal data (as well as genetic data and HBSs).

Indeed, sociological studies on the matter frequently address the issue of the willingness to provide HBSs for research and biobanking purposes together with health or genetic data, thus providing support for the idea of processing them under the same governance regime.[423] Moreover, these studies find in most of the cases that participants' concerns that may possibly affect their trust are the same.[424]

6 CONCLUSION

In conclusion, it appears both possible and justifiable to apply the legal framework for personal data, and genetic data more specifically, also to the collection, storage and processing of HBSs. Provided that interventional consent should always be acquired, no matter the Scenario applicable, the decision on the use of the detached sample should be taken following the data protection norms, and interventional biobank consent required by most soft instruments on the matter may still be acquired as an additional measure according to Art. 89 GDPR.

This solution, feasible from a legal and practical point of view, does not have particular consequences on trust, provided that such impact is evaluated when choosing the model for collecting and processing the HBSs as personal data.

The following part B will therefore be devoted to this end, i.e. to describe the legal framework applicable to the processing of personal data for biobanking purposes, applicable to HBSs as well.

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[423] Brall, Caroline, et al. "Public Willingness to Participate in Personalized Health Research and Biobanking: a Large-Scale Swiss Survey." *Plos One,* vol. 14, n. 4, 2021, pp. 1-17; Pronicki, Lukasz, et al. "Awareness, Attitudes and Willingness to Donate Biological Samples to a Biobank: a Survey of a Representative Sample of Polish Citizens." *Healthcare,* vol. 11, 2021, pp. 1-20; Ursin, Lars et al. "«If You Give Them Your Little Finger, They'll Tear Off Your Entire Arm»: Losing Trust in Biobank Research"; Domaradzki, Jan, and Pawlikowsi, Jakub, "Public Attitudes Toward Biobanking of Human Biological Material for Research Purposes: a Literature Review." *International Journal of Environmental Research and Public Health,* vol. 16, 2019, pp. 1-11.

[424] Brall, Caroline, et al. "Public Willingness to Participate in Personalized Health Research and Biobanking: a Large-Scale Swiss Survey."; Toccaceli, Virgilia et al. "Attitudes and Willingness to Donate Biological Samples for Research Among Potential Donors in the Italian Twin Register." *Journal of Empirical Research on Human Research Ethics: JERHRE*, vol. 9, n. 3, 2014, pp. 39-47; Pawlikowski, Jakub, et al. "Associations Between the Willingness to Donate Samples to Biobanks and Selected Psychological Variables." *International Journal of Environmental Research and Public Health*¸ vol. 19, 2022, pp. 1-11; Pronicki, Lukasz, et al. "Awareness, Attitudes and Willingness to Donate Biological Samples to a Biobank: a Survey of a Representative Sample of Polish Citizens"; Kettis-Lindblad, Asa, et al. "Genetic Research and Donation of Tissue Samples to Biobanks. What Do Potential Sample Donors in the Swedish General Public Think?" *European Journal of Public Health,* vol. 16, n. 4, 2005, pp 433-441.

PART B – BIOBANK DATA

Summary of Part B: 1 Introduction; 2 Types of biobank data; 3 Preliminary considerations – (A) The actor classification system applied to biobanking; 3.1 ...(B) Biobanking purposes v. Scientific research purposes; 4 Collecting biobank data – (I) The legal framework at the supranational level; 4.1 Consent-based model – 4.1.1 Withdrawal of consent; 4.2 ... and the Necessity-based model; 4.2.1 The legal bases of Art. 6(1) GDPR; 4.2.2 The exemptions of Art. 9(2) GDPR; 4.2.2.1 Art. 9(2)(i) Public interest in the area of public health; 4.2.2.2 Art. 9(2)(j) Scientific research; 4.2.3 Possible consequences of the Necessity-based model; 4.2.3.1 (A) Derogations derived from provisions of the GDPR; 4.2.3.2 (B) Derogations derived from enacted Union or Member States law; 5 ...(II) The legal framework at the national level; 6 The secondary use of personal data in biobanking; 6.1 The supranational level – Art. 5(1)(b) and 6(4) GDPR; 6.2 The national level – Art. 110 and 110-bis Italian Privacy Code and the General Authorisations; 6.3 The duty to provide information according to Art. 14(4) GDPR in case of further processing of personal data; 7 Assessing the framework for the biobank choice; 7.1 The participants' right to data protection; 7.2 The choice at the supranational level – Between the necessity-based model and the consent-based model; 7.3 The choice at the national level – Alternative models for collecting informational consent; 7.3.1 Broad consent model; 7.3.2 Dynamic consent model; 7.3.3 Choosing an alternative model for collecting informational consent for biobanking; 7.3.4 An alternative solution . Specific informational consent for biobanking; 8 The DGA and the EHDS; 8.1 Data Governance Act; 8.1.1 Specificities of the DGA system for data altruism; 8.1.2 Applying the DGA's data altruism mechanism to biobanks; 8.2 The European Health Data Space; 8.2.1 Applying the EHDS to biobanks; 8.2.2 The proposed amendments to the EHDS Proposal

1 INTRODUCTION

As extensively underlined, in order to create a biobank HBSs and data should be collected from participants, either during or after a medical procedure, a clinical trial or otherwise, and stored for present and future use (Scenarios 2 and 3). Therefore, when defining a biobank governance model, alongside the collection of HBSs it should also be evaluated how to collect and store the personal data (as well as the data linked to HBSs).

The legislative framework to refer to in this regard is Regulation EU 2016/679 (GDPR), which lays down the rules for the legitimate processing of all personal data, at the

European level, and the Italian Privacy Code at the national one. Moreover, other soft law instruments should be taken into consideration.[425]

Indeed, the material scope of the GDPR defined in Art. 2(1) GDPR may be divided into two cumulative applicability criteria.[426] Indeed, the GDPR applies to any activity that qualifies as *processing* within the definition of Art. 4(2)[427] GDPR, performed on data that are *personal* according to the definition provided for by Art. 4(1)GDPR, which forms part of a filing system.[428] Consequently, any processing of data that does not meet the double standard (for instance, the processing of *non-personal data*) is free provided to comply with the Regulation (UE) 2018/1807 on a framework for the free movement of non-personal data in the European Union.[429]

In general terms, collecting data for implementing a biobank falls within the definition of *processing* according to art. 4(2) GDPR, which establishes that it is "any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction". While critiques to this provision highlight that this definition is so broad that "every type of biobanking processing will qualify as processing",[430] it appears that biobanking activities are rightfully included among those that should comply with the data protection regulation.

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[425] However, soft law instruments in this context, i.e. For the collection of biobank data, do not have the same level of impact on the biobank governance as in the context of HBSs. Indeed, while in the latter case there is no general hard law regulation applicable, when it comes to personal data the GDPR shall be complied with, also in the context of biobanks. Consequently, the focus will be mainly on the latter.

[426] Hallinan, Dara *Protecting Genetic Privacy in Biobanking through Data Protection Law*.

[427] Art. 4(2) GDPR "'processing' means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction."

[428] If not part of a filing system, the processing should be conducted by automated means, which is usually not the case for biobanking. However, it appears reasonable to include biobanks among those entities whose processing forms part of a filing system or are intended to this end. Rapisarda, Ilenia "Ricerca Scientifica e Circolazione dei Dati Personali. Verso il Definitivo Superamento del Paradigma Privatistico?" *Europa e Diritto Privato*, vol. 2, 2021, pp. 301-347

[429] Irti, Claudia "Personal Data, Non-personal Data, Anonymised Data, Pseudonymised Data, De-identified Data." *Privacy and Data Protection in Software Services*, edited by Senigaglia, Roberto, et al. Springer, 2022, pp. 49-58.

[430] Hallinan, Dara *Protecting Genetic Privacy in Biobanking through Data Protection Law*.

The present Part B is devoted to presenting the legal models identified in the framework of the GDPR for the collection and storage in a biobank of biobank data to conduct future undefined research projects, and consequently the one chosen by the Italian legislator.

After having analysed some preliminary concepts useful for the discussion, I will first of all concentrate on the primary use of biobank data for biobanking purposes and to this end describe in detail at the supranational level the two main models identified, the consent-based model and the necessity-based model, the first one based on the consent of the data subject to the processing of the personal data, and the second on the concept of the necessity of the processing, addressing the advantages and disadvantages of adopting either one of them. I will then provide an overview of the national approach adopted in Italy for such a processing, and therefore the legal framework that more specifically Italian biobanks should comply with.

Secondly, I will turn to the secondary processing of biobank data for biobanking purposes, both at the supranational level and at the national one, in order to identify similarities and differences.

The analysis will show that while at the supranational level biobanks may choose between asking for the informational consent of the data subject or processing biobank data on the grounds of different legal bases/exemptions, at the national one the general rule is adopting the consent-based model. Consequently, in order to provide a guidance for the choice of the model to be concretely adopted in the biobank governance at the supranational level, and of the model for acquiring informational consent at the national one, I will analyse the individual right to data protection to determine how it is conceptualised, what protective measures might be necessary and to what extent it might be restricted in the balancing exercise against other fundamental rights and interests, with the final aim to facilitate biobanking and conducting scientific research projects.

Finally, to complete the overview of the legal framework applicable to processing these data for the mentioned purpose, I will also describe the new provisions established by the Data Governance Act and the Proposal for the European Health Data Space, for the parts relevant to biobanking. Indeed, some of the requirements included therein either might be applied to research biobanks in general (as for the DGA) or will apply to it at the end of the legislative procedure (as for the EHDS) and therefore will be relevant for the assessment conducted in the next Chapter on the concrete balance between the various

interests at stake. These provisions are the starting point for an analysis of the current level of protection of the data subject's right to data protection.

Throughout the analysis, whenever relevant, reference will be made not only to the impact of legislative or possible data controller's choice on fundamental rights, but also on participants' trust, according to the trust test developed in Chapter II.

2 TYPES OF BIOBANK DATA

As mentioned in Chapter I, various types of data may be possibly stored in a biobank. However, these data will mainly be referred to specific participants or patients and provide information about their health status.

It appears safe to affirm that the almost totality of the biobank data will be qualified as *personal data* according to the GDPR.[431] Indeed, Art. 4(1) defines *personal data* as "any information relating to an *identified or identifiable natural person* ('data subject')".[432] Precisely the reference to the general term *information* should be intended as reflecting "the aim of the EU legislature to assign a wide scope to that concept, which is not restricted to information that is sensitive or private, but potentially encompasses all kinds of information, not only objective but also subjective".[433] The mentioned Art. 4(1) GDPR subsequently proceeds to list possible identifiable elements: "an identifiable natural person is one who can be identified, *directly or indirectly, in particular by reference to an identifier such as a name, an identification number*, location data, an online identifier or to one or more factors specific to the *physical, physiological, genetic, mental*, economic, cultural or social identity of that natural person".[434]

The key concept in deciding whether the definition of *personal data* is met is that of *identifiability*, meaning that in order for the provisions of the GDPR to be applicable, it is sufficient that data are related directly or indirectly to an individual.[435]

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[431] Hallinan, Dara *Protecting Genetic Privacy in Biobanking through Data Protection Law*. When the biobank collects and stores data that do not qualify as personal data, the legal provisions to comply with are radically different and usually provides for a legal regime less restrictive than the one here taken into consideration. Therefore, only personal data will be the focus of the present work, because of the substantially differences between the two types of data, which render them not comparable.

[432] Emphasis added.

[433] CJEU *Novak case* (C-343/16).

[434] Emphasis added.

[435] Thanks to the identifiability criterion, the CJEU qualified as personal data various information that would not *prima facie* be qualified as such, for instance *ex multis* the IP address in the Breyer case (analysed in the following paragraphs) and Benedik v. Slovenia (App. n. 62357/14), a Vehicle Identification Number in the case C-319/22, the log data generated by a computer in the Pankki S. case (C-579/21) Extensively

Moreover, most of the data stored in a biobank will also qualify as *sensitive personal data* (or special categories of data). Indeed, while not providing an explicit definition, the GDPR indirectly identifies this category in Art. 9(1) GDPR when it provides for a special regulatory framework for "(...) genetic data, biometric data to uniquely identify a natural person, data concerning health (...)".

First of all, *data concerning health* are defined in Art. 2(15) GDPR as "personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status".[436] Recital 35 GDPR helps further define this category by establishing that "[p]ersonal data concerning health should include all data pertaining to the health status of a data subject which reveal information relating to the *past, current or future physical or mental health status* of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services as referred to in Directive 2011/24/EU of the European Parliament and of the Council to that natural person; a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test."

Therefore, it appears evident that some data may be included in this category with a high degree of certainty, such as any information on the physical or mental health of a person, whether present, past or future, data collected during the provision of healthcare and linked to the person in a way that permits her identification, clinical data or data resulting from medical analyses, diagnostic tests, etc.[437]

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on the definition of personal data, see Lodie, Alexandre "Are Personal Data Always Personal? Case T-557/20 SRB v. EDPS or When the Qualification of Data Depends on Who Holds Them." *European Law Blog*, blogpost 45, 2023; Ouarab, Yacine "Identifying the Identified: Unraveling the Third Element of Personal Data in EU Law." *Helsinki Law Review*, vol. 1, 2021, pp. 64-80. Moreover, the concept is further elaborated upon in Chapter IV.

[436] This definition is the only one binding in the context of the processing of personal data within the scope of the GDPR. However, I believe it is worth noticing that the definition provided for in Art. 2(15) is coherent with that of the various soft law instruments, such as OECD Recommendation 2016

[437] For a more comprehensive list see Recital 35.

However, precisely delimiting such a category is a difficult task, because ordinary or neutral data (i.e. data that do not pertain to the special category of data *per se*) may become *sensitive data* given the specific circumstances of the processing.[438]

It is therefore suggested that an extensive interpretation of the category, which brings along a stricter legal regime applicable to the processing, be adopted in order to better protect the rights and interests of the persons involved.[439] This approach is also coherent with that adopted by the CJEU, which similarly applies a broad interpretation of the concept.[440]

Secondly, *genetic data* are defined in Art. 2(13) GDPR as "personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question". In particular, the provision links these data to the HBS, as mentioned in Part A, and therefore genetic data includes that specific type of data that I have called HBS data.

Genetic data are worth a higher degree of protection than "regular data" because of their characteristics, which make them a unicum among the data related to the health of a person. Indeed, not only are these data predictive, inalterable, unique to the person, and shared with the other members of the family;[441] but because of the rapid development in the fields of genetics and information technology it might be possible in the future to impact on the rights and interests of participants "in novel ways or in a manner which cannot be anticipated with precision today",[442] partially because they identify a specific

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[438]EDPB Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak, 2020; Thiene, Arianna "La Regola e l'Eccezione. Il Ruolo del Consenso in Relazione al Trattamento dei Dati Sanitari alla Luce dell'art. 9 GDPR." *La Protezione dei Dati Sanitari: Privacy e Innovazione Tecnologica tra Salute Pubblica e Diritto lla Riservatezza*, edited by Thiene, Arianna, and Stefano, Corso, Jovene editore, 2023, pp.7-22; Hallinan, Dara *Protecting Genetic Privacy in Biobanking through Data Protection Law*.

[439] On such a rigorous interpretation of the concept specifically of data concerning health, see two sentences of the Italian Corte di Cassazione n. 10947/2014 and 30984/2017.

[440] See for instance the Lindqvist case (C-101/01). Hallinan, Dara *Protecting genetic privacy in biobanking through Data Protection Law*.

[441] Casabona, Romeo C.M. "La Protección de Datos de Salud en la Investigación Biomédica." *Protección de Datos e Investigación Biomédica*, edited by Piqueras, Gomez, Aranzadi, 2009; Bianchi Clerici, Giovanna "I Campioni Biologici nei Provvedimenti dell'Autorità Garante per la Protezione dei Dati Personali. Le Informazioni Genetiche." *Lo Statuto Etico-Giuridico dei Campioni Biologici Umani,* edited by Farace, Dario, Diritto, Mercato e Tecnologia, 2016, pp. 169-186; Azzini, Sara, "Biobanche, Consenso e Fonti del Diritto: un Caso di Eccezionale Disordine?."

[442] ECHR *Marper case,* Case of S. and Marper v. the United Kingdom, Apps. N. 30562/04 and 30566/04.

individual in a permanent way.[443] Indeed, DNA is a "future diary" of the person, because the information it provides is referred to the person's present and future medical condition.[444]

The mentioned characteristics of genetic data, and the consequent higher degree of protection have been recognised by many of the mentioned soft law instruments, such as the UNESCO International Declaration[445]

The two categories of sensitive data (data concerning health and genetic data) only partially overlap. Indeed, from the analysis and processing of genetic data, various personal unique information about the data subject may be extracted, which is only partly qualifiable as *data concerning health* for the purposes of the GDPR.[446]

As established by Art. 9 para. 1 GDPR, the processing of special categories of data shall be generally prohibited, unless one of the exceptions provided for by paragraph 2 applies.

3 PRELIMINARY CONSIDERATIONS – (a) THE ACTOR CLASSIFICATION SYSTEM APPLIED TO BIOBANKING

The GDPR generally provides a classification of actors with the aim of allocating substantive rights and responsibilities.[447] In particular, the regulation differentiates among (1) the data subject, (2) the data controller, and (3) the data processor. Identifying the roles of each entity in the biobanking field and processing activity and for the conduction of scientific research directly means allocating the various duties and responsibilities, especially for the protection and exercise of the data subject's rights.[448]

(1) The data subject is defined indirectly in Art. 4(1) GDPR and is the party of the processing whose data are processed by the data processor and whose rights may be affected by the processing itself. In biobanking, the data subject is usually the *participant,* as previously defined in Chapter I.

Moreover, the definitions of the roles of the data controller and processor are identified by the new Regulation according to the previous Directive 95/46/EC. The duties and

[443] Cippitani, Roberto "Genetic Data." *GDPR Requirements for Biobanking Activities Across Europe*, edited by Colcelli, Valentina, et al, Springer, 2023, pp. 227-232.
[444] Annas, George J. "Genetic Privacy." *DNA and the Criminal Justice System: The Technology of Justice*, edited by Lazer, David, MIT Press, 2004, pp. 337-366.
[445] See both the Preamble and Art. 7(6).
[446] See on this Corte di Cassazione, sentence of the 16th of April-13th September 2013, n. 21014.
[447] Hallinan, Dara *Protecting genetic privacy in biobanking through Data Protection Law*.
[448] Di Tano, Francesco "Protezione dei Dati Personali e Ricerca Scientifica: un Rapporto Controverso ma Necessario." *BioLaw Journal*, vol. 1, 2022, pp. 71-99.

obligations of the data controllers and data processors primarily emanate from the rights of the data subject to be protected according to the GDPR and are identified by the latter consequently.[449] Even though the literal interpretation of these definitions appears straightforward,[450] identifying each role in the context of a specific processing, in particular in the field of biobanking, might be a complex exercise, precisely because these are not fixed qualifications but depend on the concrete organisation of the processing, and the role and responsibilities of each actor involved in it.

(2) The data controller is the natural or legal person who determines the purposes and means of the processing (Art. 4(7) GDPR). The concept has been further clarified by the CJEU firstly in the *Google Spain case* and then in the *Wirtschaftsakademie case*, where the Court established that the concept should be interpreted broadly. In the biobanking context, both the *biobank* itself and the external researchers are possible data controllers,[451] for the same or different processing activities. Indeed, as it has been authoritatively highlighted, "[t]his role is based on a notion of control which can stem from any form of legal entitlement" and depends on the concrete ability and power of an actor to define the "substantive content of the data processing". When applied to biobanking, the controller is the entity that has the power to decide on the legal basis of the processing, the length of the time of the storage, and particularly who may access the HBSs and personal data.[452]

(3) The data processor is defined in Art. 4(8) GDPR as the natural or legal person that processes personal data on behalf of the controller. Consequently, two conditions should be respected to qualify as data processor: being a separate legal entity from the data controller, and processing data on behalf of the latter.[453] The data controller and the data processor are those whose processing impacts on the personal data of the data subject.[454]

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[449] Nordberg, Ana "Biobank and Biomedical Research: Responsibilities of Controllers and Processors Under the EU General Data Protection Regulation."

[450] *Ibid*

[451] The possibility of having more than one data controller is explicitly recognised by Art. 26(1) GDPR. In this case, the two natural or legal persons are *joint controllers.* Hallinan, Dara *Protecting Genetic Privacy in Biobanking through Data Protection Law*; Nordberg, Ana "Biobank and Biomedical Research: Responsibilities of Controllers and Processors Under the EU General Data Protection Regulation."

[452] Nordberg, Ana "Biobank and Biomedical Research: Responsibilities of Controllers and Processors Under the EU General Data Protection Regulation."

[453] *Ibid*

[454] Hallinan, Dara *Protecting Genetic Privacy in Biobanking through Data Protection Law*.

According to Art. 26 GDPR the role of the controller may also be exercised by two or more entities, that therefore qualify as joint controllers. Indeed, two entities qualify as joint controllers when they jointly "determine the purposes and means of processing" and in this case they shall "in a transparent manner determine their respective responsibilities for compliance with the obligations" under the GDPR.[455]

Moreover, in the context of joint-controllership, Art. 26 GDPR further requires an agreement to be in place between the controllers, in which the respective responsibilities are identified in a transparent manner "in particular as regards the exercising of the rights of the data subject and their respective duties to provide the information referred to in Article 13 and 14".[456] The essence of the arrangement should be made available to the data subject.

Therefore, joint controllership arises in processing whose purposes or means are jointly determined. As for the first case (purpose), in light of the CJEU case law it is not necessary that the entities have the same purpose for the processing, but it is sufficient that "a mutual benefit arising from the same processing operation". As for the second one (means), the CJEU clarified that it is possible that the various entities are involved at different stages of the processing and also to a different degree or extent, and consequently they define the means to a different extent as well.[457]

On the matter, the EDPB specified that the final decision could take the form of a common decision or the result of converging separate decisions that complement each other and both impact on the determination of the purposes and means of the processing, and that a useful criteria to assess the existence of a joint-controllership is that "the processing would not be possible without both parties' participation in the sense that the processing by each party is inseparable, i.e. inextricably linked".[458]

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[455] Art. 26 paragraph 1 GDPR.

[456] See also on this topic Kuner, Chritsopher "The European Commission's Proposed Data Protection Regulation: a Copernican Revolution in European Data Protection Law." *Bloomberg BNA Privacy and Security Law Report*, vol. 1, n. 7, 2012.

[457] To this end, see for instance the *Wirtschaftsakademie case* (C-210/16), there the Court established that Facebook and the administrator of a fan page were joint-controllers, because the latter defined the parameters based on its target audience and the objectives of managing and promoting its activities. EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR Version 1.0, 2020.

[458] EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR Version 1.0, 2020.

The relationship between the two controllers shall be regulated in a transparent manner through an agreement, whose legal form is not specified in the GDPR, but the form of a binding document such as a contract is suggested by the EDPB.[459]

As for the entities that qualify as data controllers and data processors, or the "joint" version of the formed, the evaluation depends on a case-by-case assessment and, in particular, on the concrete allocation of the responsibilities and tasks to be complied with.[460] Indeed, this evaluation should be based on the factual characteristics of the processing, that shall prevail over a mere abstract analysis, in compliance with the accountability principle.[461] The matter is complicated by the fact that the same entity within the same research project may qualify as a data controller for some specific processes and as data processor for others,[462] depending on the concrete agreements, interests and allocations of responsibility.[463]

In general terms, qualifying the biobank as a data controller has been defined as straightforward,[464] mainly because the biobank determines how and why the personal data are collected and stored and, more importantly, which third parties, i.e. researchers, might have access to them.[465]

Moreover, researchers usually meet the definition of data controllers as well, even though they might not have complete and free access and the right to use the content of a biobank[466] for their own purposes, which might be slightly different from those of the biobank. Indeed, the researchers-data controllers define the means and purposes of the processing of the data stored in the biobank for their own specific scientific research

[459] EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR Version 1.0, 2020.
[460] EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR Version 1.0, 2020; Nordberg, Ana "Biobank and Biomedical Research: Responsibilities of Controllers and Processors Under the EU General Data Protection Regulation."
[461] Di Tano, Francesco "Protezione dei Dati Personali e Ricerca Scientifica: un Rapporto Controverso ma Necessario."
[462] *Ibid*
[463] EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR Version 1.0, 2020. See for instance the case *Fashion ID case* (C-40/17) where the CJEU established that a website operator qualified as joint-controller by embedding a social plug-in on a website with the aim of optimizing the publicity of its goods.
[464] Hallinan, Dara *Protecting Genetic Privacy in Biobanking through Data Protection Law*.
[465] It is important here to underline that in order to be qualified as *data controller* it does not matter whether the natural or legal person, entity or otherwise has legal personhood according to a Member State. See lastly on this CJEU C-231/22.
[466] Hallinan, Dara *Protecting Genetic Privacy in Biobanking through Data Protection Law*.

purpose, but in compliance with the rules for access to these data identified and decided by the biobank governance.

Consequently, the possible roles cannot, in principle, be schematised with sufficient precision and clarity without running the risk of oversimplifying the matter or omitting the evaluation of essential biobanking characteristics. However, I will attempt to provide some clarifications and examples.

Some authors believe that in the context of research biobanking usually both the biobank itself and the researchers can qualify as data controllers, while no data processors are in principle identifiable.[467] Differently, others believe that they can both assume the role of controllers, either jointly or autonomously, or controller and processor respectively, and that only an assessment conducted on a case-by-case basis can help clarify the matter in the context of each specific processing.[468]

The EDPB, in its Guidelines 07/2020, provides various examples of joint controllerships, in particular, that of a research project conducted by two research institutes using the existing platform of only one of them. In this case, both institutes qualify as joint-controllers, if they both provide personal data into the platform and use those provided by others through the platform.[469] Also in a clinical trial, in which a health care provider participates as investigator and a university as sponsor, if they both collaborate in the drafting of the study protocol, they identify as joint-controller, while the health care provider qualifies as processor if her only task is providing the data.[470]

In the biobanking field specifically, I believe that the mentioned analysis to be conducted on a case-by-case basis should take into consideration each processing activity specifically, as well as their final purposes, and the entities involved.

In particular, I suggest that two stages of the biobanking research processing may be identified: (a) collecting and storing data for future research purposes, and (b) processing the biobank data for a specific research project.

For the purposes of allocating responsibilities and identifying the various roles of the entities involved, a fundamental distinction might be provided.

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[467] Hallinan, Dara *Protecting Genetic Privacy in Biobanking through Data Protection Law.*

[468] Nordberg, Ana "Biobank and Biomedical Research: Responsibilities of Controllers and Processors Under the EU General Data Protection Regulation."

[469] EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR Version 1.0, 2020.

[470] *Ibid*

If the biobank conducts both activities alone,[471] thus deciding autonomously the purposes and means of both processing activities, it is possible to qualify the whole process (from the collection to the actual research project) as a unicum, whose characteristics in terms of purpose definition are specified through time every time a research project is identified. Indeed, the entity running the biobank aims at conducting various research projects, and implementing a collection of biobank data is the first step of a much bigger processing. This is the approach adopted by the Italian DPA in the Provvedimento n. 238/2022. In this case, the Azienda Ospedaliera Universitaria Integrata di Verona was left with the choice of the legal basis for the creation of the biobank between asking for the informational consent of the data subject or using the research exemption, when the first one was not a viable option. In case the biobank chose the research exemption, the favourable opinion forwarded by the geographically competent ethics committee and the prior consultation with the supervisory authority were deemed sufficient for both (a) collecting the biobank data to implement the biobank and (b) processing the stored data for conducting the research project subsequently identified. I believe this approach demonstrates that the two processing activities (a and b), under certain circumstances, may be considered as a unicum, whose characteristics are specified through time by the data controller, who should then comply with the duty to provide the relevant information as soon as available.

However, if external research entities are involved in the decision of the purposes and means of the processing of the biobank data for conducting a scientific research project, I believe it is necessary to keep separate (a) the *biobanking* activity and (b) conducting a *scientific research project* with the HBSs and biobank data already stored. In this case, assessing the roles of the parties involved depends on the concrete responsibilities and degree of decision-making power in conducting the second processing. In particular, two scenarios might be envisioned: (b1) the processing may be conducted by a research entity alone, merely using the biobank data already stored, in which case the latter qualifies as *data processor*, while the research entity is the sole *data controller* of the scientific research processing, or (b2) the biobank and the researcher may jointly decide the purposes and means of the research project, thus qualifying as *joint-controllers*.

[471] However, this example applies as well in cases in which third parties are involved in the concrete scientific research project, with minor tasks or responsibilities and thus assuming the role of data processors.

However, the first processing is always conducted by the biobank alone, which consequently is frequently the sole entity that qualifies as *data controller* for that specific purpose.

3.1 ... (B) BIOBANKING PURPOSES V. SCIENTIFIC RESEARCH PURPOSES

Linked to the analysis conducted above, I believe it is useful for proceeding in the analysis of the GDPR models for collecting biobank data, to evaluate the preliminary distinction on the type and purpose of the processing already mentioned, in the light of the GDPR provisions.

Research biobanks are infrastructures established to facilitate the conduction of scientific research projects and the development of science at large. In this regard, as mentioned, they provide a fundamental service in particular for developing personalised medicine, by storing large quantities of biological samples and (related) personal health data.

As such, I believe that the activity of *biobanking*, i.e. collection of personal data to be stored for future undefined scientific research purposes, does not *per se* meet the definition of *scientific research*, either in the general meaning of the term, as underlined elsewhere in this work, or in that of the one specific of the data protection regulation.

Indeed, a specific and clear definition of what constitutes *scientific research* is not included in any of the provisions of the GDPR even though the concept is frequently mentioned throughout the text and is the conceptual and legal basis for the applicability of many of its provisions, and such a definition is generally difficult to be achieved,[472] mainly because of ongoing changes of the field in terms of ways of conducting research, involvement of new actors, and increasing relevance and amount of data.[473] Moreover, neither the DGA nor the EHDS provides for any definition or further guidance on this.

However, both the specifications in the relevant documents for biobanking and their use of the concept may be relevant arguments to assess the matter. Indeed, they demonstrate the constant development in the ways scientific research is conducted, in particular as for

[472] Comandè, Giovanni, and Giulia, Schneider "Differential Data Protection Regimes in Data-Drive Research: Why the GDPR Is More Research-Friendly Than You Think." *German Law Journal,* vol. 23, 2022, pp. 559–596.

[473] Indeed, identifying the clear boundarise of the legal notion of research has been defined as a "highly challenging interpretative battlefield at both international and supra-national level." Comandè, Giovanni, and Giulia, Schneider "Differential Data Protection Regimes in Data-Drive Research: Why the GDPR Is More Research-Friendly Than You Think."

the type of data processed and their relevance, the involvement of various and new actors, public and private stakeholders, and the nature of the projects themselves. In turn, this renders the legal notion of *research* "a highly challenging interpretative battlefield at both the international and supra-national level."[474]

Indeed, the GDPR includes *scientific research* as one of the possible exemptions listed in Art. 9(2) (in particular, letter j) and as an exemption for the duty to conduct the compatibility test for the *secondary use* of data (Art. 5(1)(b) and Recital 50 GDPR).

However, the GDPR does not provide a complete definition of what constitutes *scientific research.* Recital 159 calls for a broad interpretation of the term, by establishing that "the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research. (…) Scientific research purposes should also include studies conducted in the public interest in the area of public health". To avoid misinterpretation of the term, the Article 29 Working Party first,[475] and subsequently the EDPB[476] stated that "the notion may not be stretched beyond its common meaning" and broadly required *scientific research* in the context of data protection to be understood as "a research project set up in accordance with relevant sector-related methodological and ethical standards, in conformity with good practice". As a consequence, the EDPS established that the GDPR scientific research regime might be applicable whenever the following three conditions are met: (a) personal data are processed; (b) relevant sectoral standards of methodology and ethics apply (including the notion of informed consent); (c) the research is carried out with the aim of growing society's collective knowledge.[477]

In the absence of further and more specific guidance on the definition and interpretation of the term, considering that under a normative point of view the concept remains

[474] Comandè, Giovanni, and Giulia, Schneider "Differential Data Protection Regimes in Data-Drive Research: Why the GDPR Is More Research-Friendly Than You Think."

[475] EDPB, Guidelines 05/2020 on Consent Under Regulation 2016/679, 2020; EDPB, Guidelines 03/2020 on the processing of Data Concerning Health for the Purpose of Scientific Research in the Context of the COVID-19 Outbreak, 2020; EDPB, Opinion 3/2019 of the EDPB from 23.1.2019 on concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR), 2019.

[476] EDPB, Opinion 3/2019 of the EDPB from 23.1.2019 on concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR), 2019.

[477] EDPS, a Preliminary Opinion on data protection and scientific research, 2020.

undefined,[478] Colcelli highlights that usually the main purpose of scientific research is the advancement of knowledge.[479] Moreover, based on the CJEU and the ECHR case law on the matter, Bentzen identified three elements that may be used to assess what constitutes scientific research, and in particular: (1) the role of the legal entity, i.e. usually public research entities, but also private entities are covered by the term under certain circumstances, (2) the role of those carrying out the activity, and (3) quality standards including scientific methodology and scientific publication.[480]

I believe that the information provided above on the matter is sufficient to determine that collecting personal data to be stored in a biobank for subsequent scientific research use does not constitute *per se* processing for a *scientific research purpose*. A careful analysis of the General Authorisations relevant to the processing of genetic data also supports this interpretation. Indeed, on the one hand, the General Authorisation n. 9/2016 titled "Prescriptions on the processing of personal data for scientific research purposes" not only never mentions the collection and storage of the samples and data, but also in paragraph 5.2 defined its material scope as being referred to research projects conducted with HBS data or left-over data, or with data referred to data subjects unable to provide consent, and establishes that the scientific research shall be conducted on the basis on a project previously approved by the competent ethics committee, thus clearly underlying the necessity of having a project already in place when the purpose of the processing is the *scientific research*. On this point, the same can be said for paragraph 4.11 of the General Authorisation n. 8/2016, which refers to the processing of genetic data for scientific research or statistical purposes.

On the other hand, and differently from the n 9/2016, the General Authorisation n. 8/2016, titled more generally "Prescriptions on the processing of genetic data", addresses explicitly storing genetic data and biological samples in biobanks and registries and asks for the adoption of encryption or pseudonymisation techniques, and other safety

[478] Slokenberga, Santa "Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject that the Proposed EHDS Regulation Promises to Bring Along."

[479] Colcelli, Valentina "Future Research." *GDPR Requirements for Biobanking Activities Across Europe*, edited by Colcelli, Valentina, et al. Springer, pp. 217-226.

[480] Bentzen, Heidi Beate "In the Name of Scientific Advancement: How to Assess What Constitutes 'Scientific Research' in the GDPR to Protect Data Subjects and Democracy." *Disinformation and Digital Media as a Challenge for Democracy*, edited by Terzis, Georgios, et al. Intersentia, 2020, pp. 341-366; Bentzen, Heidi Beate "Context as Key: The Protection of Personal Integrity By Means of the Purpose Limitation Principle." *Research Handbook on EU Data Protection Law*, edited by Kosta, Eleni, et al. Elgaronline, 2022, pp. 381-404.

measures,[481] and these prescriptions are kept separate from those related to the processing of samples and genetic data for scientific research purposes.

As a consequence, it seems that the provisions specifically referred to *scientific research* do not in principle apply to biobanking.

However, as mentioned, a recent Opinion of the Italian DPA on the creation of a biobank for scientific research purposes (Provvedimento n. 238/2022) seems to move in a different direction. Indeed, the Italian DPA allowed the implementation by the Azienda Ospedaliera Universitaria Integrata di Verona of a biobank for future research purposes, adopting as a legal basis either the informational consent of the participants, for prospective data, or the exemption from consent established by Art. 110 Italian Privacy Code for scientific research, for the retrospective data and particularly those for which asking for consent was not a viable option.

The decision of the Italian DPA was different for the two types of data collected. For prospective data, it established that while it was lawful for the Azienda Ospedaliera Universitaria Integrata di Verona to collect personal data based on broad consent, i.e. more generally provided on the basis of general information about the processing, in order to process them for specific research projects subsequently identified it was compulsory to either ask for a new specific informational consent or apply Art. 110 Italian Privacy Code.

On the contrary, for retrospective data, the Italian DPA allowed the collection and storage of personal data in a biobank based on the procedure established specifically for scientific research by Art. 110 of the Privacy Code. In this case, the initial approval by the ethics committee and the prior consultation of the Italia DPA is deemed to be sufficient for storing the data for future undefined scientific research purposes, while concretely using them in a scientific project could qualify as secondary processing, according to Art. 5(1)(b). Figure 3 will help better understand the decision of the Italian DPA.

[481] Paragraph 4.2f General Authorisation n. 8/2016.

<table>
<tr><td>Processing activity</td><td colspan="2">Legal basis</td><td></td></tr>
<tr><td rowspan="2">Collecting data to be stored in a biobank for future undefined research purposes</td><td colspan="2">Prospective data</td><td>Retrospective data</td></tr>
<tr><td colspan="2">Informational (broad) consent</td><td>Art. 110 Italian Privacy Code for scientific research</td></tr>
<tr><td>Processing personal data already stored in a biobank for a specific research project.</td><td>A) If recontacting data subject is possible

Informational specific consent</td><td>B) If recontacting data subject is not possible

Art. 110 Italian Privacy Code for scientific research</td><td>Presumption of compatibility – evaluation ethics committee only</td></tr>
</table>

Figure 3

Accordingly, this might be interpreted as meaning that, in the case concerned, the mere activity of collecting and storing personal data in a biobank was considered *scientific research,* at least in broad terms and within the meaning of the GDPR. Indeed, this seems to be the only explanation for permitting the applicability of art. 110 Italian Privacy Code to the mere activity of collecting and storing data in a biobank.

I believe the mentioned approach might encounter some criticisms. In particular, the type of processing under consideration, i.e. collecting data to be stored in a biobank for future research purposes, does not comply with almost any of the characteristics of a project to qualify as "research project", as previously mentioned.

Therefore, the approach of the Italian DPA runs the risk of stretching the notion of scientific research beyond its common meaning, against the warning of the EDPB.

However, the usual approach adopted for biobanking is to consider the scientific research regime applicable, even though the nature of a biobank as an autonomous research project *per se* is usually excluded. Reasons for such a conclusion might be found in either a particularly broad interpretation of the term or in assuming that the biobank is the entity that both collects and stores the biobank data and (at least partially) conducts the specific research projects. According to this approach, the general purpose of the processing conducted by the biobank is "scientific research", within which the activity of collecting and storing the data is merely an intermediate step.

Indeed, this approach has the merit of rendering it possible for biobanks to apply the scientific research regime, which, as I will extensively explain in the following pages, includes various exemptions to some of the core GDPR principles and of the data subject's fundamental rights, and therefore is mainly in favour of the advancements of science and scientific research to the benefit of society at large. Greater possibilities of processing personal and health data for scientific research purposes are also the more general aim of the European legislation on data protection (see for instance the provisions of the DGA and the EHDS, analysed at the end of this Part B).

This goal, albeit legitimate provided that a fair balance is struck between the contrasting interests at stake, in my opinion may run the risks of excessively stretching the interpretation of the provisions of the GDPR.

Moreover, I believe that the differentiation between the various purposes of the processing activities (biobanking on the one hand, and scientific research on the other), is necessary because some of the difficulties in this field might arise from the attempt to apply to biobanks the rules and provisions tailored to traditional scientific research.

On this, I strongly agree with Maestri in believing that this approach forced the interpreter to create scientific and legal fictions,[482] to stretch the conditions for applying "traditional" scientific research provisions to include biobanking research. On the contrary, biobanking is a way of enabling the conduction of scientific research, or directly conducting it with specific peculiarities, that only in some instances resemble those of traditional scientific research. In particular, a first processing is always conducted in order to create a biobank, that is subsequently used for various specific research projects conducted by possibly a wide range of entities. Both elements, the existence of different steps or processing and the involvement of various entities, complicate the matter for the interpreter.

Moreover, I believe some of the issues on the applicability of certain provisions to biobanking, such as that of *specific* informational consent, might be caused by this approach that considers traditional research and biobanking research as substantially equivalent.

In this regard, adopting a careful approach might be beneficial, and therefore constantly assessing on a case-by-case basis the concrete way in which the biobank is implemented and the subsequent characteristics of the specific research projects, and in particular

[482] Maestri, Enrico "Biobanche e Consenso Informato tra Finzioni Scientifiche e Finzioni Giuridiche."

whether the allocation of the responsibilities and the various roles in the processing activities might justify using Art. 9(2)(j) as a legal basis and applying the various exemptions provided for by the GDPR for scientific research.

As a consequence, in order to provide a comprehensive analysis, I will include in the following pages also the provisions applicable to a scientific research project. Consequently, I will present both alternatives: on the one hand, the legal basis and exemptions available if biobanking qualifies as scientific research, and on the other the legal framework when it does not.

Finally, a further specification is necessary. In order to foster scientific research at large, biobanking implies sharing data previously collected for undefined research purposes with the researchers or research institutions that carry out the specific research project identified.[483] Therefore, in this case, the biobank would have to identify a set of criteria for determining who may have access to the data, for which research project and under what conditions. Indeed, the sharing of data in the context and for the purposes of scientific research is also mandated under a quasi-constitutional point of view[484] by Recital 159 of the GDPR that, in the context of scientific research, refers to Art. 179(1) of the TFEU, which establishes "the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely."

In this regard, a last requirement should be highlighted. It is important here to underline that according to the General Authorisation n. 8/2016, genetic data processed for scientific research purposes might be communicated or transferred to research entities or institutes, associations and other government and private organisms only within joint projects and according to Art. 26 GDPR (paragraph 4.11.4 General Authorisation n. 8/2016). As an exemption to this general provision, genetic data collected for scientific research purposes may be shared with or transferred to third parties, i.e. research institutions that are not part of a joint project (and therefore are data controllers of a different one) under the following conditions: the genetic data should be non-identifiable; they should be processed for research purposes directly related to the original one and

[483] The situation is slightly different whenever the biobank both collects and stored the samples and data and conducts scientific research projects. However, this scenario is usually not the one prevailing.

[484] Comandè, Giovanni, and Giulia, Schneider "Differential Data Protection Regimes in Data-Drive Research: Why the GDPR Is More Research-Friendly Than You Think."

established in writing in the request.[485] Consequently, theoretically, the possibility for the biobank to share personal data with researchers should be subject to the mentioned requirements. However, I believe that the intention of the Italian DPA in issuing the General Authorisation n. 8/2016 was to protect the rights and interests of participants from unwanted and unknown processing of their data, whenever sharing data with or transferring them to third parties was an activity to be performed within the context of a specific research project. There, the instances worthy of protection are those related to the right of the data subject to be informed of the possible use of her personal data.

Indeed, when data are collected for "traditional" scientific research purposes, the data subject is aware of a specific and defined purpose of the processing of her data (i.e. the specific research project), because of the informational duties established by Art. 13 and 14 GDPR. Therefore, the Italian DPA allows the sharing of the data already collected exclusively with a third party that participates in the "original" processing in order to prevent possible processing of these data for purposes not known by the data subject. For the same reason, when the recipient entity does not participate somehow in the original purpose (the research project), the possibility of transferring or sharing the data is subject to the condition of anonymising them, which is the traditional instrument used to prevent possible negative impact on the rights and interests of the data subject.

However, as mentioned and further explained in the following paragraphs, when personal data are collected for biobanking purposes, even in cases where it is possible to apply the specific research regime envisioned by the GDPR for *scientific research*, the purpose of the collection includes the possibility of enabling access to such data by third parties for undefined research purposes. Consequently, the data subject is aware of such a possibility from the start, because it is part of the processing to which she has consented or of which she has been informed according to Art. 13 or 14 GDPR.

Interpreting the mentioned provisions under the specific lenses of biobanking might therefore help in mitigating it and fair balancing the interests of scientific research against those of the data subject.

[485] Cannovo, Nunzia, et al. "Ethical and Deontological Aspects of Pediatric Biobanks: The Situation in Italy." *Cell Tissue Bank,* vol. 21, n. 3, 2020, pp. 469-477.

4 COLLECTING BIOBANK DATA – (I) THE LEGAL FRAMEWORK AT THE SUPRANATIONAL LEVEL

I will now move to analysing the various modes for the collection and storage of personal data in a biobank that may be identified in the applicable legal framework, as described in Chapter I. The analysis will be divided between the legal framework established by the GDPR at the supranational level, and the Italian Privacy Code at the national one, and between primary processing, whose analysis is devoted this paragraph 4, and secondary processing, discussed in paragraph 6.

At the European level, as mentioned, the collection of biobank data falls within the scope of the GDPR, and the requirements and provisions of the latter should be complied with. In particular, the GDPR is a principle-based regulation[486] and its Art. 5 lays down the principles that shall be respected in the processing of personal data: (a) lawfulness, fairness and transparency; (b) purpose limitation; (c) data minimisation; (d) accuracy; (e) storage limitation; (f) integrity and confidentiality. Among the general principles, it is also worth mentioning the additional accountability principle, whose consequence is to make the data controllers responsible for complying with the mentioned principles (Art. 5(2) GDPR).

From a general point of view, the collection of biobank data to be stored in a biobank for future research purposes qualifies as *primary use* in Scenario 1 – collection for biobank purposes with a high degree of certainty, while usually Scenarios 2 and 3 qualify as *secondary use* within the meaning of the GDPR, but the concrete qualification may only depend on a case-by-case analysis.

The principle of lawfulness is further expanded in Art. 6 GDPR, which enumerates the six possible legal grounds for lawful processing, i.e. the legal *bases*. Neither the GDPR itself nor further commentaries or guidelines specify any hierarchy among the legal bases listed in Art. 6(1)[487] GDPR and this is also the most shared view among scholars on the matter.[488]

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[486] Tzanou, Maria *Health Data Privacy Under the GDPR: Big Data Challenges and Regulatory Responses*; Hoofnagle, Chris Jay, et al. "The European Union General Data Protection Regulation: What It Is and What It Means." *Information & Communications Technology Law*, vol. 28, n. 1, 2019, pp. 65-98.

[487] EDPB, Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak, 2020.

[488] Among many others Gefenas, Eugenijus "Controversies Between Regulations of Research Ethics and Protection of Personal Data: Informed Consent at a Cross-Road"; Dove, Edward S., and Jiahong, Chen

Therefore, the data controller may freely choose the best-suited legal ground before processing starts and should document the choice, bearing in mind that each legal basis has different consequences in terms of conditions for its applicability and rights of the data subject under the GDPR.[489] This is because in the legal framework provided for by the GDPR, the protection of personal data is based on the principle of accountability, i.e. that the controller should implement appropriate technical and organisational measures in order to protect the rights of the data subject (such as pseudonymisation and data minimisation) (Art. 25(1) GDPR).[490]

The choice, however, cannot be driven by the aim of better pursuing mere economic interests or otherwise subjective interests of the controller, but it should be appropriate for the processing at stake.[491]

Moreover, when the data processed falls into the definition of "special categories of data", such as genetic data[492] or data concerning health,[493] Art. 9 GDPR shall also be complied with.[494] This will usually be the case for biobanks, given the types of data traditionally

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"Should Consent for Data Processing Be Privileged in Health Research? a Comparative Legal Analysis." *International Data Privacy Law*, vol. 10, n. 2, 2020, pp. 117–131; Zanovello, Francesca "Misure di Garanzia e Rischio di Data Breach in Ambito Sanitario." *La Protezione dei Dati Sanitari: Privacy e Innovacione Tecnologica tra Salute Pubblica e Diritto alla Riservatezza*, edited by Thiene, Arianna, and Stefano, Corso, Jovene editore, pp. 129-156; Florea, Marcu "Withdrawal of Consent for Processing Personal Data in Biomedical Research." *International Data Privacy Law*, vol. 13, n. 2, 2023, pp. 107–123; Thiene, Arianna "La Regola e l'Eccezione. Il Ruolo del Consenso in Relazione al Trattamento dei Dati Sanitari alla Luce dell'art. 9 GDPR"; Gefenas, Eugenijus "Controversies Between Regulations of Research Ethics and Protection of Personal Data: Informed Consent At a Cross-Road." Moreover, explicitly established such absence of a hierarchy for the legal bases in Art. 6 GDPR the EDPB in the Guidelines 8/2020 on the targeting of social media users, of 2021.

[489] Gonzalez, Elena Gil, and Paul, de Hert "Understanding the Legal Provisions That Allow Processing and Profiling of Personal Data—An Analysis of GDPR Provisions and Principles" *ERA Forum*, vol. 19, 2019, pp. 597–621; See also EDPB, Statement on the processing of personal data in the context of the COVID-19 outbreak, 2020, where the authority affirms that "under those circumstances [i.e. when another legal basis is applicable] there is no need to rely on consent of individuals."

[490] Sirgiovanni, Benedetta "Informed Consent to Processing of Genetic Data." *Italian Law Journal*, vol. 8, n. 2, 2022, pp. 955-975.

[491] EDPB, Binding Decision 4/2022 on the dispute submitted by the Irish SA on Meta Platforms Ireland Limited and its Instagram service (Art. 65 GDPR), 2022.

[492] Art. 4(13) GDPR: "personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question."

[493] Art. 4(15) GDPR: "personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status."

[494] in this work, I adhere to the interpretation supported by the *traveaux preparatoires* of the GDPR, the guidance of the Information Commissioner's Office in the UK (ICO), the EDPB and EDPS according to which both a legal ground according to Art. 6(1) GDPR and an exemption of Art. 9(2) GDPR shall be identified when health data are processed. Moreover, it is worth underlying that the list of personal data that should be considered *sensitive data* cannot be expanded by means of interpretation of analogy. On this

stored therein, as previously mentioned. The following analysis, therefore, will only consider the processing of sensitive personal data, especially genetic data, given that such a processing is subject to more stringent requirements and provisions and the cause of an intense debate among researchers and scholars.

In particular, Art. 9 establishes a general prohibition to processing special categories of data,[495] and such a prohibition constitutes the general rule applicable to the processing of these types of data.[496] The ratio behind this provision that establishes a two-tier system of protection (one for normal data and the other for sensitive data)[497] is the more significant impact of the processing of such data on the fundamental rights of the data subject.[498]

The exceptions to the ban are those processing for purposes listed in paragraph 2.[499] In this regard, with an approach analogous to the one adopted for the legal bases, the GDPR does not establish a hierarchy among the exemptions provided for in Art. 9 either.[500]

It is worth mentioning the contrary opinion of Hallinan, who affirmed that among the exemptions of Art. 9(2) GDPR a "two-level hierarchy exists, with consent under Article 9(2)(a) at the top".[501] Indeed, the author based this thesis on the following arguments. First of all, in terms of legal arguments and from a fundamental rights perspective, the foundation of the general ban on processing sensitive data rests on the necessity to more

point, see Thiene, Arianna "La Regola e l'Eccezione. Il Ruolo del Consenso in Relazione al Trattamento dei Dati Sanitari alla Luce dell'art. 9 GDPR."

[495] Art. 9(1) GDPR: "Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited."

[496] Thiene, Arianna "La Regola e l'Eccezione. Il Ruolo del Consenso in Relazione al Trattamento dei Dati Sanitari alla Luce dell'art. 9 GDPR."

[497] Hallinan, Dana, and Michael, Friedewald "Open Consent, Biobanking and Data Protection Law: Can Open Consent Be 'Informed' Under the Forthcoming Data Protection Regulation?" *Life Sciences, Society and Policy*, vol. 11, n. 1, 2015, pp. 1-36.

[498] Bianchi Clerici, Giovanna "I Campioni Biologici nei Provvedimenti dell'Autorità Garante per la Protezione dei Dati Personali. Le Informazioni Genetiche."

[499] Art. 9(2) GDPR: "Paragraph 1 shall not apply if one of the following applies (…).

[500] Dove, Edward S., and Chen, Jiahong "Should Consent for Data Processing Be Privileged in Health Research? a Comparative Legal Analysis"; Florea, Marcu "Withdrawal of Consent for Processing Personal Data in Biomedical Research"; Thiene, Arianna "La Regola e l'Eccezione. Il Ruolo del Consenso in Relazione al Trattamento dei Dati Sanitari alla Luce dell'art. 9 GDPR"; Zanovello, Francesca "Misure di Garanzia e Rischio di Data Breach in Ambito Sanitario"; Sirgiovanni, Benedetta "Informed Consent to Processing of Genetic Data."

[501] Hallinan, Dara "Broad Consent Under the GDPR: an Optimistic Perspective on a Bright Future." of the same idea, Maestri, Enrico "Il Feticcio della Privacy nella Sanità. Cura del Paziente e Biobanking Genetico Prima e Dopo L'entrata in Vigore del GDPR." *La Protezione Dei Dati Sanitari: Privacy e Innovazione Tecnologica Tra Salute Pubblica E Diritto Alla Riservatezza*, edited by Thiene, Arianna, and Corso, Stefano, Jovene editore, 2023, pp. 23-58.

carefully protect the rights of the data subject in this context.[502] Consequently, Hallinan suggests that consent prevents the infringement of such right from coming into existence, while any other exemption in Art. 9 merely renders this infringement legitimate under certain conditions.[503] Secondly, consent is usually a requirement for genomic research according to different ethical and legal norms.[504] Moreover, from a practical point of view, consent should be preferred because for applying the other exemptions a Member State's law should be in place. Therefore, not only is consent the only exemption not subordinated to different conditions,[505] but it is also the only one that may guarantee uniformity among Member States.[506]

However, contrary to this opinion, both the literal interpretation of Art. 9, in which no preference is expressed whatsoever, and a teleological interpretation of this provision in the more general context of the GDPR concur in sustaining the opposite approach, which is usually adopted by the majority of the scholars.[507] Moreover, also Art. 8 of the Charter of Fundamental Rights establishes in paragraph 1 that everyone has the right to the protection of personal data, but in paragraph 2 that in order to lawfully process these data either consent is provided or the processing is based on "some other legitimate basis laid down by law".

If and under which condition a certain preference should be granted to any of the listed exemptions in specific circumstances might depend primarily on the concrete balance of the various rights and interests at stake in the context of a specific processing and subordinately on its impact on participants' trust.

As mentioned, research biobanks usually store both genetic data and special categories of data. Therefore, the collection and storage of data for the purpose of creating a biobank

[502] Hallinan, Dara "Broad Consent Under the GDPR: an Optimistic Perspective on a Bright Future."
[503] *Ibid.* Of the same idea, Maestri, Enrico "Il Feticcio della Privacy nella Sanità. Cura del Paziente e Biobanking Genetico Prima e Dopo L'entrata in Vigore del GDPR."
[504] Hallinan, Dara "Broad Consent Under the GDPR: an Optimistic Perspective on a Bright Future."
[505] Maestri, Enrico "Il Feticcio della Privacy nella Sanità. Cura del Paziente e Biobanking Genetico Prima e Dopo L'entrata in Vigore del GDPR."
[506] Hallinan, Dara "Broad Consent Under the GDPR: an Optimistic Perspective on a Bright Future"; Maestri, Enrico "Il Feticcio della Privacy nella Sanità. Cura del Paziente e Biobanking Genetico Prima e Dopo L'entrata in Vigore del GDPR."
[507] Among many others, see Molnár-Gábor, Fruzsina, et al. "Harmonization After the GDPR? Divergences in the Rules for Genetic and Health Data Sharing in Four Member States and Ways to Overcome Them by EU Measures: Insights from Germany, Greece, Latvia and Sweden." *Seminars in Cancer Biology*, vol. 84, 2022, pp. 271-283.

shall be compliant with both Art. 6(1) (list of legal bases) and Art. 9(2) (list of exemptions) GDPR.

Moreover, the GDPR contemplates the possibility of an even stricter regime applicable to the processing of special categories of data, by including Art. 9(4) that gives Member States the possibility of introducing further conditions or limitations for the processing of genetic data, biometric data or data concerning health. The Italian legislator made extensive use of this possibility, as explained in the following pages.

Within the legal framework underlined by the GDPR, Nordberg conceptualised two general models for processing biobanking data: (1) the consent-based model and (2) the necessity-based model.[508] I will now proceed to analyse the two models separately. Stemming from the assumption that there is no *legal* obligation to ask for informational consent if feasible in the specific case, I will describe in detail both models in the following paragraphs.

4.1 CONSENT-BASED MODEL

The acquisition of prior, informed consent for the processing of data to be stored in a biobank for future use is usually a requirement of soft-law instruments for the processing of personal data. In particular, it is provided for by the UNESCO Universal Declaration on Human Genome specifically for genetic data,[509] the UNESCO International Declaration,[510] the CIOMS International Ethical Guidelines, the Declaration of Taipei,[511] the OECD Recommendation 2009, and the OECD Recommendation 2017, among others. As a matter of example, Art. 6(d) of the UNESCO International Declaration requires the previous informed consent of the person both at the time of the collection of the samples

[508] Nordberg, Ana "Biobank and Biomedical Research: Responsibilities of Controllers and Processors Under the EU General Data Protection Regulation." These models have also been theorised by Comandè and Schneider in which however they been addressed to as "data subjected-oriented regime." "public interest-oriented regime" and "research-based regime" Comandè, Giovanni, and Giulia, Schneider "Differential Data Protection Regimes in Data-Drive Research: Why the GDPR Is More Research-Friendly Than You Think."

[509] Art. 7 of the UNESCO Universal Declaration on Human Genome "Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law."

[510] Art 8(a) "Prior, free, informed and express consent, without inducement by financial or other personal gains, should be obtained for the collection of human genetic data, human proteomic data or biological samples, whether through invasive or non-invasive procedures, and for their subsequent processing, use and storage, whether carried out by public or private institutions. Limitations on this principle of consent should only be prescribed for compelling reasons by domestic law consistent with the international law of human rights." Moreover, the same provisions on the change of purpose are applicable.

[511] Paragraph 12, already analysed for the collection of HBSs in Part A.

and data (and data derived from the sample), and for their disclosure to third parties, and Art. 17 establishes that the processing of the samples for extracting genetic data should be based on the consent of the participant. An exception in this regard could be the case in which, according to national law, the genetic data have "significance for medical and scientific research purposes", in which case they may be used for such purposes, following a consultation procedure with an ethics committee.

On the other hand, the Oviedo Convention does not apply in the context of the collection of biobank data, given that such a collection does not qualify as *intervention* within the meaning of the Convention.[512]

Moreover, when it comes to data protection regulation, consent is one of the possible legal bases listed by Art. 6(1) GDPR to ensure the respect of the principle of lawfulness. Indeed, according to art. 6(1)(a) processing of personal data is lawful, among others, when "the data subject has given consent to the processing of his or her personal data for one or more specific purposes". Consent is also listed as one of the exemptions provided in Art. 9(2)(a) GDPR to the general prohibition on processing special categories of data.

As a consequence, asking for the consent of the donor meets at the same time the condition of finding a legal basis according to Art. 6(1) GDPR and an exception to the general prohibition of processing special categories of data of Art. 9(2) GDPR.[513] As extensively explained in the General Introduction to this Chapter, this consent will be referred to as *informational consent.*[514]

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[512] Pormeister, Kärt "Genetic Research and Consent: on the Crossroads of Human and data research."

[513] Before the entry into force of the GDPR and right after its full applicability, there was an ongoing debate concerning whether the legal bases of Art. 6 and the exemptions of Art. 9 GDPR should have applied cumulatively or alternatively, namely that only Art. 9 should have been applied in case of processing of sensitive data. I believe nowadays the issue has been solved in favour of a cumulative application of those provisions. Moreover, while the question was of great theoretical importance, it has little practical relevance in the present scenario and thus for the processing of health and genetic data. Indeed, as underlined by Hallinan, in the context of clinical trials the EDPB suggested that the processing of sensitive data could find an exemption under Art. 9(2)(a) and (j) and identified the corresponding legal bases in Art. 6. Most scholars agree however on the joint application of Art. 6 and Art 9 for the processing of special categories of data. Se among many others, Smit, Julie-Anne R., et al. "Specific Measures for Data-Intensive Health Research Without Consent: a Systematic Review of Soft Law Instruments and Academic Literature." *European Journal of Human Genetics: EJHG*, 2023; Shaw, David, and David, Townend "30. Research With Human Participants in the European Union." *the Oxford Handbook of Comparative Health Law*, edited by Orentlicher, David, and Tamara K., Hervey, Oxford Academic, 2020.

[514] The definition of the consent to be asked for processing personal data in terms of *informational consent* is of Gefenas, Eugenijus "Controversies Between Regulations of Research Ethics and Protection of Personal Data: Informed Consent at a Cross-Road."

This type of consent should not be confused with *interventional research consent,* i.e. the consent usually asked for participating in a research project or clinical trial. In this regard, the European Commission clarified the relationship between *interventional research consent* and *informational consent*. Indeed, it was established that the interventional consent[515] required by the Clinical Trial Regulation and thus in order to participate in a clinical trial "must not be confused with consent as a legal ground for processing personal data set out in Article 6(1)(a) of the GDPR" and "is a safeguard not a legal basis for data processing".[516] As mentioned, the same approach has been suggested for harmonising the interventional biobank consent established as a requirement by the soft law instruments applicable to the collection and processing of HBSs in Part A.

Having this distinction in mind between the various types of consent is essential not only for the sake of general clarity but also to avoid the so-called consent misconception, i.e. the idea that "because consent is the favoured mechanism and key ethical-legal norm in research ethics governance, it is perceived that it must also be the case for data protection purposes",[517] especially in the actual normative framework for research traditionally defined as consent-centred.[518]

The characteristics and conditions for consent to the data processing to be valid are included respectively in the definition provided by art. 4(11) and in art. 7 GDPR.

Art. 4(11) of the GDPR defines consent as: "any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her". Further information and specifications on ensuring respect of such conditions for consent are provided by the Article 29 Working Party in its Guidelines on Consent under Regulation 2016/679, issued in 2018 and subsequently amended by the

[515] The asked to participate in a clinical trial is named in the document "informed consent." However, as I anticipated in Part A, I qualified this type of consent as *interventional consent.*

[516] in its document "Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation." That informed consent might serve as an appropriate safeguard of the rights of the data subject according to the GDPR is also reaffirmed by the EDPS in a preliminary Opinion on Data Protection and Scientific Research, 2020, paragraph 21.

[517] Lalova-Spinks, Teodora, et al. "The Application of Data Altruism in Clinical Research Through Empirical and Legal Analysis Lenses"; Dove, Edward S., and Jiahong, Chen "Should Consent for Data Processing Be Privileged in Health Research? a Comparative Legal Analysis"; Gefenas, Eugenijus "Controversies Between Regulations of Research Ethics and Protection of Personal Data: Informed Consent at a Cross-Road."

[518] Gefenas, Eugenijus "Controversies Between Regulations of Research Ethics and Protection of Personal Data: Informed Consent at a Cross-Road."

European Data Protection Board (EDPB) in Opinion 03/2019.[519] Moreover, when consent is chosen as the exemption for the processing of sensitive data (Art. 9(2)a GDPR), it should also be *explicit.*

In general, consent can be collected once for multiple processing at the same time. However, precisely from the need to collect a free, specific, and informed expression of consent derives the duty to separate the different purposes of the processing to comply with the principle of the granularity of consent.[520]

4.1.1 WITHDRAWAL OF CONSENT

According to any of the mentioned documents, whenever the processing is based on the consent of the data subject, the latter should be provided with the possibility of withdrawing it freely at any time.[521] From the moment of the withdrawal of consent, the EDPS clarifies that the data controller should stop the processing of the relevant personal data that was based on the withdrawn consent and should also delete them.[522]

As for the effect of such a withdrawal, it is established that it should not affect the processing already performed on the data before the decision of the data subject to withdraw it.[523] Moreover, in the case of HBS data, the withdrawal of consent usually also means the necessity of destroying the HBS correlated.

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[519] EDPB, Opinion, 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)), 2019. the Article 29 Working Party was the body responsible for the EU level interpretation of the previous Directive 95/46. In 2018, after the entry into force of the GDPR, this role was taken by the European Data Protection Board (EDPB), which has adopted all of the Working Party's recent opinions and guidance documents, including the mentioned Guidelines on consent. Even though guidance documents issued by the Article 29 Working Party or the EDPB are not legally binding, it has been underlined that the EDPB is a "strong and standalone Board (…) capable of deciding (…) and enforcing (…) opinions." On the topic, De Hert, Paul, and Vagelis, Papakonstantinou "The New General Data Protection Regulation: Still a Sound System for the Protection of Individuals?" *Computer Law and Security Review*, vol. 32, n. 2, 2016, pp. 179–194.

[520] Recital 43 GDPR.

[521] The legal right to withdraw consent is in particular established by Art. 7(3) GDPR.

[522] EDPS a preliminary opinion. This approach is based on Art. 17(1)(b) and (3) GDPR. However, some authors believe in the clear separation between the right to withdraw consent and that to erasure, and therefore according to the exercise of the former does not automatically entail the duty of the data controller to delete the data, being a positive action on the part of the data subject being necessary on this regard. See Florea, Marcu "Withdrawal of Consent for Processing Personal Data in Biomedical Research." The authors in favour of such an approach thus consider it problematic the case in which the data controller does not find the concrete case a different legal basis on which to continue the processing, but at the same time, the data subject had not asked for the erasure of the data according to Art. 17(1)(b) GDPR. Indeed, in this eventuality, the data controller would not be able to continue the processing, while not being under any duty to delete the data.

[523]Art. 7(3) GDPR; EDPB, Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak, 2020; Fanni, Simona "Le Biobanche di

However, according to Art. 17(1)(b) GDPR, the erasure of personal data following the withdrawal of consent is not compulsory, if another legal ground for the processing is applicable. Indeed, according to the EDPS, the data controller that receives a withdrawal of consent to data processing faces two alternatives: (I) to find a different legal basis applicable, which in the framework developed in this paper for biobanks would imply adopting the necessity-based model, if the specific conditions are met, or (II) to delete the personal data,[524] with a possible negative impact on the research project at large.

(I) To rely on a different legal basis, the data processor shall carefully evaluate the compliance with the applicable requirements and conditions, and carry out the necessity test, here also considering the will of the data subject not to have her data processed.[525] If the conditions are met, the data controller may lawfully continue the processing, somewhat against the will that the data subject expressed via the exercise of her right to withdraw a consent previously given. Moreover, according to the principle of granularity, consent might be withdrawn for certain processing operations only, and in this case the data controller may lawfully continue the processing for the part not covered by the withdrawn consent.[526]

(II) If no other legal basis is applicable, the data controller might have to delete the personal data, thus possibly compromising the integrity of the research project and its reliability,[527] especially in erasing the data is specifically asked by the data subject according to Art. 17(1)(b) GDPR. However, the GDPR establishes an *ex nunc* effect of withdrawal,[528] i.e. that it does not affect the lawfulness of the processing based on consent before its withdrawal (non-retroactive effect). The processing of biobank data for

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Popolazione al Vaglio della Suprema Corte di Cassazione: Alcune Note Critiche sull'Ordinanza n. 27325 del 7 ottobre 2021."

[524] EDPS, Preliminary Opinion on data protection and scientific research, 2020; However, some authors believe in the clear distinction between the right to (or even principle of) withdraw consent, the right to object and right to erasure. as a consequence, exercising the first would not automatically entail the deletion of the data, unless so specifically asked by the data subject in the exercise of their further right to erasure. See Florea, Marcu "Withdrawal of Consent for Processing Personal Data in Biomedical Research"; Ausloos, Jef *The Right to Erasure in EU Data Protection Law*, Oxford University Press, 2020.

[525] Ausloos, Jef *The Right to Erasure in EU Data Protection Law;* Florea, Marcu "Withdrawal of Consent for Processing Personal Data in Biomedical Research."

[526] Florea, Marcu "Withdrawal of Consent for Processing Personal Data in Biomedical Research."

[527] *Ibid.* In these cases, where withdrawal is impracticable or impossible, already the Article 29 WP stated that consent might not be the most suitable legal basis to begin with, because the control given to the data subject over the processing of their personal data would be merely illusory. Article 29 Working Party, Opinion 06/2014 on the Notion of Legitimate Interests of the Data Controller Under Article 7 of Directive 95/46/EC, 2014.

[528] *Ibid*

scientific research purposes is performed continuously over time and therefore sometimes the consequences of the processing might not be eliminated because for instance, the research results were already published or part of the study was completed before the withdrawal.[529] Therefore, withdrawing consent in the context of biobanking research calls for a challenging balancing test between the interests of the data subject in the control of the use of their data and those of researchers and society in completing the project, meeting the standards for scientific integrity and in the progress of scientific research. The latter interests might be impaired by the deletion of some of the collected data,[530] but protected by resorting to a different legal basis,[531] with possible consequences for participants' trust,[532] as analysed in the Conclusion to this paragraph.

4.2 …AND THE NECESSITY-BASED MODEL

The necessity-based model starts from the assumption that the collection and general processing of data are not based on the consent of the data subject. Therefore, one of the other legal bases must be applicable to enable the processing. This might be the case because collecting donors' informational consent is impossible or excessively burdensome, because donors deny or withdraw consent, or simply a different legal basis is more suitable for the purpose of the processing.

Differently from what is established by the GDPR, in which there is no hierarchy among the legal bases or exemptions listed in Art. 6 and 9 GDPR, usually soft-law instruments on the matter consider the necessity-based model as an exemption to the preferred consent-based model.

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[529] Staunton, Ciara "Individual Rights in Biobank Research Under the GDPR." *GDPR and Biobanking*, edited by Slokenberga, Santa, Springer, 2021, pp. 91-104, Melham, Karen, et al. "The Evolution of Withdrawal: Negotiating Research Relationships in Biobanking."

[530] Florea, Marcu "Withdrawal of Consent for Processing Personal Data in Biomedical Research."

[531] This is the position of some scholars. See for example Donnelly, Mary, and Maeve, McDonagh "Health Research, Consent and the GDPR Exemption." *European Journal of Health Law*, vol. 26, n. 2, 2019, pp. 97-119.

[532] It is worth noticing here that decisions to withdraw previous consent to biobanking activities are strongly related to the trust of participants in the processing as a whole, among other motives. See on this point Broekstra, Reinder, et al. "Motives for Withdrawal of Participation in Biobanking and Participants' Willingness to Allow Linkages of Their Data." Therefore, at least to some extent the issue might be addressed by enhancing participants' trust in biobanking and thus decreasing the number of possible withdrawals.

Indeed, the UNESCO International Declaration establishes that disclosing genetic data to third parties is possible without consent in case of an important public interest reason provided for by domestic law.[533]

Moreover, Recommendation R(2016)6 established that secondary use of the HBS data is allowed if it is within the scope of the prior consent, or if new informational consent is asked to the data subject (Art. 21). Only if re-consenting is impossible, the processing should be subject to an independent evaluation, which established that (1) reasonable efforts to re-contact the participant have been made, (2) the research addresses an important scientific interest and it is in accordance with the principle of proportionality, (3) the aims of the research could not reasonably be achieved using data for which consent has been collected, and (4) there is no evidence that the person concerned has expressly opposed such research use.

Indeed, as mentioned, there is no hierarchy among the legal bases listed in Art. 6(1) GDPR, nor does GDPR entail a preference for consent or assign to consent a supreme value, either for scientific research or in general.[534] Thus, the data controller is free to choose the legal basis most suitable to the specific purpose of the intended processing, without being legally obliged to evaluate whether asking for consent is lawfully or technically feasible.[535]

Therefore, the processing of data, including special categories of data (or sensitive data), for creating a biobank for scientific research purposes shall be based on one of the other five grounds listed in Art. 6(1) GDPR and fall within one of the other exemptions of Art. 9(2) GDPR. Both the legal grounds and exemptions relevant to creating a biobank for

[533] Art. 14(b) UNESCO International Declaration.

[534] Florea, Marcu "Withdrawal of Consent for Processing Personal Data in Biomedical Research"; Thiene, Arianna "La Regola e l'Eccezione. Il Ruolo del Consenso in Relazione al Trattamento dei Dati Sanitari alla Luce dell'art. 9 GDPR"; Zanovello, Francesca "Misure di Garanzia e Rischio di Data Breach in Ambito Sanitario." However, while recognizing that no such a hierarchy exists in the GDPR, E. Dove and Chen have argued that consent should be the preferred legal basis for the processing of personal data, and therefore that "if obtaining consent is not onerous, is ethically appropriate in the research project at hand, and will not present serious methodological problems to the project, consent should be obtained." See Dove, Edward S., and Jiahong, Chen "Should Consent for Data Processing Be Privileged in Health Research? a Comparative Legal Analysis."

[535] This interpretation is supported by the wording of Article 8 Charter "Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned *or some other legitimate basis laid down by law*" (emphasis added) and by scholars such as Dove, Edward S., and Jiahong, Chen "Should Consent for Data Processing Be Privileged in Health Research? a Comparative Legal Analysis." However, there are scholars who advocate for a moral obligation to ask for consent to data processing, whenever feasible.

scientific research purposes require the processing to be *necessary*. Indeed, according to the European Court of Justice case law, any limitation of fundamental rights protected by the Charter shall be both necessary and proportionate.[536] The Charter recognises the right to the protection of personal data in Art. 8. Therefore, any measure, in the form of national law or specific processing activity, that limits the exercise of this right shall undergo the necessity and proportionality test.[537] Conducting the necessity test, and thus assessing the necessity of the processing requires a case-by-case evaluation, particularly as to whether there are realistic and less intrusive alternatives for achieving the same goal.

4.2.1 THE LEGAL BASES OF ART. 6(1) GDPR

None of the legal bases listed in Art. 6(1) GDPR is specifically designed for biobanking or scientific research. Therefore, those hypothetically relevant for the creation of a biobank are also generally applicable to any processing of data, and in particular: (e) the processing is necessary for the performance of a *task carried out in the public interest*, among which Recital 45 GDPR lists health research[538], and in which case a Member State and/or Union law is needed; or (f) the processing is necessary for the purposes of the *legitimate interests* pursued by the controller or a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a

[536] See for example CJEU, Joined Cases C-92/09 and C-93/09, Volker und Markus Schecke GbR and Hartmut Eifert v Land Hessen, 9. November 2010; CJEU, Case C-13/16, Valsts policijas Rīgas reģiona pārvaldes Kārtības policijas pārvalde v Rīgas pašvaldības SIA 'Rīgas satiksme'.

[537] the necessity and proportionality test is extensively described specifically in the context of the right to the protection of personal data by EDPS in Assessing the Necessity of Measures that limit the fundamental right to the protection of personal data. Toolkit, 2016.

[538] Recital (45) Where (…) processing is necessary for the performance of a task carried out in the public interest (…), the processing should have a basis in Union or Member State law. This Regulation does not require a specific law for each individual processing. a law as a basis for several processing operations based on a legal obligation to which the controller is subject or where processing is necessary for the performance of a task carried out in the public interest or in the exercise of an official authority may be sufficient. (…) It should also be for Union or Member State law to determine whether the controller performing a task carried out in the public interest (…) should be a public authority or another natural or legal person governed by public law, or, where it is in the public interest to do so, including for health purposes such as public health (…).

child".[539] As it has been suggested, Art. 6(1)(e) is "one of the more suitable legal bases for biomedical research".[540]

There is a difference *ratione personae* between the two legal grounds. Indeed, while on the one hand Art. 6(1)(e) is usually considered for the lawfulness of processing carried out for public sector purposes, thus both by public authorities and private bodies vested with a relevant task,[541] the legal ground of Art. 6(1)(f) might be applied by private data controllers only, because Art. 6(3) explicitly excludes public authorities (and by analogy, private data bodies vested by law with a task in the public interest) from the possibility of relying on this legal ground.[542] As a consequence, the entity running a biobank or the biobank itself might freely choose between the two if it is not a public authority, otherwise Art. 6(1)(e) is the only iable option.

Moreover, as mentioned, in both cases a necessity test shall be carried out before the processing,[543] in which the concept of necessity shall be interpreted strictly in the light of the principle of proportionality.[544] In particular, a processing is necessary to an end if there is no better suited and less intrusive alternative available.[545]

Regarding Art. 6(1)(e), vesting the relevant task on a private entity would require a legal provision,[546] thus excluding contracts. Such a legal provision would probably not exactly

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[539] These are also the legal bases identified for the purposes of scientific research by Casonato, Carlo, and Marta, Tomasi "Diritti e Ricerca Biomedica: una Proposta Verso Nuove Consonanze." *BioLaw Journal*, vol. 1, 2019, pp. 343-359.

[540] Becker, Regina, et al. "Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers" *European Journal of Health Law*, vol 30, 2023, pp. 129-157.

[541] Midiri, Marco, and Simona, Piva "L'Interesse Pubblico Come Base Giuridica e Come Finalità del Trattamento dei Dati Personali." *Il "Nuovo" Codice in Materia di Protezione dei Dati Personali. La Normativa Italiana Dopo Il D.Lgs. n. 101/2018*, edited by Scagliarini, Simone, Giappichelli editore, 2019; Kotschy, Waltraut "Article 6 Lawfulness of Processing." *The EU General Data Protection Regulation (GDPR): a Commentary*, edited by Kuner, Christopher, et al. pp. 321-344.

[542] Recital 47 GDPR explains the reason behind this normative choice: "Given that it is for the legislator to provide by law for the legal basis for public authorities to process personal data, that legal basis [i.e. Art. 6(1)(f)] should not apply to the processing by public authorities in the performance of their tasks." On this Midiri, Marco, and Simona, Piva "L'interesse Pubblico Come Base Giuridica e Come Finalità del Trattamento dei Dati Personali."

[543] Dell'Utri, Marco "Principi Generali e Condizioni di Liceità del Trattamento dei Dati Personali." *I Dati Personali nel Diritto Europeo*, edited by Cuffaro, Vincenzo, et al, Giappichelli editore, 2019, pp. 179-248.

[544] Kotschy, Waltraut "Article 6 Lawfulness of Processing."

[545] See also Kramer, Philipp "Art. 6 Rechtmäßigkeit der Verarbeitung." *Heymanns Kommentare DSGVO BDSG*, edited by Eßer, Martin, et al. Carl Heymanns Verlag, 2017. In the context of installing video-surveillance systems, see also EDPB, Guidelines 3/2019 on processing of personal data through video devices, 2020.

[546] Art. 2 ter Italian Privacy Code. See on this also Kramer, Philipp "Art. 6 Rechtmäßigkeit der Verarbeitung." *Heymanns Kommentare DSGVO BDSG*, edited by Eßer, Martin, et al. Carl Heymanns Verlag, 2017.

define the specific tasks to be performed, but instead would authorise to put in place the activities necessary for reaching a specific objective of public interest and, according to Kotshy, would also decide whether to attribute authority to the controller at the same time.[547]

The primary issue concerning the choice of Art. 6(1)(e) as the legal basis for the processing of personal data for biobanking purposes probably is the fact that it depends on the enactment of a Union or Member State law. For this reason, Art-. 6(1)(f) is, to some extent, of a more straightforward application.

As for the applicability of Art. 6(1)(f) (legitimate interest of the controller), a legitimate interest is ”an interest which is visibly, although not necessarily explicitly, recognised by law, more precisely by Union or Member State law”, taking particularly into consideration the provisions of the EU Charter as possible sources in this regard.[548] The GDPR provides in its Recitals for some examples of legitimate interests that are considered relevant, but overall the matter shall be assessed on a case-by-case basis by the controller, thus not on abstract terms.[549]

Therefore, in order to rely on the legal ground of Art. 6(1)(f) the data controller shall firstly (I) identify the legitimate interest pursued with the processing, then (II) carry out the *necessity test*, as described above, and finally (III) the *balancing test* between the identified legitimate interest and the interests or fundamental rights and freedoms of the data subject, conducted according to the principle of proportionality.[550]

(I) As for the legitimate interest, the Article 29 Working Party clarifies that this concept is not to be confused with that of the “purpose” within the meaning of the GDPR. Indeed, while the latter is “the specific reason why the data are processed”, the formed “is the broader stake that a controller may have in the processing, or the benefit that the controller derives – or that society might derive – from the processing”.[551]

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[547] Kotschy, Waltraut “Article 6 Lawfulness of Processing.”

[548] *Ibid*

[549] EDPB, Guidelines 3/2019 on processing of personal data through video devices.” 2020. On this, also Dell’Utri, Marco “Principi Generali e Condizioni di Liceità del Trattamento dei Dati Personali.”

[550] See for the development of these three steps test the case C 13/16 of the CJEU. Kotschy, Waltraut “Article 6 Lawfulness of Processing”; Petrašević, Tunjica, and Ćosić, Romana “Legitimate Interest.” *GDPR requirements for biobanking activities across Europe,* edited by Colcelli, Valentina, et al, Springer, 2023, pp. 275-280.

[551] Article 29 Working Party, Opinion 06/2014 on the notion of legitimate interests of the data controller under Article 7 of Directive 95/46/EC, 2014.

From a general perspective, the controller's legitimate interest may be a fundamental right protected by the Charter of Fundamental Rights, a legal right provided in a EU or national law, or any other interest, including commercial ones.[552]

Recitals 47 and 48 provide some examples of legitimate interests according to the GDPR, which are mainly related to business processing activities.[553] For the purposes of our analysis, the Article 29 Working Party in its Opinion 06/2014 on Article 7 of Directive 95/46/EC listed specifically *scientific research* among the interests overall considered legitimate for the applicability of Art. 7 of Directive 95/46/EC, whose wording is almost equivalent to Art. 6(1)(f).[554]

Therefore, if biobanking is considered scientific research within the meaning of the GDPR, identifying the legitimate interest might be easier. If this is not the case, as I have stated previously in this thesis, the analysis to be conducted here should take into consideration that to qualify as a legitimate interest, the processing should "be factual and correspond to current activities or reasonably soon affect benefits" and "must be lawful or permissible under relevant EU and national law".[555]

(II) The necessity test should be conducted with the aim of establishing whether the processing under consideration is the least restrictive measure for the data subject, with a factual analysis and not on abstract terms.[556] Structured in these terms, the necessity test is in line with the principles of data minimisation and purpose limitation set out in Art. 5 GDPR.[557] In particular, among the data subjects' rights to be taken into consideration is the right to data protection, as established by Art. 8 of the Charter.

(III) The balancing test is a delicate exercise conducted prior to the start of the processing (according to the principle of accountability).[558] Among the elements to be considered, Recital 47 includes the reasonable expectation of the data subject, i.e. "whether a data

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[552] De Hert, Paul, and Irene, Kamara "Understanding the Balancing Act Behind the Legitimate Interest of the Controller Ground: a Pragmatic Approach." *Brussels Privacy Hub,* vol. 4, n. 12, 2018, pp. 321-352.
[553] Petrašević, Tunjica, and Ćosić, Romana "Legitimate Interest."
[554] Article 29 Working Party, Opinion 06/2014 on the notion of legitimate interests of the data controller under Article 7 of Directive 95/46/EC, 2014.
[555] Petrašević, Tunjica, and Ćosić, Romana "Legitimate Interest."
[556] EDPS, Developing a "Toolkit" for Assessing the Necessity of Measures That Interfere With Fundamental Rights, 2016; Mondschein, Christopher F., and Cosimo, Monda "Legitimate Interest." *Elgar Encyclopedia of law and data science,* edited by Comandè, Giovanni, Elgaronline, 2022, pp. 209-214.
[557] Mondschein, Christopher F., and Cosimo, Monda "Legitimate Interest"; De Hert, Paul, and Irene, Kamara "Understanding the Balancing Act Behind the Legitimate Interest of the Controller Ground: a Pragmatic Approach."
[558] Kotschy, Waltraut "Article 6 Lawfulness of Processing."

subject can reasonably expect at the time and in the context of the collection of the personal data that processing for that purpose may take place".[559] In the biobanking context, this might depend on the Scenario under consideration, with Scenarios 1 and 2 being those for which the data subject might expect her personal data to be stored for future scientific research uses with a higher degree of probability. Moreover, such a test should also take into account, according to the Article 29 Working Party, the safeguards adopted,[560] and for the EDPB, the "intensity of the intervention" on the rights of the data subject, in terms of types of information gathered (particular attention if sensitive data), scope of the processing, number of data subjects and their characteristics (such as vulnerable groups), possible alternative means, etc.[561]

Finally, it is relevant to underline that according to the case law of the CJEU under the previous Directive 95/46/EC, but whose reasoning appears to be valid under the GDPR as well, in case of joint-controllership the legal basis provided for in Art. 6(1)(e) may be relied upon only if "each of those controllers should pursue a legitimate interest."[562] Differently, the data processor may process personal data also for a legitimate interest of a third party that is not a joint-controller, and therefore in this case the principle established by the ECHR in this regard does not apply. However, the applicability of this specific part of Art. 6(1)(f) should be interpreted narrowly, because of its impact on the fundamental rights of the data subject, and for instance related to situations in which the legal interest of the third party cannot be reached without the processing of the personal data by the data controller under consideration.[563]

It should finally be underlined that processing data under the legal basis of the legitimate interest gives the data subject the possibility of exercising the right to object to such processing.[564] This provision aims at giving back to the data subject some control over

[559] On this also EDPB, Guidelines 3/2019 on Processing of Personal Data Through Video Devices, 2020.
[560] Safeguards in this regard may take many forms, such as anonymisation, aggregation of data, technical and organisation measures to ensure that data cannot be used to take decisions or other actions with respect to the individuals, privacy by design, data protection impact assessments, increased transparency, right to opt-out, data portability or related measures. Article 29 Working Party, Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679, 2018; Mondschein, Christopher F., and Cosimo, Monda "Legitimate Interest."
[561] EDPB, Guidelines 3/2019 on Processing of Personal Data Through Video Devices, 2020.
[562] *Fashion ID case* CJEU Case C-40/17.
[563] Kotschy, Waltraut "Article 6 Lawfulness of Processing."
[564] Art. 21(1) GDPR.

the processing of her data.[565] Indeed, the data subject has the right to ask the controller to cease the processing of her data. This imposes on the data controller a duty to comply with such a request, unless the latter "demonstrates compelling legitimate grounds for the processing which override the interests, rights and freedoms of the data subject".[566] To this end, the Article 29 Working Party Guidelines clarify that the compelling legitimate grounds cannot contrast with the first balancing test conducted, but should complement it "in the sense that, where the processing is allowed further to a reasonable and objective assessment of the different rights and interests at stake, the data subject still has an additional possibility to object on grounds relating to his/her particular situation".[567] In the biobanking context, the possibility of relying on this exemption may be only evaluated on a case-by-case basis, in particular considering the final aim of the research projects for which the biobank is developed

Overall, Mondschein and Monda warned that applying the notion of legitimate interest might be a complex exercise because of the vagueness of the provisions on legitimate interest in the GDPR and their nature as indeterminate legal concepts to be used in the assessment (necessity, legitimacy, etc).[568]

4.2.2 THE EXEMPTIONS OF ART. 9(2) GDPR

As far as the exemptions of Art. 9(2) GDPR are concerned, these may be divided into two general groups. Those related to a *private dimension,* i.e. when the processing is necessary to protect the rights and interests of a private individual (such as for instance letter c) - protection of the vital interest of the data subject), or to a *public dimension,* i.e. when the processing aims at protecting public interests thanks to the activity of an entity formally entrusted with this duty.[569]

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[565] De Hert, Paul, and Irene, Kamara "Understanding the Balancing Act Behind the Legitimate Interest of the Controller Ground: a Pragmatic Approach"; Balboni, Paolo, et al. "Legitimate Interest of the Data Controller. New Data Protection Paradigm: Legitimacy Grounded on Appropriate Protection." *International Data Privacy Law*, vol. 3, n. 4, 2013, pp. 244-261.

[566] Art. 21(1) GDPR.

[567] Article 29 Working Party, Opinion 06/2014 on the Notion of Legitimate Interests of the Data Controller Under Article 7 of Directive 95/46/EC, 2014.

[568] Mondschein, Christopher F., and Cosimo, Monda "Legitimate Interest."

[569] Colpapietro, Carlo, and Francesco, Laviola "Il Trattamento in Ambito Sanitario." *Il Nuovo Codice in Materia di Protezione dei Dati Personali: La Normativa Italiana Dopo il D. Lgs. 101/2018,* edited by Midiri, Mario, et al. Giappichelli, 2019, pp. 201-220.

The exemptions relevant to the creation of a disease-oriented biobank for scientific research purposes are included in this last category and are in particular: (i) the processing is necessary for *public interest in the area of public health*, such as ensuring high standards of quality and safety of healthcare and of medicinal products or medical devices[570]; (j) the processing is necessary for *scientific research purposes.*[571] The latter, as previously mentioned, is applicable only in so far as biobanking qualifies as *scientific research* within the meaning of the GDPR and with the doubts and issues highlighted above.

Therefore, to ensure under the necessity-based model the lawfulness of the processing (as a primary processing of the biobank data), data may be collected in order to create a biobank as either (1) a task carried out in the public interest under Art. 6(1)(e) in conjunction with Art. 9(2), (i) or (j) GDPR, or (2) a legitimate interest of the controller under Art. 6(1)(f) in conjunction with Art. 9(2)(j) GDPR.[572] Various conditions and requirements shall be met to apply either of the exemptions provided in Art. 9(2) GDPR.

4.2.2.1 ART. 9(2)(I) PUBLIC INTEREST IN THE AREA OF PUBLIC HEATH

According to Recital 54 GDPR and Regulation 2008/1338,[573] *public health* means and includes "all elements related to health, namely health status, including morbidity and disability, the determinants having an effect on that health status, health care needs, resources allocated to health care, the provision of, and universal access to, health care as well as health care expenditure and financing, and the causes of mortality". In this context, Art. 35 of the EU Charter provides "a high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities".

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[570] Art. 9(2) (i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular, professional secrecy.

[571] Art. 9 (2) (j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

[572] This is the same as what stated by the EDPB in its Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)), 2019.

[573] Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work.

This exemption is applicable especially in cases when the processing is necessary for protecting against "serious cross-border threats to health" or "ensuring high standards of quality and safety of health care and of medicinal products or medical devices",[574] as also clearly reinstated by the Article 29 Working Party.[575] However, neither the GDPR nor the interpretative documents and guidelines provide further details on the matter and therefore the exact boundaries of these terms should be identified by the data controller at the time of choosing the exemption with a case-by-case assessment.[576] However, a "Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy" is needed as the ground for the use of this exemption.

The public interest in the area of public health that may legitimise the use of exemption provided for in Art. 9(2)(i) GDPR does not have to be *substantial* according to a literal interpretation of the provision.[577]

The concept should be aligned with that of the legal basis provided for in Art. 6(1)(e) (necessary for the performance of a task carried out in the public interest), and considering an objective criterion, thus related to the characteristics of the processing itself, not on the nature as a private or public entity of the data controller.[578]

Overall, the Article 29 Data Protection Working Party under the previous Directive, established that the *public interest clause* enables the data controller to strike a concrete appropriate balance between the protection of data subjects' rights and other collective interests.[579]

Once again, the applicability of this provision to biobanking depends on a concrete assessment conducted on a case-by-case basis, taking particularly into consideration the type of scientific research projects which the biobank is implemented for supporting.

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[574] Art. 9(2)(i) GDPR.
[575] Article 29 Working Party, Annex-Health Data in Apps and Devices, 2015.
[576] Comandè, Giovanni, and Giulia, Schneider "Differential Data Protection Regimes in Data-Drive Research: Why the GDPR Is More Research-Friendly Than You Think."
[577] Differently, the document Statement on the processing of personal data in the context of the COVID-19 outbreak, the EDPB refers to "reasons of *substantial* public interest in the area of public health."
[578] Comandè, Giovanni, and Giulia, Schneider "Differential Data Protection Regimes in Data-Drive Research: Why the GDPR Is More Research-Friendly Than You Think."
[579] Article 29 Working Party, Annex-Health Data in Apps and Devices, 2015.

4.2.2.2 ART. 9(2)(J) SCIENTIFIC RESEARCH

If a biobank is built via the collection of health data based on the scientific research exemption (Art. 9(2)(j)), the so-called scientific research regime[580] might be applicable. The latter is built on the assumption that the rights of the data subject/donor, namely the right to privacy, the right to protection of personal data and the right to the integrity of the person, are not absolute and especially in the context of scientific research they should be balanced against other rights and interests at stake, such as in particular the freedom of the arts and science. Indeed, in the GDPR scientific research occupies a privileged position and lighter legal requirements,[581] because it has the potential to provide knowledge to improve the quality of life of society as a whole.[582] In this regard, the GDPR has been said to have adopted a "research-friendly approach".[583]

At the same time, Recital 157 highlights the importance of registries, among which biobanks may be included, by affirming that "by coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer and depression". Therefore, in the intention of the European legislator, the potential benefits of scientific research for society as a whole are worth supporting, even if the price to be paid is a (balanced) restriction of individual rights.

The scientific research regime is built on several building blocks, which entail in particular (I) the definition of scientific research, (II) the lawfulness of the processing, (III) individual rights of the data subject and (IV) appropriate safeguards.[584] The first two are worth mentioning here, while the third will be analysed in the following pages, and the value of the appropriate safeguards will be addressed in the analysis of the right to

[580] Slokenberga, Santa "Setting the Foundations: Individual Rights, Public Interest, Scientific Research and Biobanking."
[581] Di Tano, Francesco "Protezione dei Dati Personali e Ricerca Scientifica: un Rapporto Controverso ma Necessario."
[582] EDPS, a Preliminary Opinion on Data Protection and Scientific Research, 2020.
[583] Shabani, Mahsa, and Pascal, Borry "Rules for processing Genetic Data for Research Purposes in View of the New EU General Data Protection Regulation." *European Journal of Human Genetics: EJHG,* vol. 26, n. 2, 2018, pp. 149-156; Gefenas, Eugenijus "Controversies Between Regulations of Research Ethics and Protection of Personal Data: Informed Consent at a Cross-Road."
[584] Slokenberga, Santa "Setting the Foundations: Individual Rights, Public Interest, Scientific Research and Biobanking"; Slokenberga, Santa "Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject that the Proposed EHDS Regulation Promises to Bring Along."

data protection, being their implementation a reasonable measure to counterbalance the restriction of this right for the processing for scientific research purposes.

(I) As already mentioned, using the scientific research exemption depends on the qualification of the data processing activity as *scientific research.* Here, I refer to the arguments already presented above on my opinion on the difficulties in defining the activity of collecting and storing data for future and undefined research purposes as *scientific research* , especially when the biobank is not directly involved in determining the purposes and means for processing the biobank data for a specific and identified research project, and on the necessity to conduct a case-by-case evaluation.

(II) As for the lawfulness of the processing, we have already analysed which legal basis of Art. 6(1) might be applicable in the processing of health data for biobanking research. However, further conditions enshrined in Art. 9(2)(j) should be met: the data controller should act (a) act in accordance with Art. 89(1) GDPR, and (b) based on a Union or Member State law. Moreover, the processing should be (c) necessary for the scientific research purpose, (d) proportionate to the aims pursued, (e) and respect the essence of the right to data protection,[585] with an evaluation to be conducted on a case-by-case basis, especially in the biobanking context.

(a) Art. 89(1) provides that the processing shall be subject to appropriate safeguards for the rights and freedoms of the data subject. These safeguards shall be adopted through technical and organisational measures to ensure respect for the principle of data minimisation, including pseudonymisation.

(b) Moreover, the processing must be based on a Member State and/or Union law compliant with three conditions: the law shall also (1) be proportionate to the aim pursued, (2) respect the essence of the right to data protection, and (3) provide for suitable and specific measures to safeguard the fundamental rights and interests of the data subject.

As for requirements (c), (d), and (e), it is generally simple to comply with them whenever a biobank is directly connected solely with a specific research project,[586] which however is not the case for the biobanks under consideration in this work. Consequently, especially

[585] Nordberg, Ana "Biobank and Biomedical Research: Responsibilities of Controllers and Processors Under the EU General Data Protection Regulation."
[586] *Ibid*

the *proportionality* and *necessity* elements should be carefully analysed in the choice of the model to be adopted.[587]

4.2.3 POSSIBLE CONSEQUENCES OF THE NECESSITY-BASED MODEL

By adopting the necessity-based model, the biobank may benefit from a privileged regime, based on exemptions from some of the individual rights of the data subject provided for in Chapter II of the GDPR. Among those listed, there are some relevant in the context of biobanking: the right to information (Art. 12-14), the right to access (Art. 15), the right to rectification (Art. 16), the right to erasure (so-called right to be forgotten, Art. 17), the right to restriction of processing (Art. 18), the right to data portability (Art. 19), the right to object (Art. 21).[588] In this regard, two sets of derogations are theoretically possible: (a) those adopted invoking directly provisions of the GDPR, and (b) those based on a Union or Member State law. Such laws may be adopted in accordance with either Art. 23 GDPR for processing necessary to safeguard "important objectives of general public interest of the Union or of a Member State, (…) including (…) public health (…)"[589] or Art. 89(2) GDPR for processing carried out specifically for scientific research purposes.

In general terms, the derogations to be analysed, if implemented and adopted, should be paired with the compliance with Art. 89(1) GDPR and with the enactment of appropriate measures to safeguard data subjects' fundamental rights and freedoms.

4.2.3.1 (A) DEROGATIONS DERIVED FROM PROVISIONS OF THE GDPR

Possibilities of exemptions derived directly from provisions of the GDPR depend either on the legal basis of Art. 6(1) or the exemptions of Art. 9(2) chosen for the specific processing.

Indeed, Art. 21 provides for the right of the data subject to object to any processing concerning her personal data if the legal basis for the processing is either the public interest (Art. 6(1)(e)) or the legitimate interest of the controller (Art. 6(1)(f)). However,

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[587] Nordberg, Ana "Biobank and Biomedical Research: Responsibilities of Controllers and Processors Under the EU General Data Protection Regulation."

[588] Staunton, Ciara, et al. "The GDPR and the Research Exemption: Considerations on the Necessary Safeguards for Research Biobanks." European Journal of Human Genetics, vol. 27, n. 8, pp. 1159-1167.

[589] Art. 23(1)(e) GDPR. For a broader description of the individual rights provided to the data subject by the GDPR, in the context of biobanking, see Staunton, Ciara "Individual Rights in Biobank Research Under the GDPR."

as mentioned, the data controller may continue the processing either by demonstrating compelling legitimate grounds that override the interests, rights and freedoms of the data subject, or if the processing is necessary for the performance of a task carried out for reasons of public interest (therefore when the legal basis is Art. 6(1)(f)). It is worth reminding here that Recital 45 lists health research among possible public interests within the meaning of the GDPR.

Moreover, processing carried out for scientific research purposes, if and when applicable to biobanking, may be the reason for derogating from the duty to provide information when data are not collected directly from the data subject, for example in case of left-over samples or data (Art. 14) and the right to erasure (Art. 17). The latter may also be exempt from in case of processing carried out in the public interest or for reasons of public interest in the area of public health (Art. 17(3)). The conditions for the applicability of such exemptions are the processing being in accordance with Article 89(1), that the exercise of the right shall be likely to render impossible or seriously impair the achievement of the objectives of that processing. Moreover, in case of the derogations to Art. 14 GDPR, providing the information shall be proven impossible or that it would involve a disproportionate effort and "the controller shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available".[590]

Furthermore, some rights are simply not applicable to biobanks that adopt the necessity-based model, as in the case of the right to data portability (Art. 20 GDPR) to be complied with only when data are collected on the basis of consent. Moreover, Art. 20 expressly applies only in cases where data are provided by the data subject. In the context of biobanking research, data are sometimes derived from biological samples (HBS data). Therefore, independently of the chosen model for collection, Art. 20 would not be applicable in these situations, given that Art. 29 Working Party made it clear that "inferred data and derived data are created by the data controller".[591]

[590] While demonstrating that providing the information according to Art. 14 GDPR has been said to be particularly burdensome, it might be easier to assert that it would involve a disproportionate effort. See Staunton, Ciara "Individual Rights in Biobank Research Under the GDPR."

[591] Article 29 Working Party, Guidelines on the Right to Data Portability, 2017; Staunton, Ciara "Individual Rights in Biobank Research Under the GDPR."

Finally, a further advantage is specific to the scientific research regime (therefore if Art. 9(2)(j) is applicable), i.e. that data might be stored for longer periods as an exception to the principle of storage limitation (Art. 5(1)(e) GDPR (storage limitation exemption).
The storage limitation exemption is provided for by Art. 5(1)(e), that permits the storage of personal data for periods "longer than is necessary for the purposes for which the data are processed".
The conditions to comply with in order to apply both exemptions are those that usually accompany the scientific research purpose, and therefore compliance with Art. 89(1) and implementation of appropriate technical and organisational measures to safeguard the rights and freedoms of the data subject.
Both exemptions are of particular importance for biobanking. Indeed, as mentioned, biobanks have an inherent prospective nature, in the sense that the samples and data stored therein may be used for potentially indefinite research purposes. As a consequence, the possibility to reuse the collected data and to store them for a longer period of time is essential for biobanks to comply with their ontological purpose.
However, the relevance of the storage limitation principle depends on whether the activity of implementing a biobank qualifies as scientific research.

4.2.3.2 (B) DEROGATIONS DERIVED FROM ENACTED UNION OR MEMBER STATE LAW

As mentioned, two more sets of derogations are possible, which derive from Union or Member State laws enacted according to either Art. 23 or Art. 89(2) GDPR.
Indeed, on the one hand, legislators at the Union or national level may decide to permit derogations from any of the rights in Art. 12 to 22 GDPR, Art. 34, and/or Art. 5 in order to safeguard "important objectives of general public interest of the Union or of a Member State, (…) including (…) public health (…)".[592] Conditions for the legitimacy of such derogations are the respect of the essence of the fundamental rights and freedoms and the necessity and proportionality of the measure. As a consequence, biobanks may benefit from derogations of this kind, if considered to protect *general public interests* in the area of *public health* by national or Union legislators.

[592] Art. 23(1)(e) GDPR.

Moreover, other derogations may be established by national or European laws enacted according to Art. 89 GDPR. In particular, for the purpose of this analysis, Art. 89(2) establishes this possibility when the processing is carried out for scientific research purposes. The chance to derogate from individual rights according to Art. 89(2) constitutes building block III of the *scientific research regime.*

In this case, the rights that may be derogated from are only the following: the right to access (Art. 15), the right to rectification (Art. 16), the right to restriction of processing (Art. 18), and the right to object (Art. 21). However, relying on these exemptions is possible under three conditions: that the processing complies with Art. 89(1) (and therefore that appropriate safeguards are in place), that the derogations are necessary, and that the achievement of the purpose of the processing would be rendered impossible by the exercise of those rights. Reasoning by way of analogy with the already mentioned consequences of the withdrawal of consent in the consent-based model, the exercise of some of the data subject's rights, and in particular the right to rectification, to restrict the processing and to object, may in fact render impossible the achievement of the biobanking research purposes, by reducing the amount of data necessary to meet research standards or to reach significant results.

5 ... (II) THE LEGAL FRAMEWORK AT THE NATIONAL LEVEL

The Italian legislator made use of the possibility enshrined in Art. 9(4) GDPR by introducing Art. 2-septies and Art. 2-quater in the Legislative Decree 101/2018.[593] According to Art. 2-quarter, the Italian DPA should publish deontological and ethical rules applicable to the processing under consideration. Moreover, Art. 2-septies establishes that the processing of genetic data and health-related data should not only respect Art. 9 GDPR but also the specific safeguards published by the Italian DPA to this end, which should take into consideration among others the scientific and technological developments and the interest in the free circulation of data.[594] The same article mentions some security measures that might be relevant: encryption and pseudonymisation techniques, minimisation, methods for selective access to data and for making

[593] Casonato, Carlo, and Marta, Tomasi "Diritti e Ricerca Biomedica: una Proposta Verso Nuove Consonanze."

[594] This latter element to be considered in the development of the mentioned safeguards should be interpreted narrowly, given the general prohibition of processing special categories of data enshrined in Art. 9(1) GDPR.

information available to interested parties. However, the DPA has not published the safeguards requested by Art. 2-septies yet.[595] The mechanism envisioned by Art. 2-septies of the Legislative Decree 101/2018 is the same as the one provided for by the Legislative Decree under Directive 95/46/EC. Critiques of this system and approach focus on the lack of harmonisation and legal certainty, but at the same time, it has the merit of constituting a fast and effective way of regulating the matter, characterised by rapid development and high heterogeneity.[596]

In order to clarify the processing of data concerning health in the medical sphere, the Italian DPA issued the Provvedimento 55/2019.

As mentioned, pending the issuing of these guidelines and rules, according to Art. 21(1) GDPR the Italian DPA established with Provvedimento n. 146/2019, which General Authorisations previously issued by the Italian DPA under Directive 95/46/EC should have been confirmed under the GDPR, among which both General Authorisation n. 8/2016 and 9/2016 are included (the latter referred to the processing of left-over data or left-over HBSs for scientific research purposes).

The national provisions relevant for biobanking as a primary processing (but also scientific research more generally) are those included between art. 104 and art. 110 Italian Privacy Code, and the General Authorisations n. 8/2016 on the processing of genetic data. Considering that these were norms of the previous version of the Italian Privacy Code, adapted to the provisions of the GDPR after it entered into force, their autonomous applicability, as well as their interplay, is often debated among scholars. The same can be said for the secondary processing of personal and sensitive data, analysed below.

In particular, for what is relevant to our analysis, according to Art. 13 and 14 GDPR Art. 105 Italian Privacy Code establishes the duty to provide the data subject with relevant information on the processing, whose purposes should be clearly specified.

However, the fundamental norm that regulates processing for scientific research purposes is Art. 110 Italian Privacy Code, which resembles the content that the General Authorisation n. 9/2016 for the secondary processing of left-over biobank data and HBSs (in Scenarios 2 or 3). Indeed, it is established that the informational consent of the data

[595] Zanovello, Francesca "Misure di Garanzia e Rischio di Data Breach in Ambito Sanitario."
[596] Casonato, Carlo, and Marta, Tomasi "Diritti e Ricerca Biomedica: una Proposta Verso Nuove Consonanze."

subject is the rule for conducting scientific research with health-related data, thus adopting a particularly restrictive approach.

However, with the aim of finding the right balance between the rights and interests of the data subject to the protection of her personal data, and those of society at large in the advancement of scientific research, Art. 110 Italian Privacy Code also establishes some derogations.[597] In particular, it is possible to derogate to the general rule of asking for informational consent only in the following alternative scenarios.

(a) A first exemption is established when the research is conducted based on EU or national law, provided that a privacy impact assessment is conducted and made public according to Art. 35 and 36 GDPR. In this case, reference is made to Art. 9(2)(j), and consequently to the conditions of necessity, proportionality and adoption of necessity of adopting suitable and specific measures to safeguard the rights and interests of the data subject. Consequently, these will be the elements addressed by the impact assessment.[598]

(b) The second exemption concerns the case in which exceptional circumstances are applicable in the case concerned, related to (b1) the impossibility of asking for the data subject's consent, or (b2) the fact that recontacting the data subject would involve a disproportionate effort, or finally (b3) the fact that asking for consent would run the risk of rendering impossible or seriously impair the research purpose. These exceptional reasons shall be documented in the research project and may for instance be referred to

- ethical reasons related to the ignorance of the data subject of her medical condition, such as when asking for consent would entail disclosing information on the research study, with possible serious material or psychological damage to the data subject or
- organisational issues of the specific project (for instance excessive total number of participants or objective impossibility of contacting them) or
- health reasons related to the seriousness of the condition of the data subject, under certain conditions. [599]

In these cases, appropriate technical and organisational measures should be adopted to protect the rights and interests of the data subject according to Art. 89 GDPR, the

[597] Taddei Elmi "Art. 110."
[598] *Ibid*
[599] For instance, this was the case of the Authorisation n. 6503991/2017. Stefanelli, Stefania, "Italy."

geographically competent ethics committee should approve the project and a prior consultation with the Italian DPA should be conducted according to Art. 36 GDPR.[600]
Moreover, in the case of processing data for scientific research purposes, Art. 99 Italian Privacy Code includes at the national level the storage limitation principle, while the General Authorisation n. 9/2016 requires the HBSs and the personal data to be anonymised after the period of time strictly necessary to reach the purpose for which they were collected.
Finally, the processing of genetic data is subject to the specific provisions of the General Authorisation n. 8/2016, up to the issuing of the order by the Italian DPA laying down safeguards for this kind of processing,[601] concerning security measures to be adopted regarding each category of personal data to be processed,[602] such as encryption and pseudonymisation techniques, minimisation, methods for selective access to data, etc.[603]
The reasons for these tailored provisions are related to the particularly sensitive nature of genetic data, which therefore deserves a higher degree of protection.
In particular, alongside general precautionary requirements for guaranteeing the safety and custody of genetic data, HBS data and HBSs,[604] for what is relevant to our analysis paragraph 4.5 establishes that informational consent is required for processing of personal data for scientific research purposes. Consequently, such a provision would be applicable only if the activity of collecting biobank data and HBSs qualifies as scientific research within the meaning of the GDPR.
According to paragraph 4.11, the only research purposes considered legitimate are those aiming at safeguarding the health of the data subject, third parties or society as a whole. The processing should be based on a research project drafted according to the applicable standard in the relevant sector. Specific measures should be adopted to keep the HBSs and the HBS data separate from the collection if identifying the data subject is necessary

[600] Di Tano, Francesco "Protezione dei Dati Personali e Ricerca Scientifica: un Rapporto Controverso ma Necessario." Here, doubts arise on the duty to the Italian DPA only if the impact assessment results in a high risk for the processing, or under any circumstances. However, a literal and teleological interpretation of Art. 110 of the Italian Privacy Code seems to validate the second hypothesis. On this, Taddei Elmi "Art. 110."
[601] As provided for by Art. 2 septies Italian Privacy Code.
[602] Explanatory Report on Legislative Decree n. 101 of 10 August 2018.
[603] Art. 2 septies paragraph 5 Italian Privacy Code.
[604] In particular, the General Authorisation n. 8/2016 in paragraph 4.2 asks for a documented procedure established by the data controller for accessing the premises where the data and HBSs are stored; complying with specific provisions on the storage, use and transport of the HBSs,

for the purposes of the research. Such a processing should be grounded on the informational consent of the data subject.[605]

As already mentioned, whenever the data subject withdraws a previously provided consent, the HBSs which the HBS data refer to, should be either rendered anonymous or destroyed.[606]

Finally, paragraph 4.11.4 of the General Authorisation n. 8/2016 establishes that genetic data collected for scientific research purposes may be shared with or transferred to research institutions under the following conditions: the research institution should be a join-controller; the genetic data should be non-identifiable; they should be processed for research purposes directly related to the original one and established in writing in the request. It is interesting to note that the General Authorisation here refers to non-identifiable data and not anonymous data.[607]

From the analysis of the mentioned provisions, it may be inferred that at the national level the Italian legislator maintained a strong preference for the informational consent of the data subject as the ground for the processing of personal data (and genetic data),[608] and reaffirmed the adoption of a hybrid model for biobanking, because parts of the functions are delegated to the competent administrative authority.[609]

To reduce the requirements to be complied with for the processing of the data for scientific research purposes specifically, Art. 99 Italian Privacy Code established that "processing of personal data (...) for scientific (...) research purposes (...), may also be carried out for longer than is necessary for achieving the individual purposes for which the data had been previously collected or processed",[610] a provision resembled by the Deontological Rules in Art. 11 and that resembles the storage limitation principle enshrined in the GDPR.

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[605] Paragraph 4.5 of the General Authorisation n. 8/2016. Moreover, paragraph 4.11.2 establishes provisions applicable in case of data subjects not able to provide consent.

[606] Paragraph 4.11.2 of the General Authorisation n. 8/2016.

[607] In Italian: "informazioni prive di dati identificativi":

[608] Taddei Elmi "Art. 110." Moreover, Pelino criticised this approach as being in contrast with the one adopted by the GDPR, which seems to favour scientific research and the law as a legal basis, over consent. Pelino, Enrico "Commento all'art. 110." *Il Regolamento Privacy Europeo: Commentario Alla Nuova Disciplina Sulla Protezione Dei Dati Personali,* edited by Bolognini, Luca, et al. Giuffrè editore, 2016, pp. 123-125.

[609] Penasa, Simona and Marta, Tomasi "The Italian Way for Research Biobanks After GDPR: Hybrid Normative Solutions to Balance the Protection of Individuals and Freedom of Research."

[610] Translation of Stefanelli, in Stefanelli, Stefania, "Italy."

Applying the described legal framework to biobanking might have serious consequences in terms of the protection of the advancement of research. Indeed, the biobank would have to demonstrate the existence of the conditions to apply the exemption mentioned above, in order to be able to derogate to the duty to ask participants to provide informational consent to the processing. Such conditions might be related to an objective impossibility[611] or organisational, economic reasons, as well as reasons related to the resources of the project or the biobank.[612]

On the contrary, this is always the case if the biobank collects and stores genetic data, no matter the purpose of the processing.

Asking for the informational consent of the data subject might be problematic for biobanking, because of the disadvantages of the consent-based model as presented in the following pages, and in particular for those related to factual dependence of the specific research project to be conducted with the biobank data and the biobank itself on the willingness of the participant not to withdraw a previously provided consent, as well as the duty to erase the biobank data and destroy the HBS in case of exercising of the right of withdrawal.

However, as mentioned, Art. 110 Italian Privacy Code applies to biobanking only in so far as it qualifies as *scientific research.* If this condition is not complied with, the suitability of other exemptions provided for in Art. 9(2)(i) should be evaluated, which however requires a Union or Member State law which provides for suitable and specific measures.

6 THE SECONDARY USE OF PERSONAL DATA IN BIOBANKING

As mentioned, the above models are those that are possibly applicable for the primary use of personal data for biobanking purposes and future research projects. To complete the analysis, it is now necessary to highlight the data protection regime applicable to the *secondary use* of these data for the same purposes. The secondary use of personal data has been defined as an "essential component of the research arsenal for tackling health

[611] Italian DPA Provvedimento 433/2023 and 285/2023
[612] Italian DPA Provvedimento 118/2022.

and health care questions".[613] However, it raises several sensitive issues, especially related to the balance of the various interests to be protected.[614]

The provisions applicable in this regard are devoted to establishing a legal framework for processing already collected personal data without asking for (a new) informational consent from the data subject. Therefore, in this regard, the choice of the biobank is between asking for a new informational consent or adopting another procedure which does not require an active intervention by the data subject.

As further explained in the following paragraphs, qualifying a processing as a *primary* or a *secondary use* of personal data in the context of research biobanking is essentially a matter of assessment on a case-by-case basis,[615] according to the concrete characteristics of the biobank, of the context where it is implemented, etc. However, an overview of the matter will help understand if, how and under which conditions the GDPR provisions on the *secondary use* of data may be applicable to research biobanks. Indeed, the matter is frequently the object of conflicting interpretations among scholars because of the lack of clear regulatory guidance and definitions of the legal concepts relevant to the applicability of the mentioned exemption.[616] In this regard, both the EHDS and the DGA aim at increasing harmonisation and providing a more precise legal framework for the secondary use of personal health data. However, in this section, the matter will be analysed according to the provisions of the GDPR, and the relevant specification will be added in the part devoted to the analysis of the two additional legal instruments.

6.1 THE SUPRANATIONAL LEVEL – ART. 5(1)(B) AND 6(4) GDPR

There is no clear and shared definition of *secondary use* of personal data, either in the applicable legal instruments or in scientific literature. In general terms, the *secondary use*

[613] Stefanelli, Stefania, "Italy"; Black, Nick "Secondary Use of Personal Data for Health and Health Services Research: Why Identifiable Data Are Essential." *Journal of Health Services Research & Policy,* vol. 8, n. 1, 2003, pp. 36-40.
[614] Cippitani, Roberto "Genetic Data."
[615] See also the Article 29 Working Party in its Opinion 03/2013 on purpose limitation, based on Directive 95/46/EC but still applicable for the GDPR provisions, to some extent.
[616] Becker, Regina, et al. "Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers"; Dove, Edward S., and Jiahong, Chen "Should Consent for Data Processing Be Privileged in Health Research? a Comparative Legal Analysis"; Cole, Amanda, and Adrian, Twose "Data Protection in the European Union Post- General Data Protection Regulation (GDPR): a Barrier or an Enabler of Pharmaceutical Innovation?" *International Journal of Technology Assessment in Health Care,* vol. 37, n. 51, pp. 10-11.

of personal data is the processing of such data for a purpose different from the original one for which the data were collected or generated.[617]

The CIOMS International Ethical Guidelines establish in Guideline 11 that generally the secondary use of stored data is allowed

- when the new intended use falls within the scope of the original (broad) informed consent, or
- by the research ethics committee if the data offer important and otherwise unobtainable information, when asking for a new informational consent would be impracticable or prohibitively expensive, and the research has important social value and poses no more than minimal risks to participants or to the group from which the participant originates.

The secondary use of personal data is prohibited according to the GDPR, in compliance with the principle of purpose limitation (Art. 5(1)(b) GDPR), which has been defined as a "cornerstone of data protection, and a prerequisite for most other fundamental requirements".[618]

However, three exemptions to this rule are included in the GDPR in Art. 6(4) and Recital 50, whose ratio is to strike a fair balance between the private interests of the data subject and more general public interests[619]: (1) the secondary use is provided by a Union or Member State law which constitutes a necessary and proportionate measure in a democratic society to safeguard, in particular, important objectives of general public interest", (2) the data subject consented to the secondary use, and (3) the secondary purpose is compatible with the primary one.

In the first case, since a Member State law is specifically authorising such a re-purposing of personal data, the legislator has already conducted a specific balancing test between

[617] Becker, Regina, et al. "Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers." The term used by the GDPR to refer to this concept is "further processing" referred to in Recital 50.

[618] De Terwangne, Cécile "Article 5 Principles Relating to Processing of Personal Data." *the EU General Data Protection Regulation (GDPR): a Commentary*, edited by Kuner, Christopher, et al. Oxford Academic, 2020, pp. 309-320.

[619] Meszaros, Janos, and Chih-hsing, Ho "Big Data and Scientific Research: The Secondary Use of Personal Data under the Research Exemption in the GDPR." *Hungarian Journal of Legal Studies*, vol. 59, n. 4, pp. 403-419.

the various contrasting interests at stake.[620] Indeed, this is reflected in the requirement that such a law should constitute "a necessary and proportionate measure".

In all the other scenarios, for secondary processing of personal data, the data controller may choose between (2) asking for additional specific informational consent for this (secondary) purpose or (3) conducting the compatibility test.

Indeed, in the last case (3), the data controller should conduct a formal compatibility assessment (purpose compatibility test)[621] between the two purposes on a case-by-case basis,[622] taking into account the elements listed in both Art. 6(4) and Recital 50 of the GDPR, and namely:

- any link between the primary and secondary purposes;
- the context in which the personal data have been collected, in particular regarding the relationship between data subjects and the controller, and also any imbalance of powers between the two, as underlined by the Article 29 Working Party.[623] Under this element, Recital 50 includes also the evaluation of the data subject's reasonable expectations;
- the nature of the personal data, in particular whether special categories of personal data are processed. The inclusion of this element among those to be considered indirectly allows the possibility of secondary use of sensitive data.[624] However, "the more sensitive the information involved, the narrower the scope for compatible use would be",[625] given that the evaluation to be conducted for assessing compatibility should ensure that no substantively higher risk than the initial lawful processing should be envisioned;[626]
- the possible consequences of the intended secondary use of the data for the data subjects;

[620] Becker, Regina, et al. "Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers."
[621] Meszaros, Janos, and Chih-hsing, Ho "Big Data and Scientific Research: The Secondary Use of Personal Data under the Research Exemption in the GDPR."
[622] Marelli, Luca, and Giuseppe, Testa "Scrutinizing the EU General Data Protection Regulation." *Science (New York, N.Y.),* vol. 360, n. 6388, 2018, pp. 496-498.
[623] the Article 29 Working Party in its Opinion 03/2013 on purpose limitation, based on Directive 95/46/EC but still applicable for the GDPR provisions, to some extent.
[624] Meszaros, Janos, and Chih-hsing, Ho "Big Data and Scientific Research: The Secondary Use of Personal Data under the Research Exemption in the GDPR."
[625] Article 29 Working Party, Opinion 03/2013 on Purpose Limitation, 2013.
[626] Kotschy, Waltraut "Article 6 Lawfulness of Processing."

- the existence of appropriate safeguards, which may include encryption or pseudonymisation.

Contrary to this general rule for the secondary use of personal data, Art. 5(1)(b) establishes that compatibility is presumed if the secondary use is for scientific research purposes. In this case, therefore, a compatibility assessment should not be conducted,[627] and this provision led many scholars to believe that the GDPR grants a special status to *scientific research* when it comes to the processing of personal data for this purpose.[628] However, the presumption of compatibility excludes only the duty to conduct the compatibility assessment, while the definition of a specific, explicit and legitimate secondary purpose by the data controller is still necessary, as well as the implementation of specific safeguards.[629] Indeed, Art. 89(1) GDPR should be complied with, and in particular the duty to ensure that "technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation".

However, "the presumption is not a general authorisation to further process data in all cases for (...) scientific purposes. Each case must be considered on its own merits and circumstances. But in principle, personal data collected in the (...) healthcare context, for example, may be further used for scientific research purposes, by the original or a new controller, if appropriate safeguards are in place".[630]

As for the concrete conduction of the compatibility test, it is debated the case in which sensitive data are transferred to a third-party for the recipient's own research purposes,[631] as it may happen if the biobank chooses to clearly separate the processing, collection and storage on the one hand and processing for an actual research project on the other, for the purposes of choosing the correct legal basis and exemption. In this eventuality, indeed it

[627] Becker, Regina, et al. "Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers."

[628] Chico, Victoria "The Impact of the General Data Protection Regulation on Health Research." *British Medical Bulletin,* vol. 128, n. 1, 2018, pp. 109-118; Quinn, Paul "Research Under the GDPR - a Level Playing Field for Public and Private Sector Research?" *Life Sciences, Society and Policy* vol. 17, n. 4, 2021, pp. 1-33; Ducato, Rossana, "Data Protection, Scientific Research and the Role of Information." *Computer, law and security review,* vol. 37, 2020, pp. 1-16.

[629] EDPS, a Preliminary Opinion on data protection and scientific research, 2020; Bincoletto, Giorgia "Scientific Research Processing Health Data in the European Union: Data Protection Regime vs. Open Data." *Journal of Open Access to Law*, vol. 11, 2023, pp. 1-24.

[630] EDPS, a Preliminary Opinion on data protection and scientific research, 2020. On this, see also Di Tano, Francesco "Protezione dei Dati Personali e Ricerca Scientifica: un Rapporto Controverso ma Necessario."

[631] Becker, Regina, et al. "Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers."

is unclear which entity's safeguards should be considered for the conducting of the compatibility test (data controller or third-party).

Another issue for the applicability of the scientific research exemption from the compatibility test is whether it is possible to apply it only to further processing conducted by the *original* data controller or also to third parties. In this regard, the EDPS in the above-mentioned document establishes that "in principle, personal data collected in the (…) healthcare context, for example, may be further used for scientific research purposes, *by the original or a new controller".*[632]

It seems from this extract that the research exemption for secondary use may be applied in both the mentioned cases (original data controller and third-party). However, authors believe that "the collection by a downstream controller [i.e. a data controller who receives existing data from another controller, as opposed to the data subject] effectively marks a "reset" in the chain to the extent that it takes place for a primary purpose, which needs a legal basis on its own". According to this interpretation, downstream data controllers could not benefit from the scientific research exemption from the compatibility test.

I believe that this question derives from the more general issue of establishing in practice when a processing constitutes *secondary use.* The matter is further complicated by the consideration that it is also possible to collect personal data for multiple primary purposes at the same time.[633]

In some instances, the solution appears straightforward,[634] such as whenever a hospital decides to use for research purposes data previously collected and used to administer medical examinations.[635]

However, more generally, Becker et al. suggested two questions that may be asked in order to assess whether the processing to be conducted on personal data is (a) a secondary use of personal data, or (b) a parallel primary use.

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[632] EDPS, a Preliminary Opinion on data protection and scientific research, 2020.

[633] See in particular the use of the plural *purposes* in Art. 5(1)(b). On this, Becker, Regina, et al. "Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers."

[634] This is also confirmed by the Article 29 Working Party in its Opinion 03/2013 on purpose limitation, based on Directive 95/46/EC but still applicable for the GDPR provisions, to some extent.

[635] Becker, Regina, et al. "Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers."

As for the first one (a), the question to be asked is the following: "Would purpose Y still be achieved in the absence of processing activity P?". In this case, if the answer is "yes", processing P is a secondary use of the data previously collected.
Considering the second (b), the question identified by Becker et al. is the following: "Would the data collection for purpose X still take place in the absence of purpose Y?". In case of positive answer (yes) both the purpose X and Y are prima y purposes.
It appears thus clear that, once again, the applicability of the mentioned provisions depends on a case-by-case evaluation, which I attempt to schematise at the end of this paragraph 6.

6.2 THE NATIONAL LEVEL – ART. 110 AND 110-BIS ITALIAN PRIVACY CODE AND THE GENERAL AUTHORISATIONS

At the national level, the secondary processing of left-over data and HBSs is regulated by both Art. 110, under an objective point of view and therefore considering the type of processing, and Art. 110-bis Italian Privacy Code, under a subjective one and thus focusing on the data processor.[636]
Art. 110 Italian Privacy Code was analysed in the previous pages for its normative content. The article has been applied by the Azienda Ospedaliera Universitaria Integrata di Verona and approved by the Italian DPA in the Provvedimento n. 238/2022, precisely for the retrospective collection for biobanking purposes (and future scientific research purposes) of left-over data already at the disposal of the Azienda. Indeed, in this case, the processing under consideration was a secondary processing from an objective point of view because the data processor remained the same. In this case, the Azienda had proven that it was objectively impossible to recontact the data subjects to ask for their informational consent to the biobanking processing and therefore applied the second exemption for the general duty to acquire informational consent provided for in Art. 110 Italian Privacy Code.[637]
Differently, Art. 110-bis establishes the conditions for the secondary use of personal data for research purposes by *third parties*, i.e. data controllers different from the one of the original purposes (primary purpose), in cases in which asking for informational consent

[636] Stefanelli, Stefania, "Italy."
[637] On the applicability of Art. 110 Italian Privacy Code, see also Provvedimento n. 433/2023; 402/2022; 238/2022 among others.

is impossible or entails a disproportionate effort or is likely to render impossible or seriously impair the research purpose. Indeed, the article gives the Italian DPA the power to issue either specific or General Authorisations that permit such a processing under the condition of adopting adequate measures to safeguard the rights and interests of the data subject according to Art. 89 GDPR, such as data minimisation or anonymisation.[638]

Under Art. 110-bis Italian Privacy Code the secondary nature of the processing is evaluated on subjective terms, [639] i.e. considering whether the entity carrying out the processing qualifies as "third party" when compared to the one that conducted the primary processing. According to Art. 4(10) a "third party" is a natural or legal person, public authority, agency or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorised to process personal data".

However, as an exception to the general framework established, in its last paragraph Art. 110-bis Italian Privacy Code clarifies that this procedure is not applicable to scientific research conducted on left-over samples previously collected for providing medical care, by Research Hospital, whether public or private. The reason for this exemption is the fact that conducting scientific research is already within their purposes. However, in practice, it may be relied upon by a very small number of entities.[640]

In the context of Art. 110-bis Italian Privacy Code, both General Authorisations n. 8/2016 and n. 9/2016 are relevant.[641]

On the one hand, General Authorisation n. 8/2016 establishes in paragraph 4.11.3 that the storage and further use of genetic data is first of all possible with the consent of the data subject, or as exceptions to this general principle (a) in case of scientific research established by the EU or Italian law or regulation, (b) for scientific research purposes *directly related* to those for which a previous consent has been already collected, (c) for

[638] Casonato, Carlo, and Marta, Tomasi "Diritti e Ricerca Biomedica: una Proposta Verso Nuove Consonanze." Considering that the processing that anonymised data should not comply with the GDPR, it seems reasonable to assert that anonymisation is a measure that, when relevant, should be applied by the data recipient-third party. Melchionna, Silvia "Art. 110-bis." *Commentario al Codice della Privacy*, edited by Sciaudone, Riccardo, Pacini giuridica, 2023, pp. 340-348.

[639] Stefanelli, Stefania, "Italy."

[640] Di Tano, Francesco "Protezione dei Dati Personali e Ricerca Scientifica: un Rapporto Controverso ma Necessario"; Guarda, Paolo, *Il Regime Giuridico dei Dati della Ricerca Scientifica*.

[641] Melchionna, Silvia "Art. 110-bis"; Di Tano, Francesco "Protezione dei Dati Personali e Ricerca Scientifica: un Rapporto Controverso ma Necessario."

scientific research purposes *different* from those for which a previous consent has been already collected, but under the following conditions:

- It is impossible to re-contact the data subject, notwithstanding a reasonable effort in this regard,
- A research project with the same purpose cannot be conducted with personal data of data subjects that provided or can provide consent;
- The processed samples and personal data cannot be used to identify the data subject, or the research project has been authorised by the competent ethics committee and Art. 36 GDPR has been complied with.

On the other, as for the secondary use of personal and sensitive data, and in particular left-over data and HBS data, the relevant provisions are included in the General Authorisation n. 9/2016, which is frequently criticised for having introduced a legal regime stricter than the one adopted by the GDPR on the issue.[642]

According to this Authorisation as well, informational consent is the role in case of processing for scientific research purposes of left-over HBSs and biobank data. However, as mentioned, some exceptions to this rule are provided, which essentially coincide with those established by Art. 110 Italian Privacy Code.[643]

It is worth here reminding the mentioned Opinion 238/2022. In that case, the biobanking processing (i.e. for the creation of the biobank itself) was based on informational consent for prospective personal data and art. 110 Italian Privacy Code for prospective data. While the Italian DPA agreed with this approach for the primary use of the data concerned, as for the processing of the data stored for a scientific research project, applying the mentioned provisions for the secondary processing of data for scientific research purposes has not been accepted. Indeed, the Italian Privacy Code asked for a second informational consent (which constitutes the specification of the first one) or for a new application of Art. 110 Italian Privacy Code.

As a general rule, it may be said that a *secondary use* may only happen if a data controller intends to process for a second time personal data that she had previously collected and processed for a different purpose. In this regard, the data controller should be the same entity in the first and second processing. Consequently, when a different entity requests

[642] Di Tano, Francesco "Protezione dei Dati Personali e Ricerca Scientifica: un Rapporto Controverso ma Necessario."
[643] *Ibid*

access to a dataset for its own purpose, this generally constitutes *secondary use* of these data.[644]

6.3 THE DUTY TO PROVIDE INFORMATION ACCORDING TO ART. 14(4) GDPR IN CASE OF THE FURTHER PROCESSING OF PERSONAL DATA

Finally, it is worth underlying that the secondary use of previously collected and processed data should respect Art. 14(4) GDPR and in particular the duty to inform the data subject in advance on the further processing to be conducted.[645] More generally, Art. 14 GDPR on the information to be provided to participants should be complied with any time the personal data to be processed are not collected directly from the data subject, which would often be the case for scientific research according to the EDPB.[646] However, express derogations to this duty are provided for by paragraph 5. The hypotheses relevant to our analysis are the following: (a) the data subject already has the information; (b) the provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for scientific research purposes, subject to the conditions and safeguards referred to in Art. 89(1) or in so far as this obligation is likely to render impossible or seriously impair the achievement of the objectives of the processing. In such cases, the controller shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available. The latter is applicable, in particular, in cases where the impossibility or disproportionate effort depends on the number of data subjects or the age of the data,[647] which may frequently be the case in the field of biobanking.

In practice, the exemption (b) includes three different cases: (b1) the impossibility of providing the information; (b2) when such an activity constitutes *disproportionate effort*; or (b3) it would likely render impossible or seriously impair the processing.

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[644] Becker, Regina, et al. "Secondary Use of Personal Health Data: When Is It "Further Processing" Under the GDPR, and What Are the Implications for Data Controllers."

[645] Art 14(4) GDPR "Where the controller intends to further process the personal data for a purpose other than that for which the personal data were obtained, the controller shall provide the data subject prior to that further processing with information on that other purpose and with any relevant further information as referred to in paragraph 2." on this, Fanni, Simona "Le Biobanche di Popolazione al Vaglio della Suprema Corte di Cassazione: Alcune Note Critiche sull'Ordinanza n. 27325 del 7 ottobre 2021."

[646] EDPB, Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak, 2020.

[647] Recital 62 GDPR.

In this regard, the EDPB clarifies further under which conditions the mentioned exemption is applicable, by frequently referring to what already established by the Article 29 Working Party on the Guidelines regarding the principle of transparency. On the one hand, the EDPB states that exemption (b1) applies in "all or nothing situation[s] because something is either impossible or it is not; there are no degrees of impossibility. Thus, if a data controller seeks to rely on this exemption, it must demonstrate the factors that prevent it from providing the information in question to data subjects." Moreover, the impossibility might be temporary, and consequently the data controller should evaluate its persistence through time, because if providing the information becomes possible, she should "immediately do so". The EDPB finally establishes that "[i]n practice, there will be very few situations in which a data controller can demonstrate that it is actually impossible to provide the information to data subjects."[648] Moreover, as for (b2) the Guideline establishes that a balancing exercise is needed to assess the effort of providing the information of Art. 14 GDPR against the impact and effects on the data subjects' rights and interests if no information is provided.[649] Finally, exemption (b3) is applied if the data controller is able to demonstrate that it is the activity of providing the information as per Art. 14 GDPR *per se* that would cause such an impossibility or impairment.[650]

Analogously, at the national level, Art. 105 Italian Privacy Code establishes that in case of second processing, it is possible not to provide information to the data subject whenever it requires a disproportionate effort compared to the protected right, provided that appropriate forms of advertising/publicity are adopted. The same is established by Art. 6 of the Deontological Rules for processing for statistical or scientific research purposes.[651]

In the majority of cases, the mentioned exemptions might apply in the context of biobanking. Indeed, independently of the described Scenarios in Chapter I, the biobank collects personal data from a vast number of participants in a wide range of different circumstances. Moreover, the collection is usually spread through time, sometimes

[648] EDPB "Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak." 2020.
[649] *Ibid*
[650] *Ibid*
[651] Indeed, the mentioned article provides that if providing the information entails a disproportionate effort compared to the right protected, the data controller should adopt suitable forms of publicity when the data to be processed for scientific research purposes were collected for other purposes.

decades.[652] In these circumstances, notwithstanding the fact that it would be necessary to conduct an analysis on a case-by-case basis, it is possible to predict that in a high percentage of cases, providing information would be impossible or would require a substantial effort on the part of either the biobank or of the researchers.

7 ASSESSING THE FRAMEWORK FOR THE BIOBANK CHOICE

As it appears evident from the analysis conducted above on the data protection regimes applicable to biobanking, there is a substantial difference between the national and the European level.

Indeed, the latter establishes a legal framework that leaves data controllers (as well as Member States) with a choice as to the legal basis and exemption to apply to ensure the lawfulness of the processing, also in the context of biobanking. Therefore, if only the provisions of the GDPR are concerned, the data controller still needs to choose between the consent-based model and the necessity-based one. Such a choice should be based on the evaluation and balancing of the contrasting rights and interests of the specific processing activity to be conducted. Moreover, all things being equal, the decision to be implemented should be the one that better protects participants' trust in biobanking.

At the national level, the situation for biobanks is different. Indeed, the biobank may still choose the legal basis among those presented as feasible in the national necessity-model for the collection of biobank data. However, as for the exemptions, in the absence of a specific national law enabling the application of Art. 9(2)(i), the choice is reduced to the consent-based model or applying the scientific research regime, which however in Italy requires acquiring the informational consent of the participant most of the time.

Apart from possible issues related to the legitimacy of such a choice on the part of the Italian legislator, it appears evident that biobanks that should comply with the Italian data protection regime would need to ask for the informational consent of participants, at least when (a) processing personal data in the context of biobanking if considered "scientific research", (b) processing genetic data, no matter the qualification of the purpose, and (c) secondary processing left-over HBSs or data. Here, the Italian legislator used the

[652] See for instance the case decided by the Italian DPA in its Opinion 238/2022, where the biobank intended to collect personal data for a period of time of 25 years.

considerable room for manoeuvre left by the European legislator to the Member States[653] and intervened in normatively conducting the balancing test of the possible contrasting rights and interests at stake. However, acquiring the participants' specific informational consent in the context of biobanking for any new research project might be particularly burdensome, and might excessively limit the biobanking activities and the advancing of scientific research conducted thanks to them, in the absence of a justified counterbalance in the protection of a fundamental right or interest of the data subject. As a consequence, alternative models for the collection of such consent are frequently proposed.

Therefore, I will now attempt to provide a guidance for biobanks in making the following choices for the biobank governance: (a) the choice between the necessity-based model and the consent-based model at the supranational level, and (b) that among the various models for informational consent at the national one.

To this end, after having provided a general overview of the interpretation and protection of the right to data protection, of fundamental importance for both evaluations, I will proceed to address the two choices separately.

7.1 THE PARTICIPANTS' RIGHT TO DATA PROTECTION

There are various rights, interests and values that should be taken into account when processing data for biobanking purposes and that contribute to the applicable "axiological framework",[654] among which are particularly relevant the protection of science and scientific research and the individual's right to data protection.

First of all, in any processing of personal data, issues related to the protection of the right to data protection of the participant arise. The autonomy of the mentioned right from the umbrella[655] right of the right to privacy has long been debated among scholars, at least up to the EU Charter that codified the latter in Art. 7 and the former in Art. 8. From that moment onwards, the right to data protection has acquired the autonomous status of

[653] For overviews of the national approaches to GDPR compliance Slokenberga, Santa, et al., *GDPR and Biobanking*, Springer, 2021; Hansen, Johan, et al. *Assessment of the EU Member States' rules on health data in the light of GDPR*, 2021. Moreover, specifically on biobanking Colcelli, Valentina, et al. *GDPR Requirements for Biobanking Activities Across Europe*, Springer, 2023.

[654] Ricci, Cristoforo, and Pietrantonio, Ricci "Le Biobanche di Ricerca: Questioni e Disciplina." *Rivista Italiana di Medicina Legale*, vol. 1, 2018, pp. 93-143.

[655] Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context." On the matter, the Author states that "data protection is only one planet in the privacy galaxy".

fundamental right,[656] recognised also by Art. 16 TFUE and in Art. 8 ECHR.[657] In this regard, the GDPR provides a comprehensive framework on how this right may be protected and exercised.[658]

The right to data protection and the right to privacy shares some common characteristics, but the latter is much broader.[659] In particular, the right to privacy might be understood as a "constellation of rights"[660] and has in two separate souls.[661] On the one hand, the right to be let alone,[662] which is the negative aspect of the right because it entails the right not to suffer from interference,[663] and on the other the right to data protection, understood as right to control the flow of one's personal data[664] and the right to informational self-determination, both qualified as the positive aspects of the right to privacy because they give data subject the possibility of acting according to her will and referred to as the right to data protection[665] (positive aspect of the right to privacy).

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[656] The added value of having the two rights separate in the EU Charter rests on the fact that even if a processing does not infringe the right to data protection, it should still be evaluated for its compliance with the provisions that protect the right to private life in Art. 7. Naef, Tobias *Data Protection without Data Protectionism. The Right to Protection of Personal Data and Data Transfers in EU Law and International Trade Law*.

[657] Indeed, the ECHR does not include a specific right for data protection but protects it under the right to respect for private and family life. For instance, in the already mentioned *Marper case* the Court include the protection of informational privacy in the interpretation of Art. 8 ECHR. See on the protection of personal data under Art. 8 ECHR not only the *Marper case*, but also the case Z. v. Finland

[658] Reichel, Jane, "Allocation of Regulatory Responsibilities: Who Will Balance Individual Rights, the Public Interest and Biobank Research Under the GDPR?" *GDPR and Biobanking*, edited by Slokenberga, Santa, Springer, 2021, pp. 421-434.

[659] Tzanou, Maria "Data Protection as a Fundamental Right Next to Privacy? "Reconstructing" a not so new right."; Kokott, Juliane, and Christoph, Sobotta "The Distinction between Privacy and Data Protection in the Jurisprudence of the CJEU and the ECtHR." *International Data Privacy Law*, vol. 3, n. 4, 2013, pp. 222-228. The right to informational self-determination was first introduced by the German Constitutional Court (Bundesverfassungsgericht) in its landmark Census decision (Volkszählungsurteil, 65 BVerfGE 1) in 1983.

[660] Modugno, Franco *I Nuovi Diritti nella Giurisprudenza Costituzionale*, Giappichelli, 1995.

[661] Zorzi Galgano, Nadia "Le Due Anime del GDPR e la Tutela del Diritto alla Privacy." *Persona e Mercato dei Dati. Riflessioni sul GDPR*, edited by Zorzi Galgano, Nadia, Wolters Kluwer, 2019, pp. 35-94. Mollo, Francesca "Il Trattamento dei Dati Genetici tra Libera Circolazione e Tutela della Persona." *Juscivile*, vol. 1, 2022, pp. 70-96.

[662] Warren, Samuel, and Louis, Brandeis "The Right to Privacy" *Harvard Law Review*, vol. 4, n. 5, 1890, pp. 193-220.

[663] Naef, Tobias *Data Protection without Data Protectionism. The Right to Protection of Personal Data and Data Transfers in EU Law and International Trade Law*, Springer, 2023.

[664] Rodotà, Stefano *Tecnologie e Diritti*, Il Mulino, 1995. On the fact that the right to privacy includes the right of the data subject to control the processing of her data, also Constitutional Court n. 2022/2019 and n. 20/2019, in which it is established that the flow of personal data on which the data subject retains control is governed by the GDPR norms and the principles enshrined therein.

[665] Rapisarda, Ilenia "Ricerca Scientifica e Circolazione dei Dati Personali. Verso il Definitivo Superamento del Paradigma Privatistico?"; Scagliarini, Simone "La Tutela della Privacy e dell'identità Personale nel Quadro dell'evoluzione Tecnologica." *Consulta Online*, vol. II, 2021, pp. 489-532.

The features of the right to data protection may be identified from the two parts of Art. 8 EU Charter. On the one hand, paragraph 1 establishes that everyone has the right to the protection of personal data concerning her, and therefore the so-called passive side of the right. This side specifically resembles the right to privacy in its original formulation as the right to be let alone and in the context of biobanking entails the right of the participant to have information on the technical measures implemented by the biobank to ensure the confidentiality of the data (such as anonymisation, data circulation and conditions to access the data), in order for the data subject to make an informed decision.[666] As for specifically this part of the right to data protection, there is no need to be informed also on the characteristics of the research projects to be conducted with the data, given that this information does not change the risk of intrusion and unlawful use of the data that Art. 8 paragraph 1 intends to protect against.[667]

On the other hand, paragraph 2 states that personal data may be processed with the consent of the data subject or based on other legitimate bases laid down by law, thus establishing for the participant an active right of control (active side of the right to data protection).[668] Indeed, the right to data protection is in particular about informational privacy, i.e. managing one's personal data and controlling their processing and use through time, and informational autonomy, i.e. the right to informational self-determination.[669] The latter ensures the data subject with the power to determine the data to be disclosed disclosure and how these data may be used,[670] and thus ultimately with control over them,[671] and with the right to self-determine herself in relation with the use of her personal information.[672] Indeed, paragraph 2 of Art. 8 EU Charter is based on the assumption that personal data and especially sensitive data concur in informing the

[666] Macilotti, Matteo "Informed Consent in the Biobanking Context."
[667] *Ibid*
[668] *Ibid*
[669] Tzanou, Maria "Data Protection as a Fundamental Right Next to Privacy? "Reconstructing" a not so new right." *International Data Privacy Law*, vol. 3, n. 2, 2013, pp. 1-24.
[670] Maestri, Enrico "Il Feticcio della Privacy nella Sanità. Cura del Paziente e Biobanking Genetico Prima e Dopo L'entrata in Vigore del GDPR."
[671] Tzanou, Maria "Data Protection as a Fundamental Right Next to Privacy? "Reconstructing" a not so new right." *International Data Privacy Law*, vol. 3, n. 2, 2013, pp. 1-24. Extensively on the topic, see Finocchiaro, Giusella Dolores "Introduzione al Regolamento Europeo sulla Protezione dei Dati." *Le Nuove Leggi Civili Commentate*, vol. 1, 2018, pp. 1-18; Cuffaro, Vincenzo "Il Diritto Europeo sul Trattamento dei Dati." *Contratto e Impresa*, n. 1, 2018, pp. 1098-1119; Naef, Tobias *Data Protection without Data Protectionism. The Right to Protection of Personal Data and Data Transfers in EU Law and International Trade Law*.
[672] Finocchiaro, Giusella Dolores "Introduzione al Regolamento Europeo sulla Protezione dei Dati."

identity of the person, and therefore that the data subject has the right to control her external image through control of her personal information.[673] Such control is not only expressed via informational consent, but also via a bundle of other specific rights such as the right to access the data, right to withdraw consent, right to ask for a rectification, etc.[674]

As the data protection legal framework, the GDPR does not aim at protecting the individual right to data protection exclusively, but it intends to provide norms that at the same time ensure the free movement of personal data, including for scientific research purposes, [675] and to strike a fair and adequate balance between these frequently contrasting interests.[676] Indeed, the Regulation clearly underlines that the right to data protection is not absolute, but shall be balanced against (Recital 4), provided that "the essence of the fundamental right to respect for private life" is respected.[677]

Indeed, evidence of the mentioned approach may be found in the fact that the GDPR permits to conduct processing activities without informational consent,[678] it establishes a framework in which the data subject is given control over the use of the personal data referred to her and the right to data protection is safeguarded by not only the possibility of providing informational consent but also through other instruments or rights at the disposal of the data subject, as well as general principles to be complied with by the data controller, in particular those established by Art. 5, and by various general principles to be complied with in every data processing, such as the accountability principle, the transparency principle, the principle of privacy by design or by default, and the duty to provide information according to Art. 13 and 14 GDPR.[679]

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[673] Macilotti, Matteo "Informed Consent in the Biobanking Context."

[674] Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*; Macilotti; Matteo "Informed Consent in the Biobanking Context."

[675] Reichel, Jane, "Allocation of Regulatory Responsibilities: Who Will Balance Individual Rights, the Public Interest and Biobank Research Under the GDPR?"

[676] Mollo, Francesca "Il Trattamento dei Dati Genetici tra Libera Circolazione e Tutela della Persona." On this, see also Corte di Cassazione sentence n 10280/2015.

[677] Case C-362/14 Schrems v Data Protection Commissioner, EU:C:2015:650. The Court affirmed the principle regarding Art. 7 EU Charter.

[678] Stressing on the change of paradigm in the GDPR, Messinetti claims for a right to process personal data. Messinetti, Raffaella "Circolazione dei Dati Personali e Autonomia Private." *Federalismi.it*, vol. 21, 2019, pp. 1-23.

[679] Rapisarda, Ilenia "Ricerca Scientifica e Circolazione dei Dati Personali. Verso il Definitivo Superamento del Paradigma Privatistico?"; Maestri, Enrico "Il Feticcio della Privacy nella Sanità. Cura del Paziente e Biobanking Genetico Prima e Dopo l'entrata in Vigore del GDPR."; Naef, Tobias *Data Protection without*

As for the latter in particular, it has been authoritatively claimed that the information duties established by the GDPR have a "crucial role for the data subject", because it makes her aware of the existence of the processing and gives her the possibility of acting consequently,[680] therefore attempting at reducing the imbalance of powers existing between the data controller and the data subject.[681]

This is exacerbated in the context of scientific research.

Freedom of science and scientific research, especially in the medical field, is protected as well by international treaties and national documents. In particular, Art. 13 of the EU Charter proclaims the freedom of constraints of scientific research and resembles Art. 15 of the International Covenant on Economic, Social and Cultural Rights on the duty of Member States to "respect the freedom indispensable for scientific research and creative activity". Moreover, Art. 35 of the EU Charter ensures a high level of human health protection. At the national level, Art. 33 of the Italian Constitution establishes the principle of freedom of science, while Art. 9 requires the Republic to promote "the development of culture and scientific and technical research". As it has been highlighted, while these provisions do not provide for an individual right for researcher, they nonetheless recognise the importance and value of scientific research for society.[682]

Scientific research has been defined as the "prerequisite to ensure the development of knowledge".[683] After the Treaty of Lisbon, scientific research acquired a new status in the EU,[684] as support for the achievement of the EU objectives[685] by being mentioned for

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Data Protectionism. The Right to Protection of Personal Data and Data Transfers in EU Law and International Trade Law.

[680] Ducato, Rossana "Data Protection, Scientific Research, and the Role of Information." *Computer Law Security Review*, vol. 37, 2020, pp. 1-16.

[681] Naef, Tobias *Data Protection without Data Protectionism. The Right to Protection of Personal Data and Data Transfers in EU Law and International Trade Law*.

[682] Reichel, Jane, "Allocation of Regulatory Responsibilities: Who Will Balance Individual Rights, the Public Interest and Biobank Research Under the GDPR?"

[683] Bincoletto, Giorgia, and Guarda, Paolo, "A Proactive GDPR-Compliant Solution for Fostering Medical Scientific Research as a Secondary Use of Personal Health Data." *Opinio Juris In Comparatione*, vol.1, 2021, pp. 43-76.

[684] Fanni, Simona, and Lorenzo, Marilotti "Ricerca Genetica e Tutela dei Dati Personali nel Diritto dell'Unione Europea e nel Diritto Italiano: è Possibile un Bilanciamento?" *Federalismi.it,* vol. 8, 2021, pp. 82-116.

[685] See for instance Art. 179(1) TFUE "The Union shall have the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry, while promoting all the research activities deemed necessary by virtue of other Chapters of the Treaties." More extensively on this, see Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea*.

the first time in the Treaties and included in the EU Strategy 2020, presented already in 2010.[686]

The GDPR does not provide for a clear definition of the interplay between privacy or the right to data protection and scientific research, but establishes a framework possibly in favour of the latter, by enabling the balancing of these two contrasting interests in various occasions.[687] The presumption of compatibility renders evident the loss of the centrality of informational consent in the data protection framework, which at the same time still protects the fundamental rights of the data subjects by including the data controller's duty to provide information according to Art. 14 GDPR and by providing the data subject with the right to object to the processing.[688]

The GDPR changed the equilibrium and counterbalanced the loss of participants' complete control over their use of their personal data by setting a regulatory system in which the data subject maintains control by retaining the possibility of always challenging the concrete processing implemented by the data controller.[689] In turn, the latter shall conduct the processing under the general obligation to always respect the essence of the right of data protection.[690] As a matter of example, independently of the legal basis adopted in the concrete processing, the data subject may always rely on the individual rights of Chapter 3 GDPR to build her personal identity.[691]

Therefore, at least in this context, the GDPR envisions a framework for informational self-determination which is radically different from the one traditional self-determination related to one's body.[692] Indeed, while for the latter, consent is the general rule, when it

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[686] Cippitani, Roberto "Il Trattamento dei Dati Genetici a Fini di Ricerca Scientifica." *Diritto e Processo*, 2018, pp. 95-133. The importance of data in this context has also been underlined by Recital 159 GDPR.

[687] This approach has been confirmed by the CJEU in the *Google Spain case* (C-131/12 Google Spain SL and Google Inc. v Agencia Española de Protección de Datos (AEPD) and Mario Costeja González).

[688] Rapisarda, Ilenia "Ricerca Scientifica e Circolazione dei Dati Personali. Verso il Definitivo Superamento del Paradigma Privatistico?".

[689] *Ibid*

[690] Vlahou, Antonia et al. "Data Sharing Under the General Data Protection Regulation: Time to Harmonize Law and Research Ethics?" *Hypertension*, vol. 77, n. 4, 2021, pp. 1029-1035; Maestri, Enrico "Il Feticcio della Privacy nella Sanità. Cura del Paziente e Biobanking Genetico Prima e Dopo L'entrata in Vigore del GDPR."

[691] Pelino, Enrico "I Diritti dell'Interessato." *Il Regolamento Privacy Europeo. Commentario alla Nuova Disciplina sulla Protezione dei Dati Personali*, edited by Pelino, Enrico, et al. Giuffrè Editore, 2016; Rapisarda, Ilenia "Ricerca Scientifica e Circolazione dei Dati Personali. Verso il Definitivo Superamento del Paradigma Privatistico?"; Ricci, Annarita "I Diritti dell'Interessato." *La Protezione dei Dati Personali in Italia. Regolamento UE N. 2016/679 e D.Lgs. 10 Agosto 2018, n. 101*, edited by Finocchiaro, Giusella, Zanichelli, pp. 392-472.

[692] Rapisarda, Ilenia "Ricerca Scientifica e Circolazione dei Dati Personali. Verso il Definitivo Superamento del Paradigma Privatistico?".

comes to the former, the data protection regulation considers it one of the various instruments for controlling the circulation of use of one's data and, therefore, safeguards the right to data protection.[693]

As highlighted by Rodotà, today the relationship between a person and her personal data may be explained in terms of "person-information-circulation-control" and not as "person-information-secrecy or privacy" anymore.[694] Differently from the previous approach that entitled the data subject essentially with the right to prevent intrusions on her right to privacy, nowadays the data subject retains the power to control the life-cycle of the data referred to her, not only by providing consent, whose importance in the system actually in place has been diminished, but especially with the right to be informed about the processing, control it (via the right to ask for rectification, data portability, etc), or interrupt it.[695] Moreover, the system envisioned by the GDPR constitutes a step away from the approach focused on the centrality of the individual towards one that includes also, and largely relies upon, duties and responsibilities of the data controller, according to the principle of accountability.[696]

7.2 THE CHOICE AT THE SUPRANATIONAL LEVEL – BETWEEN THE NECESSITY-BASED MODEL AND THE CONSENT-BASED MODEL

As mentioned, at the supranational level the biobank may freely choose the model for the collection of HBSs and biobank data, as there is no preference for informational consent in the GDPR.[697]

As it appears evident, the advantages of the consent-based model are primarily focused on the participants, who are greatly protected in their right to self-determination and autonomy by the possibility of choosing for which research projects their samples and

[693] Chieffi, Lorenzo "La Tutela della Riservatezza dei Dati Sensibili: le Nuove Frontiere Europee." *Federalismi.it,* vol. 4, 2018, pp. 1-52.
[694] Rodotà, Stefano *Tecnologie e Diritti.*
[695] Chieffi, Lorenzo "La Tutela della Riservatezza dei Dati Sensibili: le Nuove Frontiere Europee."
[696] Mollo, Francesca "Il Trattamento dei Dati Genetici tra Libera Circolazione e Tutela della Persona."; Comandè, Giovanni "Ricerca in Sanità e Data Protection: Un Puzzle…Risolvibile." *Rivista Italiana di Medicina Legale,* vol. 1, 2019, pp. 187-210.
[697] Among many others, Taddei Elmi "Art. 110." *Commentario al Codice della Privacy,* edited by Sciaudone, Riccardo, Pacini giuridica, 2023, pp. 326-339.

data might be used.[698] At least in the context of HBSs it has been highlighted that there is a "strong ethical rationale for obtaining donor consent for the future research use".[699]

Moreover, asking for consent helps protect participants from the imbalance of informational powers that inevitably permeates their relationship with the researchers. Indeed, while the former own all the technical information about the processing and the scientific project more generally, the latter are usually not provided with such information or do not have the competencies to fully understand them and their consequences.[700]

The consent-based model also presents some downsides. First of all, consent is not a viable option in cases where there is a clear concrete imbalance of power between the data subject and the controller because it might not be freely given and therefore not comply with one of the core characteristics of valid consent according to the GDPR. Such an imbalance might exist whenever a participant is in a poor health condition or in clinical trials where there is no other available therapeutic treatment.[701] Indeed, this might be particularly the case for the type of biobanks considered in this work, where samples and data are usually collected from subjects already affected by a given disease and whose hope of finding a treatment thanks to biobanking research might affect the voluntariness of their consent. In this case, consent would not meet the requirements of Art. 4 GDPR[702] because not freely given or not fully informed.

Moreover, in the context of biobanking research, a major downside is the possibility of withdrawals, provided by Art. 7(3) GDPR with no exceptions,[703] which might have serious consequences on the possibility of carrying on or concluding the research project.

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[698] Indeed, autonomy is widely considered the predominant rationale for informed consent. See Chen, Jiahong, et al. "Explicit Consent and Alternative Data Protection Processing Grounds for Health Research." *Research Handbook on EU Data Protection Edward Elgar Publishing*, edited by Kosta, Eleni, et al. Elgaronline, 2022, pp.474-502; Dove, Edward S., and Jiahong, Chen "Should Consent for Data Processing Be Privileged in Health Research? a Comparative Legal Analysis."

[699] Wiertz, Svenja, and Boldt, Joachim "Evaluating Models of Consent in Changing Health Research Environments." Medicine, Health Care and Philosophy, vol. 25, 2022, pp. 269-280.

[700] Chen, Jiahong, et al. "Explicit Consent and Alternative Data Protection Processing Grounds for Health Research."

[701] EDPS, Preliminary Opinion 8/2020 on the European Health Data Space, 2020; EDPB, Opinion 3/2019 Concerning the Questions and Answers on the Interplay Between the CTR and the GDPR, 2020.

[702] Schermer, Bart W., et al. "The crisis of Consent: How Stronger Legal Protection May Lead to Weaker Consent in Data Protection."

[703] Bernes, Alessandro "Dati e Ricerca Genetica. Dalla Tutela Individuale alla Gestione Procedurale." *BioLaw Journal,* vol. 1, 2022, pp. 67-82; Comandè, Giovanni "Ricerca in Sanità e Data Protection: Un Puzzle…Risolvibile.".

On the other hand, the main advantage of the necessity-based model is processing the biobank data being only slightly influenced by the (possibly changing) participants' will, both at the beginning of the processing and for its continuation, as well as for the subsequent research projects. Indeed, no consent is asked to start collecting the biobank data, and no withdrawals could prevent the research from proceeding further or being concluded. Therefore, the advantages of this model are focused on researchers and society as a whole.

Moreover, by adopting the necessity-based model, if the biobank qualifies as "scientific research" it may benefit from a privileged regime based on exemptions to some of the individual rights of the data subject as described above. A more relaxed privacy regime might result in an increased number of data processing activities for biobanking purposes and, therefore, greater advances in scientific research and, ultimately, public health. Here, the interests of scientific research and society at large are clearly preferred when balanced against those of the data subject,[704] provided that safeguards for the fundamental rights involved are adopted.

However, it has been pointed out that the scope of the possible exemptions, particularly for scientific research, is so wide it might render the research itself unethical and not in compliance with various European and international treaties or instruments, as well as research-related soft legal tools.[705] Indeed, if the research regime is applied to its full extent, the data subject could remain with very few instruments and rights, namely the right to receive information and the possibility of lodging a complaint with the data protection authority. According to the framework described above, the same might be said for processing conducted in the public interest, with possible negative consequences in both cases on participants' trust under the participation aspect. However, such an approach might contrast with the principle of transparency established by the GDPR and more generally with Art. 52(1) EU Charter. Therefore, even though the GDPR permits a wide range of exemptions, these should be applied for biobanking purposes and thus in actual processing activities in compliance with the general principles governing the matter.

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[704] Pormeister, Kärt "Genetic data and the Research Exemption: Is the GDPR Going Too Far." *International Data Privacy Law*, vol. 7, n, 2, 2017, pp. 137–146.

[705] Staunton, Ciara, et al. "The GDPR and the Research Exemption: Considerations on the Necessary Safeguards for Research Biobanks."

In particular, as mentioned, concerning the right to receive information, while theoretically the processing for scientific research purposes would still need to comply with Art. 13 and 14, these articles might not be applicable for left-over data in biobanking or more generally in case of secondary use, in particular because it might be impossible or constituting a disproportionate effort to recontact the participants.[706] In this eventuality, the data subject may not be aware at all of the processing of her data and consequently not have the knowledge necessary to exercise her rights.[707] This approach would seriously adversely diminish participants' trust, because the data subject would have little or no control over how her biobank data are used for research purposes or for purposes related to public health,[708] being left with the possibility of lodging a complaint as the sole instrument to this purpose. [709] However, this lack of information and control might endanger participants' trust in the researchers/physicians-participants/patients relationship and in biobanking in general.

Both models theoretically comply with the duty to protect and carefully balance the various rights and interests at stake in biobanking. Indeed, the GDPR clearly affirms its aim of not protecting the right to data protection as an absolute fundamental right, but considering it for its function in society, thus balancing it against "other fundamental rights, in accordance with the principle of proportionality" (Recital 4 GDPR). The other mentioned rights might well include the protection and enhancement of scientific research, as previously seen.

Indeed, the lawfulness of the scientific research regime, which permits exemptions more than other legal grounds for the processing of sensitive data, is in principle guaranteed by the provisions of the GDPR, as confirmed by the EDPS in its Preliminary Opinion on

[706] Pormeister, Kärt "Genetic data and the Research Exemption: Is the GDPR Going Too Far." While demonstrating that providing the information according to Art. 14 GDPR has been said to be particularly burdensome, it might be easier to assert that it would involve a disproportionate effort. See Staunton, Ciara "Individual Rights in Biobank Research Under the GDPR."

[707] Slokenberga, Santa "You Can't Put the Genie Back in the Bottle: on the Legal and Conceptual Understanding of Genetic Privacy in the Era of Personal Data Protection in Europe." *BioLaw Journal*, vol. 1, 2021, pp. 223-250. If the data subject is not informed about processing, it is very difficult to request further details and explore whether any violation could have occurred. Staunton, Ciara "Individual Rights in Biobank Research Under the GDPR"; Pormeister, Kärt "Genetic data and the Research Exemption: Is the GDPR Going Too Far."

[708] Pormeister, Kärt "Genetic data and the Research Exemption: Is the GDPR Going Too Far."

[709] Staunton, Ciara, et al. "The GDPR and the Research Exemption: Considerations on the Necessary Safeguards for Research Biobanks"; Staunton, Ciara "Individual Rights in Biobank Research Under the GDPR."

data protection and scientific research, where it is clearly affirmed that the scientific research regime complies with the principle of proportionality because of the existence of Art. 89(2) GDPR. Indeed, the latter ensures that exemptions to the rights of the data subject (in particular Art. 15, 16, 18 and 21, as mentioned) are applicable in so far as "such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes", which is an expression of the principle of proportionality required by Art. 52(1) EU Charter for lawfully restrict the right included by the latter.[710] Indeed, under Art. 89(2) GDPR the absence of informational consent is balanced by the establishment of a set of substantive and procedural (appropriate measures).

The same reasoning can be applied whenever the necessity-based model is chosen over the consent-based one. Indeed, processing sensitive data without the consent of the data subject and also applying the exemptions provided for thereby is in principle lawful, provided that adequate safety and organisational measures are adopted, in order to adequately protect the right to data protection and respect the principle of proportionality. Such an evaluation (i.e. respecting the proportionality of the concrete modalities of the processing) should be conducted on a case-by-case basis according to the characteristics of the given biobanking activity. However, in this regard, the trust test may represent a theoretical tool possibly useful to assess whether one model should be preferred over the other, all things considered and therefore having verified the lawfulness of the choice and that appropriate safeguards are in place.

Indeed, as mentioned giving participants control over their data is a way to improve their trust in the processing under the participation aspect, and for this reason, consent, and consequently the consent-based model, is usually considered an instrument to restore and maintain trust between researchers and participants.[711]

However, here, information on the true boundaries of this power should be clearly provided from the outset in order to prevent participants from having a false idea of the type of control they are entitled to. For instance, after withdrawal, the data controller may under certain conditions rely on a different legal basis and continue the processing. This

[710] On the duty to respect the principle of proportionality, also Cippitani, Roberto "Il Trattamento dei Dati Genetici A Fini di Ricerca Scientifica."

[711] Chen, Jiahong, et al. "Explicit Consent and Alternative Data Protection Processing Grounds for Health Research."

choice, albeit lawful according to the GDPR and perfectly legitimate, might decrease participants' trust, under both the participation and the transparency aspect, because it might provide the data subject with a false sense of control.[712] To solve the issue, Florea suggests providing more information to the data subject on the limits of her consent and its possible withdrawal.[713] However, on the contrary, I believe that this approach might, in some cases, decrease participants' trust in the consenting mechanism as a whole because it would render evident from the beginning that the processing might start or continue independently of the will of the data subject.

Differently from above, preserving trust in biobanking when the necessity-based model is adopted might be a more difficult task. In this case, participation by the data subjects in the activities of the biobank is decreased from the outset and exemptions to the duty to provide information are theoretically possible. As a consequence, in order to avoid possible negative impact on trust, the biobank should have in place a system for sharing information on the processing activities conducted with the biobank data, at least publicly (i.e. on a website), if providing it individually is impossible or excessively burdensome (information aspect of trust). Participants also need to be adequately informed about the other instruments at their disposal for managing the life cycle of the data related to them in order to feel somehow empowered and included in the biobank activities (participation aspect of trust).

Admittedly, this task is even more complicated in the case of secondary use of left-over HBSs and data, because here the identity of the data subject might be unknown from the outset. Providing publicly general information seems to be an appropriate measure to preserve public trust in the biobanking activities, but it may difficult be considered useful for preserving individual's trust. Therefore, the biobank needs to be aware that collecting data using the GDPR regime for secondary use might negatively affect participants' trust in the biobanking activities as a whole.

[712] Florea, Marcu "Withdrawal of Consent for Processing Personal Data in Biomedical Research"
[713] *Ibid*

7.3 THE CHOICE AT THE NATIONAL LEVEL - ALTERNATIVE MODELS FOR COLLECTING INFORMATIONAL CONSENT

At the national level, as mentioned, acquiring informational consent for scientific research seems to be the preferred ground for the processing of personal data when the purpose is related to scientific research[714] both as primary or secondary processing, or biobanking, thus differently from the approach adopted by the GDPR which does not include any hierarchy among the various legal bases in Art. 6 or exemptions 9 GDPR. In any case, informational consent may be chosen specifically by the data controller (Art. 6(1)(a) and Art. 9(2)(a)).

However, informational consent has been modelled from interventional consent or interventional research consent and their specificities.[715] For the latter types, it was, and still is, necessary to acquire *specific* consent, i.e. a consent fully informed on all the characteristics and risks of the medical intervention or the research project, because it aimed at protecting the physical integrity and self-determination of the person.[716] Indeed, both in cases of medical interventions or of scientific research on human subjects, the act for which the person has to provide consent directly affects her physical integrity, and thus, a careful evaluation of the concrete risks and benefits possibly associated with the specific intervention is necessary.[717]

However, through time, developments in how scientific research is conducted have changed, moving progressively away from the body of the person and towards the use of biological samples and, ultimately, data, with little or no impact on the physical integrity

[714] Fanni, Simona "Le Biobanche di Popolazione al Vaglio della Suprema Corte di Cassazione: Alcune Note Critiche sull'Ordinanza n. 27325 del 7 ottobre 2021"; Di Tano, Francesco "Protezione dei Dati Personali e Ricerca Scientifica: un Rapporto Controverso ma Necessario."

[715] Wiertz, Svenja "How to Design Consent for Health Data Research? An Analysis of Arguments of Solidarity." *Public Health Ethics*, 2023, pp. 1.10; Comandè, Giovanni, and Giulia, Schneider "Differential Data Protection Regimes in Data-Drive Research: Why the GDPR Is More Research-Friendly Than You Think."

[716] Bjerregaard Mikkelsen, Rasmus, et al. "Broad Consent for Biobanks Is Best – Provided It Is Also Deep." *BMC Medical Ethics*, vol. 20, n. 71, 2019.

[717] Wiertz, Svenja "How to Design Consent for Health Data Research? An Analysis of Arguments of Solidarity"; Paris, Chiara "Biobanche di Ricerca e Banca Dati Nazionale del DNA: Un Difficile Bilanciamento tra Interessi Contrapposti"; Hallinan, Dara, and Michael, Friedewald "Open Consent, Biobanking and Data Protection Law: Can Open Consent Be 'Informed' Under the Forthcoming Data Protection Regulation?"; Bjerregaard Mikkelsen, Rasmus, et al. "Broad Consent for Biobanks Is Best – Provided It Is Also Deep"; Hendriks, "Convention for the Protection of Human Rights and Dignity of the Juman Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine." *European Journal of Health Law*, vol. 4, n. 1, 1997, pp. 89-100.

of the person. This evolution challenged the traditional definition and modes for the collection of consent,[718] and brought along the necessity of adapting the standard requirements and procedures prescribed for traditional consent to the biobank one to acknowledge the specificities of the biobanking field. Indeed, as mentioned, the model adopted for the informational consent for biobanking should keep into consideration the ontological trait of biobanks as collections of HBSs and data for an undefined range of future research projects, which renders it particularly complex to meet the requirement of consent being both *specific* and *informed,*[719] and forces to re-think study-specific consent.[720]

Indeed, if applied to biobanking, the traditional form of specific consent would entail that a first consent should be asked to include the HBSs and biobank data in the biobank and that the participant should be recontacted to acquire a new consent every time the HBS of biobank data is used for a different research project.[721] This approach adopted in biobanking would be the result of an imbalanced balance between the rights of the participant and the interests of society at large. Indeed, in the context of medical interventions of scientific research on humans, specific consent is necessary because there is a certain degree of physical experimentation or direct impact on the physical integrity of the person,[722] and consequently asking consent for every intervention is meant to protect the right to self-determination of the person and her personal autonomy, declined as the right of an individual to determine "what shall be done with their body".[723] To respect the autonomy of an individual would mean to give her the possibility of choosing the degree of involvement in research, and to do so, it is necessary to provide her with adequate information about the research project itself.[724] However, in biobanking there is

[718] Kaye, Jane et al. "Dynamic Consent: a Patient Interface for Twenty-First Century Research Networks." *European Journal of Human Genetics: EJHG*, vol. 23, n. 2, 2015, pp. 141-6.
[719] Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context."
[720] Bjerregaard Mikkelsen, Rasmus, et al. "Broad Consent for Biobanks Is Best – Provided It Is Also Deep."
[721] Azzini, Sara, "Biobanche, Consenso e Fonti del Diritto: un Caso di Eccezionale Disordine?"
[722] Caulfield, Timothy "Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas." *Medical Law International*, vol. 10, 2009, pp. 85-100.
[723] Walker, Leslie, and Barbara, Blechner "Continuing Implementation of the Patient Self-Determination Act in Nursing Homes: Challenges, Opportunities, and Expectations." *Generations*, vol. XIV, 1995, pp. 73-77; Caulfield, Timothy "Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas."
[724] Elger, Bernice, and Arthur, Caplan "Consent and Anonymization in Research Involving Biobanks: Differing Terms and Norms Present Serious Barriers to an International Framework." *EMBO Reports*, vol. 7, n. 7, 2006, pp. 661-666.

little or no impact on the physical integrity of participants, and if any it is limited to the act of collecting the sample, which is permitted only if the participant provided interventional consent (as extensively explained in Part A).

On the contrary, biobanks and the research projects to be conducted, thanks to them, never involve the person as a body *per se*, but only either parts of it (i.e. the biological samples) or its digital representation (i.e. personal data). Consequently, the risks associated with biobanking scientific research changed as well, moving from physical risks to mainly informational ones.[725]

In the specific context of data-intensive research, the expansion of the border of research and the amount of data to be processed are "becoming structurally unsuitable with respect to the consent paradigm, designed for specific and "closed" research projects",[726] and therefore when applied to biobanks *specific consent* has been defined as unsuitable[727] as well, because of various reasons, both specific to biobanking and more general. The former derives from the very nature of biobanks as collections of samples and data for future research projects, undefined at the time of collection.[728] Indeed, biobanks have three general characteristics that make them different from normal medical interventions and clinical research, (1) their HBSs being possibly stored for hundreds of new projects per year; (2) their HBSs being stored for long periods of time; (3) the collection and storage of HBSs happening before the research comes into existence.[729] These characteristics make it almost impossible to provide participants with adequate information on the use of their samples at the time of collection.[730]

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[725] Bjerregaard Mikkelsen, Rasmus "Broad Consent for Biobanks is Best – Provided It Is Also Deep"; Meslin, Eric M., and Kimberly, Quaid. "Ethical Issues in the Collection, Storage, and Research Use of Human Biological Materials." *the Journal of Laboratory and Clinical Medicine*, vol. 144, n. 5, 2004, pp. 229-34; Wiertz, Svenja "How to Design Consent for Health Data Research? An Analysis of Arguments of Solidarity"; Caulfield, Timothy "Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas." However, it should be reminded here that the physical risk of the medical procedure itself is somewhat "covered" by the *interventional consent*, which is always asked.

[726] Metcalf, Jacob, and Crawford, Kate "Where Are Human Subjects in Big Data Research? the Emerging Ethics Divide." *Big Data and Society*, 2016, pp. 1-14.

[727] Hansson, Mats G., et al. "Should donors be allowed to give broad consent to future biobank research?" *Lancet Oncology*, vol. 7, 2006, pp. 266–269.

[728] Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context."

[729] Bjerregaard Mikkelsen, Rasmus, et al. "Broad Consent for Biobanks Is Best – Provided It Is Also Deep."

[730] Hofmann, Bjørn "Broadening Consent--And Diluting Ethics?" *Journal of Medical Ethics*, vol. 35, n. 2, 2009, pp. 125-129; Casado Da Rocha, Antonio, and José, Antonio Seoane "Alternative Consent Models for Biobanks: The New Spanish Law on Biomedical Research." *Bioethics*, vol. 22, n. 8, 2008, pp 440–447.

This might not comply with the requirement of consent being both *specific*, or *informed.* Indeed, it has been affirmed that "the stringent conditions of the traditional concept of consent in medical research stand in direct contradiction to the prospective collection approach" of biobanks.[731] Moreover, this type of consent might be excessively costly in the context of biobanks, because of the duty to continuously re-contact participants,[732] and thus disproportionately balanced in favour of the interests of participants. The protection of the interests of scientific research would depend entirely on both the willingness of the participant to provide consent and the practical ability and possibility of the biobank to re-contact the person,[733] also keeping in mind that asking for frequent re-consents might lead to consent fatigue or routinisation,[734] and thus decrease the level of patient participation.[735]

As a consequence, precisely because the great promises of research biobanks for society are possibly hindered by strict consent requirements,[736] possibly not justified because of the low level of physical risk involved,[737] different models of consent have been theorised, and adopted in some Member States,[738] both in the context of data-intensive research and

[731] Hallinan, Dara, and Michael, Friedewald "Open Consent, Biobanking and Data Protection Law: Can Open Consent Be 'Informed' Under the Forthcoming Data Protection Regulation?"

[732] Casado Da Rocha, Antonio, and Seoane, José Antonio, "Alternative Consent Models for Biobanks: The New Spanish Law on Biomedical Research, Bioethics." Indeed, it has been pointed out the costs of this procedure proportionally increase with the number of re-consenting being necessary. Grady, Christine et al. "Broad Consent for Research with Biological Samples: Workshop Conclusions." *the American journal of bioethics: AJOB,* vol. 15, n. 9, 2015, pp. 34-42; Helgesson, Gert "In Defense of Broad Consent." *Cambridge Quarterly of Healthcare Ethic: CQ: The international journal of healthcare ethics committees,* vol. 21, n. 1, 2012, pp. 40-50; Hofmann, Bjørn "Broadening Consent--And Diluting Ethics?"; Kaye, Jane et al. "Dynamic Consent: a Patient Interface for Twenty-First Century Research Networks."

[733] Indeed, it has been pointed out that many of the original participants might be difficult to be re-contacted. Elger, Bernice, and Arthur, Caplan "Consent and Anonymization in Research Involving Biobanks: Differing Terms and Norms Present Serious Barriers to an International Framework"; Knoppers, Bartha Maria et al. "Sampling Populations of Humans Across the World: ELSI Issues." *Annual Review of Genomics and Human Genetics*, vol. 13, 2012, pp. 395-413; Azzini, Sara, "Biobanche, Consenso e Fonti del Diritto: un Caso di Eccezionale Disordine?"; Hofmann, Bjørn "Broadening Consent--And Diluting Ethics?"

[734] Ploug, Thomas, and Søren, Holm, "Meta Consent: a Flexible and Autonomous Way of Obtaining Informed Consent for Secondary Research." *BMJ (Clinical research ed.),* vol. 350, 2015.

[735] Bjerregaard Mikkelsen, Rasmus, et al. "Broad Consent for Biobanks Is Best – Provided It Is Also Deep."

[736] Hansson, Mats G, et al. "Should donors be allowed to give broad consent to future biobank research?"

[737] Wiertz, Svenja "How to Design Consent for Health Data Research? An Analysis of Arguments of Solidarity"; Mascalzoni, Deborah, et al. "Informed Consent in the Genomics Era" *PLOS Medicine,* vol. 5, n. 9, 2008, pp. 1302-1305. the author here suggests that physical risks is more troublesome than informational risks and therefore is worth a greater level of protection, which justifies stricter consent requirements.

[738] Wiertz, Svenja, and Boldt, Joachim "Evaluating Models of Consent in Changing Health Research Environments."

biobanks. These models of consent are less informed than specific consent, but their development tries to find an acceptable level of information to be provided for consent.[739] Indeed, the new models for interventional biobank consent are based on the mentioned premises of the changed framework in which they are included.[740] Confirming this tendency, recently the European Data Protection Supervisor (EDPS) affirmed that new forms of consent in research activities are "promising practices that should be further encouraged and developed",[741] thus providing legitimacy for the abandonment of specific consent. These models have been identified originally for the collection of HBSs for biobanking purposes but may be applicable to data-driven research as well.

First of all, on the other side of the spectrum to *specific* consent are *presumed* consent, which when applied to biobanks entails storing left-over biological samples or data directly after the medical procedure or the primary use in general, without asking the patient and leaving the latter only with the possibility of opting out from certain uses of her HBSs,[742] and *blanket* consent, i.e. the authorisation from the participant to use her sample for an unlimited range of options, and has been suggested as a means to facilitate research.[743]

These types of consent can be understood as being the opposite of specific consent because it maximises the use of biological samples and personal data giving patients little or no control over them. According to Hallinan et al., in 2015 this was the "most prominently used of the novel forms of consent".[744]

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[739] Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context." Wiertz, Svenja, and Boldt, Joachim "Evaluating Models of Consent in Changing Health Research Environments."

[740] Other types of consent are tiered-consent and meta-consent, respectively proposed by Wolf, Leslie E, and Bernard, Lo. "Untapped Potential: IRB Guidance for the Ethical Research Use of Stored Biological Materials." *IRB*, vol. 26, n. 4, 2004, pp. 1-8, Nembaware, Victoria, et al., "A Framework for Tiered Informed Consent for Health Genomic Research in Africa." *Nature Genetics*, vol. 51, n. 11, pp. 1566-1571, and Ploug, Thomas, and Søren, Holm, "Meta Consent: a Flexible and Autonomous Way of Obtaining Informed Consent for Secondary Research, which are however specifications of various degrees of the broad consent. For an analysis on the point, see Bjerregaard Mikkelsen, Rasmus, et al. "Broad Consent for Biobanks Is Best – Provided It Is Also Deep." Furthermore, also the model of waived consent and verbal consent are sometimes identified. On the topic, Thompson, Rachel, and Michael J., McNamee. "Consent, Ethics and Genetic Biobanks: The Case of the Athlome Project." *BMC Genomics*, vol. 18, n.8, 2017, pp. 49-58.

[741] EDPS, a Preliminary Opinion on Data Protection and Scientific Research, 2020.

[742] Azzini, Sara "Biobanche, Consenso e Fonti del Diritto: un Caso di Eccezionale Disordine?"

[743] Hofmann, Bjørn "Broadening Consent--And Diluting Ethics?"; Paris, Chiara "Biobanche di Ricerca e Banca Dati Nazionale del DNA: un Difficile Bilanciamento tra Interessi Contrapposti."

[744] Hallinan, Dara, and Michael, Friedewald "Open Consent, Biobanking and Data Protection Law: Can Open Consent Be 'Informed' Under the Forthcoming Data Protection Regulation?"

This model of consent may be considered somewhat similar to the *opt-out* model (or *presumed* consent), where consent is presumed and participants are provided with the possibility of opting out from the use of their samples and data in a particular research project if they decide not to participate.[745] The difference between *presumed* consent and *blanket* consent is, therefore, that only in the latter model does the participant actually provide an active consent and make the choice in advance.[746]

Frequently proposed balanced alternatives[747] to both *specific* consent and *blanket* consent are *broad* consent,[748] and *dynamic* consent, the latter being frequently proposed as a solution for the issues identified in adopting the broad consent model. Both broad consent and dynamic consent will be analysed in detail in the following paragraphs.

Both in the case of broad consent and dynamic consent, some of the mentioned characteristics or opinions on the matter have been introduced on interventional biobank consent, and thus I will refer to them here with the necessary adjustments.

In order to establish the governance system, the biobank needs to choose among the main types of informational consent theoretically available and described above.

7.3.1 BROAD CONSENT MODEL

Broad consent enables participants to consent to a group or framework of future research projects of certain types,[749] not precisely described at the time of collection.[750] Various definitions of this type of consent have been provided for through time,[751] from "consent to a wide (broadly specified) range of options"[752] to consent to "an unspecified range of

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[745] Brothers, Kyle B., et al. "Patient Awareness and Approval for an Opt-Out Genomic Biorepository." *Personalized Medicine*, vol. 10, n. 4, 2013, p. 349-359.

[746] Hallinan, Dara, and Michael, Friedewald "Open Consent, Biobanking and Data Protection Law: Can Open Consent Be 'Informed' Under the Forthcoming Data Protection Regulation?"

[747] Hofmann, Bjørn "Broadening Consent-And Diluting Ethics?"; Hansson, Mats G, et al. "Should donors be allowed to give broad consent to future biobank research?"

[748] Admittedly, the line that divides *blanket consent* and *broad consent* is frequently blurred. For instance, Hallinan considers them as the same type of consent in Hallinan, Dara, and Michael, Friedewald "Open Consent, Biobanking and Data Protection Law: Can Open Consent Be 'Informed' Under the Forthcoming Data Protection Regulation?"

[749] Azzini, Sara, "Biobanche, Consenso e Fonti del Diritto: un Caso di Eccezionale Disordine?"

[750] Caulfield, Timothy "Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas"; Solum Steinsbekk, Kristin, et al. "Broad Consent Versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem?" *European Journal of Human Genetics,* vol. 21, 2013, pp. 897–902.

[751] For an overview of the various definitions, see Hallinan, Dara, and Michael, Friedewald "Open Consent, Biobanking and Data Protection Law: Can Open Consent Be 'Informed' Under the Forthcoming Data Protection Regulation?"

[752] Hofmann, Bjørn "Broadening Consent--And Diluting Ethics?"

future research subject to a few content and/or process restrictions".[753] The element shared by all the definitions is that consent is provided for multiple undefined uses of their samples at the same time but in a more narrow way than *blanket* consent.*[754]*

Differently from the other models, broad consent is not provided for any possible use of the HBSs or biobank data, but only for those that are included in certain categories described in the consent form.[755] In this case, the HBSs and personal data stored in the biobank can be used for research projects that fall within the scope of the consent previously obtained,[756] with re-consenting being necessary only if the framework changes, in order to comply with the requirement of consent being *informed.*[757] The premises for its applicability have been authoritatively identified in (1) the safety in the handling of personal information, (2) granting donors the right to withdraw consent; (3) approval of the new research projects by an ethics committee.[758]

While generally soft law instruments require specific consent to be provided, broad consent is envisioned for instance to collect interventional biobank consent by the Declaration of Taipei, which takes a novel approach to consent[759] and provides for two distinct types of interventional biobank consent. On the one hand, there is *specific* consent, that should be obtained according to the Declaration of Helsinki for specific research projects, which in principle does not directly apply in the case of biobanking for the reasons underlined above. On the other, the requirement for specificity may be derogated from, and thus the biological material may be stored in the biobank for future undefined research uses if the participant is adequately provided with the specific information listed in paragraph 12. Therefore, in this case, the Declaration of Taipei permits the use of *broad* consent and thus acknowledges the fact that HBSs may be stored for future research purposes, which are undefined at the time of the collection.[760]Similarly, the CIOMS International Ethics Guidelines provide that

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[753] Grady, Christine et al. "Broad Consent for Research with Biological Samples: Workshop Conclusions."
[754] *Ibid*
[755] Guidelines 11 of the CIOMS International Ethical Guidelines.
[756] Bjerregaard Mikkelsen, Rasmus, et al. "Broad Consent for Biobanks Is Best – Provided It Is Also Deep."
[757] Solum Steinsbekk, Kristin, et al. "Broad Consent Versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem?"
[758] Hansson, Mats G, et al. "Should donors be allowed to give broad consent to future biobank research?"
[759] Chassang, Gauthier, and Emmanuelle, Real-Sebbag "Research Biobanks and Health Databases: The WMA Declaration of Taipei, Added Value to European Legislation (Soft and Hard Law)."
[760] *Ibid*; Hallinan, Dara "Broad Consent Under the GDPR: an Optimistic Perspective on a Bright Future."

- Donated samples and personal data should be collected and stored with prior informed consent either *specific* or *broad*;
- Left-over samples and data can be stored for future research after prior *specific*, *broad* or *presumed* consent. However, informed *presumed* consent should fulfil specific conditions, such as (1) the patient needs to be aware of its existence; (2) sufficient information needs to be provided; (3) the patient needs to be informed of her right to withdraw consent; (4) the possibility of opting-out should be genuine.

Finally, the information to be provided in case broad informational biobank consent is asked is specifically listed in the Commentary on the Guideline 11 and includes information on the biobank itself, such as its purpose; the conditions and duration of storage; the ways in which the donor can remain informed about the future use of her samples; the rules of access to the biobank; foreseeable uses of the materials and data; the intended goal of such use, whether only for basic or applied research or also for commercial purposes.

Similarly, Recommendation R(2016)6 in Art. 11 addresses specifically interventional research consent as well as informational consent, i.e. "for storage for future research," thus authorising the use of broad consent.[761] When it comes to donated samples and data, Art. 11 paragraph 1 specifies that in order to be *informed* consent should be "i) specific to the intervention carried out to remove the materials or collect the data and ii) as precise as possible with regard to the envisaged research use". In this regard, it may be said that Recommendation R(2016)6 enables the possibility of asking for broad consent, precisely because it does not require consent to be specific on the future research projects in which the samples will be used. It seems reasonable to consider that the same could be said for left-over samples.

Such an alternative model applied in the context of data protection and the GDPR would imply a partial derogation from the principle of purpose limitation[762] and could in principle be applied to informational consent as well, under the condition that the provisions set forth in the GDPR are adequately complied with. Indeed, Recital 33 seems to support broad consent by establishing that "it is often not possible to fully identify the

[761] Hallinan, Dara "Broad Consent Under the GDPR: an Optimistic Perspective on a Bright Future."
[762] Comandè, Giovanni, and Giulia, Schneider "Differential Data Protection Regimes in Data-Drive Research: Why the GDPR Is More Research-Friendly Than You Think."

purpose of personal data processing for scientific research purposes at the time of data collection", as it happens in the biobanking field. Therefore, "data subjects should be allowed to consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to consent only to certain areas of research or part of research projects to the extent allowed by the intended purpose". This led some scholars to argue that "the agreed text permits broad consent".[763]

However, this interpretation was first challenged by the Guidelines on consent issued by the Article 29 Working Party, updated with minimal adjustments in 2020 by the EDPB in its Guidelines 05/2020 on consent under Regulation 2016/679, and by the EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, adopted in 2021. Indeed, on the one hand, the scope of applicability of Recital 33 was restricted by allowing descriptions of research projects on a more general level only if they cannot be specified at the outset.[764] On the other hand, the Guidelines ask the data controller to provide subsequent information on the research project as soon as it is available, thus *de facto* asking the data controller to re-contact the participants and eliminating one of the main advantages of adopting this model for consent.[765] Moreover, it is clearly stated that broad consent in cases of processing of sensitive categories of data should be subject to stricter scrutiny.[766] Therefore, in this context, the EDPB permits only the choice of asking for

[763] Rumbold, John Mark Michael, and Barbara, Pierscionek. "The Effect of the General Data Protection Regulation on Medical Research." *Journal of medical Internet research* vol. 19, n. 2, 2017. of the same idea, Hallinan, Dara "Broad Consent Under the GDPR: an Optimistic Perspective on a Bright Future."

[764] Article 29 Working Party, Guidelines on consent under Regulation 2016/679: "First, it should be noted that Recital 33 does not disapply the obligations with regard to the requirement of specific consent. This means that, in principle, scientific research projects can only include personal data on the basis of consent if they have a well-described purpose. For the cases where purposes for data processing within a scientific research project cannot be specified at the outset, Recital 33 allows as an exception that the purpose may be described at a more general level."

[765] Article 29 Working Party, Guidelines on consent under Regulation 2016/679, 2017 "When research purposes cannot be fully specified, a controller must seek other ways to ensure the essence of the consent requirements are served best, for example, to allow data subjects to consent for a research purpose in more general terms and for specific stages of a research project that are already known to take place at the outset. as the research advances, consent for subsequent steps in the project can be obtained before that next stage begins." For a critical interpretation of this approach and arguments in favour of the legitimacy of broad consent to data processing see Hallinan, Dara "Broad Consent Under the GDPR: an Optimistic Perspective on a Bright Future."

[766] EDPB Guidelines 05/2020 on consent under Regulation 2016/679, 2020.

broad *gradual* consent, where the purposes of the processing are specified gradually as soon as determined by the data controller.[767]

Notwithstanding the mentioned documents, some authors still believe in the theoretical applicability of the broad consent model to informational consent. Indeed, Hallinan clearly defends this opinion from three different perspectives.

According to the principled perspective, from a human rights perspective, informational consent enables the protection of the data subject's right to informational self-determination. In this regard, considering that restrictions to such a right are in principle undesirable, so should be restrictions to the way consent may be expressed. The author believes that the prospective benefit of research for society may well be adopted as a justification for this model for informational consent.[768]

According to the legal technical perspective, Hallinan suggests that a closer look at the possible ways of interpreting the Article 29 Working Party guidelines,[769] as well as a contextual reading of the document, reveals that no exclusion of broad consent from the GDPR is possible. Moreover, according to the author the EDPB "does not have the power to move against the express wishes of the legislator", who clearly wanted to admit the use of broad consent, as evident from the wording of Recital 33 GDPR.[770]

Finally, the practical perspective mainly focuses on the strong support of the scientific community in general to the use of such a model of consent for genomic research. [771]

It is interesting in this regard that the approach of the Italia DPA in the mentioned Opinion 238/2022 confirms the possibility of asking for granular broad consent in the context of biobanking while at the same time providing additional requirements for conducting scientific research. Indeed, the Italian DPA authorised the implementation of a biobank with the participants' initial broad consent for storing personal data for future undefined research purposes. However, the authority established that processing these data for a

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[767] Casonato, Carlo, and Marta, Tomasi "Diritti e Ricerca Biomedica: una Proposta Verso Nuove Consonanze." This approach has been adopted by the Italian DPA.

[768] Hallinan, Dara "Broad Consent Under the GDPR: an Optimistic Perspective on a Bright Future." Already in 2006 Hansson, Mats G, et al. "Should donors be allowed to give broad consent to future biobank research?"

[769] The wording of the Article 29 Working Party guidelines is the same as the one adopted by the EDPB.

[770] Hallinan, Dara *Feeding Biobanks with Genetic Data: What role can the General Data Protection Regulation play in the protection of genetic privacy in research biobanking in the European Union?,* PhD Thesis, Brussels: Vrije Universiteit Brussel, 2018; Hallinan, Dara "Broad Consent Under the GDPR: an Optimistic Perspective on a Bright Future."

[771] Hallinan, Dara "Broad Consent Under the GDPR: an Optimistic Perspective on a Bright Future"; Hansson, Mats G, et al. "Should donors be allowed to give broad consent to future biobank research?"

specific research project would not constitute *secondary use* for a purpose (specific scientific research project) compatible with the original one (general storage in a biobank for future research use). On the contrary, in that case, the Italian DPA asked for acquiring a new specific consent, or for the data controller to undergo the procedure of Art. 110 Italian Privacy Code whenever asking for consent was impossible or impracticable. In the reasoning of Opinion 238/2022, the requirements of consent necessary for its validity will be complied with progressively and as soon as further specifications are added to the research project. Only by asking for the "second" consent related to the specific research project would the biobank finally comply with the requirements of consent being specific and informed.[772]

More generally, various scholars have "widely defended"[773] broad consent as the appropriate alternative to specific consent for biobanking and health data research.[774]

The major criticism of broad consent is that it cannot be said to be informed, considering that most of the characteristics of future research projects at the time of consent are unspecified and to some extent unforeseeable, and therefore not known to participants.[775]

7.3.2 DYNAMIC CONSENT MODEL

As an alternative to both specific consent and broad consent, it is often proposed the so-called *dynamic* consent, because of the characteristics of this type of consent, which enables constant communication between the biobank, researchers and participants, and thus the possibility to adapt the information to be provided and the type of consent according to the specific use of personal data. Indeed, dynamic consent is used "to describe personalised, online consent and communication platforms (…) designed to achieve two objectives: 1) facilitate the consent process and 2) facilitate two-way,

[772]The same approach is adopted by the Italian DPA in Provvedimento 285/2023.

[773] Wiertz, Svenja, and Joachim, Boldt "Evaluating Models of Consent in Changing Health Research Environments."

[774] Among many others Bjerregaard Mikkelsen, Rasmus, et al. "Broad Consent for Biobanks Is Best – Provided It Is Also Deep."; Wiertz, Svenja, and Joachim, Boldt "Evaluating Models of Consent in Changing Health Research Environments."; Hansson, Mats G., et al. "Should donors be allowed to give broad consent to future biobank research?".

[775] Indeed, it is argued that "informed broad consent' to biobank research [is] a contradiction in terms. Caulfield, Timothy, et al. "DNA Databanks and Consent: a Suggested Policy Option Involving an Authorization Model." *BMC Medical Ethics,* vol. 4, n. 1, 2003, pp. 1-4; Hofmann, Björn "Broadening Consent--And Diluting Ethics?"; Hofmann, Björn "Consent to Biobank Research: One Size Fits All?" the *Ethics of Research Biobanking,* edited by Solbakk, Jan Helge, et al. Springer, 2009, pp 3-23; Wiertz, Svenja, and Joachim, Boldt "Evaluating Models of Consent in Changing Health Research Environments."

ongoing communication between researchers and research participants".[776] With the adoption of this model, consent becomes an ongoing process of communication between the biobank and the participant.[777] Indeed, the term was first coined in 2008 in the Ensuring Consent and Revocation project, whose aim was to enable participants to turn consent decisions on and off "as easily as turning on a tap".[778]

Such a model of consent might be implemented using a web-based communication platform, where, by way of example, software or tools may be used to explain the consent form to participants and answer possible questions, manage consent withdrawal, and finally to communicate research progress to participants in real-time.[779] Moreover, it can be used to enable research participants to use different types of consent for different research objectives and contexts,[780] or modify their consent preferences if some conditions of the research project change.[781]

Dynamic consent would also enable compliance with the EDPB's interpretation of Recital 33 GDPR, because researchers would be able to provide new information to the donors as soon as available, more suitably and cost-effectively, and with the approach adopted by the Italian DPA, since it would be possible to update the previously broad consent already asked as soon as specific information on the research project is available. This type of consent is said to provide "a personalised communication interface to enable greater participant engagement and places the participant at the centre of the decision-making process".[782] The platform so created may be used not only for providing

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[776] Budin-Ljøsne, Isabelle, et al. "Dynamic Consent: a Potential Solution to Some of the Challenges of Modern Biomedical Research." *BMC Medical Ethics*, vol. 18, n. 4, 2017, pp. 1-10; Fletcher, Ben et al. "Improving the Recruitment Activity of Clinicians in Randomised Controlled Trials: a Systematic Review." *BMJ Open*, vol. 2, n. 1, 2012, pp.1-14.

[777] Mascalzoni, Deborah, et al "Consenting in Population Genomics as an Open Communication Process, Studies in Ethics, Law and Technology." *Studies in Ethics, Law, and Technology*, vol. 3, n. 1, 2009, pp. 1-16.

[778] EnCoRe — Ensuring Consent and Revocation. the EnCoRe Project. 2008. https://www.hpl.hp.com/breweb/encoreproject/about.html. Lastly access 10th December 2023. Teare, Harriet J., et al. "Reflections on Dynamic Consent in Biomedical Research: The Story So Far." *European Journal of Human Genetics*, vol. 29, 2021, pp. 649-656.

[779] Kaye, Jane et al. "Dynamic Consent: a Patient Interface for Twenty-First Century Research Networks."

[780] Budin-Ljøsne, Isabelle, et al. "Dynamic Consent: a Potential Solution to Some of the Challenges of Modern Biomedical Research."

[781] van Zimmermen, Esther "8. Generating Trust in Biobanks within the Context of Commercialization: Can Dynamic Consent Overcome Trust Challenges?" *Global Genes, Local Concerns: Legal, Ethical, and Scientific Challenges in International Biobanking*, edited by Minssen, Timo and Jens, Schovsbo, Edward Elgar Publishing, 2019, pp. 130-155.

[782] van Zimmermen, Esther "8. Generating Trust in Biobanks within the Context of Commercialization: Can Dynamic Consent Overcome Trust Challenges?"; Budin-Ljøsne, Isabelle, et al. "Dynamic Consent: A Potential Solution to Some of the Challenges of Modern Biomedical Research."

informational consent but also for establishing and improving communication between those involved in the research project. Indeed, it may be used to give participants updates on the project, to ask for new data or information, to set up preferences for access to the information and samples provided, and to decide how often it occurs. In this regard, dynamic consent enables the creation of a personalised communication system for participants.[783]

Indeed, as well as broad consent, dynamic consent would facilitate scientific research and biobanking activities, but differently from that model it allows at the same time a more active patient participation,[784] by making it possible for researchers to regularly update participants about early findings, key outcomes, etc, and for participants to communicate with researchers and eventually among them.[785]

Therefore, overall, because of its characteristics and the possibility of protecting and enhancing both the interests of participants and researchers, it has been claimed that "the Dynamic consent model should be firmly embedded within the governance framework of the biobank and be instrumental for the framework" given that "Dynamic consent could play a major role in terms of allowing for differentiation in terms of consent processes and other trust challenges, tailoring them to the needs of local participants". So far, various research projects have implemented a dynamic-consent model, with positive results in terms of response and participation of the population,[786] and it appears that also the Istituto Superiore di Sanità in its Rapporto ISS Covid-19 n. 13/2020 opens on the possibility of adopting a dynamic consent model.

Three major general criticisms may be identified for dynamic consent. On the one hand, there is the possibility that participants experience consent fatigue, i.e. the fact that by being asked to provide an excessive amount of informational consent, the participants might not make truly informed decisions about them but simply being used to provide

[783] Budin-Ljøsne, Isabelle et al. "Genome Sequencing in Research Requires a New Approach to Consent." *Tidsskrift for Den Norske Laegeforening : Tidsskrift for Praktisk Medicin, Ny Raekke*, vol. 135, n. 22, 2015, pp. 2031-2032; Budin-Ljøsne, Isabelle, et al. "Dynamic Consent: a Potential Solution to Some of the Challenges of Modern Biomedical Research."

[784] van Zimmermen, Esther "8. Generating Trust in Biobanks within the Context of Commercialization: Can Dynamic Consent Overcome Trust Challenges?"

[785] Budin-Ljøsne, Isabelle, et al. "Dynamic Consent: A Potential Solution to Some of the Challenges of Modern Biomedical Research."

[786] On this, Teare, Harriet J. A., et al. "Reflections on Dynamic Consent in Biomedical Research: The Story So Far."

them.[787] However, studies conducted on the topic have found no evidence of the mentioned problem.[788]

On the other hand, it has been said to be excessively expensive to implement,[789] but I believe this might be a concrete and practical element not to be included in the theoretical evaluation of the admissibility and lawfulness of the model.[790]

Finally, adopting a dynamic consent model based on the digitalisation of the consent process may deepen the already existing digital divide.[791]

The dynamic consent model for informational consent has sometimes been adopted in research studies or biobank projects, such as the Italian-based CHRIS study, the RUDY (UK rare diseases) study and the Oxford-based SPRAINED study.[792]

7.3.3 CHOOSING AN ALTERNATIVE MODEL FOR COLLECTING INFORMATIONAL CONSENT FOR BIOBANKING

The following analysis is devoted to understanding whether it is feasible to ask for informational consent adopting a model different from the traditional specific one. While concretely relevant to the European framework for data protection, this study is however merely theoretically applicable in the national one. Indeed, as previously highlighted, the Italian legislator, as well as the Italian DPA, always requires *specific* informational consent. The only exemption to this general rule is the case of scientific research, for which it is possible to acquire broad informational consent, provided that a new specific consent is asked as soon as the new information on the specific research project is available.

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[787] Grady, Christine, et al. "Broad Consent for Research with Biological Samples: Workshop Conclusions".

[788] Muller, Sam, et al. "Dynamic Consent, Communication and Return of Results in Large-Scale Health Data Reuse: Survey of Public Preferences." *Digital Health*, vol. 9, 2023 pp. 1-14; Mascalzoni, Deborah, et al. "Ten Years of Dynamic Consent in the CHRIS Study: Informed Consent as a Dynamic Process." *European Journal of Human Genetics: EJHG*, vol. 30, n. 12, 2022, pp. 1391-1397; Solum Steinsbekk, Kristin, et al. "Broad Consent Versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem?"; Kaye, Jane et al. "Dynamic Consent: a Patient Interface for Twenty-First Century Research Networks."; Teare, Harriet J., et al. "Reflections on Dynamic Consent in Biomedical Research: The Story So Far.".

[789] Steinsbekk, Kristin Solum et al. "Broad Consent Versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem?".

[790] At the same time, Wiertz and Boldt point out the administrative advantages of adopting the model, such as the comparatively low time consumed for the collection of the consent models, low costs of maintenance in the long run, etc. Wiertz, Svenja, and Joachim, Boldt "Evaluating Models of Consent in Changing Health Research Environments."

[791] Prictor, Megan, et al. "Equitable Participation in Biobanks: The Risks and Benefits of a "Dynamic Consent" Approach." *Frontiers in public health*, vol. 6, n. 253, 2018, pp. 1-6.

[792] Teare, Harriet J., et al. "Reflections on Dynamic Consent in Biomedical Research: The Story So Far.".

However, according to the legal framework for the processing of personal data envisioned by the GDPR, acquiring informational consent is "not a necessity" for the lawfulness of the processing.[793] Indeed, the GDPR envisioned a legal regime that provides for various possible legal bases (Art. 6) and exemptions (Art. 9) among which it is possible to (almost) freely choose, and numerous exemptions to some of its core principles.[794] Nor is informational consent specifically required for the lawfulness of processing personal data according to any of the mentioned articles devoted to the protection of the participant's right to data protection.

In this sense, as it has been authoritatively highlighted, "informed consent is an instrument", not "a value *per se*".[795] and what it needs to be established in order to evaluate whether a less specific consent (such as broad consent or dynamic consent) may be legitimate is (a) whether the information about the specific project may have an impact on the external image of the participants, and therefore on her informational identity, and in case of positive answer (b) whether providing informational specific consent is necessary for protecting her right to informational self-determination or the other instruments at her disposal according to the GDPR are sufficient.

(a) To understand the first question, the two parts of the right to data protection should be considered. In this regard, the information on the specific research project is not important if the passive side of the right is considered (Art. 8 paragraph 1 EU Charter), given that this information does not change the risk of intrusion and unlawful use of the data that Art. 8 paragraph 1 intends to protect against.[796] This reasoning is particularly relevant for informational consent in biobanking, because in this case the risks are primarily related to the functioning of the biobank itself and on the safety measures, as well as criteria for granting access to the data, adopted.

However, concerning the active side of the right to data protection (Art. 8 EU Charter), according to Macilotti the information about the specific research projects might have an impact on the external image of the data subject and therefore the latter might have an

[793] Raichel, Jane "Allocating of Regulatory Responsibilities: Who Will Balance Individual Rights, the Public Interest and Biobank Research Under the GDPR?"
[794] Comandè, Giovanni, and Giulia, Schneider "Differential Data Protection Regimes in Data-Drive Research: Why the GDPR Is More Research-Friendly Than You Think."
[795] Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context."
[796] Macilotti, Matteo "Informed Consent in the Biobanking Context."

interest worth of protection in controlling the use of her data, and therefore providing informational consent, to this end.[797]

(b) However, under the GDPR as previously mentioned, the right to data protection may be exercised with and protected by various instruments at the disposal of the data subject, and provided for by the GDPR, among which informational consent is merely one. Indeed, the control of the data subject over her data may be still exercised via the right to receive information on the processing (Art. 13 and 14 GDPR), the right to access the stored biobank data (Art. 15 GDPR), the right to rectification (Art. 16 GDPR), the right to obtain the erasure of her data (Art. 17 GDPR), the right to restrict the processing (Art. 18 GDPR), the right to data portability (Art. 20 GDPR), the right to object to the processing (Art. 21 GDPR) and ultimately the right to withdraw informational consent at any time, thus prohibiting the further processing of her data.[798] As a consequence, considering that the right to data protection is not exclusively protected by the possibility of providing informational consent, but by a bundle of rights and principles established by the GDPR, it appears possible to resort to less stringent forms of informational consent, especially if acquired in the context of scientific research (as in the Italian legal system), which is autonomously lawful of protection.

The same line of reasoning may be adopted in conducting the trust-test. In particular, less stringent forms of informational consent still protect the participatory aspect of trust, considering that they enable an active participation and choice of the participants in the biobanking activities especially when coupled with the other mentioned rights, and the transparency aspect of trust, under the condition of coupling it with an adequate system for providing informational about the specific research projects, about the other rights at the disposal of the participant for controlling the use of her biobank data, and the possible consequences of the exercise of the right to withdraw it.

According to some scholars, the broad consent model might not sufficiently protect the informational self-determination of participants[799] or provide them with an adequate level

[797] *Ibid.* The author however expressed his opinion when the previous Directive 95/46/CE was in force.

[798] For a comprehensive overview of the individual rights of the data subject in the framework provided for by the GDPR and particularly in biobanking, see Staunton, Ciara "Individual Rights in Biobank Research Under the GDPR." In particular, it is important here to underline that whenever consent is withdrawn, the data subject has also the right to ask for the erasure of the related data, but that usually this is not considered as an automatic consequence of the withdrawn.

[799] Hofmann, Bjørn "Broadening Consent-And Diluting Ethics?".

of control over the use of their data.[800] However, according to Wiertz and Boldt, broad consent might at the same time respect the informational self-determination and trust of participants if accompanied by "contextual changes", such as regular updates, publicly available information on the scientific research projects that process the biobank data, etc,[801] in line with the double nature of the right to data protection described above. Moreover, other guarantees that are not envisioned by the GDPR but frequently suggested by scholars relate to the ethical evaluation by an Ethics Committee of the biobanking activities, and especially of the approval of the research projects to enable access to the biobank consent.[802]

Being somewhat in between specific consent and broad consent, dynamic consent mostly shared the same considerations now provided for broad consent. However, this model for informational consent may more greatly protect, or enhance, participants' trust by creating a system of ongoing communication and active engagement in the biobanking activities.[803] Moreover, as it has been rightly pointed out, much of the evaluation of the dynamic consent model depends on the specific implementation of the platform in each situation.[804]

Indeed, I believe that after having established the theoretical legitimacy of asking for "less informed informational consent", the concrete choice of the one to be adopted depends on the given concrete circumstances in which the biobank is created. Therefore, there might be cases in which broad consent is the only viable alternative (for instance in cases where implementing the IT system for dynamic consent is excessively expensive or otherwise impossible or would increment an already existing important digital divide of the specific population from which samples and data are collected) and others in which the contrary is true.

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[800] Caulfield, Timothy "Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas.".

[801] Wiertz, Svenja, and Joachim, Boldt "Evaluating Models of Consent in Changing Health Research Environments."

[802] Among many others Fanni, Simona *La Donazione dei Materiali Biologici Umani ai Fini della Ricerca Biomedica nell'Ambito del Diritto Internazionale e del Diritto dell'Unione Europea.* The involvement of Ethics Committees in biobanking is also suggested by

[803] Prictor, Megan, et al. "Equitable Participation in Biobanks: The Risks and Benefits of a "Dynamic Consent" Approach."; Wiertz, Svenja, and Joachim, Boldt "Evaluating Models of Consent in Changing Health Research Environments."; Dankar, Fida K., et al. "Informed Consent in Biomedical Research.".

[804] Wiertz, Svenja, and Joachim, Boldt "Evaluating Models of Consent in Changing Health Research Environments.".

7.3.4 AN ALTERNATIVE SOLUTION – SPECIFIC INFORMATIONAL CONSENT FOR BIOBANKING

I suggest here that a possible solution to this problem might derive from trying to ontologically and legally separate biobanking and scientific research (understood as "research project"), as already mentioned above. In particular, I believe in the benefits of not qualifying biobanking as a "research project with specific peculiarities", but as a different way of conducting scientific research or of rendering traditional scientific research possible. This way, it may be feasible under given circumstances to ask for specific informational consent, if understood as consenting to a specific and detailed biobank governance.[805]

Indeed, any biobank needs to have in place a governance system for the organisation of the biobank itself, the measures for the collection and storage of the samples and data, safeguards for ensuring the quality and safety of its content, and (more importantly for our purposes) the criteria for granting researchers with access to its content, in terms of type of research and researchers, method for its conduction, requirements for the scientific project to be considered valid, etc.

Consequently, at the moment of the collection of the HBSs and the personal data, the biobank might provide detailed information on its governance and its functioning, and in particular on the types of research that will be conducted with the collected content, thus acquiring a consent informed enough to be specific.

Further information on the specific project might be then provided by the researcher in compliance with her duty according to Art. 13 or 14 GDPR, throughout the whole period of storage of the samples and data in the biobank.

Indeed, as mentioned, the very existence of informational consent depends on the rights and interests it aims at protecting, and more importantly the lawfulness of models for its collection different from the traditional specific informed consent should be assessed by

[805] Melham, Karen, et al. "The Evolution of Withdrawal: Negotiating Research Relationships in Biobanking"; Rapisarda, Ilenia "Brevi Note sullo Statuto Giuridico del Materiale Biologico Umano." Morresi also refers to this conceptualisation of consent as "consent to a specific biobank charter of intent or ethical charter". Morresi, Assuntina "L'Accesso al Materiale Biologico. Il Consenso: Requisiti e Divieto di Corrispettivo."

evaluating whether the amount and type of information provided are appropriate to that end.[806]

This approach may contrast with that of the Italian DPA provided above, where the only flexibility about informational consent was to collect it gradually but considering that the information on the specific research project was necessary for the informational consent to be truly specific and valid.

However, as already mentioned, I believe it is possible to link this approach to informational consent to the more general qualification of biobank processing as scientific research processing.

Indeed, if biobanking (i.e. the collection of HBSs and personal data to be stored in a biobank for future research use) is qualified as "scientific research" for the purposes of the GDPR or otherwise, the informational consent to be provided should be *specific* on *scientific research*, and therefore not only on the functioning of the biobank, but also the future research projects, because the two moments represent a unicum.

On the contrary, if biobanking is not considered equivalent to a scientific research project (not even within the meaning of the GDPR), but as a separate type of processing with autonomous characteristics, such as for instance to enable future research projects, the informational consent to be provided should be informed on the characteristics of the specific processing concerned and therefore merely as specific as possible on the functioning of the biobank, the chosen criteria for the selection of the projects to which permit access, etc.

The approach so described would avoid resorting to novel models of informational consent to adapt requirements provided for scientific research projects, to an activity in which there is (yet) no project at all, in the traditional sense, while at the same time complying with the legal framework described in this Part B. This would be particularly useful for Italian biobanks, for which asking for informational consent is the standard unless exemptions are applicable in a given case.

Conceptualised in this way, this model for acquiring consent would also not impact negatively on participants' trust, given that adequate information is provided on the processing (i.e. biobanking) and further information would be provided as soon as available (transparency aspect), and participants would still have a high degree of control

[806] Macilotti, Matteo "Reshaping Informed Consent in the Biobanking Context."

over the use of their HBSs and data by providing consent and possibly exercising any of the rights recognised by the GDPR (participatory aspect).

However, the proposed approach, as mentioned, is in direct contact with that of the Italian DPA, and therefore its adoption should be carefully evaluated, especially in the light of the concrete characteristics of the biobanking processing to be conducted and prioritising the protection of the fundamental rights of the participants involved, however carefully balanced against the interests of society in conducting scientific research.

8 THE DGA AND THE EHDS

I will now provide an overview of two relatively new regulations applicable to the processing of personal data, possibly also in the field of biobanking: Regulation 2022/868, the so-called Data Governance Act (DGA), and Proposal for a Regulation on the European Health Data Space (EHDS).

These legal instruments might on the one hand change the possible approach of biobanks to the processing of HBSs and biobank data for future scientific research project, and on the other are examples of the contemporary approach to the right to data protection.[807]

As mentioned, the aim of both regulations is to increase trust in data sharing and give data subjects control over personal data, and many of provisions included therein are (at least possibly) applicable to biobanking. The analysis will be conducted on each legal instrument separately, before attempting at evaluating their impact on the conceptualisation of the participant's right to data protection and its possible balance against other protected fundamental interests.

8.1 DATA GOVERNANCE ACT

The aim of the DGA is to provide a framework to enhance trust in voluntary data sharing by promoting the re-use of publicly held data, increasing trust in the newly introduced data intermediation services,[808] and encouraging the sharing of data for altruistic

[807] Scagliarini, Simone "La Tutela della Privacy e dell'identità Personale nel Quadro dell'evoluzione Tecnologica.".

[808] According to Art. 2(11) a data intermediation service is "a service which aims to establish commercial relationships for the purposes of data sharing between an undetermined number of data subjects and health data holders on the one hand and health data users on the other (…)."

purposes. In particular, relevant to this analysis is the introduction of the concept of *data altruism*, aimed at facilitating data subject's control over their data.[809]

The DGA defines data altruism in Art. 2(16) as "the *voluntary* sharing *on the basis of the consent of data subjects* to process personal data pertaining to the (…) *without seeking or receiving a reward* that goes beyond compensation related to the costs that they incur where they make their data available *for objectives of general interest* as provided for in national law, where applicable, *such as healthcare* (…) or *scientific research purposes in the general interest*" (emphasis added).[810]

The data altruism mechanism thus seems to open up to the possibility of using a broad consent model, at least for research purposes. However, it relies on consent within the meaning of Art. 6(1)(a) and Art. 9(2)(a) GDPR,[811] and it is explicitly states that the DGA does not provide for an additional legal ground within the meaning of the GDPR.[812] Therefore, in case of conflict, the latter shall prevail (Recital 4 DGA), and consequently, the issues of the interpretation of Recital 33 GDPR remain.[813]

It would thus be by providing consent that the data subjects would manifest their intention of sharing their data on a voluntary basis for purposes of general interest, such as healthcare or scientific research, and in this regard in their Joint Opinion 03/2021, the EDPB and EDPS clarify that the GDPR still applies when the data subject has given consent to the data altruism organisation.[814] However, it has not been clearly defined whether the data altruism consent mechanism constitutes an alternative model of consent or another requirement for the lawfulness of sharing personal data.[815]

To this end, a European data altruism consent form will be developed, i.e. a uniform format for collecting consent to provide uniformity throughout Europe, created by adopting a modular approach that permits customisation for specific sectors and different

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[809] Re Ferrè, Giulia "Data Donation and Data Altruism to Face Algorithmic Bias for an Inclusive Digital Healthcare." *BioLaw Journal*, n. 1, 2023, pp. 116-131.

[810] Data altruism is also applicable to non-personal data. However, I will focus only on personal data, being the latter the majority of the data to be included in a biobank and used for research purposes.

[811] Recital 50 DGA.

[812] Bincoletto, Giorgia "Scientific Research Processing Health Data in the European Union: Data Protection Regime vs. Open Data."

[813] *Ibid*

[814] EDPB-EDPS, Joint Opinion 03/2021 on the Proposal for a regulation of the European Parliament and of the Council of European data governance (Data Governance Act), 2021.

[815] Vardanyan, Lusine, and Hovsep, Kocharyan, "The GDPR and the DGA Proposal: Are They in Controversial Relationship?" *European Studies*, vol. 9, n. 1, 2022, pp. 91-109.

purposes.[816] In the idea of the DGA, adopting a uniform format for data altruism would contribute to additional transparency for data subjects and would therefore ultimately increase their trust in the process (Recital 52).

The data altruism consent forms are then collected by the data altruism consent organisations, which can then make these data available to health data users for the purposes of general interest specified by the data subject while providing consent.[817] In order to be recognised as *data altruism consent organisations*, it is compulsory to register in a public national register upon compliance with specific requirements, primarily related to transparency and intended to increase and maintain the trust of the people and entities involved in the correct handling of the consent forms and data, further analysed in the next paragraph.

As also established by the GDPR for consent to data processing, data subjects can always withdraw consent from a specific data processing operation.

The main issues of the data altruism mechanism are related to the lack of definitions of some fundamental concepts included in Art. 2(16) DGA. In particular, the DGA explicitly establishes that the data made available with the data altruism consent should be used for *objectives of general interest* among which *scientific research for the general interest* is explicitly included, without providing for a clear definition of these concepts.[818] This, in turn, might lead to differences in the interpretation of the concept and an increased lack of harmonisation, especially considering that the GDPR frequently uses the adjective public when referring to interest instead of *general.*[819]

However, the DGA and the GDPR are closely linked to one another,[820] and frequently the former makes reference to the definition and requirements of the latter. Therefore, it appears safe to establish that the same applies for what can be considered *scientific research.* Even though, as mentioned, a clear definition is not provided for by the GDPR

[816] Art. 25 DGA.
[817] Art. 21 DGA.
[818] Bincoletto, Giorgia "Scientific Research Processing Health Data in the European Union: Data Protection Regime vs. Open Data."
[819] Shabani, Masha and Sami, Yilmaz "Lawfulness in Secondary Use of Health Data – Interplay Between Three Regulatory Frameworks of GDPR, DGA EHDS."
[820] Kruesz, Corina, and Felix, Zopf. "The Concept of Data Altruism of the Draft DGA and the GDPR: Inconsistencies and Why a Regulatory Sandbox Model May Facilitate Data Sharing in the EU." *European Data Protection Law Review (EDPL)*, vol. 7, no. 4, 2021, pp. 569-579.

either, the interpretation of the concept in that framework may be used for the implementation of the DGA as well.

8.1.1 SPECIFICITIES OF THE DGA SYSTEM FOR DATA ALTRUISM

Some aspects explicitly included in the DGA are worth further commenting on (1) the nature and obligations of the data altruism organisations, (2) the information requirements, and (3) the adoption of a uniform consent model.

(1) As mentioned, in order to register as data altruism organisation Chapter IV of the DGA establishes an official registration system composed of (a) requirements to be complied with for registering, and (b) transparency obligation

(1.a) The requirements provided for by the DGA to register are listed in Art. 18 and in particular these entities should:

- Carry out data altruism activities;
- Be a legal person established pursuant to national law to meet objectives of general interest as provided for in national law, where applicable;
- Operate on a not-for profit basis and be legally independent from any entity that operates on a for-profit basis;
- Carry out its data altruism activities through a structure that is functionally separate from its other activities;
- Comply with the rulebook referred to Article 22(1) and adopted by the Commission laying down information requirements to be provided to the data subject before the data altruism consent, technical and security requirements, etc.

If an entity complies with all the listed requirements, an application to be recognised may be submitted (Art. 19) and, in order to meet the transparency requirements of the system established by the DGA, the recognised data altruism organisations are then included in a public national register. The registration obtained in a Member State is valid across the Union, with the aim of facilitating cross-border data use (Recital 46).

From the moment of registration, the data altruism organisations should comply with a set of requirements established by the DGA, devoted to enhancing transparency and trust in the processing of the data made available for altruistic purposes, which should serve an objective of general interest.

Indeed, according to the DGA the organisations shall only refrain from making the data available for purposes other than the general interest.[821]

(2) Moreover, Art. 20-22 establish the transparency obligations that the data altruism organisations should comply with in order to ensure that the data subject is aware of how her data are being used and by whom.[822] Once again, these obligations are designed to increase data subjects' trust in the data organisations' activities.

In particular, Art. 20 lists the information that the data altruism organisation should keep record of, which is information about the processing, such as who got access to the data, the date or duration of the processing, the purpose of the processing, as well as fees eventually paid. Moreover, the organisation should transmit to the competent authority an annual activity report which includes in particular information about the activity of the organisation and a description of the way in which the objectives of general interest for which data was collected have been promoted, and a summary of the results of the data processing allowed.

Moreover, Art. 21 establishes the obligations that the data altruism organisation should comply with in order to safeguard the rights and interests of the data subject. In particular, paragraph 1 is devoted to the obligation to provide information to the data subject, related to (a) the objectives of general interest and, if applicable, the specified, explicit and legitimate purpose for which personal data is to be processed, and for which it permits the processing of their data by a health data user; (b) the location of and the objectives of general interest for which it permits any processing carried out in a third country. It is a general obligation of the data altruism organisation not to allow the processing of personal data for purposes other than those consented to by the data subject.

In this regard, it is not entirely clear from the text of the regulations how these provisions interact with the rights of the data subjects provided for by the GDPR and in particular Art. 20-22 and the possible exemption from the information requirements of Art. 13 and 14. However, the DGA clearly states that its norms are without prejudice to those of the GDPR and do not amend "the information requirements laid down in Regulation (EU)

[821] See to this end Art. 18(d) and Art. 21 DGA. Lalova-Spinks, Teodora, et al. "The Application of Data Altruism in Clinical Research Through Empirical and Legal Analysis Lenses."

[822] See in particular Art. 20-22 DGA. Kruesz, Corina, and Felix, Zopf "The Concept of Data Altruism of the Draft DGA and the GDPR: Inconsistencies and Why a Regulatory Sandbox Model May Facilitate Data Sharing in the EU."

2016/679" (Recital 4 and Art. 1(3)). Therefore, the joint applicability of the GDPR's and DGA's provisions on the information requirements seems plausible both from a textual and teleological point of view.[823]

(3) The DGA intends to increase harmonisation by adopting a uniform data altruism consent model, which in turn will increase the possibilities of sharing data within the EU[824] and among biobanks to conduct scientific research for the general interest. Moreover, uniformity of the consent format might increase their understandability and transparency (Recital 39). To this end, however, the DGA does not establish any requirements to ensure the achievement of this objective effectively.

8.1.2 APPLYING THE DGA'S DATA ALTRUISM MECHANISM TO BIOBANKS

The mechanism so described resembles to some extent the functioning of a biobank, in the terms described above, especially in Scenario 1 – collection for biobanking purposes. Indeed, in this case, biobanks receive donated data from participants in various ways and have a system in place to grant access to them to researchers to conduct scientific projects. However, the DGA's scheme might be applied in the other two Scenarios as well, provided that the data altruism consent is asked directly to participants.

Therefore, at least theoretically, the framework provided for by the DGA may be applicable to biobanking, and biobanks themselves, or the entity that operationalises them, may register as data altruism organisations and handle altruistically shared personal data for biobanking purposes.

In this sense, the possible purposes for the processing of the altruistically shared biobank data may well be scientific research in the general interest. To this end, the biobank would need to provide access to the personal data altruistically shared only to scientific research projects that are conducted in the general interest.

Applying the DGA's data altruism mechanism to biobanks brings some technical and legal challenges.

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[823] Kruesz, Corina, and Felix, Zopf "The Concept of Data Altruism of the Draft DGA and the GDPR: Inconsistencies and Why a Regulatory Sandbox Model May Facilitate Data Sharing in the EU."

[824] Vardanyan, Lusine and Kocharyan, Hovsep "The GDPR and the DGA Proposal: are They in Controversial Relationship?"; Shabani, Mahsa "The Data Governance Act and the EU's Move Towards Facilitating Data Sharing." *Molecular Systems Biology*, vol. 17, n. 3, 2021, pp. 1-3.

In particular, in order to register as a data altruism organisation, the biobank shall have a not-for-profit nature, and issues arise on how to operationalise the concept of data altruism in practice[825]. For instance, according to the specificities of the concrete case under consideration, data altruism organisations may qualify as either data controller or data processor (or joint controller/processor), and therefore be obliged to comply with the respective duties and obligations.[826]

Moreover, and under a more general perspective, the issue of *secondary use* of the biobank data contrasts with some of the provisions of the DGA, such as for instance the duty of the data altruism organisations not to use the shared data for other objectives than those of general interest for which the data subject or data holder allows the processing.

However, apart from the difficulties of harmonisation between regulations and of general application of the DGA, this regulation is important for our discussion because it provides an example of processing personal data for purposes of public interest via a system that foresees the existence of an intermediate entity devoted to ensuring that personal data are processed for the public good. At the same time the trust of the data subjects who provided the data is preserved mainly by imposing duties of transparency on such an entity.

I believe that registering as data altruism organisations might be highly beneficial for biobanks, even though the actual consequences of the system provided for by the DGA are to be monitored over time. However, even if not directly applied, the mechanism envisioned by the DGA might be reproduced by the biobank in taking the relevant decision on the models for collecting HBSs and biobank data and ultimately setting its governance. Indeed, the DGA's requirements on the provision of information and transparency to be complied with by the data subject are devoted to increasing participant's trust in the activities of the organisation (*rectious*, biobank), thus addressing the transparency aspect of trust, and the inclusion of the consent mechanism alongside the right to withdraw it at any time, reinforce the participation aspect.

[825] Lalova-Spinks, Teodora, et al. "The Application of Data Altruism in Clinical Research Through Empirical and Legal Analysis Lenses"; Kruesz, Corina, and Felix, Zopf. "The Concept of Data Altruism of the Draft DGA and the GDPR: Inconsistencies and Why a Regulatory Sandbox Model May Facilitate Data Sharing in the EU."

[826] Recital 50. On this, see Kruesz, Corina, and Felix, Zopf. "The Concept of Data Altruism of the Draft DGA and the GDPR: Inconsistencies and Why a Regulatory Sandbox Model May Facilitate Data Sharing in the EU."

8.2 THE EUROPEAN HEALTH DATA SPACE

The EHDS is a health-sector specific regulatory proposal and the first proposal of a domain-specific common European space.[827] As a sector-specific legislation, it builds upon other horizontal relevant regulations such as the GDPR and the DGA,[828] which together contribute to the new "scientific research regime 2.0".[829]

The EHDS applies exclusively to *electronic* health data, both personal and non-personal (Art. 2(2)(c)), and it aims at regulating primary[830] and secondary uses of electronic health data, i.e. processing to support among others health research and innovation, personalised medicine, while at the same time protecting the data subjects' rights in the context of health data sharing.[831] Provisions of Chapter IV EHDS related to the secondary use of health data may be relevant for biobanks and will be further discussed.

It is worth underlying from the beginning that within the legal framework created by the EHDS the permitted *secondary processing* activities of electronic health data are listed in Art. 34 and the prohibited ones in Art. 35. The data to be processed for these purposes may be collected for EHDS primary purposes, i.e. for providing medical care, or directly from the data subject for one of the EHDS secondary purposes.[832] This may cause difficulties in interpreting and harmonising concepts between the EHDS and the GDPR, given that *secondary processing* in the GDPR, while not precisely defined, refers exclusively to the further processing of data previously collected for another specific purpose, as previously underlined. [833]

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[827] Bincoletto, Giorgia "The EDPB-EDPS Joint Opinion on the Commission Proposal for a Regulation on the European Health Data Space: Key Issues to be Considered in the Legislative Process," *European Data Protection Law Review*, n. 3, 2022, pp. 398-404.

[828] Shabani, Masha and Sami, Yilmaz "Lawfulness in Secondary Use of Health Data – Interplay Between Three Regulatory Frameworks of GDPR, DGA EHDS"; EDPS, Preliminary Opinion 08/2020 on the European Health Data Space, 2020.

[829] Slokenberga, Santa "Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject that the Proposed EHDS Regulation Promises to Bring Along."

[830] The primary use relates to the processing of health data to provide health services to the natural person to whom the data relates (Art. 2(2)(d)) and therefore will not be included in the analysis, because it does not pertain to biobanking activities.

[831] Shabani, Masha and Sami, Yilmaz "Lawfulness in Secondary Use of Health Data – Interplay Between Three Regulatory Frameworks of GDPR, DGA EHDS"; Slokenberga, Santa "Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject that the Proposed EHDS Regulation Promises to Bring Along"; Lalova-Spinks, Teodora, et al. "The Application of Data Altruism in Clinical Research Through Empirical and Legal Analysis Lenses."

[832] Art. 2(2)(e) EHDS.

[833] EDPB-EDPS, Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, 2022; Slokenberga, Santa "Scientific Research Regime 2.0? Transformations of the Research

As far as the EHDS framework is concerned, the secondary purposes relevant in the context of biobanking are scientific research (Art. 34 (1)(e)) and "activities for reasons of public interest in the area of public and occupational health, such as (…) ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices" (Art. 34(1)(a)).

The mechanism envisioned by the EHDS comprises three main actors:[834] (1) the data holder that has the data and makes them available for secondary use; (2) the data access bodies that grant access to the data of the data holder by issuing data permits or evaluating data requests submitted by the (to be) data user; and (3) the data user that submits an application to the data access body or a request, in order to process the data of the data holder for secondary purposes.

(1) The data holder is the natural or legal person who has the right or duty to make the electronic health data available (Art. 2(2)(y)). The data holder may be an entity or a body in the health or care sector or performing research in relation to these sectors. The data to be made available are listed in Art 33, among which there are electronic health data from biobanks and human genetic data, and electronic health data from medical registries for specific diseases or clinical trials. The data listed in Art. 33 shall be put at the disposal of the health data access body (Art. 41(4)) by the data holder.

(2) The EHDS does not explicitly define the health data access bodies. Still, it can be inferred from provisions of Chapter IV that they are entities designated by each Member State to grant access to electronic health data for secondary use and supervise the functioning of the system (Art. 36 and 37 EHDS). They are *de facto* health data managers and administrators.[835] In particular, they are responsible for issuing data permits and accepting data requests submitted by the data user. Generally, according to the principle of data minimisation and purpose limitation, data access bodies provide access to the data in anonymised format, unless the purpose of the processing cannot be reached with

Regime and the Protection of the Data Subject that the Proposed EHDS Regulation Promises to Bring Along."

[834] For a more comprehensive analysis, see Slokenberga, Santa "Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject that the Proposed EHDS Regulation Promises to Bring Along."

[835] Terzis, Petros "Compromises and Asymmetries in the European Health Data Space." *European Journal of Health Law*, vol. 30, n. 3, 2022, pp. 345-363

anonymised data, in which case access is granted to pseudonymous data according to the information provided for by the data user on the application (Art. 44).

Following the issuance of the data permit, the health data access body requests the electronic health data from the data holder (Art. 46), in the correct format, i.e. anonymised or pseudonymised according to the type of access granted and the decision taken (always anonymised in case of data request, and either anonymised or pseudonymised in case of data permit according to the specificities of the secondary processing).

Moreover, the health data access bodies are responsible for processing the data for the purposes of Art. 34, including the collection and disclosure of those data for secondary use based on a data permit (Art. 37).

(3) Finally, the data user is the natural or legal person with lawful access to electronic health data (listed in Art. 33) for one of the secondary uses listed in Art. 34 (Art. 2(2)(z)). To this end, a data user may choose between submitting to the data access body a data access application (Art. 45)[836] for a data permit (Art. 46), or a data request thanks to which data are accessed in an anonymised statistical format (Art. 47). If the aim of the processing cannot be reached with anonymised data, the data user should specify in the application the reasons why access should be granted to data in pseudonymous format (Art. 45).

In particular, the data permit specifies the terms and conditions that should be complied with by the data user in the secondary processing of the data (Art. 46). The data to which access is granted via a data permit should be processed only in line with the latter, in compliance with the principles of purpose limitation and data minimisation.[837]

The EHDS provides clarifications in Recital 37 about the lawfulness of the processing activities conducted by the mentioned actors according to the GDPR. In particular, for the processing of electronic health data for secondary purposes, the data holder can comply with her duty of sharing the data by relying on the EHDS as both a legal basis under Art. 6(1)(c) GDPR (legal obligation) and an exemption under either Art. 9(2)(j), (h) or (i) GDPR.[838] At the same time, the EHDS assigns tasks in the public interest to the health data access bodies, such as processing data before they are used or running the

[836] If the data to be accessed are related to a single country or single order, the application may be submitted to the data holder. Art 45(1) and 49(1) EHDS.
[837] EDHS Art. 44. Bincoletto, Giorgia "Scientific Research Processing Health Data in the European Union: Data Protection Regime vs. Open Data"; De Hert, Paul, and Irene, Kamara "Understanding the Balancing Act Behind the Legitimate Interest of the Controller Ground: a Pragmatic Approach."
[838] Recital 37 EHDS.

secure processing environment, and therefore the processing activities conducted by the health data access bodies are based on Art. 6(1)(e) and Art. 9(2)(h),(j) or (i) GDPR.
However, the same is not true for the data user, for whom the EHDS works only as an exemption according to Art. 9(2) GDPR. Indeed, Art. 45(4)(a) EHDS establishes that in the data access application, the data user shall specify the appropriate legal basis of Art. 6 GDPR to rely upon. Usually, this would entail the applicability of the necessity-based model.[839]

Some issues are worth commenting on more specifically.

First of all, the whole EHDS seems to rest on the assumption that scientific research is always conducted for the public good and for the benefit of society. [840] Consequently, it does not sufficiently address the interests of the individuals not to have their data processed.[841] However, this idea may be troublesome without a clear definition of what constitutes scientific research, especially if such a concept is taken as the reason for restricting participants' rights.

Moreover, the EHDS concretely attempts to ensure transparency on the use of electronic health data for the public good, by establishing in Art. 46 that data users shall make public the anonymised results or output of the secondary use and shall inform the health data access body of "any clinical significant findings that may influence the health status of the natural persons whose data are included in the dataset". At the same time, however, the Proposal reduces the obligations to provide information directly to the data subject, by establishing in Art. 38(2) that the health data access bodies shall not be obliged to provide the specific information under Art. 14 GDPR to each natural person concerning the use of their data for projects subject to a data permit.[842] Instead, they shall provide general public information on the legal basis of data permit, the rights of the data subjects arising from the secondary use of electronic health data, the mechanisms available for data subjects to exercise their rights, the technical and organisational measures taken to protect data subjects' rights, and the results of the relevant health research, as provided

[839] See in this regard Recital 37 EHDS.
[840] Slokenberga, Santa "Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject that the Proposed EHDS Regulation Promises to Bring Along."
[841] *Ibid*
[842] Martìnez, Ricard "Anonymisation (Part I): What Is the State-Of the Art of Anonymisation in Data-Driven Health Research and Its Role in the "European Health Data Spare Regulation"?" *GDPR Requirements for biobanking activities across Europe,* edited by Colcelli, Valentina, et al. Springer, 2023, pp. 21-30.

for in Art. 38 and 39 EHDS.[843] However, the data holder would still be under the duty to comply with Art. 14 in case of an active expression of interest by the data subject.[844]
In this sense, "personalised" information on the authorised use of one's data is substituted with a more generalised transparency requirement.[845] In this regard, the EDPB and the EDPS in their Joint Opinion on the EHDS call for further specifications on situations when such an exemption may be relied upon because its systematical application might otherwise have possible "unintended consequences for the fundamental rights and freedoms of the data subject".

8.2.1 APPLYING THE EHDS TO BIOBANKS

The EHDS framework for the secondary use of electronic health data might be applied in the context of biobanking, at least in the two following scenarios.
(1) Creating a biobank might qualify as a secondary use in the meaning of the EHDS, as either one of the mentioned relevant purposes of Art. 34 EHDS. Indeed, as seen, the mere activity of collecting data to be stored in a biobank may be considered *scientific research* if a broad interpretation of the term is adopted.
Moreover, the EHDS could potentially apply in Scenarios 2 and 3. Indeed, as previously highlighted, collecting data to be stored in a biobank is a secondary use of these data within the meaning of the EHDS (Art. 34), but at the same time may qualify as primary or secondary use according to the GDPR and depending on the Scenario applicable. To simply:
Scenario 2 – collection for scientific research purposes: if the data fall within one of the categories of Art. 33 EHDS, re-using such data to implement a biobank is a *secondary use* according to the EHDS and either a *primary* or a *secondary use* under the GDPR.
Scenario 3 – collection for other purposes: in this case usually left-over data are under consideration. The processing of these data to provide medical care is a *primary use* under both the EHDS and the GDPR. These data may be included in various of he categories listed in Art. 33 and therefore their processing for implementing a biobank qualifies as a

[843] Shabani, Masha and Sami, Yilmaz "Lawfulness in Secondary Use of Health Data – Interplay Between Three Regulatory Frameworks of GDPR, DGA EHDS."
[844] Slokenberga, Santa "Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject that the Proposed EHDS Regulation Promises to Bring Along."
[845] Shabani, Masha and Sami, Yilmaz "Lawfulness in Secondary Use of Health Data – Interplay Between Three Regulatory Frameworks of GDPR, DGA EHDS."

secondary use under the EHDS and either as a *primary* or as a *secondary use* according to the GDPR and depending on the concrete characteristics of the given case.

Therefore, in both cases, the natural or legal person responsible for implementing the biobank would qualify as a health data user and should identify a GDPR legal basis, while the EHDS works as an exemption according to Art. 9(2) GDPR.

(b) Moreover, considering the case in which a biobank has already been implemented, any subsequent use of the data stored therein might itself constitute secondary use (for example for purposes of scientific research related to health Art. 34(e)). However, in this case the biobank qualifies as a data holder and as such would be under the duty to make the data available according to Art. 33 EHDS. In this scenario, the EHDS provisions would qualify as a legal basis and an exemption according to the GDPR.

However, in both cases, when the EHDS applies to biobanks there are various issues to be addressed, In particular, the interplay between consent as a legal basis and the EHDS framework for secondary use remains to be clarified, even though it is addressed on a general level by Art. 33(5) EHDS.[846] Indeed, the EHDS itself "puts strong emphasis on moving away from consent as an empowering mechanism"[847], specifically for secondary use of data, and consequently its relationship with the adoption of the consent-based model for the implementation of a biobank might be problematic. On the other hand, in scenario (b), the EHDS provisions for secondary use qualify as both a legal basis and an exemption, and therefore, no consent is asked of the participants for sharing their electronic health data stored in the biobank. The impact of this approach on the rights and interests of the participants, as well as on their trust in the biobanking activities should be carefully addressed.

Theoretically, the system envisioned by the EHDS might apply in order to address some of the issues related to the secondary processing of sensitive data according to the GDPR, in particular when referred to the participant's trust. However, the mentioned substitution of a "personalised" informational with a more generalised one might negatively impact on the transparency aspect of trust, as well as potentially on the participation one,

[846] EDPB-EDPS, Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, 2022; Slokenberga, Santa "Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject that the Proposed EHDS Regulation Promises to Bring Along."

[847] Lalova-Spinks, Teodora, et al. "The Application of Data Altruism in Clinical Research Through Empirical and Legal Analysis Lenses."

especially in the absence of a clear definition of when scientific research is in the public good. Of the same opinion appears to be are the EDPB and the EDPS in their Joint Opinion on the EHDS, where they questioned the necessity and justification of such a restriction, a position supported by many authors.[848] In this regard, the fact that the data holder would need to comply with Art. 14 in case of an active expression of interest by the data subject,[849] and this should not be considered sufficient to ensure participants' trust. Indeed, if not modified in the final version, this exemption may also be against the principle of transparency according to the GDPR.[850]

8.2.2 THE PROPOSED AMENDMENTS TO THE EHDS PROPOSAL

In December 2023, the European Parliament approved various substantial amendments to the text of the original EHDS Proposal, which will be further discussed within the legislative procedure before being adopted. As a consequence, in the work, I will consider only the provisions included in the Proposal, while being aware of possible substantial changes in the near future in this regard.

However, I believe it might be interesting to provide a general overview of the main amendments proposed by the European Parliament so far.

In particular, alongside with changes in the nomenclature (for instance, data users are addressed as health data users), the amendments take into consideration most of the critiques to the original approach.

For instance, among the most important changes, the duty of impartiality and independence of the health data access bodies is particularly highlighted, and the bodies themselves are granted substantial supervisory powers, such as that of conducting audits on the data users to verify compliance with the data permit, listed in the new Art. 37.

Moreover, both an *opt-in* and an *opt-out* mechanism are introduced. Indeed, the new Recital 39a and Art 33 establish a differentiated system of protection, according to the type of electronic health data to be processed for secondary use. The general rule grants patients the right to opt-out of the processing of their data for secondary use for some or

[848] See for instance de Miguel Beriain, Inigo, "The Use of Health Data for Biomedical Research in the Light of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space", *Revista juridica de Castilla y Leòn,* vol. 60, 2023, pp. 7-35.

[849] Slokenberga, Santa "Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject that the Proposed EHDS Regulation Promises to Bring Along.

[850] de Miguel Beriain, Inigo, "The Use of Health Data for Biomedical Research in the Light of the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space"

all purposes. However, the processing of genomic and proteomic data, as well as data from biobanks is subject to an opt-in mechanism, whereby the data subjects explicitly consent or give their permission to the processing of their data for all or some of the secondary purposes. This new approach restores data subjects' control over the use of their data, of a proportionate intensity according to the sensitivity of the data processed and the possible impact of the processing on their rights and interests.

Other amendments relate to the interplay between the EHDS and the GDPR and a greater attention to the anonymisation process of data and the provisions to be complied with for granting access to data in pseudonymised format.

CHAPTER IV – ANONYMITY

Summary: 1 Introduction; 2 Anonymity of HBSs; 3 Anonymity of biobank data; 3.1 The anonymisation process according to the GDPR; 3.1.1.1 The approach of the Article 29 Working Party – The zero-risk test; 3.1.2 The CJEU approach – The risk-based and dynamic approach; 3.2 The evaluation to the conducted for considering data anonymous; 3.3 Anonymisation in the EHDS and the DGA; 4 Legal and practical issues of anonymity; 5 Possible concrete strategies to be adopted for biobanking

1 INTRODUCTION

After having analysed the possible scenarios for the collection of HBSs and biobank data, especially in relation to the provisions of the GDPR, the analysis will now move onto evaluating the possibility of anonymising the collection samples and data in biobanking. Indeed, anonymity is the technical solution usually identified in hard and soft law documents for both biological samples and biobank data to protect the rights and interests of the participant and at the same time regulate their processing with fewer restrictions and obligations. Indeed, in the framework of the GDPR anonymisation and pseudonymisation are key security techniques that facilitate the processing of personal data while at the same time protecting the data subject.[851]

The ratio of the provisions and requirements included in the legislative framework applicable to biobanks is the necessity to protect the rights and interests of the people involved, balancing them against the interests of society at large in the advancement of medical research. As a consequence, whenever and if the content of a biobank is anonymous or has been anonymised and therefore cannot be linked to any participant

[851] Majeed, Abdul, and Sungchang, Lee "Anonymization Techniques for Privacy-Preserving Data Publishing: a Comprehensive Survey." *IEEE ACCESS,* vol. 9, n. 1, 2020 pp. 8512-8546; Zhicheng, He "From Privacy-Enhancing to Health Data Utilization: The Traces of Anonymisation and Pseudonymisation in EU Data Protection Law" *Digital Society,* vol. 2, n. 17, 2023, pp. 1-18. It is worth remembering here Paragraph 4.2 of the General Authorisation n. 8/2016 which establishes the duty to render temporarily *non-intelligible* the biological samples and the genetic data stored in the biobank by pseudonymizing the data or using other encryption techniques. the same principle is established by paragraph 5.4 of the General Authorisation n. 9/2016.

(with a reasonable effort, as it will be explained below), it is established that no risks or a sufficiently low level of risks may arise from their use for the individual and therefore that fewer or no restrictions should be applicable. This brings along, as the main consequence, that samples and data may be freely used and processed for the purposes of the biobank.

However, from a strictly terminological point of view, *anonymity* refers to a spectrum of scenarios, where the two extremes are irreversible and absolute anonymisation, and identifying samples/data using codes that are kept separately and not at the researcher's disposal.[852]

At the same time, however, anonymisation has been defined as a technical-scientific illusion,[853] especially when applied to HBSs, because truly and concretely anonymising the content of a biobank is impossible.

Given the importance of the instrument of anonymisation for identifying the concrete legal framework and provisions applicable, and thus ultimately for the advancement of scientific research, I will devote this Part to the analysis of the issues related to the anonymisation of both HBSs and related personal health data. The reason for the inclusion of this Part is that in case a complete and absolute anonymisation of the content of a biobank is possible, the analysis of the appropriate balancing exercise to be conducted in the biobanking context would be superfluous, because the processing and handling of absolute anonymous information has no impact on the rights and interests of participants. Therefore, this part will be structured as follows. After having generally underlined the matter separately for HBSs and personal health data, I will describe the issues related to anonymisation, stressing in particular on the impossibility of reaching factual absolute anonymisation. Consequently, the last paragraph is devoted to proposing an approach to the matter.

2 ANONYMITY OF HBSS

In general, a HBS is anonymous if it cannot be linked to the person it belonged to. Linking the two is usually rendered possible thanks to the genetic data and the DNA information

[852] Elger, Bernice, and Arthur, Caplan "Consent and Anonymization in Research Involving Biobanks: Differing Terms and Norms Present Serious Barriers to an International Framework"; Casonato, Carlo, and Marta, Tomasi "Diritti e Ricerca Biomedica: una Proposta Verso Nuove Consonanze."

[853] Maestri, Enrico "Digibodies. Biobanche e Consenso Informato Tra Finzioni Scientifiche e Giuridiche." *Filosofia del Diritto e Nuove Tecnologie. Prospettive di Ricerca tra Teoria e Pratica,* pp. 511-524.

that may be extracted from the sample itself. Therefore, anonymising the HBS would mean, in general, deleting the genetic data and the information related to the person.[854]
Various are the documents that consider the possibility of anonymising HBSs.
In particular, it is useful to analyse Recommendation R(2016)6, which recalls Recommendation R(2006)4, and extensively elaborates on the anonymisation of HBSs. The Recommendation divides between *identifiable* and *non-identifiable biological material.*
Identifiable biological materials are those HBSs that, alone or in combination with data, allow the identification of the persons from whom the materials have been removed. Such identification may be possible either directly or through the use of codes directly accessible by the user (coded materials) or of the material itself or under the control of a third party (linked anonymised materials).[855]
On the contrary, *non-identifiable biological materials* are those biological materials that, alone or in combination with data, do not allow, with reasonable effort, the identification of the persons from whom the materials have been removed (unlinked anonymised materials). As a consequence, no more links between the person and the HBS exist. Indeed, the material link was destroyed at the moment of collection, and the informational one either never existed or has been deleted. Consequently, according to Recommendation R(2016)6 the samples may theoretically be used with fewer restrictions and requirements to be complied with, because no risks may derive from their storage in the biobank and their subsequent use for research. Indeed, they may be

- stored without the consent of the participant, but subject to authorisation provided for by law,[856]
- kept for research purposes after the participant has withdrawn her consent,[857]

[854] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona.*
[855] "Coded materials" and "linked anonymised materials" are not specifically used by Recommendation R(2016) but were included in the definitions and provisions of Recommendation R(2006)4.
[856] Art. 11 para. 3 "Biological material previously removed for another purpose and already non-identifiable may be stored for future research subject to authorization provided for by law."
[857] Art. 13 para. 1 "When identifiable biological materials are stored for research purposes only, the person who has withdrawn consent should have the right to have, in the manner foreseen by law, the materials and associated data either destroyed or rendered non-identifiable."

- used for such purposes under the condition of non-violating any restrictions defined by the person concerned before the materials have been rendered non-identifiable".[858]

From these provisions it appears clear that according to Recommendation R(2016)6 while on the one hand, fewer restrictions are in place, HBSs may be processed in the context of biobanks only if the desires of the participant are respected, which are an expression of her right to self-determination.

Moreover, also the General Authorisation n. 8/2016 recognises the possibility of anonymising the HBS. In particular, paragraph 4.5.1 inextricably links the fate of the HBS to that of the genetic data extracted, by establishing that whenever consent to the processing of the data for research purposes is withdrawn, the sample should be either destroyed or anonymised or rendered anonymous. Different from Recommendation R(2016)6, the General Authorisation does not include provisions on the use of the samples after anonymisation because of a lack of competence in this regard.

Therefore, usually anonymisation is presented as the instrument that protects at the same time both "parties" involved in biobanking. Indeed, it enables the use of the samples for research, thus protecting the interest of society in the advancement of scientific research and ultimately medicine, while at the same time not affecting those of the participants, because the latter are not identifiable (or not anymore).

3 ANONYMITY OF BIOBANK DATA

Similarly to what is established by Recommendation R(2016)6 for HBSs, among the other documents the UNESCO International Declaration provides for genetic data the same classification for data that might be extracted from HBSs, by dividing them among

- *data linked to an identifiable person*, i.e. data that contain information (...) by which the person from whom the data were derived can be identified;
- *data unlinked to an identifiable person*, i.e. data that are not linked to an identifiable person, through the replacement of, or separation from, all identifying information about that person by use of a code;

[858] Art. 21 para. 4 "Non-identifiable biological materials may be used in a research project provided that such use does not violate any restrictions defined by the person concerned before the materials have been rendered non-identifiable and subject to authorisation provided for by law."

- *data irretrievably unlinked to an identifiable person*, i.e. data that cannot be linked to an identifiable person, through destruction of the link to any identifying information about the person who provided the sample.

This differentiation resembles the one provided for by the GDPR among *personal*, *pseudonymised* and *anonymised data.*

When data are irretrievably unlinked to the person, genetic data can be used without the participant's consent[859] or may continue to be used even after the participant's withdrawal,[860] and access to one's genetic data can be denied by the entity performing the processing.[861] The regime applicable therefore imposes fewer obligations on the entity processing the data, because of the reduced impact of such a processing on the rights and interests of the participant.

Precisely concerning the biobank data, it is worth reminding as mentioned that as for the material scope of the GDPR, it applies only to *personal data*,[862] thus any information related to an identified or identifiable natural person[863] (i.e. *data linked to an identifiable person* in the division of the UNESCO International Declaration). The listed parameters for identifying the data subject are then included in Art. 4(1) as "a name, an identification number, location data, an online identifier, or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural, or social identity of that natural person".

Therefore, as it has been underlined, the GDPR adopts a strictly binary approach for its material scope, differentiating between personal data, to which it applies, and non-personal data, to which it does not. The GDPR does not consider a third category of data

[859] Art. 16 lett. b UNESCO International Declaration "When prior, free, informed and express consent cannot be obtained or in the case of data irretrievably unlinked to an identifiable person, human genetic data may be used in accordance with domestic law or following the consultation procedures set out in Article 6(b)."

[860] Art. 9 lett. b UNESCO International Declaration "When a person withdraws consent, the person's genetic data, proteomic data and biological samples should no longer be used unless they are irretrievably unlinked to the person concerned." and lett. c "If not irretrievably unlinked, the data and biological samples should be dealt with in accordance with the wishes of the person. If the person's wishes cannot be determined or are not feasible or are unsafe, the data and biological samples should either be irretrievably unlinked or destroyed."

[861] Art. 13 UNESCO International Declaration "No one should be denied access to his or her own genetic data or proteomic data unless such data are irretrievably unlinked to that person as the identifiable source or unless domestic law limits such access in the interest of public health, public order or national security."

[862] See the scope of application as established in Art. 1(1) GDPR.

[863] Art. 4(1) and Recital 26 GDPR.

for defining its applicability.[864] However, this binary setting contrasts with the spectrum of identifiability that concerns data in general, and which includes pseudonymised data between personal and anonymous data.[865] Indeed, while the GDPR identifies the category of pseudonymous data, it does not establish for them a specific and tailored regime, but qualifies pseudonymous data as personal data, as explained in the following paragraphs.

Indeed, according to the GDPR, pseudonymous data are personal data that "can no longer be attributed to a specific data subject without the use of additional information".[866] The process of pseudonymisation is "the conversion about an identified person into data about a merely "identifiable" person with the condition that the additional data necessary for re-identification are kept safely inaccessible for the users of "pseudonymised data".[867] Therefore, pseudonymisation is not a process, but a successful state of *non-identifiability without additional information*, which should be protected against re-identification by technical and organisational measures.[868] As such, it is a tool that "helps controllers and processors comply with their data protection obligations",[869] i.e. a technical measure for the purposes of the GDPR.

Concerning the applicability of the GDPR, pseudonymised data are personal data,[870] because they may be traced back to the data subject and therefore are worth the protection granted to personal data. However, while the GDPR in general applies to these data, some flexibility is linked to the processing that involves pseudonymisation when compared to the legal regime applicable to identifiable information.[871]

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[864] Bincoletto, Giorgia "Scientific Research Processing Health Data in the European Union: Data Protection Regime vs. Open Data"; Comandè, Giovanni, *Elgar Encyclopedia of Law and Data Science*, Edward Elgar Publishing, 2022.

[865] Purtova, Nadezhda "The Law of Everything. Broad Concept of Personal Data and Future of EU Data Protection Law." *Law, Innovation and Technology*, vol. 10, n. 1, pp. 40-81; Finck, Michèle, and Frank, Pallas "They Who Must Not Be Identified – Distinguishing Personal from Non-Personal Data Under the GDPR." *International Data Privacy Law*, vol. 10, n. 1, 2020, pp. 11–36; Colonna, Liane "Privacy, Risk, Anonymisation and Data Sharing in the Internet of Health Things." *Journal of Technology Law and Policy*, vol. XX, 2019-2020, pp. 148-177.

[866] Art. 4(5) GDPR.

[867] Colonna, Liane "Privacy, Risk, Anonymisation and Data Sharing in the Internet of Health Things."

[868] Irti, Claudia "Personal Data, Non-personal Data, Anonymised Data, Pseudonymised Data, De-identified Data." Indeed, Art. 4(5) GDPR provides that "such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person."

[869] Recital 28 GDPR.

[870] Shabani, Mahsa, and Luca, Marelli "Re-Identifiability of Genomic Data Under the GDPR. Assessing the Re-Identifiability of Genomic Data in Light of the EU General Data Protection Regulation" *EMBO Reports*, vol. 20, 2019.

[871] for instance, processing pseudonymous data can satisfy (1) the data protection by design requirement in Art. 25(1) GDPR, (2) the "appropriate safeguards" requirement for the processing of personal data for

Precisely the possibility of reversing the de-identification process, and thus of tracing the data back to the data subject, is what differentiates *pseudonymous data* and *anonymous/anonymised data*, to which the GDPR does not apply.

However, the qualification of data as personal data is dynamic,[872] as evident from the definition provided for above and further specified in the following paragraphs, and data may be *personal* or *anonymous* depending on the context and time of the processing, the person who undergoes it, etc. Therefore, no clear and definite dividing line between the concepts may be drawn.

The difference between anonymous and anonymised data is that the former does not identify a specific person from the outset or already at the moment of collection, while the latter has undergone a process aimed at the permanent de-identification of the data.[873] Anonymisation is thus a form of processing of personal data whose aim is to "remove or obscure any personally identifiable disclosure of individuals' identities and information about them",[874] and it should thus comply with the GDPR since this activity constitutes *processing* of personal data.[875]

archiving purposes in the public interest, scientific or historical research purposes or statistical purposes" according to Art. 89(1) GDPR, (3) the data security requirements according to Art. 32 GDPR, etc. Brasher, Elizabeth A. "Addressing the Failure of Anonymization: Guidance from the European Union's General Data Protection Regulation." *Columbia Business Law Review*, vol. 2018, n. 1, 2018, pp. 209-254; Colonna, Liane "Privacy, Risk, Anonymisation and Data Sharing in the Internet of Health Things."

[872] Finck, Michèle, and Frank, Pallas "They Who Must Not Be Identified – Distinguishing Personal from Non-Personal Data Under the GDPR."

[873] Purtova, Nadezhda "The Law of Everything. Broad Concept of Personal Data and Future of EU Data Protection Law."

[874] Irti, Claudia "Personal Data, Non-personal Data, Anonymised Data, Pseudonymised Data, De-identified Data." Some techniques to anonymise personal data are proposed by El Emam, Khaled, et al. "Anonymising and Sharing Individual Patient Data." For a comprehensive analysis of the possible methods to anonymise data, especially health data, see Zuo, Zheming, et al. "Data Anonymization for Pervasive Health Care: Systematic Literature Mapping Study." *JMIR medical informatics*, vol. 9, n. 10, 2021; Wanvik Stenersen, Håvard, *Anonymization of Health Data Anonymization Approaches, Data Utility and the GDPR*, PhD thesis, University of Oslo, 2020; Colonna, Liane "Privacy, Risk, Anonymisation and Data Sharing in the Internet of Health Things."

[875] Bincoletto, Giorgia "Scientific Research Processing Health Data in the European Union: Data Protection Regime vs. Open Data"; Shabani, Masha, et al. "The Impact of the GDPR on the Governance of Biobank Research." *GDPR and Biobanking. Individual Rights, Public Interest and Research Regulation Across Europe*, edited by Slokenberga, Santa, et al. Springer, 2021, pp. 45-60. Article 29 Working Party, Opinion 5/2014 on Anonymisation techniques, 2014.

4 THE ANONYMISATION PROCESS ACCORDING TO THE GDPR

Various techniques and operations are available to achieve the anonymisation of personal data,[876] and in the process, four categories of variables of the dataset may be addressed to reach the desired result, according to the recent categorisation provided for by Majeed and Lee: direct identifiers, quasi-identifiers, sensitive attributes, and non-sensitive attributes.[877] As for the first two in particular, on the one hand, *direct identifiers* are the elements that enable a direct recognition of an individual (for instance personal names, email addresses, telephone numbers, and social insurance numbers),[878] and on the other, the *quasi-identifiers* are those elements that identify an individual indirectly (for instance date of birth, death, or clinic visit, residence postal code, and ethnicity),[879] alone or in combination with other quasi-identifiers (also called *indirect identifiers*). The latter category includes demographics and socioeconomic information and should be considered as important as the former, given that re-identification attacks are usually performed using quasi-identifiers.[880]

The provisions of the GDPR do not apply altogether to both anonymous and anonymised data.[881]

In order to decide whether a natural person is identifiable, account should be taken to Recital 26 GDPR which provides the criteria of the "means reasonably likely to be used", either directly or indirectly, considering "objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments".

Therefore, according to the GDPR (1) *anonymous/anonymised data* are those that do not contain any information that could lead to the identification of the data subject (directly

[876] Arora, Dilpreet Kaur, Bansal, Divya, and Sofat, Sanjeev, "Comparative Analysis of Anonymisation Techniques." *International Journal of Electronic and Electrical Engineering*, vol. 7, n. 8, 2014, pp. 773-778; Majeed, Abdul, and Sungchang, Lee "Anonymization Techniques for Privacy-Preserving Data Publishing: a Comprehensive Survey."

[877] Majeed, Abdul, and Sungchang, Lee "Anonymization Techniques for Privacy-Preserving Data Publishing: a Comprehensive Survey."

[878] Colonna, Liane "Privacy, Risk, Anonymisation and Data Sharing in the Internet of Health Things."

[879] El Emam, Khaled, et al. "Anonymising and Sharing Individual Patient Data."

[880] El Emam, Khaled, et al. "Anonymising and Sharing Individual Patient Data."

[881] Recital 26 GDPR "(...) the principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. This Regulation does not therefore concern the processing of such anonymous information, including for statistical or research purposes."

or indirectly), i.e. are or have been de-identified; (2) such de-identification process is irreversible if means reasonably likely to be used are considered, (3) and the evaluation focuses on the outcomes and not on the means or the procedure for reaching such status.[882]
It appears thus evident that understanding whether data are *personal data* and whether in the concrete case, a person is identified or identifiable with reasonable effort is therefore of paramount importance because it defines the boundaries of the right to data protection of the data subject and consequently the limit for the applicability of the GDPR. According to a literal interpretation of the provisions of the GDPR, the evaluation to be conducted is outcome and context-dependent,[883]
However, the Regulation does not provide a clear and precise definition or criteria to be used, which should then be inferred from the CJEU's case law[884] and relevant guidelines or documents of authoritative bodies on the matter.

4.1 THE APPROACH OF THE ARTICLE 29 WORKING PARTY – THE ZERO-RISK TEST

In particular, the analysis should start from the definition of *personal data* provided for by the Article 29 Working Party, which dissected it into four elements: "any information", "relating to", "identified or identifiable", and "natural person".[885] While any of the mentioned elements would require an extensive analysis as to their exact definitions, the most problematic is the concept of identifiability, and the definition of the criterion to adopt for the definition of the "reasonable probability of identification".[886]

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[882] Shabani, Mahsa, and Luca, Marelli "Re-Identifiability of Genomic Data Under the GDPR. Assessing the Re-Identifiability of Genomic Data in Light of the EU General Data Protection Regulation."
Shabani, Mahsa, and Luca, Marelli "Re-Identifiability of Genomic Data Under the GDPR. Assessing the Re-Identifiability of Genomic Data in Light of the EU General Data Protection Regulation."
[884] in this regard, when relevant, the CJEU's sentences considered will be both those issued under the GDPR and under the previous Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. Indeed, the definition of "personal data" provided for by the latter in art. 2(a) coincides with that of the GDPR, which however only further elaborated on the parameters of identifiability of the data subject. On this point, see Ouarab, Yacine "Identifying the Identified: Unraveling the Third Element of Personal Data in EU Law."
[885] Article 29 Working Party, Opinion 4/2007 on the concept of personal data, 2007. as mentioned, given that the definitions of personal data provided for by both the Directive and the Regulation, this opinion might still be considered relevant. However, it is not legally binding, because the CJEU is the only authority holding the power to interpret EU legislation.
[886] Irti, Claudia "Personal Data, Non-personal Data, Anonymised Data, Pseudonymised Data, De-identified Data."

To help conduct such an assessment, under the previous Directive 95/46/EC the Article 29 Working Party adopted a strict interpretation of, and a high threshold on the concepts of *identifiability* in its Opinion 05/2014 on Anonymisation Techniques.[887]

Indeed, as for the criteria to consider when assessing if a person is identified or might be identifiable, Article 29 Working Party in Opinion 05/2014 referred to three prevailing re-identification risks, namely (a) the possibility of singling out an individual from a group (*singling out*); (b) possibility of linking two records relating to an individual within a dataset (or between two separate datasets) (*linkability*); and (c) possibility of inferring information concerning the individual in such dataset (*inference*).[888] The Article 29 Working Party thus adopted what had been called the *singling out approach*, which is a high standard for achieving anonymisation, because it essentially requires no re-identifiability at all possible.[889]

Indeed, the latter document establishes that an individual is identified when "there are means to distinguish them from other members of a group" in a given context.[890] According to the Article 29 Working Party, both the context and the identifiers are critical elements for the evaluation of the identifiability of a person.[891]

Because of the mentioned elements, the approach of the Article 29 Working Party was defined as a "zero-risk test"[892] for anonymisation. Indeed, it requires anonymisation to be the result of "processing personal data in order to *irreversibly* prevent identification"[893] and a "technique applied to personal data in order to achieve *irreversible de-identification*".[894] It aims to reach a complete and absolute anonymisation of the data.[895]

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[887] in the Guidelines 04/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak, the EDPB still refers to Opinion 05/2014 of the Article 29 Working Party even under the GDPR and this makes it worth being mentioned here. See for instance EDPB Guidelines 05/2020 on consent under Regulation 2016/679, version 1, adopted on 4 May 2020. For an extensive analysis on the concept of anonymisation pre-GDPR, see Zhicheng, He "From Privacy-Enhancing to Health Data Utilization: The Traces of Anonymisation and Pseudonymisation in EU Data Protection Law."

[888] Martìnez, Ricard "Anonymisation (Part I): What Is the State-Of the Art of Anonymisation in Data-Driven Health Research and Its Role in the "European Health Data Spare Regulation"?"

[889] Zhicheng, He "From Privacy-Enhancing to Health Data Utilization: The Traces of Anonymisation and Pseudonymisation in EU Data Protection Law."

[890] Working Paper 136. Ouarab, Yacine "Identifying the Identified: Unraveling the Third Element of Personal Data in EU Law."

[891] Working Paper 136.

[892] Finck, Michèle, and Frank, Pallas "They Who Must Not Be Identified – Distinguishing Personal from Non-Personal Data Under the GDPR."

[893] Article 29 Working Party, "Opinion 4/2007 on the concept of personal data", 2007.

[894] *Ibid*

[895] "The outcome of anonymisation as a technique applied to personal data should be, in the current state of technology, as permanent as erasure, i.e. making it impossible to process personal data." Article 29

Such an approach has been criticised for expanding the concept of *personal data* too broadly,[896] as well as that of *identifiability,* and not being able to work in practice.[897] Moreover, if applied in practice, it would render the data completely useless, because anonymisation qualified in these terms and therefore the process to be adopted destroys the value of data.[898]

In particular, by applying the ”zero-risk test” to anonymisation, the Article 29 Working Party considers that “when a data controller does not delete the original (identifiable) data at even-level, and the data controller hands over part of this dataset (for example after removal or masking of identifiable data), the resulting dataset is still personal data”.[899] For instance, this approach would render it impossible for hospitals to make available anonymised datasets for research purposes and at the same time retain the personal data to provide healthcare[900] and this conclusion applies in the exact same manner to biobanks who wish to provide anonymised data for research purposes.

However, and as it has been authoritatively pointed out, neither the CJEU has ever directly referred to it in any of her judgements nor has the EDPB endorsed or adopted it, thus therefore reducing the impact of such an approach on the actual interpretation of the concept.[901]

4.2 THE CJEU APPROACH – THE RISK-BASED AND DYNAMIC APPROACH

The CJEU adopted a more nuanced[902] and pragmatic[903] approach to anonymisation.

Working Party, Opinion 4/2007 on the concept of personal data, 2007. On the topic, Finck, Michèle, and Frank, Pallas “They Who Must Not Be Identified – Distinguishing Personal from Non-Personal Data Under the GDPR”; Weitzenboeck, Emily M., et al. “The GDPR and Unstructured Data: Is Anonymization Possible?” *International Data Privacy Law*, vol. 12, n.3, 2022, pp. 183-206.

[896] Purtova, Nadezhda “The Law of Everything. Broad Concept of Personal Data and Future of EU Data Protection Law.”

[897] El Emam, Khaled, and Álvarez, Cecilia “A critical Appraisal of the Article 29 Working Party Opinion 05/2014 on Data Anonymization Techniques.” *International Data Privacy Law*, vol. 5, n. 1, 2015, pp. 73–87.

[898] Weitzenboeck, Emily M., et al. “The GDPR and Unstructured Data: Is Anonymization Possible?”

[899] Article 29 Working Party, Opinion 4/2007 on the concept of personal data, 2008.

[900] Finck, Michèle, and Frank, Pallas “They Who Must Not Be Identified – Distinguishing Personal from Non-Personal Data Under the GDPR.”

[901] Ouarab, Yacine “Identifying the Identified: Unraveling the Third Element of Personal Data in EU Law.”

[902] Groos, Daniel and van Veen, Evert-Ben “Anonymised Data and the Rule of Law.” *European Data Protection Law Review*, vol. 6, n. 4, 2020, pp.498-508.

[903] European Parliament, “How the General Data Protection Regulation Changes the Rules for Scientific Research.” Study, Panel for the Future of Science and Technology, ERPS, European Parliamentary research service, scientific foresight unit (STOA), 2019.

Indeed, on the other hand, as for the criteria identified by the CJEU, already under Directive 95/46/EEC, the Court decided on the matter in the *Breyer case* (Case C-582-14),[904] defined as a "pivotal moment in the Court's interpretation" of the identified/identifiable element.[905] The case concerned the possibility of considering a dynamic IP address as personal data. The dynamic IP address is not directly related to information personally identifiable, because the holder of the IP address information is the website operator, who in turn does not possess any other information to be used with the IP address to identify the internet use (i.e. the data subject).[906]

In this case, the Court established that in order to conduct such an evaluation "consideration should be given to the totality of the means likely reasonably to be used by the controller or others to identify the person". In particular, according to paragraph 46 of the sentence this last element (availability of means likely reasonably to be used) is not satisfied "if the identification of the data subject [is] prohibited by law or practically impossible on account of the fact that it requires a disproportionate effort in terms of time, cost, and manpower so that the risk of identification appears in reality to be insignificant". Moreover, in this case the Court answers the question of "who the relevant agents of identification are", which is particularly important to assess the matter whenever the natural or legal person who processes the data is not the one who has the additional data or elements that may possibly re-identify the data subject.[907] In paragraph 43 of the *Breyer case*, the Court stated that "for information to be treated as "personal data" (…), it is not required that all the information enabling the identification of the data subject must be in the hands of one person". Consequently, account should be taken to all the various information to which the entity who processes the data might have access under more general terms.

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[904] For an extensive analysis of the case, see Reid, Alan "The European Court of Justice case of Breyer." *Journal of Information Rights, Policy and Practice*, vol. 2, 2017; Zuiderveen Borgesius, Frederik J. "The Breyer Case of the Court of Justice of the European Union: IP Addresses and the Personal Data Definition." *European Data Protection Law Review*, vol. 3, n. 1, pp. 1-18. the case was issued under the Directive 95/46/EEC but it is still considered applicable to the processing under the GDPR. See EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, 2021; Groos, Daniel and van Veen, Evert-Ben "Anonymised Data and the Rule of Law." Indeed, this sentence has been recently confirmed with some adjustments by the CJEU in the SRB v. EDPS case.

[905] Ouarab, Yacine "Identifying the Identified: Unraveling the Third Element of Personal Data in EU Law."

[906] Reid, Alan "The European Court of Justice case of Breyer."

[907] Weitzenboeck, Emily M., et al. "The GDPR and Unstructured Data: Is Anonymization Possible?"

More recently, the CJEU issued a sentence on an analogous matter in the *SRB v. EDPS case* (Case t-557/20).[908] In the case concerned, the Single Resolution Board (SRB), i.e. the central resolution authority within the EU Banking Union, had asked to a third party (Deloitte) to assess some of the comments submitted by shareholders and creditors to a privacy statement regarding the processing of personal data in the course of the right-to-be-heard process. The relevant comments were transmitted to Deloitte to this end, with an alphanumeric 33-digit code that could identify the person. However, these codes were stored in an identification database, to which only the SRB had access. The CJEU therefore had to decide as to whether these comments were to be qualified as personal data according to the GDPR and in particular if anonymous/anonymised or pseudonymised data,[909] considering that Deloitte was not able to associate each comment to a person.

In this case, the Court mainly reaffirmed the principles already established in the Breyer case. Indeed, it is stated that:

- comments of the type shared by SRB could theoretically be *personal data* and the evaluation in this regard should be conducted taking into consideration the specific context. Here, the Court evaluated both the *data* per se and the environment of the processing;
- the possibility of re-identification should be evaluated by taking the point of view of the recipient and considering the additional information that could be combined with the received data. These additional data should not necessarily be in the hands of the recipient herself;
- data are *personal data* if the possibility to combine the received data with the additional ones is a means likely reasonably to be used to identify the person, with *likely reasonably* being interpreted as *not disproportionate effort concerning time, cost and manpower*.[910]

[908] For a more comprehensive analysis of the case, see Lodie, Alexandre, "Are personal data always personal? Case T-557/20 SRB v. EDPS or when the qualification of data depends on who holds them."
[909] The decision was issued on the basis of Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data and repealing Regulation. However, the Court had to judge on the qualification of these data as personal data and therefore the judgement is relevant for the material scope of the GDPR as well.
[910] On the 4th of August 2023, the sentence was submitted for appellate review by the CJEU – Case C-413/23 P – EDPS v. SRB.

It appears thus evident that the Court adopted in both cases a risk-based approach to the issue of anonymity and personal data.[911] Indeed, even when data are considered anonymous there might remain a particular risk of identification of the person from the data,[912] but if this risk is limited, i.e. if it remains only a theoretical possibility of identification after an evaluation conducted on a case-by-case basis, the provisions of the GDPR do not apply.[913] The same might be said for anonymised data: the process of de-identification is successful "when there is no reasonable basis to believe that the information remaining in the records can be used to identify an individual record."[914]

According to some authors, in particular, the *Breyer case* rendered inadequate and obsolete[915] the absolute approach adopted by the Article 29 Working Party regarding anonymised data,[916] and the risk-based and dynamic approach adopted by the GDPR seems more useful for the processing of personal data in general.[917]

This criterion of the *reasonable probability of identification* depends on the context of the processing under both a practical and a more technical point of view (also referred to as *reasonability test*)[918].[919] Indeed, anonymity is not related to the absolute impossibility of tracking the data back to the person they originated from, but it is connected to the notion of *reasonable effort*s in attempting to do so and such an evaluation should be conducted taking into consideration the concrete context of the processing, including the technological tools available and those under development during the time of the processing.[920]

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[911] Weitzenboeck, Emily M., et al. "The GDPR and Unstructured Data: Is Anonymization Possible?"; Finck, Michèle, and Frank, Pallas "They Who Must Not Be Identified – Distinguishing Personal from Non-Personal Data Under the GDPR."

[912] AEPD-EDPS, Joint paper on 10 misunderstandings related to anonymisation, 2021; El Emam, Khaled, et al. "Anonymising and Sharing Individual Patient Data."

[913] Irti, Claudia "Personal Data, Non-personal Data, Anonymised Data, Pseudonymised Data, De-identified Data."

[914] *Ibid*

[915] Groos, Daniel and van Veen, Evert-Ben "Anonymised Data and the Rule of Law." Contrary to this opinion see Zuiderveen Borgesius, Frederik J. "The Breyer Case of the Court of Justice of the European Union: IP Addresses and the Personal Data Definition."

[916] Irti, Claudia "Personal Data, Non-personal Data, Anonymised Data, Pseudonymised Data, De-identified Data"; Zhicheng, He "From Privacy-Enhancing to Health Data Utilization: The Traces of Anonymisation and Pseudonymisation in EU Data Protection Law."

[917] Groos, Daniel and van Veen, Evert-Ben "Anonymised Data and the Rule of Law"; Irti, Claudia "Personal Data, Non-personal Data, Anonymised Data, Pseudonymised Data, De-identified Data."

[918] EDPB, Guidelines 04/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak, 2020.

[919] Irti, Claudia "Personal Data, Non-personal Data, Anonymised Data, Pseudonymised Data, De-identified Data."

[920] Recital 26 GDPR.

The approach adopted by the CJEU is coherent with not only the provisions of the GDPR on the matter of the anonymisation of personal data, but also more generally with the setting of the entire Regulation. Indeed, Art. 5 of the GDPR establishes the principle of accountability, according to which the data controller should "control in a formal and structured way, the *risks* to the rights and freedoms of data subjects arising from data processing operations",[921] further emphasised in Art. 24 on the responsibilities of the data controller and Art. 25(1) on Privacy by Design.[922]

4.3 THE EVALUATION TO BE CONDUCTED FOR CONSIDERING DATA ANONYMOUS

Therefore, in general terms, the assessment as to whether data are anonymous (1) should be conducted on a case-by-case basis, (2) taking into account the means reasonably likely to be used by the recipient and (3) is a dynamic evaluation.

(1) Indeed, such an assessment on a case-by-case basis should take into consideration two elements: the type of data processed (*nature* of the data) and "the 'environment' in which the data are to be shared and released" (*context* of the processing).[923]

In this regard, it has been suggested that not only are genetic data highly identifying per se, and thus considering the *nature* of the data, but the context in which these data are processed is highly relevant for the evaluation of their anonymity.

Indeed, "no single piece of data taken in isolation represents an inherent or perfect identifier",[924] because it depends on a combination of factors, such as the data, the nature of the connection between the data and the context of the processing, thus rendering identifiability the "outcome of a network of associations.[925] The contextual factors of the processing should therefore be taken into consideration. These factors are, in general, (a) other data to which the data recipient might have access (i.e. data available in the environment where the dataset under scrutiny is placed), (b) the data users, (c) the

[921] Colonna, Liane "Privacy, Risk, Anonymisation and Data Sharing in the Internet of Health Things."
[922] Indeed, in this regard, Spina refers to the "riskification" of the EU data protection law. See on the topic Spina, Alessandro, "A regulatory Mariage de Figaro: risk regulation, data protection and data ethics." *European Journal of risk regulation,* Vol. 8, n. 01, pp. 88-94.
[923] Weitzenboeck, Emily M., et al. "The GDPR and Unstructured Data: Is Anonymization Possible?" In statistical confidentiality, data environment consists of four key elements: other data, data users, governance processes, and infrastructure.
[924] Shabani, Mahsa, and Luca, Marelli "Re-Identifiability of Genomic Data Under the GDPR. Assessing the Re-Identifiability of Genomic Data in Light of the EU General Data Protection Regulation."
[925] PHG Foundation, "Identification and genomic data." 2017.

governance processes (i.e. "how the users' relationships with the data are managed"), and (d) the infrastructure in place (i.e. the physical and software processes).[926]

All these elements should be related specifically, according to Shabani and Marelli, to the concrete institutional setting, such as health care or research, because of the possible various additional requirements and safeguards for the data subject that may be applicable there.[927] The authors make the example of the processing of genetic data in the biomedical research setting, where an ethics review of the research project is compulsory and there are well-established ethics standards in place.[928] These considered altogether are further safety measures against possible attempts at re-identifying the data subjects.[929] The same can easily be said for biobanks, where usually an ethical evaluation is always conducted for the ethical and legal legitimacy of the biobanking activities.

(2) The means reasonably likely to be used to identify the data subject include not only those specifically listed in Recital 26 (costs of and among of time required for identification, the available technology at the time of the processing and technological developments) but also those listed by the Article 29 Working Party, i.e. the intended purpose of the processing ("where the purpose of the processing implies the identification of individuals, it can be assumed that the controller or any other person involved have or will have the means likely reasonably to be used to identify the data subject"),[930] the risk of organisational dysfunctions and technical failures, the technical and organisational measures in place to prevent identification.[931]

Moreover, the means to be considered are those concretely available for the recipient of the data, and consequently, according to the Court in the *Breyer case*, the evaluation is subjective. Indeed, specific data may be considered *anonymous* for one recipient but might be personal for another, depending on the concrete means available to that particular recipient (*relative identification* or *criterion*).[932]

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[926] Weitzenboeck, Emily M., et al. "The GDPR and Unstructured Data: Is Anonymization Possible?"
[927] Shabani, Mahsa, and Luca, Marelli "Re-Identifiability of Genomic Data Under the GDPR. Assessing the Re-Identifiability of Genomic Data in Light of the EU General Data Protection Regulation."
[928] *Ibid*
[929] *Ibid*
[930] WP 136 (n.27)
[931] *Ibid*
[932] Lodie, Alexandre "Are Personal Data Always Personal? Case T-557/20 SRB v. EDPS or When the Qualification of Data Depends on Who Holds Them."

(3) Finally, this evaluation is *dynamic*, and therefore, its conclusion may change over time because of technological advancements.[933] Moreover, precisely the dynamic character of the evaluation forces the parties in the processing of anonymous data to reconfirm such an evaluation on an ongoing basis to verify that they did not become data controllers of the data previously considered anonymous because of some technological development or otherwise.[934]

Moreover, and in this context, the EDPB in its Guidelines 04/2020 established some more specificities, namely that it is possible to reach anonymisation only if the entire dataset as a whole is anonymised,[935] and that on the contrary interventions on a single data pattern may only be considered pseudonymisation, if the related requirements are complied with.[936]

5 ANONYMISATION IN THE EHDS AND THE DGA

The concept of anonymisation has also been included in the new European instruments applicable to the processing of personal data for biobanking purposes, described in Part B, the EHDS and the DGA.

First of all, Art. 44 of the EHDS adopts an approach consistent with Art. 89 GDPR[937] and prioritises anonymisation of electronic health data by establishing that the health data access bodies may grant the applicants permits to access the electronic health data exclusively in an anonymised format (paragraph 2). Access to electronic health data in pseudonymised format may be provided only in cases where the purpose of the processing cannot be achieved with anonymised data (paragraph 3). In this latter case, according to Art. 45 EHDS extra requirements should be complied with, and in particular the data user should include in the data application

[933] AEPD-EDPS, Joint Paper on 10 Misunderstandings Related to Anonymisation, 2021; El Emam, Khaled, et al. "Anonymising and Sharing Individual Patient Data"; Irti, Claudia "Personal Data, Non-personal Data, Anonymised Data, Pseudonymised Data, De-identified Data."

[934] EDPB, Document on Response to the Request from the European Commission for Clarifications on the Consistent Application of the GDPR, Focusing on Health Research, 2021.

[935] Bincoletto, Giorgia "Scientific Research Processing Health Data in the European Union: Data Protection Regime vs. Open Data."

[936] EDPB, Guidelines 04/2020 on the Use of Location Data and Contact Tracing Tools in the Context of the COVID-19 Outbreak, 2020. This approach is also confirmed by the EHDS, where in Art. 2(2)(b) in the definition of *non-personal* electronic health data it clarifies that "where personal and non personal data in a data set are inextricably linked, the entire dataset shall be processed as *personal* electronic health data." as well as Recital 4.

[937] Martìnez, Ricard "Anonymisation (Part I): What Is the State-Of the Art of Anonymisation in Data-Driven Health Research and Its Role in the "European Health Data Spare Regulation"?"

- reasons why the purpose of the processing cannot be achieved with anonymised data;
- information on the chosen legal basis according to Art. 6(1) GDPR for the processing;
- information on the ethical assessment conducted on the processing of the data, if applicable.

Therefore, EHDS establishes a scenario of "functional separation"[938] between the various entities involved in the processing of the electronic health data to preserve anonymisation. Indeed, it provides that the health data access body holds the identifiers and enables the data user to access anonymised data with a commitment to non-reidentification, or data in a pseudonymised format but in this case only after having conducted an ethical assessment and includes information on the latter in the data application.[939]

Finally, the EHDS recognises the impossibility of reaching absolute and irreversible re-identification for certain categories of data "particularly sensitive",[940] for which not even the use of state of the art anonymisation techniques can completely eliminate the residual risk of re-identification, beyond the means reasonably likely to be used. The Proposal establishes that this might be the case for certain types of data, depending on the level of granularity and description of the characteristics of the data subjects, the number of people affected, etc. This is for instance the case for rare diseases data, "where the limited numbers of case reduce the possibility to fully aggregate the published data in order to preserve the privacy of natural persons while also maintaining an appropriate level of granularity in order to remain meaningful". Moreover, the same risk is present in cases of data stored in specific ways, such as in biobanks, where the identification characteristics are broader, and information might be combined also thanks to technological evolution of methods" not yet available.

It appears thus evident that the EHDS heavily relies on the concepts of pseudonymisation and anonymisation without providing any specification for the definitions of these terms, but merely making reference to those of the GDPR.[941] However, this implies that

[938] Martìnez, Ricard "Anonymisation (Part I): What Is the State-Of the Art of Anonymisation in Data-Driven Health Research and Its Role in the "European Health Data Spare Regulation"?"
[939] Art. 45 EHDS.
[940] Recital 64 EHDS.
[941] Zhicheng, He "From Privacy-Enhancing to Health Data Utilization: The Traces of Anonymisation and Pseudonymisation in EU Data Protection Law."

anonymisation remains without a normative definition, either in general or for the specific context defined by the EHDS. Addressing the critiques that every data access body would have therefore needed to identify autonomously the criteria for considering data anonymous or pseudonymised, and the specific conditions or techniques to be used in this regard, with severe consequences and possible issues related to the lack of uniformity and harmonisation on the matter at the supranational level,[942] the amendments proposed by the European Parliament on the 13th of December 2023 include paragraph 3b of Art. 44. According to the latter,[943] the Commission should establish procedures and requirements and provide technical tools for a unified procedure for anonymisation, as well as pseudonymisation.

Analogously, also the DGA attaches great importance to anonymisation and pseudonymisation requirements in order to allow the re-use of personal data.[944] Indeed, these measures might be imposed by public sector bodies on the re-use of personal data.

6 LEGAL AND PRACTICAL ISSUES OF ANONYMITY

For both HBSs and genetic data, the possibility of reaching real anonymisation is frequently debated. Indeed, multiple studies have been conducted on the re-identification of genetic data and HBSs to demonstrate how easy it could be in certain circumstances.[945] For instance, Gymrek et al. already proved in 2013 that it is possible to reidentify participants by linking STRs on the Y chromosome with data found in publicly available datasets.[946]

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[942] Zhicheng, He "From Privacy-Enhancing to Health Data Utilization: The Traces of Anonymisation and Pseudonymisation in EU Data Protection Law."

[943] Martìnez, Ricard "Anonymisation (Part I): What Is the State-Of the Art of Anonymisation in Data-Driven Health Research and Its Role in the "European Health Data Spare Regulation"?"

[944] Zhicheng, He "From Privacy-Enhancing to Health Data Utilization: The Traces of Anonymisation and Pseudonymisation in EU Data Protection Law."

[945] Among many others Erlich, Yaniv et al. "Identity Inference of Genomic Data Using Long-Range Familial Searches." *Science (New York, N.Y.)*, vol. 362, n. 6415, 2018, pp. 690-694; Lippert, Christoph et al. "Identification of Individuals by Trait Prediction Using Whole-Genome Sequencing Data." *Proceedings of the National Academy of Sciences of the United States of America*, vol. 114, n. 38, 2017, pp. 10166-10171; Shringarpure, Suyash S, and Carlos D., Bustamante. "Privacy Risks from Genomic Data-Sharing Beacons." *American journal of human genetics*, vol. 97, n. 5, 2015, pp. 631-46; Schloissnig, Siegfried et al. "Genomic Variation Landscape of the Human Gut Microbiome." *Nature*, vol. 493, n. 7430, 2013, pp. 45-50; Im, Hae Kyung et al. "On Sharing Quantitative Trait GWAS Results in an Era of Multiple-Omics Data and the Limits of Genomic Privacy." *American Journal of Human Genetics*, vol. 90, n. 4, 2012, pp. 591-8.

[946] Gymrek, Melissa et al. "Identifying Personal Genomes by Surname Inference." *Science (New York, N.Y.)*, vol. 339, n. 6117, 2013, pp. 321-4.

Consequently, some authors believe that the very concept of anonymity cannot be effectively applied to genetic data, biological samples or biobank processing more generally and that the provisions of the GDPR should always be complied with from the moment of collection and throughout the lifetime of storage and further processing of all samples and data,[947] and Schadt in 2012 re-identified an individual in large-scale collections of genomic profiles by deriving genotypic information from RNA data that were publicly available.[948]

On the one hand, when it comes to HBSs, from a practical point of view, already in 2012 Sàndor claimed "[i]t is well known" that to identify a person from HBSs, it is sufficient to compare it with another sample of the same person, even without personal data.[949]

Moreover, it has been suggested that as long as a DNA sequence may be extracted from the sample, it does not matter that the (related) genetic data and other information on the participant are deleted because the sample itself cannot be truly anonymised.[950] This is because phenotypical and genotypical data could always be traced back to the person the sample belonged to, especially if one takes into consideration possible future advancements in the technologies possibly used in this regard.[951]

The same is usually claimed for biobank data. Here, the fact that it might not always be possible to reach a sufficient level of anonymisation in general is indirectly recognised by the AEPD-EDPS Joint paper on anonymisation, where it is established that at times "depending on the *context* or the nature of the *data*, the re-identification risks cannot be sufficiently mitigated".[952]

In this regard, Ohm especially criticised the idea of data being truly anonymous because of the increasing possibility of linking an individual to her data through reidentification in the Age of Big Data, especially thanks to and because of modern database

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[947] Hallinan, Dara, and Friedewald, Michael "Open Consent, Biobanking and Data Protection Law: Can Open Consent Be 'Informed' Under the Forthcoming Data Protection Regulation?"

[948] Schadt, Eric E. "The Changing Privacy Landscape in the Era of Big Data." *Molecular Systems Biology*, vol. 8, n. 612, 2012. Maestri, Enrico "Digibodies. Biobanche E Consenso Informato Tra Finzioni Scientifiche E Giuridiche."

[949] Sàndor, Judit, et al. "The case of biobank with the law: between a legal and scientific fiction." *Journal of Medical Ethics*, vol. 38, 2012, pp. 347-350.

[950] Maestri, Enrico "Digibodies. Biobanche E Consenso Informato Tra Finzioni Scientifiche E Giuridiche."

[951] Maestri, Enrico "Il Feticcio della Privacy nella Sanità. Cura del Paziente e Biobanking Genetico Prima e Dopo L'entrata in Vigore del GDPR"; Tallachini, Maria Chiara, "Retorica Dell'anonimia E Proprietà Dei Materiali Biologici Umani." *Corpo Esibito, Corpo Violato, Corpo Venduto, Corpo Donato*, edited by D'Agostino, Francesco, Giuffrè Editore, 2003, pp. 171-192.

[952] AEPD-EDPS, Joint Paper "10 Misunderstandings Related to Anonymisation", 2021.

technologies.[953] And this, already in 2010. From his formalist perspective, his suggestion at the time was to stop considering anonymisation as a "privacy-providing panacea",[954] thus completely abandoning it, and to adopt a risk assessment strategy to weigh "the benefits of unfettered information flow against the costs of privacy harms".[955] Subsequently, authors criticised this approach and adopted a more pragmatical one that took into consideration the value of data sharing for the public good as worth of protection in itself[956] and affirmed the necessity to mitigate it by adopting the more realistic risk of identification as criteria against which parameter the measures to prevent re-identification.[957]

Concerning the nature of the biobank data, questions arise as to whether it is possible in general to irretrievably de-identify genetic data specifically and more generally data concerning health, under both a technical and a legal point of view, and thus be considered anonymous for the purposes of the GDPR.[958] As for the technical point of view, Quinn and Quinn believe that anonymisation of genetic data is unrealistic because it has been rendered increasingly difficult, if not impossible, by developments in computational genetics, such as in particular the increased possibility of sharing and accessing data, growing computing powers, and the development of powerful algorithms capable of re-identify individuals in new ways previously unknown.[959] Consequently, we may now be able to identify individuals from samples of genetic code that we used to consider anonymous thanks to, and because of, the use of these new tools, publicly available data,

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[953] Ohm, Paul "Broken Promises of Privacy: Responding to the Surprising Failure of Anonymisation." *UCLA Law Review*, vol. 57, 2010, pp. 1701-1778. Against his approach, see Schwartz, Paul M., and Daniel J., Solove "The PII Problem: Privacy and a New Concept of Personally Identifiable Information." *New York University Law Review*, vol. 86, 2011, pp. 1814-1895 and Schwartz, Paul M., and Daniel J., Solove "Reconciling Personal Information in the United States and European Union." *California Law Review*, vol. 102, 2014, pp. 877-917.

[954] Ohm, Paul, "Broken Promises of Privacy: Responding to the Surprising Failure of Anonymisation."

[955] *Ibid*

[956] Yakowitz, Jane "Tragedy of the Data Commons." *Harvard Journal of Law and technology*, vol. 25, n. 1, 2011, pp. 1-67.

[957] Schwartz, Paul M., and Daniel J., Solove "The PII Problem: Privacy and a New Concept of Personally Identifiable Information." and Schwartz, Paul M., and Daniel J., Solove "Reconciling Personal Information in the United States and European Union."

[958] Check Hayden, E., "Privacy Protections: The Genome Hacker." *Nature*, vol. 497, 2013, pp. 172–174; Shabani, Mahsa, and Luca, Marelli "Re-Identifiability of Genomic Data Under the GDPR. Assessing the Re-Identifiability of Genomic Data in Light of the EU General Data Protection Regulation."

[959] Quinn, Paul, and Liam, Quinn "Big Genetic Data and Its Big Data Protection Challenges." *Computer Law & Security Review*, vol. 34, n. 5, pp. 1000-1018.

among which data processed in previous research projects are included, and an increased number of samples collected generally.[960]

Moreover, some authors claim that it is impossible to anonymise a specific type of biobank data, namely unstructured data, i.e. data that does not follow a predefined data model (such as text documents, images, videos, and recordings) and which represents a consistent portion of the personal data. [961] These data may include personal information and provide sensitive attributes such as health conditions, all in various formulations and formats, not easily predictable.[962] Therefore, the difference between structured and unstructured data rests on the fact that in the former the identifiers are easily detectable and erasable because the data themselves follow a defined model, which is not the case for unstructured data.[963] For instance, text documents are common unstructured data, in which personal information may be included in various and not easily predictable linguistic formulations.[964] Difficulties in anonymising unstructured data derive therefore both from the technical problem that identifiers are not easy to detect, and the legal one of the interpretation of the identifiability element provided for by the GDPR.[965] Finally, from a practical point of view, unstructured data may rarely be anonymised using ordinary anonymisation operations, such as aggregation.[966]

On the other hand, anonymisation may be challenging to achieve because of the context (research biobanking) in which these data are processed, particularly taking into consideration the dynamic character of the evaluation to be conducted to consider data truly anonymous.

First of all, the increasing amount of data collected generally through time, especially with the technologies of the Internet of Health Things,[967] makes it increasingly more challenging to reach genuine irretrievability.[968] Indeed, the possibility of considering (biobank) genetic data anonymous progressively decreases over time because of the constantly increasing amount of data available from research, biobanking, and various

[960] Quinn, Paul, and Liam, Quinn "Big Genetic Data and Its Big Data Protection Challenges."
[961] Weitzenboeck, Emily M., et al. "The GDPR and Unstructured Data: Is Anonymization Possible?"
[962] *Ibid*
[963] *Ibid*
[964] *Ibid*
[965] *Ibid*
[966] *Ibid*
[967] Colonna, Liane "Privacy, Risk, Anonymisation and Data Sharing in the Internet of Health Things."
[968] Preamble of the UNESCO International Declaration.

other sources, as well as the mentioned technical developments.[969] Indeed, a set of data considered anonymous today might be easily linkable to a specific data subject in the future, and the data controller should therefore monitor the data environment once data has been shared or otherwise disclosed.[970]

Moreover, the very aim of a research biobank is to collect various types of data and samples from selected participants or large amounts of data from people of a given population and share them among researchers to conduct scientific research. It is precisely the "expanding quantity of data" collected by, and stored in the biobank and subsequently shared that poses severe doubts on the possibility of considering them anonymous at the beginning, but more importantly to maintain this status over time.[971] This is all the more true if the data shared are considered anonymous. Indeed, since such a sharing process would not be subject to the provisions of the GDPR, this might incentivise data-sharing practices by the biobank with researchers, possibly under an open-access model.[972] This, in turn, would make more (anonymous) data available in the absence of specific appropriate safeguards and, therefore, increase the likelihood of re-identification.[973]

Further risks for identification may derive from the increasing possibility of cross-referencing these data with other datasets, publicly available[974] or to which the researcher has access for various reasons. Indeed, it has been proven possible and also relatively easy to combine multiple anonymised datasets to identify an individual.[975] This hypothesis has been confirmed by a 2014 study of the Cambridge Institute of Technology (MIT), which proved the possibility of tracing a person's identity by extracting and aggregating non-identifying data. In their study, they were able to track a person from the analysis of credit card transactions over three months and metadata related to them, such as the amounts spent, the type of store, etc. These data were then related and analysed with other information about the person from different and external sources.

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[969] Quinn, Paul, and Liam, Quinn "Big Genetic Data and Its Big Data Protection Challenges"; Weitzenboeck, Emily M., et al. "The GDPR and Unstructured Data: Is Anonymization Possible?"
[970] Weitzenboeck, Emily M., et al. "The GDPR and Unstructured Data: Is Anonymization Possible?"
[971] Hallinan, Dara, and Friedewald, Michael "Open Consent, Biobanking and Data Protection Law: Can Open Consent Be 'Informed' Under the Forthcoming Data Protection Regulation?"
[972] Shabani, Mahsa, and Luca, Marelli "Re-Identifiability of Genomic Data Under the GDPR. Assessing the Re-Identifiability of Genomic Data in Light of the EU General Data Protection Regulation."
[973] *Ibid*
[974] *Ibid*
[975] Irti, Claudia "Personal Data, Non-personal Data, Anonymised Data, Pseudonymised Data, De-identified Data."

Keeping in mind once again the dynamic nature of the evaluation to be conducted, the anonymisation of biobank data may also be problematic from a more technical point of view. Indeed, in the field of biobanking research and scientific clinical research technologies are advancing rapidly and they increase the chances of re-identifying biobank data previously considered anonymous.[976] For this reason, it has been suggested to approach with caution the possibility of considering personal data anonymised in the field of scientific research.[977]

Some authors proclaim that advancement in technologies causes the end of the *consent and anonymisation approach*,[978] and others believe in the necessity not to consider anonymisation as a freeway for any subsequent use of the (anonymised) data,[979] or any possible research project for the sake of our analysis, without any consideration of the previous intentions of the data subject. Indeed, data are initially collected from the data subject for a specific purpose and are therefore *personal data.* The process of anonymising these data is itself a form of data processing and in particular of *further processing.* Consequently, anonymisation should comply with Art. 5(1)(b) and Recital 50 and thus be compatible with the original purpose".[980] From this interpretation, it derives that if personal data were collected on the basis of consent, then subsequent use of these data should not be incompatible with it, while if the first processing was based on another legal basis, anonymisation for research should still demonstrate to have social value.[981]

More generally, Savage argues that given the impossibility of reaching complete anonymisation of personal genetic data, anonymity cannot be considered a solution to privacy concerns.[982]

Two more concrete issues on the anonymity of both samples and data relate to the ways in which biobanking operates and in particular the scientific projects that are conducted thanks to biobanks. Indeed, and especially taking into consideration the vast promises of

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[976] EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, 2021. See also on this point Weitzenboeck, Emily M., et al. "The GDPR and Unstructured Data: Is Anonymization Possible?"

[977] EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, 2021.

[978] Casonato, Carlo, and Marta, Tomasi "Diritti e Ricerca Biomedica: una Proposta Verso Nuove Consonanze."

[979] EDPB, a Preliminary Opinion on data protection and scientific research, 2020; Groos, Daniel and van Veen, Evert-Ben "Anonymised Data and the Rule of Law."

[980] Groos, Daniel and van Veen, Evert-Ben "Anonymised Data and the Rule of Law."

[981] *Ibid*

[982] Savage, Neil "Privacy: The Myth of Anonymity." *Nature,* vol. 537, n. 7619, 2016, pp. 70-72.

biobank research for the advancement of precision medicine, i.e. the development of tailored treatments for any given patient, anonymising the HBS and the data from the outset would mean making it impossible to further collect data from the same patient, either general or follow-up data,[983] which however are particularly useful, especially in clinical research to better study and understand diseases, their symptoms and impact, over time.[984]

Moreover, on a general level, anonymous (genetic) data are less useful for scientific (genetic) research, which often takes advantage of and actively uses the link and connection between the data and the person.[985] Indeed, the possibility of data not being entirely useful for research if anonymised is also recognised in the AEPD-EDPS Joint paper on the 10 misunderstandings related to anonymisation, where it is stated that anonymisation in itself is "a process that tries to find the right balance between reducing the reidentification risk" and thus ensuring anonymisation, "and keeping the utility of a dataset for the envisaged purpose(s)".[986] The same can be reasonably said for HBSs. This phenomenon has been described as a negative correlation between privacy and data utility.[987]

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[983] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona;* Marilotti, Lorenzo "Ipotesi per una Gestione Partecipata delle Biobanche Genetiche Concepite Come Beni Comuni"; Anderson, Nicholas, et al. "Participant-Centric Initiatives: Tools to Facilitate Engagement in Research." *Applied & translational genomics*, vol. 1, 2012, pp. 25-29; Casonato, Carlo, and Marta, Tomasi "Diritti e Ricerca Biomedica: una Proposta Verso Nuove Consonanze"; Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: Il Possibile Ruolo delle Biobanche."

[984] Bronstein, Max G, and Emil D., Kakkis. "Patients as Key Partners in Rare Disease Drug Development." *Nature Reviews. Drug Discovery*, vol. 15, n. 11, 2016, pp. 731-732; Casonato, Carlo, and Marta, Tomasi "Diritti e Ricerca Biomedica: una Proposta Verso Nuove Consonanze."

[985] Marilotti, Lorenzo "Ipotesi per una Gestione Partecipata delle Biobanche Genetiche Concepite Come Beni Comuni"; Groos, Daniel and van Veen, Evert-Ben "Anonymised Data and the Rule of Law"; Gefenas, Eugenijus "Controversies Between Regulations of Research Ethics and Protection of Personal Data: Informed Consent At a Cross-Road"; Colonna, Liane "Privacy, risk, anonymisation and data sharing in the Internet of Health Things"; Quinn, Paul, "The Anonymisation of Research Data — a Pyric Victory for Privacy that Should Not Be Pushed Too Hard by the EU Data Protection Framework?" *European Journal of Health Law*, vol. 24, 2017, pp. 1-21; Kogut-Czarkowska, Magdalena, "Anonymisation: The Trap for Biobanking (Part II): Why the Anonymisation Could Be a Trap for the Biobanking Activity? Can There Really Be Anonymisation in the Research Biobanks." *GDPR Requirements for biobanking activities across Europe*, edited by Colcelli, Valentina, et al. Springer, 2023, pp.31-38.

[986] AEPD-EDPS Joint Paper "10 Misunderstandings Related to Anonymisation." 2021. On the same topic, see ISO/IEC 27559/2022 on Information security, cybersecurity and privacy protection — Privacy enhancing data de-identification framework.

[987] Colonna, Liane "Privacy, risk, anonymisation and data sharing in the Internet of Health Things"; Zuiderveen Borgesius, Frederik, et al. "Open Data, Privacy, and Fair Information Principles: Towards a Balancing Framework."

This is all the more true for personalised medicine, where not only is the link between the data and the participant essential, but there is also a strong need to analyse large sets of data to find correlations that are statistically valid.[988] In this context, the balance between usability and anonymisation of the dataset to be used should be established according to the "methodological requirements of the research"[989] which will set the level of granularity of the dataset to be used. The more open access the research will be, the more stringent the anonymity test to be conducted.

Finally, and in general terms, anonymising biobank data to make them available for research would also mean rendering it impossible to provide feedback to participants, especially on incidental findings.[990]

6.1 POSSIBLE CONCRETE STRATEGIES TO BE ADOPTED

However, I believe in the possibility of considering HBSs and personal (normal and genetic) data anonymous in given circumstances, adopting the risk-based approach, also sometimes referred to as *fictional approach,*[991] considering that true and irreversible anonymisation is not actually feasible for either HBSs or personal data.

Indeed, the GDPR, as interpreted, in particular, by the ECHR, does not provide for the absolute impossibility of identifying the data subject but only for a sufficiently low level of re-identification, taking into consideration the concrete characteristics of the given processing. While absolute anonymity is impossible, factual anonymity is still an option.[992] Indeed, data controllers should always consider de-identifying data as a possible risk and should deal with them appropriately and proactively.[993]

As mentioned, the analysis to be conducted is not only a case-by-case one, but it is also dynamic, and thus, it needs to be constantly re-assessed.

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[988] Groos, Daniel, and van Veen, Evert-Ben "Anonymised Data and the Rule of Law."

[989] *Ibid*

[990] Gefenas, Eugenijus "Controversies Between Regulations of Research Ethics and Protection of Personal Data: Informed Consent at a Cross-Road"; Casonato, Carlo, and Marta, Tomasi "Diritti e Ricerca Biomedica: una Proposta Verso Nuove Consonanze."

[991] Maestri, Enrico "Digibodies. Biobanche E Consenso Informato Tra Finzioni Scientifiche E Giuridiche." Critical on the possibility of considering anonymisation as an instrument to safeguards the rights and interests of the participants in their wholeness, Tallachini, Maria Chiara, "Retorica Dell'anonimia E Proprietà Dei Materiali Biologici Umani."

[992] Nasseh, Daniel, "The Mishandling of Anonymity in Terms of Medical Research within the General Data Protection Regulation." *Studies in health technology and informatics*, vol. 272, 2020, pp. 43-46.

[993] Shabani, Mahsa, and Luca, Marelli "Re-Identifiability of Genomic Data Under the GDPR. Assessing the Re-Identifiability of Genomic Data in Light of the EU General Data Protection Regulation."

This approach is in line with the risk-based approach adopted by the GDPR (and re-affirmed by the CJEU) both on the matter and more generally in the legal regime designed by its provisions and principles, such as the principles of accountability (art. 5(2) and art. 24) and data protection by design and by default (art. 25).[994]

Given that the concept of anonymity applied to HBSs refers to the possibility of not tracing the sample back to the participant using the information and data to be extracted therefrom, I believe in the legitimacy of the choice to apply the same approach adopted for personal data to HBSs as well. In this regard, in order to consider the samples anonymous, the evaluation to be conducted would be on a case-by-case basis, and there should be a sufficiently low level of risk of re-identification with the means available to the recipient of the samples in a given situation.

Therefore, in biobanking the HBSs and the personal data may be considered anonymous if the specific context of a processing the requirements underlined above can be complied with, and the specific evaluation should be re-assessed on a continuous basis at every step of the processing.[995] Indeed, as a matter of example, the re-identification demonstration by Homer and colleagues in 2008 led the National Institute of Health (NIH) and the Wellcome Trust to move from open-access to controlled-access databases.[996]

Moreover, also the needs of the specific processing and of the research projects to be conducted using the content of a given biobank should be considered.[997] Indeed, if a research project cannot be conducted unless identifiable or pseudonymous information is processed, it should be possible to do so, provided full compliance with the relevant ethical and legal requirements. At the same time, in case of incidental findings important for the health of the data subject, it should be possible to re-identify the latter.

Such an approach is confirmed by the EHDS, which bases some of its relevant provisions on the possibility of anonymising the health data with the aim of providing access to and establishes the duty to develop standard techniques and specifications in this regard.

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[994] Tzanou, Maria *Health data privacy under the GDPR: Big Data Challenges and Regulatory Responses.*

[995] Shabani, Mahsa, and Luca, Marelli "Re-Identifiability of Genomic Data Under the GDPR. Assessing the Re-Identifiability of Genomic Data in Light of the EU General Data Protection Regulation."

[996] *Ibid*

[997] Kogut-Czarkowska, Magdalena "Anonymisation: The trap for biobanking (Part II): Why the anonymisation could be a trap for the biobanking activity? Can there really be anonymisation in the research biobanks."

Finally, applying this concept to biobank has different consequences according to the chosen model for the collection of biobank data.

Indeed, in Scenario 1 – collection for biobanking purposes, it is almost impossible on a concrete level to store in the biobank HBSs and data already anonymised, considering that the biobank itself collects them in the first place. In this context, it might be possible for the latter to provide anonymised HBSs and data to the researchers to conduct their own projects.[998] As it appears evident, this would only be possible in cases where the biobank does not conduct scientific research itself.

As mentioned, the anonymisation processing should comply with the GDPR requirements, and in this regard a further protective measure against re-identification might be the clauses included in the Material or Data Transfer Agreement, in which the parties might agree that no re-identification would be attempted by the data recipient. Once again, this approach is confirmed by the newly introduced paragraph 3a of Art. 44 of the EHDS, which states that "the health data user's failure to respect the health data access body's measures ensuring anonymisation (...) shall be considered a particularly serious breach of this Regulation", thus confirming the value of this type of agreement in the context of anonymisation.

In this context, the biobank would also be able to re-identify the participant, if needed under exceptional circumstances, especially as far as incidental findings are concerned.

On the other hand, in Scenarios 2 and 3, the HBSs and data might be directly stored in the biobank anonymously and subsequently provided to researchers. However, this way, it would be more challenging to identify the participant if needed. Therefore, while it seems reasonable to apply the same approach as in Scenario 1 also in these two further cases (i.e. anonymisation conducted by the biobank in order to provide anonymised HBSs and data to researchers), the specific context of the research projects to be conducted should be carefully evaluated to assess whether this solution is feasible in a given situation.

As evident, in all the mentioned scenarios the biobank acts as an intermediate entity that protects the rights of the data subjects by anonymising the data and providing them anonymised to researchers, while at the same time foster the interests of research by not

[998] Guarino, Rosa *Biobanche di Ricerca e Tutela della Persona.*

only providing data when available, but doing so in the most appropriate way according to the concrete needs of the research project.[999]

Finally, the risk of reidentification should be assessed also by third parties receiving the anonymised data (in our case the researchers).[1000]

The approach described in this paragraph resembles, to some extent, the general idea of the EHDS. Indeed, in that context, the data access bodies are entitled to the duty to grant the data user (researcher) access to a specific dataset, usually in an anonymised format, unless required otherwise by the specific aim pursued. In that context, as well as in the one described here, the data access body (and the biobank in our analogy) would process the data to render them anonymous and thus should comply with the GDPR provisions for this specific processing. Moreover, a theoretical parallelism may be built between the Material/Data transfer agreement in the biobanking context and the data permit or approval of the data request in the EHDS legal framework. Indeed, in both cases, the provisions included therein represent the boundaries of the processing considered legitimate, and if the data shared or to which access is granted are anonymous, also an appropriate measure to prevent re-identification.

More generally, applying anonymisation and, thus, processing and sharing anonymised HBSs and personal data in biobanking becomes a balancing exercise between the various rights and interests at stake instead of being a neutral and permanent solution. Consequently, it should be considered as a technical tool to be implemented in biobanking if the concrete balancing of the various contrasting rights and interests in a given specific situation (processing for scientific research purposes) so provides. The conclusion reached, and the result of the concrete balancing exercise, may however be affected by future developments both in the technologies possibly used for re-identification and in the amount of data generally available, that may generate the necessity of adjusting the initial conclusion. Anonymisation is a dynamic evaluation that should be periodically re-assessed at every stage of the processing by the data controller.[1001]

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[999] Pacia, Romana "Campione Biologico e Consenso Informato nella Ricerca Genetica: Il Possibile Ruolo delle Biobanche"; Macilotti, Matteo "Proprietà, Informazione ed Interessi nella Disciplina delle Biobanche a Fini di Ricerca."

[1000] Martìnez, Ricard "Anonymisation (Part I): What Is the State-Of the Art of Anonymisation in Data-Driven Health Research and Its Role in the "European Health Data Spare Regulation"?"

[1001] Shabani, Mahsa, and Luca, Marelli "Re-Identifiability of Genomic Data Under the GDPR. Assessing the Re-Identifiability of Genomic Data in Light of the EU General Data Protection Regulation."

In particular, anonymisation protects the rights of the participant if the risk of re-identification is sufficiently low, while at the same time, it enables faster advancements in scientific research because a more significant amount of personal data may be used with fewer restrictions or obligations to be complied with. However, these instances may contrast with the interest of science and research in being able to collect and use follow-up data or that of participants in receiving research results in case these may have an impact on participants' health. At the same time, being anonymisation a fictional exercise, it cannot coincide with the loss of any interest or power on the part of participants over the use of their samples or personal data[1002]

From a more concrete point of view, identifiability, anonymity and re-identifiability depend on multiple factors, which include not only the nature and specific characteristics of the dataset, but also the context of the processing, the technologies available at the time of collection and in the future, as well as expertise and incentives and the mitigation strategy adopted.[1003] For this reason, in this context two sets of strategies might be adopted to pursue anonymisation: 1) the adoption of technical safeguards, or 2) the implementation of adequate biobanking governance frameworks, with a focus on the associated governance models for managing data access.[1004] Indeed, not only the provisions included in the Material and Data transfer agreements, as mentioned, but also access models can be considered organisational measures mandated by the GDPR along with technical measures for safeguarding data. These models may include institutional rules, such as the ban on attempting to re-identify the participants, and related terms and conditions of the Data Transfer Agreement, that if implemented constitute an additional protection against re-identification.

Finally, the biobank should inform participants at the moment of the collection of the possibility of anonymising their data, in order for them to be truly informed and enable their possibility of exercise the right to informational self-determination,[1005] as well as preserving their trust, particularly under the transparency aspect.

[1002] Cordiano, Alessandra "Biobanche di Ricerca e Modelli Regolativi."

[1003] Shabani, Mahsa, and Luca, Marelli "Re-Identifiability of Genomic Data Under the GDPR. Assessing the Re-Identifiability of Genomic Data in Light of the EU General Data Protection Regulation."

[1004] *Ibid*

[1005] Lucarelli Tonini, Lorenzo Maria "Regolare le Biobanche tra Interessi Pubblici e Privati: Il Nodo dei Campioni Biologici."

CONCLUSION

The field of biobanking is of great importance for the advancement of scientific research, because it ensures the availability of large quantities of personal data, in compliance with rigid standards of quality and security.

As the study demonstrated, issues in the field of biobanking arise already at the moment of defining the applicable concepts, which however is an important task for the interpreter in order to delimit the scope of the analysis. In the present work, I chose research biobanks, i.e. collections with the aim of processing the samples and data for future research purposes, because of their specificities. In particular, research biobanks need to balance the contrasting rights of the data subject, in particular that to data protection, and the interests in society at large in the advancement of scientific research and, consequently, in the protection of public health.

Because of their fundamental role in society, biobanks need to adopt a trustworthy governance model, especially for the activity that guarantees their existence, i.e. that of the collection of human biological samples and personal data to be stored for future research purposes. As described, trust is indeed of fundamental value for biobanks, because the latter should rely on the willingness of participants of making their HBSs and data available and not subsequently withdraw consent to their use or oppose to their processing, as well as ask for their destruction.

In this regard, human biological samples and personal data may be collected in various patterns (described as Scenarios throughout the text, i.e. Scenario 1 – collection for biobanking purposes, Scenario 2 – collection for scientific research purposes, and Scenario 3 – collection for other purposes) and raises (at least at first glance) different instances of protection.

Before addressing the specific issues, I stressed the importance of recognising the difference between the biobanking processing, i.e. collecting data to store them for future and undefined research purposes, and scientific research, which is the actual processing of the data for a specific research project. I believe that maintaining them separate helps avoid some of the difficulties in adapting the principles and notions developed for and

devoted to scientific research also to biobanking. However, this is not the approach adopted by the Italian DPA under the national regime and therefore throughout the study I also considered the biobanking processing as scientific research according to the GDPR. On the one hand, HBSs are parts of the human body detached from the person, which acquire autonomy from the moment of the collection and are thus created in their materiality. In this form, they may be transferred from the participant to the biobank, raising issues related to the qualification of the samples, the possibility of applying the proprietary rights paradigm, and the value of consent. To answer these questions I sustained it is necessary to conceptually divide among interventional consent (provided by the patient to authorise a medical intervention and a violation of her physical integrity), interventional research or biobank consent (i.e. consent to the use and processing of the samples after its detachment from the body) and informational consent, which is the consent provided for the processing of personal data.

While at the beginning of the discussion it seems possible to include HBSs under the proprietary regime, because they were mainly considered in their *material* nature, this solution seemed insufficient or unfeasible especially after the discovery of their *informational* nature. While at the beginning of the discussion, it seemed possible to include HBSs under the proprietary regime because they were mainly considered in their material nature, this solution seemed insufficient or unfeasible, especially after the discovery of their informational nature, which shall prevail in determining the legal qualification of the sample as a whole. Indeed, after the collection of the sample, the only risks that may derive from its processing are those related to the information that may be extracted therefrom, and therefore risks for the (genetic) identity or right to (informational) self-determination of the participant. Consequently, in order to authorise the processing of the samples for biobanking purposes, it is necessary to comply with the data protection rules, which require informational consent as a legal basis, among others. Precisely the fact that the data protection regime includes legal bases (and exemptions) different from the consent of the participant, raises possible contrast with the general requirement of soft law instruments applicable to the processing of HBSs of acquiring interventional biobank consent. In attempting to reconcile the matter, I suggested considering such a consent as an additional measure for the protection of the rights and interests of the participant in the processing of her HBS data.

As for the collection of biobank data (which are both normal and sensitive data), as demonstrated, there is a substantial difference between the supranational and national levels. Indeed, on the one hand, the GDPR mainly provides biobanks with the choice between the *consent-based model*, i.e. collecting the personal data asking for the informational consent of the data subject (Art. 6(1)(a) and Art. 9(2)(a)), and the *necessity-based model*, i.e. based on the evaluation of the necessity of the processing itself. In this regard, various legal bases and exemptions are feasible, but in the context of biobanking, these are restricted to Art. 6(1)(e) and (f) and Art. 9(2)(i) and (j). In particular, the latter renders applicable the so-called scientific research regime, i.e. a set of specific provisions and exemptions from some of the GDPR principles (such as the principle of storage limitation and purpose limitation) and individual rights, that renders manifest a general favour of the European legislator for scientific research and, more importantly, the possibility of balancing the right to data protection, not qualified as an absolute right, against the interests of scientific research in sharing and processing these data. Moreover, the biobank may also choose to process the HBSs and personal data as a secondary processing, therefore conducting the compatibility test (in general) or presuming the processing compatible, if it is considered as "scientific research" for the purposes of the GDPR.

The scenario at the national level is radically different. Indeed, for the primary collection of personal data as well as the secondary processing for scientific research purposes, and any processing of genetic data should be based on the informational consent of the data subject according to the Italian DPA and Italian Privacy Code, which is usually required in the form of a specific consent. Indeed, processing in these cases are also possible without consent, but in exceptional circumstances and usually only if acquiring the consent of the data subject is impossible or renders it difficult for the research to reach its objectives. Therefore, at the national level, the biobank may process personal data without informational consent only on rare occasions and because of this, and with the aim of trying to increase the processing of data for biobanking purposes, the biobank is left with the only choice of trying to broaden the strict boundaries of specific informational consent, and acquiring either a broad consent for a wider range of processing activities or a dynamic consent, i.e. the establishment of an ongoing communication between the

participants and the biobank for providing information, acquiring informational consent, enabling the exercise of fundamental rights, etc.

The choice, in both cases (supranational and national levels) should be made taking into account first of all the conceptualisation of the right to data protection and only subsidiary the need to protect participants' trust.

As for the first one, the right to data protection, also part of the broader right to privacy, is nowadays conceptualised as the right to control the processing of the personal data throughout their life cycle, not only by providing informational consent, but also by having the possibility of acquiring extensive information on the processing, exercising various fundamental rights (such as the right to access the data, require a rectification, oppose to the processing, etc) and finally imposing on the data controller duties related to the fair and lawful processing of the data, as well as to ensure the safety of the latter. This interpretation of the right to data processing is confirmed by the regulatory framework provided for by the GDPR, but also the DGA, the EHDS and the EU Charter.

On the other hand, participants' trust may be affected mainly by two elements if the collection of samples and data in biobank are considered: the transparency aspect and the participatory aspect. As for the former, it related to the amount of information provided to the data subject on the functioning of the biobank, its governance and the safety measures adopted. As for the latter, it requires biobank to let the data subjects participate to some extent to the biobanking activities, which does not necessarily mean providing informational consent, and make them feel empowered in the use of their data.

Moreover, the biobank regulatory landscape might be affected by the decision of the biobank itself to register as a data altruism organisation, and thus to collect data made available by the data subject via the provision of the data altruism consent and process them for the purposes in the public interests accepted by the data subject. On the other hand, when entered into force, the EHDS might affect the biobanking field in two distinct ways: (1) by considering biobanks as data holders, thus establishing for such collections a duty to share the data for scientific research purposes, or (2) by regulating the collection of the data to be stored in a biobank as secondary processing within the meaning of the new regulation. In both cases, the concrete consequences of these norms are to be seen according to the final version of the document.

Finally, I studied the topic of the possibility of anonymising personal data for biobanking purposes. In this regard, such a technique is frequently mentioned as the technical solution to most of the data protection problems. Apart from the technical difficulties associated with the processing of personal data in the context of both big data and biobanking, the evaluation of the data being anonymous is dynamic and therefore should be continuously verified through time. More importantly, its appropriateness should be evaluated according to the concrete context of the processing. Indeed, anonymising data protects the rights of the participant on the one hand, but it diminishes the value of the data for scientific research and therefore the biobank should carefully balance the different interests at stake, as well as conducting the mentioned trust test, to determine if such a procedure protects not only the participant's right to data protection, but also her trust, core value of scientific research.

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