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THE GOVERNANCE OF BIOBANKS IN THE DIGITAL SOCIETY

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Table of contents

Chapter 2

Identification of the unsolved bioethical issues related to biobank governance

SUMMARY: 1. CRISIS OF THE AUTONOMY PRINCIPLE. 2. COMMODIFICATION OF HUMAN BODIES. 3. INADEQUATE REGULATORY GUIDELINES. 4. INADEQUATE PROTECTION OF BIOBANK PARTICIPANTS. 5. INADEQUATE INFORMED CONSENT PROCEDURES AND FORMS. 6. INADEQUATE EVALUATION FOR ACCESSING BIOBANKS. CONCLUSIONS.

The fact that the governance, ethical, legal, and societal issues of biobanks are currently discussed with reference to an ethical and legal normative framework tailored for an analogue society carries with it what is perhaps the most immediate and negative consequence, namely that it is not possible to clearly see which problems do not yet have an adequate solution.

Accordingly, the aim of this chapter is two-fold. First, I seek to provide greater clarity by identifying the unsolved bioethical issues related to biobanks. The following list represents the main open and difficult questions, a list that I have compiled by relying on a mixed methodology that characterises my research: On the one hand, the literature review on biobanks' ELSIs and a normative ethical analysis of the ethical and legal frameworks applied to biomedical research and biobanks in Europe; on the other, a more practical and «field-based» approach based on my collaboration with two biobanks[14] and a close observation of their everyday practice, management and organisation.

i) The crisis of the principle of autonomy in front of the massive accumulation and processing of data and datasets.

14. The biobank of the Hospital Clinic, which is the oldest and largest in Barcelona, and the BIOGEN biobank of the Hospital Rizzoli of Bologna, which is part of the Telethon Network of Genetic Biobanks, a non-profit network founded by Fondazione Telethon interconnecting 11 Italian disease-oriented biobanks.

ii) The tendency towards the commodification of human bodies affects the human rights approach to research.

iii) The normative framework of reference does not provide adequate ethical standards and guidelines for biobank governance.

iv) The classic model of privacy protection fails to protect biobank participants.

v) The need for a transition towards new forms of informed consent and new strategies to face risks associated to secondary uses of samples and data.

vi) The evaluation procedure to access to biobank resources is inadequate, and, in turn, does not guarantee participants' protection.

The second aim of this chapter is to critically discriminate between the different natures of the unsolved issues using the philosophical angle described in Chapter 1. First, I argue that these issues belong to two different categories: i) The general issues common to biomedical research with samples and data, including research with convergent technologies that process such personal and sensitive data as genetic technologies, neurotechnology, and AI; and ii) the issues that can be inferred from the general issues, but defined as unsolved issues specific to biobank governance, namely the collection, storage, and distribution of samples and data. Secondly, I attempt to clarify the ethical dilemmas enclosed in the first category of issues. I argue that there are two issues that need clear formulation as ethical dilemmas:

i) In the digital age and in biomedical data-driven research, is it right to abandon the primacy of participant autonomy in favour of transparency?

ii) Is it right that the principle of not marketing the human body in research fields also extends to its biological samples and associated data?

An attempt to address these ethical dilemmas will be made in the second part of this book by proposing a conceptualisation of a governance model.

1. CRISIS OF THE AUTONOMY PRINCIPLE

The principle of autonomy has a long history in bioethics. It is a concept born in the last century in reference to clinical research and trials on humans,

as a response to the atrocities committed with experiments on human beings during the Second World War and up to the '70s (López Baroni et al., 2019). As theorised by Beauchamp and Childress (1979), the principle of autonomy refers to the right of competent adults to make informed decisions about their own medical care. In the context of biomedicine, this should be translated as ensuring adequate information, understanding, and voluntariness for individuals involved in biomedical research through informed consent procedures.

The significance of the principle of autonomy in research with biological samples and data, and in the context of participation in a biobank, can be framed by answering the following questions: What kind of autonomy is exercised in these areas and how is it done so? How far does the possibility of making autonomous choices on parts of one's body and associated person extend? How can the respect and guarantee of autonomy be ensured in biobank participation?

The reason behind an individual's choice to make their own biological samples and associated data available for future research purposes is the acquisition of a basic knowledge regarding diseases and treatments to yield health benefits for future patients and society at large.

The kind of autonomy that a biobank participant can exercise concerns the choices made on the collection, distribution, and use of their biological material and associated data once they are separated from the body. As detailed in the following paragraphs, the link between the principle of autonomy and the individual control over biological samples is justified by the fact that, through biobank participation, the individual is exposed to a series of risks linked to how their biological samples and personal data will be processed and used in the future. Therefore, in the context of biobanks, the respect and guarantee of autonomy in participation is ensured in two ways: First, by requesting informed consent to collect, store, distribute, and use the material taken; and second, by ensuring the participant's right to exercise control over the material and data once detached from their body. This control in the context of biobanks is expressed through the recognition of a series of rights of the participant and the establishment of governance mechanisms (Staunton et al., 2019).

In what follows, I argue that the first bioethical unsolved issue regarding biobanks is exactly the fact that the exercise of the principle of autonomy —and hence the control over samples and data— is in crisis due to the new risks brought by the digital society and data-driven research. In order

to demonstrate this, I retrace the history of the link between the nature of biological samples and the principle of autonomy in biomedical research. We are currently facing a new transition «from data to datasets» that questions the well-established framework for the exercise of individual autonomy on their samples and data (as defined at the beginning of the 21st century) with the transition from the material to informational dimension of human biological samples.

This first transition led to the recognition of the double dimension of human biological samples, which occurred at the end of the last century (Ficorilli, 2021). Before the technical and scientific advances in the field of genetics ('80s) and genomics ('90s), in the context of human research, biological samples were mainly considered in terms of their material dimension as aggregates of molecules. Accordingly, from a legal-ethical standpoint, «as a result of the detachment from the body the samples assumed the status of autonomous and independent entities with respect to the events that could affect the body and their fate had no impact on health but above all on the autonomy and the right to self-determination of the subject from which the sample came» (Faralli & Galletti, 2011, p. 19).

However, since the early 21st century, the idea has emerged that biological samples are an expression of the biological and genetic identity of the person from whom they come, as they also possess an informal dimension in addition to the material and physical. This leads to a change in the legal and ethical understanding of the sample:

> The readable data in the tissues maintain, contrary to what happens for the samples in their material dimension, even after detachment from the tissues of the body, an indissoluble relationship with the identity of the original body, as they extricate the genetic heritage of that person. From the informational point of view therefore the detachment does not sanction the complete biological of the biological sample from the body-subject but only the possibility of its autonomous circulation. (Faralli & Galletti, 2011, pp. 20-21).

Therefore, the recognition of this double dimension of human biological samples has led to a revision of the understanding of participants' self-determination. Indeed, before the possibility of genetic investigations, the reference to the principle of autonomy and participants' self-determination was centred on the question of propriety (if the sample belonged to the researcher or to the individual from whom it was extracted) (Tallacchini, 2015). When the focus shifted from the material to the informational dimension, the right to the participants' self-determination becomes relevant

regarding the choices linked to the mismanagement and misuse of biological and genetic information.

At this point, following the analysis of Ficorilli (2021) on the development of the link between the new approach to human biological samples and the relevance of the principle of autonomy and to the right to self-determination, it can be argued that the recognition of the double dimension of human biological samples (material and informational) has given rise to two important ethical changes. First, the relationship between clinicians/researchers and patients/research participants has transformed from paternalistic —i.e., the complete management of the samples by doctors and researchers— to being centred on the demand for informed consent (for the collection and use of biological samples and data for research purposes), including the will of the subject from whom the sample was derived. Second, in the practice of biomedical research on biological and genetic material, the validity of the ethical principle of autonomy of each individual on their own body was introduced, as with clinical trials or other research on the body of the participant.

Those changes started at a practical/scientific level have had a (slow) regulatory response at the level of international ethical references. In particular, starting from 2000, the World Medical Association Declaration of Helsinki included research on identifiable human material or identifiable data in its scope, and, from 2008, stated the protection of the right to self-determination within the duties of physicians participating in medical research[15].

I believe that the originality of my contribution to this debate on the unsolved ethical problems related to biobanks is the acknowledgement that we are assisting to a further transition regarding the value of samples and data made available by biobanks today. During the last decade, we have passed the age of the informational dimension of the biological sample to enter a new one in which the biological samples we seek are characterised by the presence of our biological and genetic identity in databases: Pieces of each subject, stored in numerous and different databases where the identity of the subjects is dissected and broken down (Lecuona Ramírez & Observatori de Bioètica i Dret, 2020).

15. Art. 11: It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

Consequently, we are facing a crisis of the principle of autonomy relating to how it was determined in biomedical research with samples and data at the beginning of the current century. The cause of this crisis must be identified in the emergence of the digital society and its commitment with data-driven biomedical research that advances through a massive accumulation and process of datasets containing biomedical information. Indeed, due to the large amount of personal information stored, and the development of technology and techniques with which to combine and interpret it, we, as a society, have transitioned from being isolated data to becoming sets of personal data that are candidates for exploitation by different actors with diverse and potentially conflicting interests.

Based on this premise, we can try to answer to the following questions: How and why is the respect for the autonomy of biobank participants no longer guaranteed in the digital society? As mentioned previously, the type of autonomy that a research participant can exercise in the context of a biobank is related to the control that they have over their own samples and associated data. This is a control that the participants cannot have themselves, but is instead given through the recognition of a set of rights and the guarantee of protection from exposure to risks over how their samples are treated and used in future.

Today, the classic model of privacy protection fails to protect participants' privacy and right to confidentiality in the digital age for predominantly technical reasons: the complexity of data analytics and the risks associated to data transferability, data interdependency, and links between datasets of different natures (Dankar & Badji, 2017). This is also acerbated by the fact that contemporary research is conducted in a context where the intensive exploitation of datasets and the likelihood of re-identification renders anonymisation no longer able to guarantee respect for privacy and confidentiality (Sweeney, 2000).

In conclusion, if we assume the definition of autonomy and self-determination in biomedical research to be «the right of competent adults to make informed decisions about their own medical care», it could be argued that the digital society has created new conditions that do not allow the application of the principle and exercise of this right. It fails to protect participants and guarantee control over samples and data.

Based on the above, I suggest that the overt crisis of the principle of autonomy in the field of biobanks presents us with an epochal ethical dilemma: Is it right or not to abandon the principle of autonomy as a reference for research participants' protection and control over their personal information?

My argument is that, in light of the new transition enabled by biobanks and databases —namely, the transitions from the informational dimension of biological samples to the presence of our biological and genetic identity in databases— the principle of autonomy can be abandoned as long as a transition to transparency is established along with the implementation of harm-mitigation measures against AI-based and other digital technologies.

As we shall see in Chapter 5, the identification of transparency as a pivotal principle for biobank governance aligns with the current widespread acknowledgement that, in our digital society, transparently conveying relevant information about a given organisation is considered a basic principle of good governance in many sectors, biomedical research included (Laurie et al., 2018). A general and basic definition of transparency is the «availability of information about an actor allowing other actors to monitor the working or performance of this actor» (Bovens et al., 2016, p. 3336). To comply with this principle, biobanks must make the entire process of biobanking transparent — from the collection of samples and data to the moment when external researchers deliver their discoveries to the scientific community based on biobanks' resources.

2. COMMODIFICATION OF HUMAN BODIES

The second bioethical unsolved issue for biobanks is related to the tendency towards the exploitation and monetisation of biological samples and personal data collected for research purposes and, in particular, to the case of disguised markets of biobank resources.

How biomedical research is developed from biobanks and the ways in which its goals are pursued are not neutral. Rather, they result from scientific, political, and economic commitments and decisions, strongly influenced by prevailing social and market trends. In the last decade, market and business criteria based on effectiveness and efficiency, productivity, and competitiveness have come to lead the biomedical and health sectors, taking the place of the principles and values underlying the regulation of health research and innovation. As argued by Casado et al. (2020), a real paradigm shift has occurred that has brought to «a utilitarian rationalization of research and the idea of "taking advantage" of what is not used (for example, with the "reuse" of the health data in the hands of the authorities by public/private third parties, and the establishment of "presumed consent")» (p. 34).

> Those criteria are also applied by the biomedical and health innovation system, which has a monopoly over the most cutting-edge services for the operation and storage of huge amounts of personal health data (de Lecuona, 2017).

> Therefore, market society has also extended its networks to the field of health research and innovation, generating attractive market niches based on the exploitation and marketing of personal health data.
>
> Ethically speaking, this situation raises concerns because new trends have almost completely severed the language of human rights intrinsically associated to research as emerged in the national and international ethical and legal framework of biomedical research. Casado (2017) stressed how this framework:
>
> ... places the transactions that concern the human body and its parts under a framework of no profit and solidarity. In principle, it can be said that, invoking human dignity, only things can have a price and, therefore, the human body and its components are outside the market. But this point of departure, which is generally accepted, comes into open conflict with the reality of the practices carried out in the field of health and research. […] To such an extent that, even at the theoretical level, analyses are being carried out that reformulate the established to accept profit also in this field. (p. 18)

The Council of Europe's Convention on Human Rights and Biomedicine (the Oviedo Convention, 1997) represents a cornerstone for research ethics by being the only legally-binding international instrument on the protection of human rights in the biomedical field. Its Article 2 establishes the primacy of the human being, indicating that the interests and welfare of the individual should prevail over those of society or science. Accordingly, Article 21 prohibits financial gain. As such, the human body and its parts should not be used for profit.

Similarly, the EU Recommendation Rec(2006)4 of the Committee of Ministers to member states on research using biological materials of human origin establishes in Article 7 a prohibition of financial gain: Biological materials should not, therefore, be used for financial gain[16]. In other words, the fundamental idea underlying biomedical research ethics is that the human body has a special dignity that should prevent the market from putting a price on it and commodifying it.

These considerations also apply in principle to biobanks as collections of human biological samples and associated personal data. In this regard, a valuable example of national regulation of biomedical research and biobanks is represented by the Spanish Ley 14/2007 de Investigación Biomédica (LIB). Previously (Iacomussi, 2021), I have explained that:

16. Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin and its Explanatory Memorandum

> In this regulation, free donation of human organs and tissues is a well-established ethical principle and is considered contrary to the dignity of the human being to trade with elements of the body. In particular, what stands out is the strong reference to the principle of altruism and the emphasis on no commercialisation of the human body or its parts. In line with the Council of Europe Convention for the Protection of Human Rights, in its art. 7 the LIB states that «the donation and use of human biological samples shall be gratuitous, whatever its specific origin, and the compensation that is provided for in this Law can in no way be of lucrative or commercial nature». In other words, the Spanish law allows biobanks to charge for obtaining, handling, shipping and distribution of samples for the sake of its own sustainability but, at the same time, it respects the principle of no commercialisation of the human body which is considered the bulwark of the protection of the human dignity. (p. 222)

These national and international frameworks that, in principle, should protect research participants against the commodification of their bodies, parts, and associated data, are currently clashing with the actual practice of biomedical research, giving rise to the significant contradiction reported by Casado (2017):

> How is it possible that the principles of global justice and respect for recognized human rights continue to be considered valid, and yet the commercialisation of the human body, its parts and components is increasingly accepted? (p. 18)

The reality that we must face is that the fundamental notion of the dignity of the human body that permeates biomedical research is being challenged by the combined power of two forces. First, it is under attack from the growing trend to apply criteria that prioritises commercial relationships in fields that were traditionally immune to them. In other words, under the current framework of neoliberal globalisation, the market puts a price on and objectifies human biological samples and associated personal data, and science and biotechnology become indispensable operators of this process. Second, the emergence of the digital society and the consequent datafication of health and biomedical research has created a new economically valuable asset, that of biomedical personal data, which forces us to address questions that have hitherto been unconsidered as belonging to a research-related context:

> How should we regard our role in relation to our own data and its contribution to the collective? Are we shareholders of an economically valuable asset, or are we joint owners or perhaps stewards of a public good or common resource? What new relationships —among people, populations, health care providers, researchers and companies— are created by the use of big data, or further, by its commercialisation? (Chan, 2017, p.12)

In other words, in the field of genetics research, biomedicine, and biobanks, we are already witnessing a tendency towards the exploitation and monetisation of personal data that involves extracting new value from data and making a profit from it.

> In the second place —and in line with the scope of this work— faced with this situation, it is therefore necessary to establish interpretative criteria and develop tools to assess existing tensions between the market forces and the human rights framework when it comes to regulate and evaluate biomedical research and biobanks. In particular, we are talking about freedom of research vs. privacy, collective interests vs. personal interests, gratuitousness vs. monetisation of personal data, and solidarity vs. market.

In order to provide a concrete example of what I have been explained so far, let us now turn to the «famous» case of 23andME. It concerns the tendency to accumulate personal information and monetise it through «direct to consumer (DTC) genetic testing», using genetic home-testing kits sold directly to consumers by private companies to provide insights about their genetic information (ancestry, health traits, and health risks) from saliva samples. Unlike clinical-based genetic tests which are ordered, interpreted, and disclosed by a physician or other healthcare professional, the ordering and return of results from these DTC genetic tests does not involve healthcare professional engagement and, usually, the interpretation of the results is left to the customer[17].

23andMe is a well-known DTC genetic-testing private company in the USA, which sells genetic tests online offering various services in return[18]. In particular, it promises to explore three areas from the sequencing of customers' DNA: i) Health predispositions, the test of which can provide information on the likelihood of the customer developing certain health conditions based on their DNA; ii) ancestry composition, which allows the customer to discover where in the world their DNA is «distributed» and, in turn, potentially connect with relatives comparable with ancestries and traits; and iii) traits features, which shows the customer how DNA can influence physical features (e.g., hair photobleaching, freckles). Overall, the appeal of these services lies in knowing that such information can help customers take action on their health and well-being.

After signing up to 23andMe via the company's website and placing an order, all customers need to accept its Terms of Service, which lay out the

17. The practical limitations and ethical issues of such enterprises have been discussed in the scientific literature (see, for example, Hogarth et al., 2008; Caulfield & McGuire, 2012).
18. https://www.23andme.com/?evr=epv

contractual basis for the genome sequencing services offered. At this point, a second level of customer involvement should be considered. Customers can opt into 23andMe's research activities and agree to their samples and associated personal data being retained for biobanking.

For both options —23andMe's testing service and research— personal data are said to be encrypted (not anonymised), protected, and under the consumers' control.

Customers who opt into 23andMe's research sign a research consent that «allows 23andMe researchers to use certain information (including your Genetic Information and your responses to research surveys) to study a wide variety of research topics» and are told that «taking part in this research is completely voluntary, and you can change your consent choice at any time without affecting your access to the 23andMe product or services»[19].

Regarding collaboration with third parties, the consent statement indicates that some 23andMe research is conducted in collaboration with third parties, such as non-profit organisations, pharmaceutical companies, or academic institutions, and that they «may share summaries of research results, which do not identify any particular individual, with qualified research collaborators and in scientific publications»[20].

For the purposes of my arguments, I focus on how the company uses customers' samples and associated data for research, with the aim of showing the relevance of the ethical issues at stake. First, it should be noted that the informed consent signed by customers for their samples and data to be used for 23andMe's research is based on an opt-in model and, in the case of collaboration with third parties, is reduced to an eventual disclosure ex-post, which differs from previous and specific consent (Allyse, 2013).

Second, following Stoeklé et al.'s (2016) argument, it is important to acknowledge that it may be the case that the primary objective of 23andMe was two-fold from the outset:

> Promoting itself within the market for predictive testing for human genetic diseases and ancestry at a low cost to consumers, and establishing a high-value database/biobank for research (one of the largest biobanks of human deoxyribonucleic acid (DNA) and personal information). (p. 2)

Accordingly, 23andMe have two different kinds of customers: i) Those seeking insights into their genetic make-up for a number of different reasons;

19. https://www.23andme.com/about/consent/
20. https://www.23andme.com/about/consent/

and ii) third parties, such as pharmaceutical companies, who want access to large datasets of genetic, phenotypic, lifestyle-related, and other self-reported information that the company collects from customer data and to which it sells access (Tobin et al., 2012).

On the basis of these considerations, I will now explore what is ethically questionable about 23andMe's behaviour, which was chosen as a high-profile example of several DTC practices that raise ELSIs (Tobin et al., 2012). I argue that 23andMe's research activities raise three problematic points:

- The company accumulates datasets of personal data for their commercial value. The information asked of customers goes beyond the genetic information extracted from DNA sequencing, including follow-on surveys about health and lifestyle.
- The company makes financial agreements (see below for the best-known case) to transfer the accumulated datasets to third parties that use them for research purposes.
- Even if the possibility that customers' data will be shared is contemplated by the research consent signed by them, the transfer occurs without their explicit consent.

Therefore, what is ethically questionable here is «the extent to which the company assures —or should be required to assure— that its customers are aware of how exactly their data is being used» (Raz et al., 2020, p. 462). Even if the possibility of making customers' data available to third parties is contemplated in the original agreement between the customer and the company, there is an ethical assessment of this practice that transcends legal compliance — in this case, with the conditions stated in the signed consent form.

This appears clear in the following facts. In 2018, 23andMe announced a collaboration with GlaxoSmithKline (GSK) to use its encrypted aggregated datasets to develop pharmaceutical drugs, and thus attracted a $300 million investment from the pharmaceutical giant[21]. By that time, 23andMe had collected personal data from over 8 million customers, accumulating a treasure trove of genetic data representing (by far) the largest collection of gene-linked health data anywhere in the world. The goal of this collaboration was to combine 23andMe's genetic databases with GSK's scientific knowledge and commercialisation expertise to drive disease progression research, discover novel drug targets, and develop new therapies[22].

21. https://www.nytimes.com/2021/09/20/opinion/23andme-dna.html?
22. https://www.gsk.com/en-gb/media/press-releases/gsk-and-23andme-sign-agreement-to-leverage-genetic-insights-for-the-development-of-novel-medicines/

Read against the previous ethical considerations, it should now be clear why there is still something morally problematic about this transition, although the goals of the collaboration are worthy and aimed at shared benefits and the common good.

I believe that the core of the ethical conflict lies at the level of trust — or rather, its breach. Indeed, it is difficult to imagine that 23andMe's customers, who once absently ticked a box consenting to the use of their data, do not feel that they have been exploited by their data having been sold to further enrich a commercial enterprise[23]. As mentioned above, the question of meaningful and valid consent remains relevant even if potential collaboration with third parties was contemplated in the original agreement and the operations are legally compliant. The question to be addressed is whether or not it is ethical that «people are asked to agree to something that they are unlikely to have read, and that […] may not have expected» (Raz et al., 2020, p. 462). The answer is that not all customers may have been aware of the possibility of such a commercial partnership when they signed. Thus, it could be argued that 23andMe —as well as other private companies— is an expression of digital society's tendency towards the exploitation of personal data in research contexts without the knowledge of participants.

> Let's move to the analysis of a case study concerning biobanks. As suggested by de Lecuona (2017), «from a mercantilist point of view, biobanks are gold mines to be exploited» (p. 269). The fact that biobanks have associated commercial interests should be unsurprising. Indeed, biobanks face a sustainability problem in terms of their long-term maintenance, since high-quality biobanking facilities are costly, thus requiring a need to attract public and/or private funding (Turner et al., 2013). Furthermore, it goes without saying that the process involved in translating discoveries into new innovations always requires financial investment, the interests of which may affect biobank governance (Yu, 2016).

In response, there is the possibility to directly leverage the economic value of the biobank's samples and data, transforming them —or access to them— into tradable commodities (Maseme, 2021)[24].

The case of the Italian Telethon Network of Genetic Biobanks (TNGB) provides a concrete example of the risks of the commodification of samples

23. https://www.bloomberg.com/news/features/2021-11-04/23andme-to-use-dna-tests-to-make-cancer-drugs

24. In simple terms, commodifying things amounts to a sale. In the context of this work, the commodification of biomaterials and data (interchangeably referred to as materials herein) refers to the extent to which materials become commodities of trade and are transferred for money.

and personal data in the context of biobanks, and offers a context against which the relevance of the ethical issues behind this tendency may be discussed.

The case refers to a recent study (Iacomussi et al., 2021) —to which I contributed as co-author— conducted within the TNGB focusing on the governance of access to samples and data to highlight the network's strategies for managing access to its collection. The paper discusses the main issues faced by the Access Committee —the ethical oversight body appointed to evaluate access requests from external researchers— to stress the ethical principles underlying TNGB's access policy. In reviewing the history of the assessment process for access requests, we found that the use of private intermediaries to access the biobank's resources in exchange for money has repeatedly been considered a sufficient reason to refuse such requests. Specifically, the results show that, in the last 10 years, the Access Committee rejected many requests made by individuals working for private companies that approached TNGB's biobanks with requests for huge numbers of samples (despite the rarity and scarcity of the samples, since we are talking about rare diseases biobanks) and with a poor description of the research projects for which they intended to use the requested samples. Moreover, the Access Committee was concerned about the lack of clarity over the final recipients of the samples. Accordingly, the Access Committee's reason for rejecting such requests was stated to be that controversial commercial interests had been perceived that conflicted with their mission, which focuses on the common benefits of scientific investigation and public health; for this reason, samples and data are only made available to researchers for biomedical research purposes.

I believe that the TNGB case represents an outstanding example of good governance, in the sense that both the operation manager and the Access/Ethical Committees were aware of the risk of commodification and were ready to combat this trend of profiting from samples and data. As argued by de Lecuona (2017):

> Research resources and infrastructures such as public biobanks should not be associated, for example, with what are known as intermediaries of biological samples of human origin; that is, companies whose job it is, among other services, to position the samples in return for money. These companies demand, moreover, the commercial exclusive for «placing» samples for financial gain that have been donated by citizens altruistically, free of charge. (p. 268)

Given that sharing biobank resources entails the concrete risk of the misuse of samples and data collected by a biobank, conflicts with its mission, and represents a breach of trust with research participants, it is fundamental that each biobank implements actions:

> … to guarantee that samples and data [ ] available to researchers for biomedical research purposes are based only on the respect of the principle of gratuity of the human body, which is consistent with an understanding of biobanking as a system based on altruism and solidarity and, at the same time, on the promotion of individual responsibility of each researcher [when dealing with biobanks' resources]. (Iacomussi et al., 2021, p. 8)

At this point, it is worth engaging in a critical reflection on what is ethically questionable in the use of private intermediary companies when approaching biobanks and trading their samples and data with third parties in exchange for money. I argue that the problematic element lies in breaking into a genetic and health-related data market in the guise of research in the biobanking field. The ethically controversial consequences of such inappropriate practice are at least twofold. First, the morally problematic exploitation of materials and data donated within a solidarity-based framework introduces tensions to the values and mission of biobanks by threatening to undermine both the notions of altruistic donation and that biobanks serve the scientific and public good (Turner et al., 2013).

Secondly, such practice brings inevitable harms and difficulties regarding biobank participants' control over how their samples and data are used and with whom they are shared. I refer here to the fact that commodification raises ELSIs around consent, intellectual property, and ownership. As argued by Turner et al. (2013), it may be the case that:

> Participants may not want their samples to be used for commercial research; the patenting of genes may lead to expensive therapies and diagnostic tests, which undermine the equity of biobank's benefits; or that fear of litigation may stifle innovation. (p. 73)

The relevance of the ethical issues at stake is to be found in the potential for inappropriate practices in biobanking generated by the intrusion of a data-driven market in the guise of research. Such a tendency is problematic — and hard to recognise for anyone not trained in detecting bioethical issues— because it clashes with the purpose of sharing biobank samples and data that is, as established by national and international laws, to share knowledge with the scientific community rather than to profit from it. Furthermore, it generates a problem of trustworthiness: It wrongs patients and society for a biobank to disguise the economic exchange of human biological samples as a research project.

Therefore, the case of private intermediary companies seeking access to biobank resources shows that a conceptualisation of appropriate biobank governance in the digital age should prioritise the following:

> The impact that in the context of research these practices have on people's rights calls for a change in the dynamics of who is researching, who is directing, who is assessing and controlling and who is authorizing the research. This also leads to a demand for changes in the market and to consider as a point of departure that bodies and body parts (samples included), as well as personal health data, should be kept out of commerce, and they should of course not be quoted on the stock exchange. Compliance with this condition seems impossible in the market society in which we live, where even university professors are obliged to place their knowledge and innovation on the market. (de Lecuona, 2017, p. 291)

In conclusion, I maintain that the above case leads us to reflect and face an ethical dilemma that has, for 10 years, already been affecting other fields of medicine impacted by the advancement of biotechnology: Is profit an acceptable guiding value in the field of biomedical research? Specifically, can we allow market forces to enter into biobanks? Is it right or wrong that biobanks' resources become tradable commodities?

I believe that it is of fundamental importance that those who manage biobanks and are involved in them —including their external ethics committees— share the same values and have sufficient scientific, technical, and ethical expertise to avoid chasing profit at the expense of research priorities and values.

Based on the above, I argue that we must fight for participant protection in biomedical research in general, and biobanks in particular, because the combined forces of the market and digital society allow human biological samples and health-related data to be traded in exchange for money in contexts that should be purely research-oriented and informed by values that are constitutionally extraneous to the language and logic of the market. In my view, human biological samples and the associated personal data collected by patients and participants in the context of public healthcare services, hospitals, and biobanks for research purposes —and thus, within an ethical and legal framework of non-commercialisation and respect for the dignity of the human body— should never be traded in exchange for money.

3. INADEQUATE REGULATORY GUIDELINES

The third unsolved bioethical issue related to biobanks is that the applicable ethical and legal frameworks do not provide an adequate response to the challenges faced by biobanks in the digital context. This inadequacy is nothing more than a reflection of a wider problem that concerns a lack of understanding of the changes brought about by the digital paradigm in

biomedicine and health, and the causes that underlie it. These causes are of a scientific and technical nature, and related to the specific peculiarities and impacts of the new technologies and their convergence. These must be identified and systematised in order to delve into the bioethical, legal, and social aspects that will allow for solutions to be proposed to specific problems in these complex and constantly-evolving fields.

However, despite the unceasing growth and application of emergent technologies in biomedical research and the importance and key role of biobanks within it, this topic is still being discusses in terms of an ethical and legal normative framework tailored for an analogue society. Moreover, the regulation for biomedical research and biobanks is defective, partial, and fragmented, or, in other cases, simply non-existent. In many cases, references are obsolete, due to the speed at which scientific-technical advances occur (de Lecuona, 2011). In what follows, I present an overview of the current legal and ethical frameworks applicable to biobanks.

Concerning the legal level, the literature on the topic reveals a lack of international common criteria regarding samples and data collection and sharing in terms of quality and safety, as well as a lack of harmony between legal requirements for biobanking activities at both European and national levels (Beier & Lenk, 2015; Faralli & Galletti, 2011).

To date, the European landscape of biobank regulation is characterised by a mosaic of formal legal instruments as well as informal types of governance tools (e.g., professional guidelines, best practices, and ethics documents)[25]. The literature on this topic notes the problematic nature of this regulatory diversity because it may hinder the optimal use of biobanks among the scientific community and the realisation of the full potential for biomedicine advances (Slokenberga et al., 2021).

Starting from the international level, the regulations relevant for biobanks are the European Convention on Human Rights and Biomedicine (the Oviedo Convention, 1997), Recommendation CM/Rec 2016(4) of the Committee of

25. Soft tools: WMA Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, Helsinki, Finland, 1964 (last revision 2024); WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks, Taipei, Taiwan, 2016; European Commission, *Biobanks for Europe. A Challenge for Governance: Report of the Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research*, Brussels, 2012; OECD — *Guidelines on Human Biobanks and Genetic Research Databases*, 2009; ISBER (International Society for Biological and Environmental Repositories), *Best Practices for repositories: collection, storage, retrieval, and distribution of biological materials for research*, 2012.

Ministers to member states on research on biological materials of human origin[26], and Regulation EU 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR)[27].

The Oviedo Convention is a normative document ratified by the majority of member states that is concerned with preserving rights and fundamental freedoms, such as the integrity, dignity, and identity of the human being in relation to applications of biology and medicine, and contains several provisions relevant to biobanks. In particular, two articles merit attention when applied to biobanking: Article 16 stipulates that informed consent is a general rule for research and Article 22 requires a subject's renewed (secondary) consent if their samples will be used for purposes not covered by the initial consent (Ducato, 2010). However, the Council of Europe has not updated the Convention, which continues to be the main reference in bioethics due to its binding nature for the states that have ratified it.

The Recommendation CM/Rec (2016)6 is an updated version of Rec (2006)4 — the first official European statement applying to research with human biological materials. It was intended to cover new developments in the field of biomedical research, particularly in the field of genetics and for issues regarding the protection of privacy. Its scope was expanded to cover the collection, storage, and use of biological materials of human origin for storage for future research purposes, and those that were previously obtained for another purpose, including a previous research project (secondary uses). It covers cases of secondary use of identifiable biological materials (Article 22), organisational issues (e.g., responsibility for and access to a collection, and quality-assurance measures) (Article 14), and population biobanks (Articles 17-20) (Beier & Lenk, 2015).

Finally, of significant relevance biobank regulation in recent years is the adoption of the EU GDPR in 2016 and its applicability from May 2018. It had been long-awaited by the biobank community as a catalyst towards harmonisation in biobank regulation (Chassang, 2017; Penasa et al., 2018), particularly in relation to the collection, use, and processing of personal data

26. Recommendation CM/Rec(2016)6 of the Committee of Ministers to member states on research on biological materials of human origins. Available at: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff

27. 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)

—health and genetic data and other information related to individuals—associated with biobank samples.

At the national level (European Commission, 2012), the legislation that applies to biobanks varies by country and is in a state of constant evolution, as is the implementation of the GDPR in domestic law. Specifically, we can distinguish between two main situations among the European States: i) countries where specific legislative acts were adopted focusing on biobanks, such as Spain, Portugal, Belgium, Latvia, Iceland, Estonia, Hungary, and Sweden; and ii) countries that lack bespoke legislation and rely on composite regulations and soft law tools, such as Italy, France, Germany, and the UK.

Among those countries that have implemented biobank-specific legislation, the Spanish model is one of the most significant. Indeed, Spanish biobanks have been regulated by the LIB of 2007[28], which introduced an innovative framework and legal tool to facilitate the development and regulation of the most cutting-edge fields of biomedical research to a European context[29]. In 2012, the LIB was reinforced by the Real Decreto 1716/2011[30] concerning the basic requirements for the authorisation and operation of biobanks for biomedical research purposes, the processing of human biological samples and, finally, the creation of a National Registry of Biobanks. We should also mention the Ley Orgánica 3/2018[31] on data protection and the guarantee of digital rights which was enacted in 2018 as a national implementation of the GDPR. Although it does not directly refer to biobanks, it regulates the collection, treatment, and processing of personal data in biomedical research, which concerns biobank governance.

Title V of the LIB is dedicated to genetic analysis, biological samples, and biobanks, and is divided into five chapters. Specifically, Chapter IV focuses on biobank regulation and covers many crucial aspects of biobanking, namely their definition and functioning, ethical oversight, sample ownership, data protection, and informed consent. In particular, it defines and clarifies the

28. Law 14/2007, of the 3rd July, of Biomedical Reasearch. https://www.boe.es/eli/es/l/2007/07/03/14
29. See also Casabona (2007) and Sánchez-Caro & Abellan-García Sánchez (2007).
30. Royal Decree 1716/2011, of the 18th of November, laying down the basic requirements for the authorisation and operation of biobanks for biomedical research purposes and for the processing of biological samples of human origin, and regulates the operation and organization of the National Register of Biobanks for biomedical research. https://www.boe.es/eli/es/rd/2011/11/18/1716
31. Organic Law 3/2018, of 5th of December, of Protection of Personal Data and guarantee of digital rights. https://www.boe.es/eli/es/lo/2018/12/05/3/con

legal status of biobanks and differentiates them from other collections of biological samples that could exist for biomedical research purposes. From an organisational perspective, the law states that a biobank must have a scientific director, a data controller, and two external committees —one scientific and the other ethical— that will assist the director in their functions (Art. 66). The ethical committee, in particular, plays a significant role in biobank governance since it is asked to issue a binding opinion for the authorisation and development of each research project that requests biobanked biological material and data (Art. 60.2). In addition, it exercises the right to authorise exceptions to the general principle of informed consent.

Regarding informed consent, the law states that biological samples collected by biobanks may be used for any biomedical research under the terms this law provides, but only when participants have given their consent (Art. 70.2). Accordingly, the LIB provides for a broad consent; that is, the biobank participant —by a single act of consent at the moment of collection— authorises the use of their samples and data in other future research related to that initially proposed, including research conducted by third parties, without this necessarily being expressed (Art. 60.2).

In sum, although the Spanish regulations on biobanks have yet to face the novel challenges raised by the new paradigm of data-driven biomedical research (Iacomussi, 2021), they have the merit of covering many ethical and legal concerns that are strictly correlated with biobanking activities: the legal definition of a biobank, the requirements and management of a biobank, the protection of participants' rights, and informed consent.

A diametrically opposite situation can be found in Italy, which belongs to the group of countries without bespoke biobank regulations. To date, there are no specific provisions applicable to biobanks, and the legal and regulatory frameworks regarding the use of biosamples and related data in research are fragmented[32]. Consequently, Italian biobanking activities are currently subject to rules primarily derived from legislation from other biomedical research fields or guidelines and soft law instruments (Calzolari et al., 2013). The first category includes legislation on organ transplantation[33], blood establishment[34], and medically-assisted procreation[35]. A valuable

32. To explore the Italian legal framework that regulates biobanking, see Macilotti et al. (2008) and Casonato et al. (2012).
33. Law 1.04.1999, n. 91, «Provisions on organ and tissue collection and transplantation».
34. D.m. n. 78 of 25.01.2001, «Characteristics and procedures for blood and blood component donation».
35. Law 40/2004, «Rules on medically assisted reproduction».

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Biobanks are influential infrastructures in contemporary biomedical research. By enabling the systematic collection, storage, and use of human biological samples and the associated personal data, they play a key role in translational and personalised medicine. At the same time, biobanking raises significant ethical, legal, and societal challenges, often in the absence of governance frameworks.

This monograph examines current tensions in core ethical principles and fundamental rights —such as autonomy and privacy— arising from digitalisation, commodification, and the potential secondary uses of personal data; it also analyses how these trends confront values such as solidarity and the common good. The work develops a conceptual framework grounded in bioethics and human rights.

In addition, the book discusses the evolving nature and functions of biobanks the digital age. It argues for a governance model based on transparency, data protection, and meaningful participation, aimed at balancing scientific progress with the protection of research participants and public trust. It promotes critical reflection and provides conceptual tools to rethink biobank governance in alignment with societal values and expectations. With the aim of providing conceptual tools to researchers, biobank managers, research ethics committees, policy makers it engages in the societal debate of bioethics and biobanks.

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