Bio-legal Issues in the Establishment of a Historical Collection of Human Tissues: The case of the Umbria Biobank Project

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Abstract. The aim of the Umbria Biobank Project is to set up a biobank of human tissues for research purposes. The Umbria Biobank includes a historical archive put together from the 1940s onwards by the former Institute of Pathological Anatomy of the University of Perugia, which consists of at least 2.5 million tissue blocks and approximately 8 million cytological and histological slides, with accompanying documentation. This valuable collection, which has been maintained and improved over time, has remained largely unused because of various ethical issues and a lack of specific regulation.

In particular, as with other historical archives of diagnostic documentation, the materials and data were collected at a time when there was neither an awareness about the need for patient authorisation, nor any idea that the materials and data would be useful for further research activities.

This paper describes the attempt by the Project's bio-legal team to avoid the destruction of these important historical archives and to recover them for scientific research in a legitimate way that respects fundamental rights. The solutions were worked out within the context of European Union, international and national legal regulations.

Keywords: Biobanks, Ethical issues, Protection of personal data, European Union law, Scientific research

The Umbria Biobank Project

In the town of Perugia, in the centre of Italy, a partnership between the Hospital of Perugia and the University of Perugia (Department of Medicine and Surgery, with the collaboration of the Italian National Council of Research, Institute of Applied Physics, IFAC) has been setting up a biobank of human tissues for research purposes.

The Umbria Biobank Project is funded by the Umbria Region and the European Development Regional Fund, and is being set up by a group of anatomopathologists, biotechnologists, informatics specialists and a "bio-legal team" coordinated by the authors of the present paper (1).

A very important aspect is that the Umbria Biobank includes a "historical section", which is composed of a diagnostic archive that was put together from the 1940s onwards by the former Institute of Pathological Anatomy of the University of Perugia. This collection contains at least 2.5 million tissue blocks and approximately 8 million cytological and histological slides, with accompanying documentation.

This valuable historical collection, which has been maintained and improved over time, has remained largely unused because of various ethical issues and a lack of specific regulation.

In particular, as with other historical archives of diagnostic documentation, (2) the materials and data were collected at a time when there was neither an awareness about the need for patient authorisation, nor any idea that the materials and data would be useful for further research activities.

The need for informed consent in the present legal system

Today, the national, European and international legal systems agree on the need, in order to respect the fundamental rights of the individual and, in particular, the principle of self-determination, for informed consent to be provided by the individual prior to any health treatment or the use of the individual's personal data or biological material (3).

In addition to the national constitutions (see, for example, Article 32 of the Italian Constitution in relation to health treatment), the rule of consent at international level is established by important documents such as the Declaration of Helsinki of 1964 concerning Ethical Principles for Medical Research Involving Human Subjects (see Article 26 of the most recent version of 2013), or, in Europe, by the European Convention on Human Rights and Biomedicine (approved by the Council of Europe in 1997 in Oviedo; see in particular Articles 5 and 14) and its Additional Protocols, as well as the Recommendations of the Committee of Ministers of the Council of Europe (see, for example, Recommendation of the Committee of Ministers of the Council of Europe Rec (2006) 4 of 15 March 2006, which recognises "that every person has the right to accept or refuse to contribute to biomedical research and that no one should be forced to contribute to it", and which also states, in Article 10(2), that "information and consent or authorisation to obtain such materials should be as specific as possible with regard to any foreseen research uses and the choices available in that respect").

European Union law establishes the necessity for informed consent for the involvement of individuals in research activities (see Article 3 of the Charter of Fundamental Rights), in clinical trials (see Article 28 of Regulation (EU) 536/2014), for the use of biological material (see Article 13 of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells), and for the protection of personal data (see Article 8 of the Charter of Fundamental Rights, and several parts of 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, the General Data Protection Regulation, hereinafter referred to as the "GDPR"), including health and genetic data (considered to be "sensitive data": see Article 9(1), GDPR).

For "personal health data", as well as biological material, the subject's consent should be not only clear (see Article 4(11), GDPR), but also explicit. This is because legal texts state that the form of expression of consent should depend on the importance of the interests to be protected (4).

Explicit written consent is needed for an individual's participation in biomedical scientific research (see Convention of Oviedo, Article 16(v)). In particular, consent is needed when the genetic data are "stored for diagnostic and health care purposes and for medical and other scientific research purposes, unless otherwise provided for by domestic law for compelling reasons and consistent with the international law of human rights" (see Article 22).

Normally, the legal sources provide for "specific consent", meaning that the data subject is entitled to give her/his authorisation for any specific use of his/her personal data, in order to achieve a more complete safeguarding of the autonomy of persons. In addition to the aforesaid provisions of the Convention of Oviedo and the UNESCO Universal Declaration on the Human Genome and Human Rights, the requirement for specific consent is included within EU legislation, such as Article 8(2) of the EU Charter, which states that "[personal] data must be processed fairly for spec-

ified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law". Article 4(11) GDPR provides likewise.

Therefore, the discipline of protecting personal data is based on rules of "granularity" (4), that is to say, the necessity that the consent should be given for limited aims and for specific situations. When the purposes of the processing or the situation of the data subject changes, the person should be requested to provide a new consent.

This is what emerges, for example, from the Recommendation of the above-mentioned Committee of Ministers of the of 2006 concerning research on biological material of human origin. Article 12(1) requires that biological material collected for purposes other than scientific research (i.e. for therapeutic purposes) should not be used without consent or authorisation. Thus, when subsequent activity is "substantially different" as regards that authorised by the individual (5), new consent should be given.

Consent should not be given without time limits. The European sources set out that those responsible for the processing of personal data must ask the person again to confirm her/his consent (6) if the situation of the data subject has changed (e.g., a child has become a teenager) (7).

Because of the relevance of informed consent in the legal system, as mentioned above, the use of the historical collection of the Umbria Biobank should be considered unlawful and unethical, and therefore it would be expected that the biological material and data would be destroyed.

However, the Project's bio-legal team has investigated whether there might be other solutions to avoid the loss of this important scientific resource.

Scientific research and fundamental interests

The starting point is that the individual's consent and linked rights may be subject to various exceptions to safeguard other interests recognised by constitutional norms.

National or supranational legislation may impose limitations on some individual rights to protect personal data, for reasons such as national security, defence, public security, the prevention, investigation, detection, and prosecution of criminal offences or breaches of ethics by regulated professions, important economic or financial interests, or the protection of data subjects or of the rights and freedoms of others.

Moreover, the legal sources provide an important set of exceptions if personal information and materials are used in scientific activities (8).

The legitimate purposes for which personal data (including genetic information) and biological material may be collected and processed include research activities. The acceptability of scientific purposes arises from the relevance assumed by science in society and in legal systems. Today, national and supranational constitutions, as well as international legal agreements, consider academic activity, and especially research, as a fundamental freedom (see mainly Article 13 of the EU Charter) (9).

This freedom is considered necessary for the benefit of humankind (e.g. see Article 2 of the UNESCO Universal Declaration on the Human Genome and Human Rights of 1997).

In addition, research is considered as the fulcrum of European integration. This is explained in the EU institutional documents such as the Lisbon strategy of 2000, "Europe 2020" of 2010, the proposals of the European Commission for the Multiannual Financial Framework 2021-2027, the legal base of the Framework Programme Horizon Europe (10).

In particular, the GDPR (see Recital 159) underlines the importance of the circulation of information for the building of the European Research Area (hereinafter referred to as the "ERA"), as provided for by Article 179(1), Treaty on Functioning of European Union, "in which researchers, scientific knowledge and technology circulate freely".

As a matter of fact, the GDPR itself affirms that "the legitimate expectations of society for an increase of knowledge should be taken into consideration" (Recital 113, GDPR) and also points out that "To meet the specificities of processing personal data for scientific research purposes, specific conditions should apply in particular as regards the publication or otherwise disclosure of personal data in the context of scientific research purposes" (Recital 159, GDPR).

For the above-mentioned reasons, and especially

on the basis of the particular nature of research activity, the European discipline concerning the protection of personal data and the use of human tissues provides some specific derogations or exceptions to the use of data in the case of the processing of personal data for scientific purposes.

Biobanks as a relevant instrument for research activities

If scientific research is considered as such a relevant activity, most of our current knowledge in biomedical fields arises from the systematic investigation of human biological samples stored in biobanks containing biological materials such as blood, cells, tissues, and DNA as well as associated information on the samples and the sample donors (12-14).

Biobanks also have great importance for other research disciplines, such as through the use of the "collections" of biological materials from plants and animals (see, e.g., Article 2 of the International Treaty on Plant Genetic Resources for Food and Agriculture of FAO of November 2001 and Article 2 of the Convention on Biodiversity).

Generally speaking, biobanks may be defined "any collection of biological materials, whether the source be human, plant, or animal, fungi, bacteria, microorganisms or other living families, as well as bioinformatic data on such organic materials" (15).

The collection of biological material is therefore a central piece of "infrastructure" for scientific research, as underlined by the transnational legal sources (see the OECD notion of a biological resources centre (16) and the European Union law idea of research infrastructure) (17).

Collections of biological materials have other important objectives, such as medical treatment, in the case of human cells and tissues, the conservation of biodiversity (see Article 1 Convention on BioDiversity; see also the 2014 document issued by the FAO, "Genebank standards for plant genetic resources for food and agriculture", Chapter 1, Introduction).

Biobanks are, in fact, an indispensable tool for the study of the molecular pathways underlying various pathological processes, and a necessary element for the implementation of "personalised medicine", which represents the paradigm on which, for example, the so-called "precision oncology 3.0" is based (18). Research activity related to biobanks is also the basis for innovative synergies between industry and public research structures, with the consequent possibility of consolidating the competitive capacity of health industries.

Derogations for scientific research

National or supranational legislation may impose limitations on some rights in order to protect other fundamental rights or interests in areas such as defence, public security, and the prevention, investigation, detection, and prosecution of criminal offences.

Moreover, legal sources provide an important set of exceptions if personal information is used in scientific activities (8).

The necessity for exceptions to the right of consent arises from the features of research that can only be carried out if there are data available. In fact, public policies limiting access to data (19) may adversely affect scientific research, especially in the case of genetics (20). For these reasons, legislation on privacy provides some limits to the rights of data subjects.

The GDPR, Article 89, establishes that when "personal data are processed for scientific or historical research purposes or statistical purposes", European and national laws may provide derogations from the rights normally belonging to data subjects, such as the right of access (Article 15), the right to rectification (Article 16), the right to restriction of processing (Article 18), and the right to object (Article 21). Laws may also establish a derogation from the right to erasure (the right to be forgotten), established by Article 17(1), GDPR.

Derogations from the individual rights usually accorded to data subjects are also recognised in documents issued by the Council of Europe's bodies. For instance, Article 8(2)(d), Recommendation R(97) 5 Recommendation R(97) states that access to medical data (including genetic data) and the right of rectification may be refused when "the data are used for statistical or for scientific research purposes where there is clearly no risk of an infringement of the privacy of the

data subject, notably the possibility of using the data collected in support of decisions or measures regarding any particular individual".

Due to the favourable legal and political context, the expressions "research" and "research purposes" should be considered in a broad manner, in accordance with EU law, therefore "including for example technological development and demonstration, fundamental research, applied research and privately funded research" (Recital 159, Regulation 2016/679).

In order to avoid any doubt, research activities must be formalised in a project art. 3 of Deontological rules for processing for statistical purposes or scientific research of 2018 of the Italian "Garante per la protezione dei dati personali" that is drawn up in accordance with the standards of the relevant disciplinary field (see also Article 14 of the Convention of Oviedo), in order to provide evidence that the processing of the data and the use of biological samples are carried out for suitable and effective scientific purposes.

Exception to the principle of the "granularity" of consent

The above-mentioned granularity rule for consent may constitute an obstacle to research activities. As a matter of fact, the collection of data is normally carried out in the framework of other activities, such as for diagnostic analysis, and the data are then processed for scientific purposes. These purposes are not specific at the moment of data collection, and they can change over time. Furthermore, the same database may be useful for many types of research, and even research in different fields (genetic data can be processed in the medical, biological, anthropological and sociological fields, for example). Therefore, it can be difficult if consent is acquired concerning a specific programme of research, and it can be problematic and expensive to require consent for each specific scientific activity. This is especially true for the activities of biobanks.

For those reasons, studies in the literature and praxis suggest more flexible approaches. Furthermore, from an institutional point of view, we can observe a tendency in recent years to mitigate the principle of granularity.

It is possible to find solutions that refer to enlarged or broad consent (for a range of broadly defined uses), to presumed consent (where people who do not want to be involved have to opt out voluntarily), and, in some cases, also to "blanket consent", that is to say consent to whatever future use has been outlined. According to the latter, which seems the furthest removed from specific consent, the World Health Organisation, in a document of 1998, admits that "[a] blanket informed consent that would allow use of sample for genetic research in general, including future as yet unspecified projects appears to be the most efficient and economical approach, avoiding costly re-contact before each new research project" (21). It would seem that this approach should be put in place to grant protection of personal data (21); the more widely used approach, however, is broad consent.

Therefore, the 2016 Recommendation of the Committee of Ministers of the Council of Europe has replaced the obligation to give information concerning each research activity (as established by Article 10(2), 2012 Recommendation) with the duty to inform the data subject about the more general "nature of any envisaged research use" (Article 10(1) of the Recommendation of 2016).

Also, the Draft Explanatory Memorandum to the Draft Recommendation on Research on Biological Materials of Human Origin, issued in 2015 by the Committee on Bioethics (DH-BIO) of the Council of Europe, specifies that when human biological materials or associated personal data are collected, it is good practice to obtain consent to their use for future research, even in cases where the specific research is not known. If future research cannot be identified, the consent should not be unconditional (i.e., a blanket consent) but should be as specific as possible, given the knowledge at the time the consent is obtained (22).

Additionally, the GDPR considers the situation in which it is not possible to identify fully the purpose of personal data processing for scientific research at the time of data collection. In such a case, the data subjects should be allowed to give their consent within certain areas of scientific research, provided that recognised ethical standards for scientific research are observed (Recital 33, GDPR).

On the other hand, the GDPR and other Euro-

pean sources extend the effectiveness of consent. If the principle of the limitation of purpose prescribes that "the processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected" (Recital 50), nevertheless "further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes" (Article 5(1)(b) GDPR). For purposes of this type, a sort of presumed consent is given.

The same approach is chosen by the Council of Europe in its Recommendation on the Protection of Health-Related Data of 2019 (23), which has replaced the above-mentioned Recommendation of 1997 (see Article 4(1)(b)); this also seems to consider that it may be difficult to provide detailed information to the data subject about the use of health-related data at the time of collection (see Article 11(2)).

Lack of consent

Furthermore, the above-mentioned sources show that there may be cases in which it is possible to store and process both information and material for research purposes, even without informed consent.

However, because of the ethical and legal relevance of the informed consent, some conditions have to be met.

The first case in which both materials and data may be processed is when the persons are no longer identifiable; this is provided by Article 11(3) of Recommendation No 6/2016 of the Council of Europe (see also the Italian Supervisory Authority, General Authorisation no. 8/2016, concerning the processing of genetic data).

However, the option of anonymisation as an alternative to consent may encounter some problems in the case of genetic information. First, anonymisation is never the better option from a scientific viewpoint. As shown by legal sources (see, for example, the UNESCO Declaration on genetic data), a link to an identifiable person may be acceptable "if necessary to carry out the research and provided that the privacy of the individual and the confidentiality of the data or biological samples concerned are protected in accordance with domestic law" (Article 14(d)) and for a period that does not exceed the time needed for achieving the purposes for which they were collected or subsequently processed (Article 14(e)). Complete anonymisation has some serious consequences: both the data subject and the researcher will lose important information and will not be able to obtain follow-up results (24), which are often fundamental to the optimal performance of a research project. Second, anonymity is always relative for technical reasons. The anonymisation processes are likely to be reversible, and in principle any anonymised genetic data can be linked to a person.

As underlined within the scientific community, "No responsible scientist can guarantee absolute privacy" and "Privacy and confidentiality are important principles. But being identifiable has some benefits, and being anonymous has some costs; science will be better off when it acknowledges this reality"(25).

The second case in which both data and biological material can be used for research purposes without consent is grounded on the difficulty of collecting the authorisation of the individuals.

In this respect, Recital 62 and Article 14(5)(b) of the GDPR allow derogations from the consent rule where it is impossible or would involve a disproportionate effort that could make the attainment of the research objectives impossible or seriously jeopardise it. In such cases the number of data subjects, the age of the data and any appropriate safeguards in place may be taken into account.

The Recommendation of 2016 of the Committee of Ministers of the Council of Europe follows a similar approach in the case of the collection of biological material. In these circumstances, the material "should only be used in a research project if the latter is within the scope of the consent or authorisation given by the person concerned" (Article 21(1)). However, if the proposed use is not within the scope of the prior consent or authorisation, if any, given by the person concerned, reasonable efforts should be made to contact the person concerned (para. 2(a)), and the process must be subject to an independent evaluation (para. 2(b)).

At a national level, the legislation and the provi-

sions issued by the supervisory authorities confirm the above-mentioned approach.

For example, the Italian *Garante* (see also the General Authorisations No. 8/2016 and 9/2016, as well as the "Deontological rules for processing for statistical purposes or scientific research") provides for an exception to the consent rule for the use of data and materials in research activities provided that the research cannot be carried out with data and materials for which consent can be obtained.

For "organisational impossibility" in particular, the following requirements also apply to the processing of the data of those who, despite every reasonable effort having been made to contact them (including by checking their state of life, consulting the data contained in their clinical documentation, using any telephone numbers provided, as well as obtaining their contact details from the register of patients or the resident population), turn out to be, at the time of enrolment in the study, deceased or not contactable.

The derogations mentioned above are allowed if certain measures are put in place, such as anonymisation (or at least pseudonymisation), the authorisation of ethical committees, and other measures such as publicity about the establishment of the research activity.

For example, Article 6(3) of the above-mentioned "Deontological rules" of the Italian Supervisory Authority lays down that the controller must use appropriate forms of publicity, for example, publication in newspapers.

In any case, whatever the reason for the derogation from the consent rule, and including for research purposes, general principles should be respected, such as necessity, proportionality, and precaution (26).

In particular, derogation from the law concerning data privacy is acceptable only when the granting of such rights is likely to render impossible, or seriously impair, the achievement of the objectives of the processing (see Articles 14(5)(b), 13(3)(d), 89(2), GDPR). More generally, processing of genetic data is allowed only when the protection of the rights is guaranteed (see Recital 52 GDR) and when it respects "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" (see Article 9(2)(j); see also Article 52(1) EU Charter).In respect to the matter under consideration, the principle of proportionality requires the minimisation of the quantity of gathered and processed data (see Article 89(1), GDPR). Such data must be relevant and limited to what is necessary in relation to the purposes allowed by law (see Article 5(1)(c)).

Furthermore, an evaluation in respect to proportionality and legitimacy is necessary, taking into account the principle of precaution (27, 28), that is, the risks to the protection of the fundamental rights and freedoms of individuals and, in particular, whether or not the intended purpose could be achieved in a less intrusive way.

Conclusions

The historical archive within the Umbria Biobank is made up of a very large number of samples (more than ten million blocks and slides) dating back several decades.

Contacting the individuals to whom both the data and the materials refer would be impossible or very difficult, requiring a disproportionate effort.

In order to use the historical collection, it is possible to derogate from the principle of informed consent because of the importance of the collection for biomedical research or other scientific projects (for example, in epidemiological, anthropological, legal, and economic fields). However, this would be acceptable only if it was done in strict compliance with both the principles and the rules of the applicable bio-legal framework (i.e. international, EU, and national sources).

This to make the freedom to carry out research consistent with other fundamental individual rights and interests protected by the legal framework.

Within the Umbria Biobank this equilibrium is expected to be met through the drawing-up of a protocol concerning at least the following issues: the scientific need to use the historical archives; the benefits for society as a whole from the use of the collection; the technical and organisational measures that would be taken to grant protection to the personal data and confidentiality; the modalities for access to the collection by researchers (from among the partners of the Project and from other research bodies); rules concern-

ing material and data transfer agreements; training of staff; and other relevant topics.

Particular attention will be paid to the dissemination and communication of activities concerning the re-use of the material and data contained in the historical archive, in order to make the public (as well as the professional and scientific community) aware of the importance and the benefits arising from the collection becoming available. This communication will be put in place not only in the start-up phase but also during the functioning of the Umbria Biobank. Communication activities will be carried out in collaboration with associations representing patients and professionals, and with other stakeholders.

The protocol for the use of the historical archive, in addition to the provisions concerning data and biological material acquired from patients and volunteers today, will be subject to an initial and continuous assessment by the competent Ethical Committees (that of the Hospital and of the University), as well as by other authorities such as the *Garante per la protezione dei dati personali*.

The above-mentioned approach is expected to be part of a governance framework of "trust, responsibility and accountability", in which the participation of society and the involvement of institutional review boards would be essential (29).

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