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Research biobanks and health databases: the WMA Declaration of Taipei, added value to European legislation (soft and hard law)

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Abstract

Biobanks and health databases make an essential contribution to health-related research ('5P medicine': predictive/preventive/personalised/participatory/provable). Since 1947, the World Medical Association (WMA) has addressed important issues in medical practice and scientific research, adopting guidelines that are recognised as global ethical standards. In October 2016, the WMA's 67th General Assembly, held in Taipei, Taiwan, adopted a new Declaration on the Ethical Considerations regarding Health Databases and Biobanks, revising the Declaration adopted by the 53rd WMA General Assembly in 2002. Taking into account the way health databases and biobanks are currently used in research, the new recommendations are designed to facilitate the responsible collection and storage of human samples and/or associated data, and the provision of these bioresources for scientific research aimed at benefitting patients and populations. We analyse the Declaration of Taipei's scope and content, highlighting its innovative features compared with other recent European guidelines and the General Data Protection Regulation (GDPR).

Keywords

Scientific research; biobanks; health databases; global ethics; regulation; World Medical Association (WMA)

Due to the ever-increasing use of human samples and attached data in health/medical research, biobanking has become an essential part of the 21st-century research environment. These bioresources, donated freely by patients or healthy volunteers as a gift to research, are mostly used to develop health innovations, to improve prevention, diagnosis and treatment methods, and to assess the quality of all types of medical devices and medicinal products for human use. In addition, they contribute to fundamental research aimed at unravelling complex biological issues and increasing understanding of the normal or pathological evolution of biological processes. However, until recently there was no universal legal definition¹ of what constitutes a ‘health database’ or a ‘biobank’. The World Medical Association (WMA) addressed this situation in the 2016 Declaration of Taipei,² which provides general definitions of both terms that can be used in an international regulatory context. Thus, the Declaration’s preamble defines a health database as ‘a system for collecting, organising and storing health information’, and a biobank as ‘a collection of biological material and associated data’. Earlier, the European Union’s (EU) Database Protection Directive,³ which focuses on intellectual property rights, provided a legal definition of the term “database”, which is taken to mean ‘a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means’.

In addition, several sources have proposed definitions of the term ‘biobank’. A broad definition is provided by the pan-European Biobanking and BioMolecular Resources Infrastructure⁴ (BBMRI), a European Research Infrastructure Consortium (ERIC) that was set up by the European Commission in 2013 to facilitate access to resources and facilities and to support high quality biomolecular and medical research. The BBMRI’s statutes⁵ define biobanks (and biomolecular resource centres) as ‘collections, repositories and distribution centres of all types of human biological samples, such as blood, tissues, cells or DNA and/or related data such as associated clinical and research data, as well as biomolecular resources, including model- and micro-organisms that might contribute to the understanding of the physiology and diseases of humans’. This wide-ranging definition covers structures of different types and sizes, with different organisational and technical methods, and housing different kinds of human samples, from body fluids, such as blood or fat samples, to solid samples, such as skin or even organs. These samples are associated with various types of data, generally including personal data, and/or are used to derive such data. However, all biological resource centres share the same purpose, which is to store and distribute biological materials and attached data for scientific, statistical and historical research purposes. As noted above, the Taipei Declaration defines biobanks as ‘collections of biological material and associated data’, where ‘biological material refers to a sample obtained from an individual human being,

¹ D.M. Shaw, B.S. Elger and F. Colledge, ‘What is a biobank? Differing definitions among biobank stakeholders’, *Clinical Genetics* 85(3) (March 2014) 223–227, DOI: 10.1111/cge.12268.

² WMA, ‘Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks’, adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016, available at: <https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/>, retrieved 11th January 2018.

³ Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases, JOCE L 77/20, 27.3.1996. See Article 1 and recitals 17 and 14, available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31996L0009&from=FR>, retrieved 11 January 2018.

⁴ BBMRI-ERIC is a distributed infrastructure of biobanks and biomolecular repositories composed of 19 member states and 1 international organisation, www.bbmri-eric.eu, retrieved 11 January 2018.

⁵ European Commission Implementing Decision of 22 November 2013 on setting up the Biobanks and Biomolecular Resources Research Infrastructure Consortium (BBMRI-ERIC) as a European Research Infrastructure Consortium (2013/701/EU), rev.2 (10 November 2016). Available at: http://www.bbmri-eric.eu/wp-content/uploads/2016/12/BBMRI-ERIC_Statutes_Rev2_for_website.pdf, retrieved 11 January 2018.

living or deceased, which can provide biological information, including genetic information, about that individual’.

These very general definitions are the result of the organisational and structural heterogeneity of bioresource repositories, whether they involve collections of samples or just data, and which are created as long-term structures to serve the needs of scientific research. Health databases do not store biological samples, just research data, which may be raw data or enriched, interpreted data, obtained from various health-related research activities, such as genomic databases. Although this diversity is a valuable asset, it also has drawbacks, as it creates hurdles to the efficient sharing of resources and the harmonisation of international regulations. For example, health and research legislation within the European Union (EU) remains the responsibility of individual member States, most of which have adopted national legal and ethical frameworks separate from any EU initiatives, and the EU has not enacted any Europe-wide legislation covering research biobanks⁶ and health databases. However, the EU has introduced regulations covering certain aspects of biobanking and health-related databases, such as the Clinical Trials Regulation⁷ of 2014, the Tissues and Cells Directives⁸ of 2004 and 2006, and guidelines produced by certain EU agencies.⁹ In addition, the EU General Data Protection Regulation¹⁰ (GDPR), adopted in 2016, further protects individuals’ rights and freedoms with respect to the use of their personal data in all fields, including scientific research. Nevertheless, biobanking and health databases are still widely regulated through ethical guidelines adopted by ethics committees such as the European Group on Ethics in Science and New Technologies (EGE). Even at the international level, many of the issues involved in research biobanking have been addressed only through soft law instruments adopted by intergovernmental bodies such as the Council of Europe¹¹ or the Organisation for Economic and Cooperation Development¹² (OECD), or by scientific societies such as the WMA, whose initiatives are the focus of the present paper.

The WMA is an international confederation of medical associations that promotes the respect of human rights and values in health activities performed for clinical or research purposes. The WMA is globally recognised for its contribution to establishing ethical best practices for scientific research activities involving human participants. Its Declaration of

⁶ 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, ISBN 978-92-79-22858-2, DOI: 10.2777/68942, 2012.

⁷ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ L 158/1 of 27 May 2014.

⁸ 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, OJ L 102 of 7 April 2004, p. 48–58. Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, OJ L 38/40 of 9 February 2006, pp. 40–52. Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells, OJ L 294, 25.10.2006, pp. 32–50.

⁹ E.g., European Medicine Agency, ‘ICH guideline E18 on genomic sampling and management of genomic data’, Step 5, Committee for Human Medicinal Products, EMA/CHMP/ICH/11623/2016, 1 September 2017.

¹⁰ 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 or GDPR), OJ L 119/1 of 4 May 2016.

¹¹ Council of Europe, Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin, adopted by the Committee of Ministers on 11 May 2016 at the 1256th meeting of the Ministers’ Deputies.

¹² OECD Guidelines on Human Biobanks and Genetic Research Databases, 2009.

Helsinki,¹³ drawn up in 1964 (last updated in 2013), was the first set of detailed international research guidelines to be published since the Nuremberg Code of 1946. In 2016, the WMA's continuing work on issues relating to scientific research led to the adoption of a new declaration, entitled the Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks, which updates the association's 2002 Declaration on Health Databases.

The present paper analyses the rationale and content of the Declaration of Taipei, which provides the new benchmark for biobankers and health database managers around the world. We highlight key differences between the Declaration of Taipei and other regulatory documents applicable to biobank operations, focusing on the situation in Europe, in order to determine whether there are inconsistencies or incompatibilities between the Declaration of Taipei's provisions and other sources presently used in the field.

1 Innovative features of the WMA's Declaration of Taipei

Although the Declaration of Taipei is not the only international instrument relating to biobanks and health databases, it differs from other instruments in that it incorporates both topics and that it was drawn up as a complement to the Declaration of Helsinki. In fact, the declaration's preamble clearly states: "in concordance with the Declaration of Helsinki, it provides additional ethical principles for their use in Health Databases and Biobanks". Hence, the Taipei Declaration must be read and interpreted in the light of the Helsinki Declaration. However, the new declaration is also quite innovative, both in the way it approaches the field (1.1) and in the scope of its rules (1.2).

1.1 *Biobanks and Health Databases as Singular Research Entities, the Rationale of the Declaration of Taipei*

The declaration's first unique feature is that it is entirely devoted to biobanks and health databases. This reflects both the recent trend for medical research programmes and methodologies to be centred round resources available from biobanks and databases, and the very nature of these facilities, which are set up to provide researchers with access to biological samples and/or data. This focused approach is also noticeable from a regulatory point of view, because it echoes recent changes to national legal frameworks included in so-called "Biobank Acts" (e.g., Sweden, Finland), as, until recently, most guidelines focused on research projects. However, neither biobanks nor databases are research projects *per se*: they do not rely on a protocol and they do not mandatorily perform research for their own purposes. Rather, biobanks provide expert services for preparing, storing and distributing biological resources for scientific uses. Biobanks and databases do not have predefined timelines; they operate as repositories that control access to the resources they keep for future use. Hence, they are intermediaries between source institutions, which provide the resources, and user institutions, which apply to use the resources within authorised research projects. Biobanks and databases are frequently created as part of European or international research projects, mainly as tools to support research, but very few projects have setting up a biobank or database as their sole or primary objective. In fact, a lack of standard practices for running biobanks and databases has led researchers to underestimate the potential for setting up large international biobanks and/or databases. The WMA addressed this issue directly in the Declaration of Taipei by setting out the operational principles and rules a research biobank or

¹³ WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013.

database must follow in order to respect internationally agreed ethical principles. These rules, which were needed in order to promote the creation and sustainability of international biobanks and databases, also provide an important complement to the rules for research projects contained within the Declaration of Helsinki. Therefore, the WMA's focus on bioresource centres should be welcomed as a useful tool for facilitating ambitious collaborations in the field.

The second innovative feature of the WMA's approach was to deal with biobanks and databases together, thus underlining their shared characteristics and the common ethical and human rights issues their activities trigger. Indeed, both types of facility have the same general purpose, that of ensuring the long-term preservation of and access to biological resources for scientific, statistical or historical health research. Both need to collect resources from human beings, either directly (sample procurement and data collection) or indirectly (sample collection during surgery or data collection from digital services such as social networks). Both store and provide large volumes of resources and are therefore part of the big data phenomenon¹⁴ and highly concerned by privacy protection issues.¹⁵ Here, too, the Declaration is somewhat innovative, as it takes a comprehensive, international approach to the data management/protection issue. It does this by explicitly bringing together different pieces of hard legislation (such as the EU's GDPR) and ethical principles and best practices relating to the storage and management of human biological samples. This approach is both relevant to and useful for countries wishing to adopt or develop their own legal framework on the matter.

1.2 *The Broad Scope of the Declaration of Taipei, from Scientific Research to Non-health Related Activities*

The Declaration of Taipei is intended to cover the collection, storage and use of identifiable data and biological material in health databases and biobanks. Biological material is defined as samples obtained from an individual human being, living or deceased, which can provide biological information, including genetic information, about that individual. It also sets out ethical principles for future uses of such bioresources, in addition to their use in research projects.

The WMA's innovative approach extends to the scope of the rules contained within the Declaration, which is extremely broad compared with the document's narrow frame of reference. In contrast with the Declaration of Helsinki, which focused only on research, the Declaration of Taipei covers all uses of the bioresources held by biobanks and health databases, other than individual treatment. This was done because when 'analysing the scenarios that already exist for the use (and misuse) of health data and biobanks, we [the WMA] came to the conclusion that the major risk scenarios may not result from science, but from the commercial, administrative or political use of such data'. Therefore, 'limiting our guidelines to research only would have left us blind to the imminent risk of abuse from outside the field of medicine: commercialization, cost-cutting and potential political abuse.'¹⁶ Consequently, the rules contained within the Declaration of Taipei apply to all public and private entities that envisage using a biobank or health database, including for non-research purposes, for non-health-related purposes and for commercial purposes. Again, this approach

¹⁴ E. Rial-Sebbag, 'Chapitre 4. La gouvernance des Big data utilisées en santé, un enjeu national et international', *Journal international de bioéthique et d'éthique des sciences* 28(3) (2017) 39-50.

¹⁵ Health databases and biobanks are both individual- and population-level collections and give rise to similar concerns about protecting individuals' rights and freedoms with respect to dignity, autonomy, privacy, confidentiality and discrimination.

¹⁶ WMA website: <https://www.wma.net/what-we-do/medical-ethics/declaration-of-taipei/>, accessed 19 February 2018.

is innovative because it covers potential future uses of biobanks and health databases, in addition to all their current uses, and therefore recognises the need for their activities to be carried out according to strict, internationally agreed ethical principles. Because the WMA's mandate is to establish guidelines for physicians, the Declaration is primarily aimed at physicians and other members of medical teams who gather health information, record healthcare events and collect samples while caring for patients. Their patients trust them to use these bioresources in a responsible and ethical way. On this issue, the WMA reminds physicians that they 'must consider the ethical, legal and regulatory norms and standards for Health Databases and Biobanks in their own countries as well as applicable international norms and standards' and that 'no national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for individuals and population set forth in this Declaration'. However, the Declaration's content clearly shows that its rules were not drawn up solely for physicians; they are also aimed at other professionals involved in operating biobanks and databases, including sample managers, data managers, curators, members of internal committees and the heads of projects that include building collections of bioresources.

Although some may criticise this broad approach, we believe it is the best way of ensuring efficient protections for bioresources and of promoting the standardisation of practices. It could also be asked whether the Declaration covers micro-organisms and viruses of human origin. Given the Declaration's intentionally wide scope, we would interpret the rules as covering any such biological materials that provide information about an individual. In this case, specific biosafety rules and biosecurity measures also need to be considered, in accordance with applicable laws, but such rules and measures are beyond the Declaration's scope.

2 The Content of the Declaration of Taipei

The Declaration of Taipei basically consists of two sets of rules. The first set addresses individuals' rights as donors of samples and data (2.1); the second set aims to ensure robust governance arrangements for health databases and biobanks (2.2).

2.1 Content Relating to Individuals' Rights: A European Comparison

The WMA's main objective was to achieve a balance between the rights of individuals who give samples or data, mostly for research but also for other purposes, and the value of health data as a very powerful tool for increasing knowledge. These two issues are addressed by two other pieces of European legislation, namely the GDPR¹⁷ and the Council of Europe's Recommendation on the use of human biological materials in research.¹⁸ It is interesting to compare these documents' provisions relating to biobank research.

First, the Declaration of Taipei reminds physicians of their specific obligations as stewards of the samples and data entrusted to them by patients, especially in terms of respecting and protecting each individual's human dignity, autonomy, privacy and confidentiality.¹⁹ Such duties are an integral part of good practices. Based on these fundamental principles, it reiterates the rules on obtaining prior informed consent from individuals while suggesting appropriate rules for participating in biobanks and/or health databases. According to the Declaration of Helsinki, individual consent must be given freely and voluntarily, and be informed. Given the diversity of consent regulations and mechanisms

¹⁷ EU GDPR, *Supra* note 10.

¹⁸ Council of Europe Recommendation CM/Rec(2016)6, *supra* note 11.

¹⁹ Article 9, WMA Declaration of Taipei, *supra* note 2.

around the world, the Declaration of Tapei defines two contexts in which consent can be given. First, consent can be given with respect to a specific research project with a defined purpose and duration, etc. Second, consent can be given in other contexts where samples and/or data are collected for multiple and undefined purposes. This second category includes collections assembled in the course of routine healthcare activities or by research projects involving the constitution of a biobank and/or database for use in a range of possible future studies (e.g., for broadly defined pathologies such as cancers). In the case of a specific research project, individuals have to provide explicit consent in the light of the project's objectives, as previously stipulated by the Declaration of Helsinki.²⁰ In contexts where bioresources are collected and stored in a health database or biobank for multiple and indefinite uses, consent is generally qualified as "broad consent", a form of consent that has been partly criticised as opening the door to potential abuses.^{21, 22, 23} Indeed, some authors argue that broad consent is ethically doubtful and violates the individual's right to information, which must be respected if consent is to be given freely. Not respecting this right undermines an individual's ability to refuse to participate in studies which were undefined at the time initial consent was given but which might raise moral concerns for the individual, and not just concerns about privacy.²⁴ Nevertheless, other authors argue in favour of broad consent.²⁵ In fact, no single form of consent is perfect for all situations, and the most suitable form (specific, broad or other)²⁶ must be chosen on a case-by-case basis. Furthermore, the WMA had to take into account the fact that broad consent approaches to collecting biobank samples are legal in some EU countries,²⁷ such as Finland and Estonia. Therefore, the Declaration wisely includes special conditions for the provision of broad consent, which is considered valid only if steps are taken to ensure individuals are not deprived of their right to information and that appropriate decision-making mechanisms are followed. According to the WMA, consent given for multiple and indefinite uses is valid only if the individual concerned has been adequately informed about 10 items:

1. 'The purpose of the Health Database or Biobank.' However, the Declaration does not provide any indication of the kind of information that would be acceptable in this respect, leaving this responsibility to the appropriate research ethics committees and the relevant national authorities. Nevertheless, it is clear that in many jurisdictions consenting to samples being used for research in general would not satisfy the requirement for consent to be informed. Hence, individuals have to be given more detailed information about the types of research their samples and data may be used for in order for their consent to be considered valid. From this perspective, it is interesting to note that the EU's GDPR allows data collectors to solicit consent for

²⁰ WMA Declaration of Helsinki, Articles 25-32, *supra* note 13.

²¹ T. Caulfield and J. Kaye, 'Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas', *Medical Law International* 10 (2009) 85-100.

²² R.G. De Vries, T. Tomlinson, H.M. Kim, C. Krenz, D. Haggerty, K.A. Ryan, and S.Y. Kim, 'Understanding the Public's Reservations about Broad Consent and Study-by-Study Consent for Donations to a Biobank: Results of a National Survey', *PLoS One* (2016) 11(7):e0159113, DOI: 10.1371/journal.pone.0159113.

²³ T. Tomlinson, R.G. De Vries and H.M. Kim, 'Effect of deliberation on the public's attitudes toward consent policies for biobank research', *Eur J Hum Genet.* 26(2) (2018) 176-185, DOI: 10.1038/s41431-017-0063-5.

²⁴ M.C. Gornick, K.A. Ryan and S.Y. Kim, 'Impact of non-welfare interests on willingness to donate to biobanks: an experimental survey', *J Empir Res Hum Res Ethics* 9(4) (2014) 22-33. DOI: 10.1177/1556264614544277,

²⁵ E.g., M.G. Hansson, J. Dillner, C.R. Bartram, J.A. Carlson and G. Helgesson, 'Should donors be allowed to give broad consent to future biobank research?' *Lancet Oncology* 7(3) (2006) 266-269.

²⁶ See *infra* note 27. Table classifying types of consent.

²⁷ M.A. Rothstein, B.M. Knoppers and H.L. Harrell, 'Comparative Approaches to Biobanks and Privacy', *The Journal of Law, Medicine & Ethics* 44 (2016) 161-172.

multiple purposes²⁸ when collecting sensitive personal data, and to offer data subjects the possibility of opting in to just one or several of these purposes, which can include certain types of scientific research. Where feasible, individuals may be given the possibility to consent to just certain parts of research projects,²⁹ thereby allowing for multi-layered consent, which is a form of broad consent. The GDPR stipulates that each purpose must be lawful, fair and transparent,³⁰ and that information be provided either directly to the data subject or made easily available to him/her, in order to respect his/her right to information.³¹ These procedures are mostly consonant with those included in the Council of Europe Recommendation on research on biological materials of human origin.³² In fact, the Recommendation takes a stricter stance on informed consent than the GDPR, as it does not recognise broad consent as a valid procedure *per se*.³³ Rather, if identifiable biological resources are used out of the scope of the initial consent, it strongly recommends re-contacting and informing the individuals concerned about the extended purposes of the research.³⁴ If it is impossible to re-contact the individuals concerned, using samples without consent is permissible following approval by an ethics committee, taking into account potential risks in terms of privacy and fundamental rights.³⁵

2. 'The risks and burdens associated with collection, storage and use of data and material.' This includes risks and burdens related to sample procurement and potential risks to individuals' privacy (e.g., third parties' rights to access or use the data). The GDPR addresses this issue by requiring organisations to carry out a data protection impact assessment (DPIA) before processing data, whenever data is processed on a large scale, particularly in the case of sensitive personal data. DPIAs are designed to identify and assess the data protection risks associated with a processing operation or a set of similar processing operations,³⁶ and the information they provide may prove useful in helping data subjects decide whether or not to give their consent. The Council of Europe also recommends assessing risks to fundamental rights, most notably confidentiality,³⁷ non-discrimination,³⁸ and physical risks.³⁹
3. 'The nature of the data or material to be collected'. This issue is also addressed by the GDPR⁴⁰ but not by the Council of Europe Recommendation.
4. 'The procedures for return of results including incidental findings'. There is no EU law governing this issue, but it is included in the Council of Europe Recommendation.⁴¹

²⁸ Recital 32 and 33 and Article 6, EU GDPR, *supra* note 10.

²⁹ Recital 33 and Article 89, *ibid*.

³⁰ Recital 39 and Articles 5(1) and 12, *ibid*.

³¹ G. Chassang, 'The impact of the EU general data protection regulation on scientific research', *Ecancermedicalscience* 11 (2017 Jan 3)709, doi: 10.3332/ecancer.2017.709.

³² Council of Europe Recommendation CM/Rec(2016)6, *supra* note 11.

³³ Article 11 states that "Biological materials should only be removed for storage for future research with the prior, free, express and documented consent of the person concerned". *Ibid*.

³⁴ Article 21-1 and 2a, *Ibid*.

³⁵ Article 21-2, *Ibid*.

³⁶ Article 35, EU GDPR, *supra* note 10. See also Art.29 Data Protection Working Party Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679, wp248rev.01, adopted on 4 April 2017 and last revised on 4 October 2017, available at: http://ec.europa.eu/newsroom/document.cfm?doc_id=47711, retrieved 1 February 2018.

³⁷ Article 4-2, Council of Europe Recommendation CM/Rec(2016)6, *supra* note 11.

³⁸ Article 5, *ibid*.

³⁹ Article 4-1, *ibid*.

⁴⁰ In particular where personal data have not been obtained from the data subject, see Article 14, and where the data subject exercises his/her right of access, see Article 15, EU GDPR, *supra* note 10.

⁴¹ Article 17 of the Council of Europe Recommendation CM/Rec(2016)6, *supra* note 11.

5. 'The rules of access to the Health Database or Biobank'. The Council of Europe Recommendation also includes such rules.⁴²
6. 'How privacy is protected'. Biobanks and databases must outline the organisational and technical measures in place to ensure the security and confidentiality of samples and data during both storage and use.
7. 'The governance arrangements as stipulated in paragraph 21' of the Declaration of Taipei. Given the central role of governance in biobank/database operations, we examine this item in detail in the following section.
8. 'That in case the data and material are made non-identifiable the individual may not be able to know what is done with their data/material and that they will not have the option of withdrawing their consent.' This is a novel guideline compared with other European or international laws and guidelines, which address this issue only implicitly.⁴³ The importance of considering the ethical aspects of anonymisation is often underestimated due to the advantages anonymisation provides in terms of using the bioresources concerned. Nevertheless, anonymisation takes away an individual's personal control over the bioresources he or she entrusts to a biobank or database, but it does not discharge the professionals involved in collecting, managing and using bioresources from their duty to protect the materials. Therefore it is good practice to inform individuals about anonymisation at the time of consent. Even if anonymisation needs to be regularly and contextually assessed in order to avoid breaches, it is an interesting aspect to consider when people give samples or data, as it may influence an individual's decision about whether to make a "full gift" of bioresources for use in the public interest, trusting they will be used responsibly by the professionals involved.
9. 'Their fundamental rights and safeguards established in this Declaration.' These rights and safeguards are complementary to the provisions of national and international legislation and regulations covering the obligations of people responsible for samples and data (e.g., biobankers, database managers) applicable within the jurisdiction in question. In Europe, this includes the GDPR⁴⁴ and the Council of Europe Recommendation, plus each member State's legislation.
10. 'When applicable, commercial use and benefit sharing, intellectual property issues and the transfer of data or material to other institutions or third countries.'

By embracing different modalities and validity conditions for consent, the WMA has established new standards that are well suited to biobanking and health database operations, without excluding either broad consent or specific consent, where accepted by national laws and/or ethical guidelines. Both types of consent are ethically acceptable in international law.

In line with the Declaration of Helsinki, special protection must be given to vulnerable persons, including those who, when their samples/data were collected, were not able to consent to their future reuse by a biobank or database. Vulnerable persons include the elderly, children, incompetent adults, whether or not they are affected by a disease or under special legal protection, and adults incapacitated by a medical condition such as a coma. In such cases, 'when persons who were not able to consent [...] attain or regain the capacity to consent, reasonable efforts should be made to seek the consent of those persons for continued storage and research use of their data and biological materials'.⁴⁵

In any case, individuals must, at any time and without reprisal, have the right to alter and withdraw consent to the storage and future uses of their identifiable samples and data. A

⁴² Article 10(1), *ibid.*

⁴³ See for example article 21-4, *ibid.*

⁴⁴ Articles 13, 14, 89, EU GDPR, *supra* note 10.

⁴⁵ Article 13, WMA Declaration of Taipei, *supra* note 2.

request from an individual wishing to exercise this right could lead to the total and irreversible anonymisation of the samples and data, or to the destruction of the bioresources. Exercising this right would not affect on-going uses, but the individual's wish would be respected after completion of the purpose for which the samples and data were originally processed.

In addition to its novel approach to informed consent, the WMA also recognises an individual's right to 'request for and be provided with information about their data and its use as well as to request corrections of mistakes or omissions. Health Databases and Biobanks should adopt adequate measures to inform the concerned individuals about their activities'.⁴⁶ These rights are fully in line with those included in the GDPR and the Council of Europe Recommendation, although the GDPR allows member State law to provide for derogations to a number of rights (e.g., access, rectification, limitation of processing, right to object) if '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'.⁴⁷ If the national law fixing the derogation does not respect these conditions and does not plan other safeguards to ensure the protection of personal data, the State may face legal claims and be considered liable.

2.2 Content Relating to Biobank and Database Governance

While technical measures are necessary to ensure the integrity of samples and data during storage and use, it is equally important to set up internal governance mechanisms adapted to the biobank's or database's purposes, characteristics and applicable legal environment. A general principle of the Declaration of Taipei is that 'Research and other Health Databases and Biobanks related activities should contribute to the benefit of society, in particular public health objectives'.⁴⁸ In line with this principle, the Declaration stresses the role of ethics committees:

An independent ethics committee must approve the establishment of Health Databases and Biobanks used for research and other purposes. In addition the ethics committee must approve the use of data and biological material and check whether the consent given at the time of collection is sufficient for the planned use or if other measures have to be taken to protect the donor. The committee must have the right to monitor on-going activities.⁴⁹

Recognising the crucial role played by competent ethics committees is important here. For example, an ethics committee could decide to waive the need for individuals' consent in the case of a public health emergency involving 'a clearly identified, serious and immediate threat where anonymous data will not suffice' to properly address the threat. In such cases, 'the requirements for consent may be waived to protect the health of the population' if an independent ethics committee confirms that the case is 'exceptional' and 'justifiable'.⁵⁰ Other ethical review mechanisms (e.g., institutional review boards) can be set up internally as decision-making supports. Nevertheless, they must be recognised by law and be independent from the host institution (biobank or database) and access requesters, such as projects leaders, and therefore able to make legally valid decisions.

⁴⁶ Article 14, *ibid.*

⁴⁷ Article 89(2) and (3), EU GDPR, *supra* note 10.

⁴⁸ Article 8, WMA Declaration of Taipei, *supra* note 2.

⁴⁹ Article 19, *ibid.*

⁵⁰ Article 16, *ibid.*

The WMA then goes a step further by setting out general principles⁵¹ for the internal and external governance of biobanks and health databases, in order to foster trust from participating individuals and to ensure standard rules apply to all employees, whether custodians, external samplers, or data processors, etc., and users. These principles are: protection of individuals, whose rights should prevail over the interests of other stakeholders and science; transparency, achieved by making information about the biobank's or database's activities, structure, rules and policies easily available to the public; participation and inclusion of individuals and their communities in the biobank's or database's governance; and accountability, which means the custodians of health databases and biobanks must be accessible and responsive to all stakeholders, individuals or authorities acting legitimately.

Governance must be translated into arrangements,⁵² policies, procedures, contracts and terms of use associated with the collection, storage, access, sharing and use of samples and data. A qualified professional must be responsible for assuring compliance with these arrangements within the biobank or database. This person shall be identified and identifiable for each operation. The WMA lists a number of elements that must be included within governance arrangements in order to comply with the general principles mentioned above. These elements include the health database's or biobank's purpose; the nature of the health data and biological material contained in the database or biobank; the length of time data and material will be stored; procedures for documenting, ensuring the traceability, disposing of and destroying data or material; arrangements for obtaining appropriate consent or other legal basis for data or material collection; and arrangements for protecting dignity, autonomy, privacy and preventing discrimination, including procedures for re-contacting participants where relevant. Governance arrangements must also include criteria and procedures governing access to and the sharing of health data or biological material, including the systematic use of Material Transfer Agreements (MTA) when appropriate, and security measures to prevent unauthorised access or inappropriate sharing. Finally, health databases and biobanks must also make arrangements for dealing with data and materials in the event of a change of ownership or closure.

The WMA also notes that 'special considerations should be given to the possible exploitation of intellectual property' in relation to the sharing of samples and data, and in the case of a biobank's or database's discontinuation or closure. Hence, 'protections for ownership of materials, rights and privileges must be considered and contractually defined before collecting and sharing the material. Intellectual property issues should be addressed in a policy, which covers the rights of all stakeholders and communicated in a transparent manner'.⁵³ This policy should respect, for example, ownership rights attributed to the producer, who is the author of the database in EU law.⁵⁴ Nevertheless, the WMA recalls that 'the interests and rights of the communities concerned, in particular when vulnerable, must be protected, especially in terms of benefit sharing'.⁵⁵ This is essential for ethical and fair management.

3 Conclusion

The WMA Declaration of Taipei represents a new milestone for biobanks and databases around the world, as it achieves a new level of standardisation in the field and fills a gap in

⁵¹ Article 20, *ibid.*

⁵² Article 21, *ibid.*

⁵³ Article 18, WMA Declaration of Taipei, *supra* note 2.

⁵⁴ Directive 96/9/EC, *supra* note 3.

⁵⁵ Article 17, WMA Declaration of Taipei, *supra* note 2.

international ethical guidelines. The Declaration is in line with the most recent legal developments in the EU regarding the recognition of individuals' rights, as well as the need for governance arrangements to be based on stakeholder accountability. As such, it represents a major step towards facilitating the ethical management and sharing of bioresources, while respecting human dignity and privacy.