



REGULATING MEXICAN BIOBANKS FOR HUMAN BIOMEDICAL RESEARCH: WHAT CAN BE LEARNED FROM THE EUROPEAN EXPERIENCE?

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ABSTRACT. *Biobanking presents significant governance challenges. This is especially evident in Mexico, where the legal framework has not kept up with significant industry expansion. Twenty years ago, Europe was in a similar position. More recently, Europe has developed a comprehensive framework for addressing biobank expansion within ever-growing scientific and biomedical research communities. Based on this experience, we can draw many lessons, including those involving the implementation of laws, procedures and stakeholders' consensus to ethically maximize the potential of samples. Mexican biobanking raises many issues, requiring solutions that are sensitive to its own particular needs. This article analyses the flaws of current biobanking regulations in Mexico by drawing comparisons with Europe. It pays special attention to informed consent; sample/data sharing systems; ethical tissue treatment and classification; governance models; best practices and the role of ethics committees. It argues that several European provisions regarding data protection and sharing can serve as guidelines for international research collaboration currently taking place between Mexico and Europe.*

KEY WORDS: *Bioethics, biobanking, biobanks, governance, regulation, data protection, informed consent, genetics, genomic regulation, data sharing.*

RESUMEN. *Los biobancos presentan grandes retos de reglamentación. Lo anterior es evidente en México, donde la legislación no se encuentra a la par de la creciente expansión de los biobancos. Hace veinte años, Europa se encontraba en la misma situación, pero actualmente ha desarrollado instrumentos capaces de atender tal expansión en el marco del aumento de investigación científica y biomédica. Parece haber numerosas lecciones por aprender de Europa: la materialización de leyes, procedimientos específicos y el consenso de actores para maximizar el potencial de muestras biológicas éticamente. Los biobancos mexicanos implican problemas particulares y cualquier propuesta debe responder a*

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los mismos. Este artículo identifica deficiencias legislativas actuales sobre los biobancos en México y realiza comparaciones con Europa; prestando atención a temas como consentimiento informado, sistemas de intercambio de muestras e información asociada, tratamiento ético de tejido y su clasificación, modelos de reglamentación, mejores prácticas, y el rol de los comités de ética. La propuesta radica en qué instrumentos europeos son relevantes al establecer estándares de colaboración en investigación científica (la cual actualmente sucede entre México y Europa).

PALABRAS CLAVE: Bioética, biobancos, reglamentación, regulación, protección de datos genéticos, consentimiento informado, genética, derecho genómico, intercambio de datos genéticos.

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I. THE EMERGENCE OF BIOBANKING REGULATIONS IN EUROPE

Biobanks, which include collections of biological materials and associated data for present or future research projects, have emerged to pose a challenge both to individual nations and the international community. “With the rise of biomedical technosciences and the completion of the Human Genome Project, tissue collections worldwide have become increasingly important to scientific and economic interests.”¹ As a result, most European countries have ratified basic guidelines on informed consent and research ethics, such as the Directive 2005/28/EC on human tissue and cells,² which requires that the donation of cells and/or tissues must be free and based on information provided to donors.³ Current European guideline directives are compulsory *prima facie*, “binding as to the end to be achieved, but left to national governments to determine how to achieve the proposed ends.”⁴ In most European nations, international provisions become national law after a formal ratification process. Despite basic principles agreed to within a general European framework, each Member State is required to implement specific laws on the ethics of biological research material. The Council of Europe Conventions also influences EU Member States by recommendations, including the Convention on research of biological materials of human origin (2006).⁵ The latter refers explicitly to biobanks and provides detailed advice regarding the “secondary use” of stored biological material and population biobanks.

1. *Tissue and Associated Data, the Core of Relevant Legislation*

Local apprehension regarding tissue for research purposes has given way to international concern, especially when “stakeholders have no assurance that the country of destination provides ‘adequate protection’ of their respective interests.”⁶ How these concerns are addressed and how safety can be assured are still significant issues for the ever-growing European research community.

¹ M. Bister, *Discovering Informed Consent: A Case Study on the Practices of Informed Consent to Tissue Nonation in Austria*, in HUMAN TISSUE RESEARCH. A EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES 169 (C. Lenk, N. Hoppe, K. Beier and C. Wiesemann eds., Oxford University Press, 2011).

² Commission Directive 2005/28/EC, 2005 O.J. (L 91) laying down principles and detailed guidelines for good clinical practice regarding investigative medicinal products for human use, as well as requirements for authorization of the manufacturing or importation of such products.

³ *Id.*

⁴ Mark Taylor, *Regulating Personal Data in a Shared World: Limitations of the EU’s Approach to Data Protection*, 4 PERSPECTIVE 474 (2007).

⁵ Council of Europe, Recommendation of the Committee of Ministers to Member States, Rec (2006) 4 on research on biological materials of human origin, OJ (2006).

⁶ J. Bovenberg, *How to Achieve ‘Free Movement of Tissue’ in the EU Research Area*, in HUMAN TIS-

The Directive 2004/23/EC⁷ provides general guidance regarding the exchange of tissues and cells between Member States to ensure the traceability of tissues and cells, subject to quality and safety standards. Anonymization or coding procedures for biological materials—subject to authorization by sample donors—are used to reduce the potential risk for breach of participants' privacy. The European Data Protection Directive's approach is to not cover data processing when data does not relate to an identifiable individual.⁸ When data has been made either anonymous or unidentifiable, however, this provision is subject to interpretation. "Under certain conditions two-way coded data can be considered as anonymous under the European data protection directive."⁹

2. The Need for Informed Consent, a Booster for European Regulations

Based on current research ethics within the European framework, each Member State adopts consent models based on their own specific needs. How this is achieved varies from country to country. Currently, no standard has been established for informed consent at the regional level. The diverse standards applied by each nation are in themselves subject to debate. A clear example of such variation consists of the different procedures following the adopted informed consent model. Procedures may range from "either broader, initial consent procedures or multiple requests for consent over time."¹⁰

The notable differences in informed consent regulations for biobanks—often in relation to cases of abuse—are frequently the result of national changes in medical consent. One example is the United Kingdom, where "the journey to the Human Tissue Act 2004 was driven by an ethical and legal failure to regulate the medical profession, which in turn acted in a way that society found deeply offensive."¹¹ This is a relevant point showing how common it is that solely medical regulations tend to evolve into more inclusive rules including research and therefore, biobanks. Currently, The Human

⁷ SUE RESEARCH. A EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES 13 (C. Lenk, N. Hoppe, K. Beier and C. Wiesemann eds., Oxford University Press, 2011).

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, 2004 OJ (L 102).

⁹ Taylor, *supra* note 4.

¹⁰ Evert-Ben Van Veen, *Obstacles to European Research Projects with Data and Tissue: Solutions and Further Challenges*, 44 ELSEVIER 1438 (2008).

¹¹ David M. Secko et al., *Informed Consent in Biobank Research: A Deliberative Approach to the Debate*, 68 SOCIAL SCIENCE & MEDICINE 782 (2009).

¹² José Miola, *Law, Ethics, and Human Tissue Research: Integration or Competition?*, in HUMAN TISSUE RESEARCH. A EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES 13 (C. Lenk, N. Hoppe, K. Beier and C. Wiesemann eds., Oxford University Press, 2011) 79.

Tissue Act of 2004 requires proper consent for storage and use for most purposes, including research.

II. PRINCIPLE BIOBANKING RELATED REGULATIONS IN MEXICO

The main regulation for human research in Mexico, the General Health Law, sets forth basic principles regarding informed consent. Informed consent has officially been regulated by the General Health Law (LGS)¹² and the Rules of the LGS.¹³ Informed consent has also been regulated at the institutional level. One example is the rules governing IMSS health services.¹⁴ Current health regulations require signed and written informed consent in cases such as hospitalization of psychiatric patients, surgical intervention, fertility treatment and participation in research projects. Also included are diagnostic procedures involving physical, emotional or moral risk; invasive procedures; procedures that produce physical or emotional pain; and socially invasive procedures that can provoke exclusion or stigmatization. These principles are primarily based on medical grounds. For example, the provision on consent withdrawal protects patients from discontinued treatments after they leave a study.¹⁵ There has been no clarification, however, regarding the withdrawal of a non-patient research participant, or a sample donation for purely research purposes. For this reason, a distinction must be made between medical consent and research consent. The latter could apply to biobanking. Generally, informed consent in Mexico has been used more to protect patients than research subjects.

Currently in Mexico, no further clarification has been provided in terms of preservation periods and secondary uses of biological samples within biobanks. It is also unclear whether the initial consent covers the specific research project on which the sample collection is based, or whether it can be extended to additional research projects. In contrast, European regulations present different ways to include informed consent more specifically. The extent of informed consent can vary significantly, from specific (consent for a single purpose at a specific time) to broader options (consent for mul-

¹² See Ley General de Salud [LGS] [The General Health Law], *as amended*, Diario Oficial de la Federación [D.O.], 7 de Febrero de 1984 (Mex.).

¹³ See Reglamento de la Ley General de Salud en Materia de Investigación para la Salud [RLGSMIS] [Rules of the General Health Law on Research], *as amended*, Diario Oficial de la Federación [D.O.], 14 de Mayo de 1986 (Mex.).

¹⁴ See *Manual de Investigación Médica en el IMSS* [Medical Research IMSS Handbook], Instituto Mexicano del Seguro Social [IMSS] [Mexican Institute of Social Security] 1999 (Mex.).

¹⁵ See Reglamento de la Ley General de Salud en Materia de Investigación para la Salud, *supra* at art. 21, Reglamento de la Ley General de Salud en Materia de Investigación para la Salud [RLGSMIS] [Rules of the General Health Law on Research], *as amended*, Diario Oficial de la Federación [D.O.], 14 de Mayo de 1986 (Mex.).

tiple purposes overtime). In Switzerland, consent is generally granted with the option to use additional possibility of further uses of samples and data for future research projects. Swiss biobanking rules regarding informed consent are based on a series of exceptional rules. In principle samples would be used for the primary purpose of their collection. However, exceptionally justified secondary purposes would be allowed “for further use of uncoded non-genetic health-related personal data.¹⁶” Presumed consent is sufficient for the use of pseudonymised non-genetic health-related personal data.¹⁷ If consent and information requirements cannot be satisfied, exceptions allow the use of biological material or personal health data if consent is impossible or extremely difficult to obtain; exceptional use is also allowed if informing participants about their right to withdraw the project proves to be extremely difficult;¹⁸ if no documented withdrawal is available¹⁹ or the research interest for further use of the material/data exceeds the individual interest.²⁰ A right to withdraw consent does exist, however, in cases of identifiable samples and data that involve sample destruction.²¹ In Switzerland, small amounts of post-mortem or transplantation material may be taken without consent for research purposes, whenever they have been anonymized and presumably authorized for that purpose (in the absence of any provisions on the contrary, it is assumed that donors authorize for this purpose).²²

No single law covers the wide scope of consent related to biobanking. French biobank regulations resemble the traditional legal systematization based on written civil law and fragmented regulations of the Mexican system. This has not prevented the enactment of regulations that cover potential secondary uses. The sensitive character of research material for biomedical purposes permits the potential recovery of health material through re-consent procedures under the French Bioethics Act,²³ in order to ensure “that donors are informed of any secondary uses, and that they have a right to raise objections.”²⁴ In Germany, where biobanks are also not regulated by a single law, both specific and broad consent can be justified depending on the

¹⁶ Botschaft zum Bundesgesetz über die Forschung am Menschen (Federal Council Dispatch regarding the federal law on research involving humans) 2009 art. 32, para. 1 (Switz.).

¹⁷ *Id.* at art. 32, para. 2.

¹⁸ *Id.* at art. 33, lit. a.

¹⁹ *Id.* at art. 33, lit. b.

²⁰ *Id.* at art. 33, lit. c.

²¹ Dörr B 2011 *Research with Human Biological Material and Personal Data in Biobanks: Legal and Regulatory Framework in Switzerland*, in HUMAN TISSUE RESEARCH. A EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES 13 (C. Lenk, N. Hoppe, K. Beier and C. Wiesemann eds., Oxford University Press, 2011).

²² Botschaft zum Bundesgesetz über die Forschung am Menschen (Federal Council Dispatch regarding the federal law on research involving humans) 2009 art. 32, para. 1 (Switz.).

²³ Law No. 2011-814 of July 7, 2011, *Journal Officiel de la République Française* [J.O.] [Official Gazette of France], July 7, 2011.

²⁴ *Id.*

nature of the project. “Broad consent can be given for a range of research purposes”²⁵ and requires that tissue specimens become anonymized.²⁶

Although diverse consent models now exist to protect scientific research and researchers, health regulations alone have been ineffective. The results now form an identifiable pattern: rules and regulations based mostly on medical research that evolved into more detailed rules that now applied to biobanks. These rules include procedures that help determine the scope of informed consent for sample use. In Sweden, for example, “informed consent depends on each biobank’s purpose and extent.” “If the donor has stipulated that the biological material may not be used for anything but a certain purpose, he should be able to insist on the material either being destroyed or returned if the purpose for which it is now intended does not agree with the donor’s wishes.”²⁷ The particular use of the sample must be specified in advance, as well as how the samples will be destroyed once the research objectives have been achieved.²⁸ The participant’s free decision to withdraw the research project “often entails destruction of the relevant biological samples along with any personal information relating thereto,²⁹ where possible and, in some cases, upon a specific request by the participant/data subject.”³⁰ For this reason, informed consent should be as specific as possible. If use is granted to only one institution —with no additional authorized use— this must be respected. Samples must also be prevented from freely circulating. In Mexico, nothing has been said in legal terms regarding accessibility of samples and data in practice. As of now, laws or regulations exist that govern essential matters; e.g., secondary uses of and data not established in the original informed consent, identification mechanisms (anonymity and coding) re-consent possibilities, participants’ withdrawal, accessibility and legal implications.

III. EXAMPLES OF BIOBANKING REGULATIONS IN EUROPE

“Existing biobanks differ in the way that they make their samples accessible.”³¹ Spain was a pioneer in implementing accessibility by using new

²⁵ Die (Weiter-) Verwendung von menschlichen Körpermaterialien für Zuecke medizinischer Forschung [The use of human biological material for medical research], German Zentrale Ethikkommission bei der Bundesärztekammer [Central Commission for Ethical Principles on Medicine and Related Areas] (2003a). Deutsches Ärzteblatt, A1632 (Germany).

²⁶ *Id.*

²⁷ LI WESTERLUND & ANNINA H. PERSSON, CIVIL LAW REFLECTIONS ON THE USE OF HUMAN BIOLOGICAL MATERIAL 69 (Centre for Research Ethics and Bioethics, 2001).

²⁸ WORLD HEALTH ORGANIZATION, BIORISK MANAGEMENT LABORATORY BIOSECURITY GUIDANCE 12 (2006).

²⁹ See Swedish Biobanks in Medical Care Act (2002) Ch 3 § 6, and Latvian Human Genome Research Law art. 11 (2012).

³⁰ See Lov om biobanker [LOB] 2003 02-21 nr 12 [Act relating to Biobanks] Helse-og omsorgsdepartementet [Ministry of Health Attention] 1 of July 2003 (Norway).

³¹ J. Bovenberg, *How to Achieve ‘Free Movement of Tissue’ in the EU Research Area*, in HUMAN TIS-

technologies to facilitate access to genetic information, thereby making human samples carriers.³² Casabona identifies the ethical and legal issues that led to the creation of the innovative Biomedical Research Law;³³ such as when “samples’ further uses are different from those initially agreed.”³⁴ Under the Spanish framework, expanded by the Royal Decree 1716/2011,³⁵ samples incorporated into a ‘collection’ can only be used by the soliciting researcher; they may not be transferred to third parties or used in projects not specifically cited in the original consent.³⁶ Although Casabona recognizes controversial aspects of the Spanish framework, he believes it may be useful as a model for international regulation.³⁷

Regulations in several European countries’ were enacted in response to conflicting cases of abuse; such as medical scandals within the past two decades. These have involved the retention and use of organs and tissue without proper consent. Bristol Royal Infirmary and the Royal Liverpool Children’s Hospital (Alder Hey) were highlighted in Learning from Bristol, the public inquiry into children’s heart surgery at the Bristol Royal Infirmary Inquiry (2001) and the Royal Liverpool Children’s Inquiry Report (Department of Health 2001). The UK 1961 Human Tissue Act, for example, established to regulate the removal of organs and tissue, failed to include sanctions for non-compliance. The consequence was confusion “as to whether any breach of the statute should be dealt with in the criminal or civil courts.”³⁸ The UK responded to the “emerging nature of regulatory practices” by processes carried out by different legal actors and agencies in the regulation of their clinical research trials.³⁹ The UK’s regulatory agencies currently separate tissues and cells on the basis of their potential biological “riskiness.”⁴⁰ The UK Bio-

SUE RESEARCH. A EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES 13 (C. Lenk, N. Hoppe, K. Beier and C. Wiesemann eds., Oxford University Press, 2011), 130.

³² Javier Arias Díaz et al., *Spanish Regulatory Approach for Biobanking*, 1 EUROPEAN JOURNAL OF HUMAN GENETICS (2012).

³³ Ley de Investigación Biomédica [Act of Biomedical Research] 14/2007 (Spain).

³⁴ CARLOS MARÍA CASABONA, INFORME FINAL: IMPLICACIONES JURÍDICAS DE LA UTILIZACIÓN DE MUESTRAS BIOLÓGICAS HUMANAS Y BIOBANCOS EN INVESTIGACIÓN CIENTÍFICA 7 (2007).

³⁵ Royal Decree 1716/2011 por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano [on the minimal requirements for authorisation of biobanks for biomedical research], Boletín Oficial del Estado [BOE], 18 de Noviembre de 2011 (Spain).

³⁶ Arias, *supra* note 32, at 1.

³⁷ CASABONA, *supra* note 34.

³⁸ I. Kennedy, *Further thoughts on Liability and the Human Tissue Act 1961*, in I. KENNEDY, TREAT ME RIGHT: ESSAYS ON MEDICAL LAW AND ETHICS 235 (1989).

³⁹ S. Weber, *The Regulation of Autologous Stem Cells in Heart Repair: Comparing the UK and Germany*, in HUMAN TISSUE RESEARCH. A EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES 16 (C. Lenk, N. Hoppe, K. Beier and C. Wiesemann eds., Oxford University Press, 2011).

⁴⁰ *Id.*

bank⁴¹ does not release samples to researchers but does perform analyses for third-parties, unless physical samples are deemed necessary. The choice of solely internal analyses, in which samples cannot be released, may be dictated under considerations of data protection and limits established by the sample's original informed consent. Perhaps serious cases of abuse will be required to change Mexican regulations.

In Germany, uses of cells and tissue are integrated into a unified regulation,⁴² focused mostly on advanced therapies and clinical trials. German biobanking regulations are one of the few European countries which, additionally, have established formal procedures. Switzerland has also enacted measures to reduce data protection threats, which continue to represent the main risk in biobanking. Other countries have implemented diverse frameworks, such as disseminated rules involving several legal frameworks. In this case, legal regulation remains associated to typical (civil, penal, constitutional, health and data protection) related rules and/or with references to instruments of a non-binding nature (ethical codes, recommendations and manuals).

IV. MEXICAN ETHICS COMMITTEES

The Mexican ethics committees system is based on Local Research Ethics Committees (LRECs).⁴³ Historically, the two main reasons leading to the formation of most LRECs were: 1) recommendations by medical managers who considered it necessary (11.9%); and 2) provisions set forth in institutional rules (88.1%). LRECs in Mexico emerged based on a purely medical focus. LREC practices reflect the fact that (a) committees lack specialization; and (b) they are mostly self-regulated. Ethics committees in Mexico are responsible for authorizing research projects at public health institutions only at the start of projects. The formation of other types of ethics committees with different remits; *e.g.* research ethics committees, has proven difficult.

IMSS (National Institute of Social Security) committees and guidelines concentrate mostly on health ethics, even in cases involving biomedical research.⁴⁴ In fact, IMSS medical LRECs are mainly focused on rules, regulations and law; and the final solution of local committees, far from being carefully analyzed in ethical and legal terms, is seen as merely an adminis-

⁴¹ See www.ukbiobank.ac.uk.

⁴² See The Medicines Act 1976 (Ger).

⁴³ Edith Valdez et al., *Understanding the Structure and practices of research ethics committees through research and audit: a study from Mexico*, 74 HEALTH POLICY 62 (2005).

⁴⁴ Kathrine Jáuregui-Renaud, *Health Research at the Mexican Social Security Institute, a Historical Review*, 49 REV MED INST. MEX. SEGURO SOC. 579 (2011), available at http://revistamedica.imss.gob.mx/index.php?option=com_multicategories&view=article&id=1442:la-investigacion-en-salud-en-el-imss-resena-historica&catid=518:historia-y-filosofia-de-la-medicina&Itemid=676.

trative step which they have to fulfill. For this reason, committee members are often insensitive to the needs of research participants.”⁴⁵ “The fact that LRECs are comprised exclusively of professionals makes them less responsive to vulnerable populations.”⁴⁶ This created an issue of unbalanced representation, in which the opinions and needs of those involved need to be expressed directly. Most ethical challenges in Mexico are due to growth in the number of research biobanks; for this reason alone, more research ethics committees are needed. Another problem is that only direct threats to subjects’ personal welfare are considered ethical violations. And the fact that Mexican ethics committees operate with ample discretion and little oversight continues to be problematic. Given that the only requirement for Mexican research ethics committees since 2012 is registration,⁴⁷ no sanctions currently exist for non-compliance.

V. ETHICS COMMITTEES IN EUROPE

Ethics-based authorization has gradually become mandatory for most biobanking research activities in Europe. In countries such as the UK, ethics committees are responsible for ongoing approval of research tissue bank projects. For this reason, “research tissue banks that are given generic or blanket approval subsequently bear responsibility for assessing and monitoring individual research projects that utilize them as tissue and/or data resources.”⁴⁸ In Spain, regulations require compliance with “quality, legal, and ethical requirements.”⁴⁹ The establishment of a biobank legally depends on a principal investigator (PI) responsible for the biobanks and one for data protection, management structure and two committees comprised of external experts (both scientific and ethical), whose identities are made known to the public. External committee members are independent from the biobank, and play an active decision-making role with respect to the integration of sample collections into large biobanks and sample transfers. The European experience demonstrates that research ethics depends largely on transparent rules and committees’ ability to take consistent action. The UK’s past experience with ethics committees has strong parallels with current Mexican LRECS. As a result of significant reform enacted to specify their competence and raise research standards, rather than the previous administration based on

⁴⁵ Edith Valdez et al., *Local Research Ethics Committees of the Mexican Institute of Social Security: Results of a National Survey*, 118 PUBLIC HEALTH 333 (2004).

⁴⁶ *Id.*

⁴⁷ Ley General de Salud [LGS] [The General Health Law], as amended, art. 41 bis, 98, Diario Oficial de la Federación [D.O.], 7 de Febrero de 1984 (Mex.)

⁴⁸ JANE KAYE ET AL., GOVERNING BIOBANKS. UNDERSTANDING THE INTERPLAY BETWEEN THE LAW AND THE PRACTICE 78 (Hart Publishing, 2012).

⁴⁹ Arias, *supra* note 32, at 1.

local committees, the UK's LREC system has evolved; administratively "a complex intrinsic interdependency has evolved."⁵⁰ In fact, UK policy makers (specialists in the formulation of policies), lawmakers (legislators), regulators and the regulatory framework all are meant to rely upon RECs to monitor biobanks and biobanking activities.⁵¹ In the 1970s, RECs were not formally regulated by law. Today, however, certain RECs—notably those recognized under the Clinical Trials regulations—enjoy limited binding status and authority to render ethical opinions on clinical trials involving medical product research. Rather than binding regulators, RECs are responsible for monitoring day-to-day operations, exercising significant control over biobanks and, in effect, acting as research "gatekeepers."⁵² For this reason RECs depend heavily on the existence of formal and informal outside entities and mechanisms to ensure compliance, enforce ethics and punish violators.⁵³

VI. HOW DOES MEXICO CURRENTLY DEAL WITH TISSUE AND ASSOCIATED DATA?

With respect to the transfer of tissue to foreign countries, the Mexican General Health Law⁵⁴ establishes that organs, tissues and cells may not be taken outside national territory without authorization. The General Health Law⁵⁵ states that the transport of human tissues (blood, blood components and stem cells)—all of which can be a source of genetic material (DNA)—needs to be part of an ongoing research project. This policy helps reduce risks associated with biological material. It must be noted, however, that the material must be used in population research; for which reason, material transfers realized for other purposes are not covered. Requirements for transfer authorization, however, are confusing; human research is only allowed at medical facilities under the supervision of competent health authorities and with the approval of the INMEGEN (National Institute of Genomic Medicine). It would be desirable to clarify which government agencies are authorized to grant approval. The above mentioned approval of the INMEGEN, reportedly does not happen in practice. The requirements set forth in article 317 for transferring tissue outside national territory are still unclear; *e.g.* cases requiring urgency are mentioned but not defined. Regulations enacted to protect Mexico's genomic sovereignty—an attempt to control international tissue

⁵⁰ KAYE ET AL., *supra* note 48.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ Ley General de Salud [LGS] [The General Health Law], as amended, art. 317, Diario Oficial de la Federación [D.O.], 7 de Febrero de 1984 (Mex.).

⁵⁵ *Id.* at art. 317 bis.

transfers—, has been criticized for being ineffective rules, where the bioethical approach is incipient.⁵⁶

Current methods used to obtain biological samples vary according to investigation type. Blood, followed by tissue, are the most common samples taken. Biobanks use cerebral tissue, heart tissue, skin cells, blood plasma, brain spinal fluid, DNA, RNA, immortal lymphocytes, cellular lines and bone marrow fluid, components of several public biobanks in national health institutes, social security institutes, universities and technological institutes.⁵⁷ Current guidelines set forth in related legal areas cannot be directly applied to biobanking. The General Health Law needs to differentiate between the different purposes of organs, tissues; i.e. on whether they will be used for transplantation or research purposes. As legal consequences vary considerably, each requires its own specific rules. Mexico cannot remain indifferent to potential cases of abuse.

1. *Searching for Tissue and Associated Data Sharing Options*

Although coding generally prevents tracing back to individual patients, this method fails when variables require linking to databases in widely-divergent locations.⁵⁸ The use of data protection mechanisms, such as anonymization and coding, however, is highly controversial. On the one hand, incidental (and highly relevant) findings are often lost; on the other hand, the research value of samples is diminished. This is relevant, as genomic research requires continual monitoring of research participants (*e.g.*, in relation to illness stages)—rendered impossible by anonymity. Anonymization is thus an undesirable choice because (a) its scientific value is limited;⁵⁹ and (b) true anonymization of data and samples is impossible.⁶⁰

The diverse requirements by many countries regarding the import and export of samples place countries with unclear regulations at a significant disadvantage; *e.g.*, authorization to utilize tissue for research under flexible rules must be re-evaluated by nations with stricter rules. Evidently, the absence of uniform legal requirements has had a negative effect, which has prevented

⁵⁶ Ernesto Schwartz, *Filosofía para la nueva genética* (Philosophy for the new genetics). Available at <http://www.filosoficas.unam.mx/~afmbib/mayteAFM/Ponencias/30023.pdf>.

⁵⁷ Ingrid Brena, *Legal and Social Implications in Mexico*, in *LATIN BANKS STUDY ON THE LEGAL AND SOCIAL IMPLICATIONS OF CREATING BANKS OF BIOLOGICAL MATERIAL FOR BIOMEDICAL RESEARCH* 261 (Carlos María Casabona and Jürgen W. Simon eds., Law, Science, Technology and Innovation, 2011).

⁵⁸ Marjanka K. Schmidt et al., *Regulatory Aspects of Genetic Research with Residual Human Tissue: Effective and Efficient Data Coding*, 45 ELSEVIER 2380 (2009).

⁵⁹ Stefan Eriksson & Gert Helgesson, *Potential Harms, Anonymization, and the Right to Withdraw Consent to Biobank Research*, 13 EUROPEAN JOURNAL OF HUMAN GENETICS 1074 (2005).

⁶⁰ Penélope K. Menasco, *Ethical and Legal Aspects of Applied Genome Technologies: Practical Solutions*, 5 CURRENT MOLECULAR MEDICINE 25(2005).

the development of an inclusive national infrastructure for biobanks and the sharing of data and samples from biobanks across borders for scientific purposes.⁶¹

Mutual concerns on biobank data sharing have given rise to several international agreements. Based on the “home-country principle,”⁶² “the legislation of the country where the controller is based will be applicable when data are sent to a processor in another country.”⁶³ For this reason, sending tissue from a country with strict regulations would not affect sending that same tissue to a country with less strict rules. The ethical approval obtained in a country with the most law rules would prevail. In sum, the tissue could still be used.⁶⁴ Under the principle of informed consent, the rules established by the first biobank would prevail. Principles that apply to the retention and circulation of biological samples normally coincide with those of data protection principles.

2. Data Exchange Systems

Sample exchange and data systems are governed at the European level by the Data Protection Directive (95/46/EC). Following the solution adopted by the Council of Europe Convention,⁶⁵ the Directive 95/46/EC also allows the use of personal data for research purposes (including sensitive data), providing Member States adopt suitable safeguards. The directive gives member states wide discretion in enacting measures for the processing of personal data, including scientific research purposes, with sufficient freedom. “The Directive contains a number of provisions that are broadly formulated and, explicitly or implicitly, leave Member States a margin of maneuver in adopting national legislation.”⁶⁶

Besides general guidance (provided by the European Union) on data protection, countries have also entered agreements at both local and international levels that try to balance divergent economic and scientific interests.

⁶¹ 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 47 (2012).

⁶² Evert-Ben Van Veen, *TubaFrost 3: Regulatory and Ethical Issues on the Exchange of Residual Tissue for Research across Europe*, 42 SCIENCE DIRECT 2919 (2006).

⁶³ Evert-Ben Van Veen, *Obstacles to European Research Projects with Data and Tissue: Solutions and Further Challenges*, 44 ELSEVIER 1438 (2008).

⁶⁴ P. H. J. Riegman, *TubaFrost 1: Uniting Local Frozen Tumour Banks into a European Network: an Overview*, 42 EUROPEAN JOURNAL OF CANCER 2682 (2006).

⁶⁵ The Council of Europe Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data, article 6 (1981).

⁶⁶ COMMISSION OF THE EUROPEAN COMMUNITIES, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL ON THE FOLLOW-UP OF THE WORK PROGRAMME FOR BETTER IMPLEMENTATION OF THE DATA PROTECTION DIRECTIVE 2007 COM 87 (2007).

The data confidentiality principle in France, set forth in the *Loi Informatique et Libertés*,⁶⁷ requires the submission of an official declaration in order to gather samples used in a biobank. Access to data also requires that donors are told of potential research uses of their data as well as their right to raise objections, which need to be justified and proven. Data coding is required when personal data, such as identity remains associated to participants. Many countries have ratified the EU Data Protection directive; and joint efforts have been made to resolve other relevant issues in genomic medicine. Additionally, the creation of virtual database networks to tackle issues with often conflicting frameworks is now commonplace in Europe.

Mexican law is inconsistent with respect to data protection, reflecting an absence of integral policy. It was initially unclear whether genetic data was covered under the Federal data protection regulations issued by the Federal Institute of Access to Public Data (*Instituto Federal de Acceso a la Información*). The Mexican Federal Transparency and Access to Public Government Information Law (*Ley Federal de Transparencia y Acceso a la Información Pública Gubernamental*) (2003) (LFTAIPG) was intended to promote governmental transparency and ensure fair treatment of data by government agencies. Provisions under LFTAIPG were criticized for not including genetic data. This partial coverage only included data preserved by public institutions, leaving data dealt with by private institutions unregulated. Later, the Federal Law of Protection of Individuals' Personal Data (*Ley Federal de Protección de Datos Personales en Posesión de los Particulares*) was enacted to protect personal data stored in electronic databases and related networks. Under the Federal Law of Protection of Individuals' Personal Data, "sensible data are any information that affects the most intimate sphere, or whose misuse can cause discrimination or any other risks to individuals."⁶⁸ Note that the law fails to clearly specify whether genetic data forms part of the 9 Articles. If we assume that genetic data is included in personal data, then the use of such data can be consented only if a request is made. The law applicable to private companies, enacted to attract pharmaceutical investment,⁶⁹ left public health institutions out of legal scope. Current laws on personal data have not explicitly set forth what type of samples (blood, saliva, tissue) contain health data. The law also fails to specify data protection operations, inspection, data access, rectification or sanction mechanisms. "In biobank research it is not the tangible features of biological samples that are at issue but informational content."⁷⁰ Mexican

⁶⁷ See Law No. 78-17 of January 6, 1978, *Journal Officiel de la République Française* [J.O.] [Official Gazette of France], January 7, 1978.

⁶⁸ See Ley Federal de Protección de Datos Personales en Posesión de los Particulares [LF-PDPPP] [The Federal Law of Protection of Individuals' Personal Data], *as amended*, art. 3, VI, *Diario Oficial de la Federación* [D.O.], 5 de Julio de 2010 (Mex).

⁶⁹ Eduardo Camacho, *Protecting Data will Attract foreign Investment*, *EL UNIVERSAL*, Feb. 22, 2012.

⁷⁰ EUROPEAN COMMISSION, *supra* note 61, at 38.

data protection laws refer to personal data processing in general, failing to specify biological samples used in research.

3. *Material Transfer Agreements (MTAs)*

Best industry practices require that procedures used for international sample sharing and distribution are clear and transparent. Material transfer agreements (MTAs)—contracts that allow researchers or research organizations to use tissue sent by other organizations—⁷¹ help ensure compliance with obligations owed to donor participants. These “means of defining and limiting the purposes for which the tissue will be used”⁷² involves the establishment of certain protocols including the recipient’s obligation to obtain ethical approval and its commitment to follow ethical procedures, including data protection mechanisms, detailed description of research objectives, incidental findings, etc.

VII. ABSENCE OF BIOBANKING OVERSIGHT IN MEXICO

In the absence of codified ethical standards, Mexico-based biobanks have resorted to self-regulation and internal decision-making. This said, two institutions are critical in the oversight of Mexican biobanks. First, the National Commission of Bioethics (CNB), an official advisory institute, was created to disseminate bioethical culture, with a focus on public policy, infrastructure and public awareness. Second, the Federal Commission for the Protection against Health Risk (*Comisión Federal para la Protección de Riesgos Sanitarios*) (COFEPRIS), part of the National Health Ministry, is responsible for protecting the Mexican general population against health risks. Although the National Commission of Bioethics is not an authority but an advisory institution, registration is compulsory, involving updates and academic diffusion for ethics committees. In time, it could play a more active policymaking role. The CNB could be key in providing the biobanking expertise needed by advise policymakers, lawmakers, biobanking professionals, members of the public and ethics committees in a formally established, rather than a purely advisory way.

According to the General Health Law Rules, health research through clinical trials can only be authorized by COFEPRIS, the Mexican health agency. As part of the National Health Ministry, this agency is administratively independent, responsible for protecting the population against health

⁷¹ Evert-Ben Van Veen, *Obstacles to European Research Projects with Data and Tissue: Solutions and Further Challenges*, 44 ELSEVIER 1443 (2008).

⁷² J. Bovenberg, *How to Achieve ‘Free Movement of Tissue’ in the EU Research Area*, in HUMAN TISSUE RESEARCH. A EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES 13, 131 (C. Lenk, N. Hoppe, K. Beier and C. Wiesemann eds., Oxford University Press 2011).

risks through regulations and administrative controls. In contrast to the CNB, COFEPRIS performs a monitoring function, imposing sanctions for “non-compliance with legal provisions, rules and regulations” regarding safety prevention.⁷³ Unless sanctions are established under law, this agency has limited oversight powers. Besides, COFEPRIS, as the main health care authority (in charge of drug, food and lab controls, among others) could be finding it challenging to deal with biobanks (amongst its other numerous functions) efficiently. Currently, no Mexican agency exists to regulate human tissue.

1. Governance Models

In response to challenges posed by the expansion of European biobanking infrastructure, new governance mechanisms have been proposed and adopted, mostly at the national level. In this regard, two schools of thought have arisen: (a) enact legislation that specifically deals with biobank activities (Iceland, Estonia, Hungary, Sweden, Spain and Belgium); and (b) integrate provisions that regulate biobanks or bio-collections into broader administrative regulations and laws (France and the United Kingdom).⁷⁴

Provisions that deal specifically with biobanks normally include independent oversight, regular audits, activity reports, access measures for the release of samples and procedures for transfer and biobank closure.⁷⁵ In this respect, several common features are beginning to emerge:

- Biobanks’ accreditation should be done by national authorities with specific competence.
- Notification should be given regarding biobank creation; and the authorities should establish official registries and oversight committees to monitor national data protection.
- Responsibility for biobank management should be given to a single individual or entity.
- Appropriate security measures should be implemented to protect biological samples.
- When anonymized data or biological samples are deemed unfeasible because of the type of research, stringent confidentiality rules should govern the use of data and samples after “coding.”
- Research ethics committees should assess the objectives given for the establishment of a biobank.
- Limitations and/or specific safeguards should be applied when biological samples are transferred abroad.

⁷³ See Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitarios [RCOFEPRIS] [Federal Commission for the Protection against Sanitary Risk Rules], Diario Oficial de la Federación [D.O.], 13 de Abril de 2004 (Mex).

⁷⁴ EUROPEAN COMMISSION, *supra* note 61, at 39.

⁷⁵ See Council of Europe, *supra* note 5.

- Consent should be mandatory in cases involving children or other vulnerable parties.
- Research involving the use of biological samples from deceased parties must be expressly regulated.

In many cases, however, rules on the use of biological samples for research purposes “have to be pieced together taking into account a number of different regulatory instruments.”⁷⁶ The emergence of biobanking rules in Mexico is similar what occurred in France, where biobanks are regulated not under specific biobanking laws but completely separate pieces of legislation.⁷⁷ These distinct approaches reflect different national styles, and underscore the fact that no single regulatory approach works for every country. We can only assume that each nation is justified in treating biobank research in a piecemeal fashion rather than a more integrative approach. What most matters is that regulatory bodies are established to deal with the numerous challenges associated with biobank governance.

2. European Enforcement

At the European level, the provision of common explanatory biobanking guidelines, additionally to general directives, would be essential. This necessity has already been targeted and will need of European consensus to be given effective proposals; initially at the local level. Inconsistent data protection policies may result in unfair treatment and contribute to risks of regulatory capture (the unfair preferential treatment of a public institution towards particular groups of interest). In many cases, data protection has been embraced as an investment strategy, often outweighing efforts to actually protect data. Ideally, “a dedicated, independent statutory authority could reduce this risk.”⁷⁸ Principles of “independence, oversight and efficiency of control powers, including sanctions”⁷⁹ at the internal level, would be a good start.

Although European guidelines contain no explicit penalties for noncompliance, penalties are set forth on a national level by each signatory member state. This is notable in the case of the UK, where noncompliance with the Human Tissue Act or its codes may trigger the suspension and/or withdrawal of licenses. Serious ethical violations should prompt remedial action including notification, disciplinary action for professional misconduct or adjustment of practiced procedures.⁸⁰ Regulatory bodies such as the UK Human Tissue

⁷⁶ EUROPEAN COMMISSION, *supra* note 61, at 39.

⁷⁷ Isabelle Budin-Ljøsne et al., *ELSI Challenges and Strategies of National Biobank Infrastructures*, 21 NORSK EPIDEMIOLOGI 156 (2012).

⁷⁸ Susan Gibbons, *Regulating Biobanks: A Twelve-Point Typological Tool*, 17 MLR 324 (2009).

⁷⁹ A. Cambon-Thomsen, E. Rial-Sebbag & B. M. Knoppers, *Trends in Ethical and Legal Frameworks for the Use of Human Biobanks*, 6 ERS JOURNALS 375 (2007).

⁸⁰ Human Tissue Act § 5 (UK).

Authority are considered “critical to the operation of the Act’s governance framework.”⁸¹

As for Mexico, principles such as institutional “independence of the oversight” “efficiency of control powers including sanctions”⁸² could be a good start to reform the situation of biobanks. The publication of biobanking guidelines is essential. Despite significant legal gaps, currently enforced biobanking rules need to start becoming effective through practical mechanisms. Institutional coordination would be a good first step in resolving problems on a national level. Some have commented that “as genomic medicine develops in Mexico, the need for modern legislation related to its ethical and social implications will also increase.”⁸³

3. A Single Regulation for Biobanks?

Currently, no legal rules govern biobanks in Mexico. Rules for related issues are set forth in diverse sections and subsections rather than a single unified law. Most Mexican rules for human research are inconsistent. For example, rules are normally included in amendments rather than regulations or Acts. This has resulted in a patchy and often complex framework, where rules that apply to specific areas are not set forth in a single law or provision but in disparate regulations which fail to differentiate between ideas and ways to achieve them, a common practice under Mexican law. It is very difficult to determine the availability of effective biobanking legal guidance. Given a lack of regulations that specifically focus on biobanking, guidance in this area is subject to widely-divergent interpretation.⁸⁴ It is thus critical that Mexico establish an effective regulatory agency to help resolve urgent oversight challenges.

4. E-Governance

As a result of a spade of initiatives marking the evolution of biobanking from a collection of frozen specimens to virtual biobanks, new ideas for governance have recently gained traction in Europe.⁸⁵ New “e-governance” systems have emerged that allow consortia to function through self-regulation.

⁸¹ Miola, *supra* note 11, at 83.

⁸² See Cambon-Thomsen, *supra* note 79.

⁸³ Gerardo Jiménez-Sánchez, Irma Silva-Zolezzi, Alfredo Hidalgo & Santiago March, *Genomic Medicine in Mexico: Initial Steps and the Road Ahead*, 18 GENOME RESEARCH 1196 (2008).

⁸⁴ PANORAMA SOBRE LA LEGISLACIÓN EN MATERIA DE GENOMA HUMANO EN AMÉRICA LATINA Y EL CARIBE (Alya Saada & Diego Valadés coords., UNAM, Latin American and Caribbean Bioethics Network of UNESCO, 2006).

⁸⁵ Y. G. De Souza & J. S. Greenspan, *Biobanking Past, Present and Future: Responsibilities and Benefits*, 27 AIDS 303-312 (2013).

And the internet is now used to facilitate collaboration among medical researchers and gain the consent of participants through web-based tools. One example is the EnCoRe⁸⁶ project, in which “dynamic consent,” was presented as a possible solution for the endless dilemmas of potential future re-consent; as the consent of choice participants must be continually updated. Normally, it will correspond to an ethics committee to decide on the fate of biological samples after their first determined use. For further uses, ethical controversy could emerge from the concerns involving privacy and data protection of participants who are still alive. Re-contacting them can turn too difficult or unaffordable. If samples are anonymized and no privacy risks are involved, the ethics committee could determine that no further re-consent is necessary.

VIII. THE EMERGENCE OF POPULATION BIOBANKS

Population biobanks emerged in Europe to tackle new treatment alternatives for common population diseases. Common population biobanking research, consisting of continuous life-style studies and sample donations taken on a massive scale, have resulted in a notable increase in European population biobanks. Several Eastern-European countries (*e.g.*, Estonia and Latvia) were among the first to develop efficient controls for *population-based biobanks*, given their pioneering efforts in establishing national genome projects.

Estonia has been especially innovative in this area. In 2000, through its work on the implementation of the Estonian Genome Project, the Estonian government adopted the Human Genes Research Act, the most relevant framework governing tissue and associated data in this country. Under this framework, researchers were given unlimited future potential uses of genetic samples.⁸⁷ The Human Genes Research Act contains provisions regarding data collection, storage and use; participants’ rights (consent withdrawal, the right to know and not to know (consisting of an individual’s right to be informed of incidental findings); the role of ethics review; and the ownership of data and samples.

The Latvian Human Genome Research Law and regulations cover: (a) the voluntary nature of participation; (b) prohibition of discrimination on the basis of genetic data; (c) donor rights, including withdrawal at any time and the option to perform genetic research outside Latvia and protective measures for vulnerable populations, ethical review, coding, storage and use restrictions.⁸⁸ In Estonia and Latvia, materials may be removed from deceased parties for the purpose of scientific research without the participant’s consent.⁸⁹

⁸⁶ EnCoRe / Oxford Radcliff e Biobank (UK), available at <http://cyber.hwcomms.com/cyber/DynamicConsent>.

⁸⁷ Judith Sandor & Petra Bard, *The Legal Regulation of Biobanks. National Report: Estonia*, 5 CELAB (2009).

⁸⁸ Human Genome Research Law, The *Saeima* and the President, 1 January 2004 (Latvia).

⁸⁹ Geenidoonorid kooproovi, DNA kirjelduse, terviseseisundi kirjelduse ja tagasikodeerimist

“Because health data and genetic information are particularly sensitive personal information, this information should be protected by encryption codes and only be accessible to properly authorized biobank employees and researchers under strict conditions.”⁹⁰ This includes not only individuals, but also groups; as the same risks are still involved. Group stigmatization is always an issue when samples are taken from specific individuals or populations, especially those involving vulnerable populations. In general, population are at risk of mistreatment if no data protection measures are taken. This situation becomes aggravated in the case of small isolated Mexican indigenous peoples, who may find that data conflicts with religious or cultural understandings about their ethnic, legal or political claims that relate to land or items of cultural patrimony.⁹¹ Religious established beliefs established could be opposed to genetic studies; for example, cultural customs on the treatment of tissue in general and that from the deceased. Some people may still be fearful on the donation of body parts for religious reasons. In the case of tissue sample donations, there might not be social awareness because it would be something completely new. Discouragement needs to be prevented by planned actions regarding people’s cultural views in balance with knowledge on the implications of sample donations.

The cultural background of the Latvian Human Genome Project—similar to what happened in Mexico—was closely related to issues of national identity. The HapMAP⁹² Mexican population project involved the coding of the total number of samples collected for a genetics population project. Individuals were protected, but not participating vulnerable groups. These are still in risk of stigmatization coming from the particular genetic characteristics of the group (such as race and propensity to specific illnesses). In the absence of rules, subjects may be informed, most of the times informally; *e.g.* in an oral insufficient, rather than a way that guarantees full understanding. These could imply translators or forums where information for consenting is clear and accessible on the future use of their samples.

IX. HUMAN RIGHTS AND BIOBANKING

“In Europe the laws that have been applied to biobanks have largely been drawn from the legal traditions and jurisprudence that have been developing around the protection of human rights and the advancement of public

võimaldavate andmete hävitamise kord [Decree No. 128 of the Minister of Social Affairs 2002] RTL 17 of December 2001 (Estonia).

⁹⁰ D. Blumenthal & J. Glaser, *Information Technology comes to Medicine*, 356 NEJM 2527 (2007).

⁹¹ R. R. Sharp & M. W. Foster, *An Analysis of Research Guidelines on the Collection and Use of Human Biological Materials from American Indian and Alaskan Native Communities*, 42 JURIMETRICS 165 (2002).

⁹² The International HapMap Project is a multi-country effort to identify and catalog genetic similarities and differences in human beings.

health.”⁹³ A number of biobanking human rights related instruments have been established as a result: The Universal Declaration of Human Rights 1948 and the European Convention on Human Rights (ECHR) 1950, provide bodily protection of the individual through their emphasis on freedom from inhuman and degrading treatment. Human rights in the health and research context were also developed through The Council of Europe’s Convention on Human Rights (UDHGTHR) 1997, and the Universal Declaration on Bioethics and Human Rights (UDBHR) of 2005. Human rights instruments appear to view the individual as having an a priori right to be respected.⁹⁴ The Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine⁹⁵ serves to protect the rights of human subjects regarding scientific progress within Europe; such as dignity, autonomy and privacy. This convention sets forth general principles that are supplemented by additional protocols. In the run up to the adoption of the 1998 Act, the Data Protection Register praised the Government White Paper for recognizing in its proposals the idea that individuals were entitled to a right to privacy for personal data based on the respect for private life set forth in Article 8 of the European Convention on Human Rights.

1. Human Rights Panorama in Mexico

The Mexican non-jurisdictional human rights protection system (purely based on recommendations) is still believed to be “one of the most complete.”⁹⁶ This said, the consolidation and implementation of human rights under international treaties has been severely lacking. This is partly due to the absence of a constitutional rationale on the topic. One major issue is the authorities’ misconception that international rules do not apply unless they are enacted as federal law.⁹⁷ If a meaningful transition is happening at this time (one year after fundamental human rights reforms), this situation is likely to gradually improve. One possible solution would be to train and professionalize judicial authorities at both the local and federal levels.⁹⁸

⁹³ EUROPEAN COMMISSION, *supra* note 61, at 35.

⁹⁴ Austen Garwood-Gowers, *Respect as a Precondition for Use of Human Tissue for Research Purposes*, in HUMAN TISSUE RESEARCH. AN EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES 3 (C. Lenk, N. Hoppe, K. Beier & C. Wiesemann eds., Oxford University Press, 2011).

⁹⁵ European Union, Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, Jan. 12, 1998, Europ. T.S. 168 (1998).

⁹⁶ UN High Commissioner Office Diagnostic on the Situation of Human Rights in Mexico (2003). Available at http://www.cinu.org.mx/prense/especiales/2003/dh_2003/diagnostico-completo.Pdf, 7.

⁹⁷ *Id.*

⁹⁸ *Id.*

There are three fundamental issues that hinder Mexico's adoption of human rights treaties: (1) lack of legislation to facilitate the integration of international law; (2) failure to hierarchize international treaties; and (3) wide discretionary and interpretative margins on interpretative declarations in international treaties. The consensus or political will necessary to address such deficiencies makes change unlikely at this time. A key element necessary to address the ethical and legal conflicts caused by divergent frameworks is the implementation of harmonized agreements. Other possible solutions include the development of ethical and legal attitudes towards research participants, value and nature of the research project on a culturally sensitive basis. Researchers must also explore which models would be most acceptable in the communities where they plan to realize studies.⁹⁹ Selected governance models need to be sensitive to the needs of the different actors involved in biobanking. Hence, the case of vulnerable participants requires from specific attention through enforced measures protecting their rights; such as privacy at the individual level and prevention from stigmatization at collective level. This necessarily involves social expertise in defense of human rights. This is how remaining inconsistencies can also be resolved taking into account cultural sensitivity; by the promotion of interests focused, initially, individual level; *e.g.* an individual need for welfare's protection towards associated risks. Gradually, public awareness can be constructed through public scrutiny on the defense of individual and collective rights. In this particular case, once awareness is created on the rights which can be affected by the donation of a sample, the needs of those involved can be clearly identified, demanded and be the subject of legal protection.

Ariel Dulitsky¹⁰⁰ has stated that "before thinking on new laws, it is necessary to think of ways to guarantee enforcement." Well-written laws without implementation mechanisms are insufficient to remedy continual rights violations. For such a purpose of legal or political reforms governmental powers' commitment is necessary. In the case of biobanking laws, it will be necessary adopt implementation mechanisms through secondary legislation.

2. Mexican Health Panorama

The use of biological samples for research purposes has been addressed by some countries as part of health priorities; such as healthcare and diagnosis, a fact which presupposes adequate health systems and conditions. However, each country prioritizes health needs differently. "It is necessary to recognize that the developing world presents greater challenges from those of the de-

⁹⁹ Aceme Nyika, *Ethical and Practical Challenges Surrounding Genetic and Genomic Research in Developing Countries*, 112 ACTA TROPICA § 22 (2009).

¹⁰⁰ A. DULITZKY, APLICACIÓN DE LAS NORMAS INTERNACIONALES EN DERECHO INTERNO. MEMORIA DEL FORO: EL MARCO LEGAL INTERNACIONAL DE DERECHOS HUMANOS Y LA NORMATIVIDAD INTERNA 20 (2001).

veloped world in terms of substance and structure.”¹⁰¹ For example, in national grounds, Mexico has the second highest rate of obesity. One out of 11 Mexicans suffer from diabetes, which is currently the leading cause of death in Mexico—3 times higher than in Chile. 17% of public health funds are apportioned for the treatment of diabetes. Since 1960, Mexican life expectancy increased 2.8 years in men and 3.4 in women. In countries like Japan, men have gained 7 years and women 10. The average gain in the Organisation for Economic Cooperation and Development (OECD) countries is 4.4 years for men and 5.6 for women. 6.4 of the IPB is spent in health, in comparison with 9.6% from average OECD countries’ IPB. A Mexican spends 249 dollars per year on medicines, whereas an average of OECD citizen spends 487 dollars annually. Regarding infrastructure, there are 1.7 hospital beds per 1000 habitants; whereas the average for OECD countries is 3.1.¹⁰² Despite recent advances, statistics (2012) show that health conditions in Mexico are still relatively poor. One out of 11 children has low weight when born, compared with that from Chile (1 out of 17). Mortality in children under one is ten times that of Iceland and twice Chile’s figures.

Limitations may prevail over intentions to reform biobanking regulations in a parallel form as with other health national priorities. There are still significant boundaries for the creation of specific regulations for biobanks and the most important are surrounded by the predominant cultural values. *E.g.* in the Mexican population is not aware of the risks involved by the risks of data protection when donating a sample, no protection will be demanded from authorities. Mexican biobanking requires agreements involving the sharing and exchange of materials between participants from diverse cultural backgrounds. In order for this to work, consent must be inclusive and designed according to the needs of the targeted population; “culturally sensitive.” If an indigenous population does demand data protection in the same way as other populations, it means that special measures need to be taken; 1) to make that population aware of involved risks and 2) take the necessary measures to protect the group, given its character of vulnerable. Basic consent requirements in a purely ethical way are at risk of being considered optional. Hence, other more basic legal standards are necessary to make it compulsory.¹⁰³

3. Positioning the Biobanking Agenda in the Developing World

The evolution of biobanking regulations in Europe has been largely spurred by an expansion of research activity and the priority given to biobank regulation. Emerging economies, following a delayed but similar expansion

¹⁰¹ See Nyika, *supra* note 99.

¹⁰² Miguel Carbonell, *El desafío de la salud*, El UNIVERSAL, May 17, 2012.

¹⁰³ NEIL C. MANSON & ONORA O’NEILL, *RETHINK INFORMED CONSENT BIOETHICS* 78 (Cambridge University Press, 2007).

in research, are just now confronting the often precarious balance between their homegrown legal framework and related legal and ethical issues. Ethical research, for example, requires not only recognition of the benefits of personalized medicine but also the moral issues involved. The potential of personalized medicine involves personalization and predictiveness, which is due to the ability to predict the risk of certain diseases based on “personal genome” information in combination with life style data, age, sex, occupation, etc.; and “preventiveness,” that is based on individualized risk prediction. This requires an active “participation” of the individual concerned in proactively maintaining their health.¹⁰⁴ Moral issues are also associated to many other innovations. Biobanking research involves health priority areas and techniques that have the potential to revolutionize the treatment of a wide range of diseases, such as cancer and diabetes. “It should be pointed out that the majority of the populations in the developing world may not benefit from such high tech approaches due to prevailing socioeconomic factors, and stakeholders should always make concerted collective efforts to ensure availability and affordability.”¹⁰⁵ Recognizing sensitive areas requiring protection within biological samples seems to be something difficult to afford in countries like Mexico at the moment. The Mexican health system currently faces significant challenges, in which the loaded bioethical agenda must not be left behind by policymakers next to other national areas of priority. E.g. health campaigning against chronic diseases is a priority; and so does the grounds to conduct genetic research to prevent them. Even in the face of other pressing concerns, regulatory efforts in this area may be well worth the effort. There are relevant reasons and incentives encouraging governments to be up to date with topics requiring international harmonization.

The Unification of biobanking standards in Europe currently remains unclear, due to a future consensus difficult to be envisaged at the moment. The adoption of consensual guidelines may be an interim solution. Even so, there are important lessons to learn from the European experience, but more specifically about European countries involved. The situation of each of them is different and each of them involves examples of clear similarities and discrepancies with the Mexican situation.

It is also clear that biobanking involved issues at the international level, in which the exchange of samples requires from participating countries sharing minimum standards. If rules were to be produced, more specific guidelines would still be needed to resolve ethical questions on benefit of sharing samples; e.g. whether the authorization to use tissue for research under flexible rules would have to be re-scrutinized if the material happens to be used in a country with stricter rules.

Mexico must not fall behind within this context.

¹⁰⁴ EUROPEAN COMMISSION, *supra* note 61, at 17.

¹⁰⁵ Nyika, *supra* note 99, at § 22.

Emerging nations must assume a larger role in the international harmonization of biobanking.¹⁰⁶ Collaborative research involving multiple centers *i.e.* at national and international levels is constantly increasing and producing new necessities. Even when various genomics projects are developed nationally, many of them are the result of international collaboration. The absence of consistent rules regarding research, tissue and associated data is not only a hindrance to domestic research but prevents Mexican investigators from fully participating in international projects. In the end, Mexico cannot afford to remain indifferent to the continual expansion of biomedical and biobank research.

X. WHAT CAN BE LEARNED FROM EUROPE?

Comparative law facilitates better research by placing many issues in a broader context. The main lesson learned from Europe is the need to successfully harmonize external frameworks with local contingencies. Comparative law presents advantages if implementation is developed taking into account the unique characteristics of the focused country. Every issue is based on national realities and connected to cultural and ethical perceptions. No foreign regulation can “fit” the unique conditions currently faced by Mexico. This said, many real-world initiatives have been made to inspire fresh thinking, including numerous examples of overseas biobanks. Awareness of prevailing biobanking rule limitations is critical, as biobanking must always be viewed within a larger context. The rationale of a fit for purpose proposal should combine legal and bioethical expertise and focus on limitations related to the special characteristics of Mexico, both in practical and legal terms. Since rogue companies and pirates make policing extremely difficult, it’s possible that data protection may only work when users agree to be bound by rules.¹⁰⁷ For this reason, society needs to both recognize the vital importance of personal data and start demanding personal data protection. This applies to academics, judges, lawmakers, government agencies, human rights groups and society in general.

¹⁰⁶ Billie-Jo Hardy, *The Next Steps for Genomic Medicine: Challenges and Opportunities for the Developing World*, 9 NATURE REVIEWS GENETICS §5 (2008).

¹⁰⁷ Andrew Charlesworth, *Implementing the European Data Protection Directive 1995 in UK Law: The Data Protection Act 1998*, 16 ELSEVIER SCIENCE 234 (1999).