

Genetic information and biobanking: a Brazilian perspective on biological and biographical issues

Márcia Santana Fernandes^{1,2,3,9} · Patrícia Ashton-Prolla^{4,5,6} ·
Leonardo Stoll de Moraes^{1,2} · Úrsula Silveira Matte^{4,6} ·
José Roberto Goldim^{7,2} · Judith Martins-Costa^{8,9}

Received: 5 April 2015 / Accepted: 25 May 2015 / Published online: 13 June 2015
© Springer-Verlag Berlin Heidelberg 2015

Abstract This paper aims to discuss the duties of biological resource centres and their administrators concerning the protection of the privacy of the research subjects. Our aim is to discuss the interfaces between biological and biographical issues, related to the social, ethical and legal dimensions of biobanking activity.

Introduction

In 1890, Samuel Warren and Louis Brandeis recognised privacy as a right. They described their fear that new technologies and approaches, as “instantaneous photographs and newspaper enterprise, have invaded the sacred precincts of private and domestic life; and numerous mechanical devices threaten to make good the prediction that what is whispered in the closet shall be proclaimed from the house-tops” (Warren

and Brandeis 1890). With the introduction of biobanking, data banks and internet, such fears are likely to increase.

The storage of human biological material and associated information in biobanks not only enables biological research but also the development and use of new diagnostic and therapeutic techniques in specimens previously stored. On the other hand, the protection of personal genetic information is one of the main areas of concern around such research.

Genetic data generates genetic information (Taylor 2012). The interpretation of genetic data, related to biological issues, provides genetic information, related to biographical issues. Biological issues are related to life itself, considered as bare life, but biographical issues are involved with relational aspects, understanding life as living and as social relationships (Agamben 1998). It is possible that, to a research participant, biographical information could be more important and more sensitive than biological data. For this reason, research pro-

This article is part of the special issue on “Genetics and Ethics in Latin America”

✉ Márcia Santana Fernandes
marciasantanafernandes@gmail.com; marcia_fernandes@uniritter.edu.br

Patrícia Ashton-Prolla
pprolla@hcpa.edu.br

Úrsula Silveira Matte
umatte@hcpa.edu.br

José Roberto Goldim
jrgoldim@gmail.com; jrgoldim@hcpa.edu.br

Judith Martins-Costa
judith@jmartinscosta.adv.br; judithmc@terra.com.br

¹ Uniritter - Laureate International Universities, Porto Alegre, Brazil

² Laboratório de Pesquisa de Bioética e Ética na Ciência (LAPEBEC) at Hospital de Clínicas de Porto Alegre (HCPA), Porto Alegre, Brazil

³ Law School of Universidade Federal do Rio Grande do Sul – UFRGS, Porto Alegre, Brazil

⁴ Universidade Federal do Rio Grande do Sul – UFRGS, Porto Alegre, Brazil

⁵ Genetics Department, Mount Sinai School of Medicine, New York, NY, USA

⁶ Department of Genetics, UFRGS, Porto Alegre, Brazil

⁷ Medical School of UFRGS, Porto Alegre, Brazil

⁸ Universidade de São Paulo, São Paulo, Brazil

⁹ Instituto de Estudos Culturalistas (IEC), Canela, Brazil

jects that involve biological materials stored in biobanks always have ethical and legal dimensions.

Genetic information retrieves the past of a person, their biological inheritance in terms of individual, family and lineage history. Human biological material and related information stored in biobanks have more than merely biological aspects. Biographical repercussions also arise, generating new social, ethical and legal discussions. Privacy and confidentiality are the main concerns: privacy as a human right and confidentiality as a professional *prima facie* duty (Ross 2002). The repercussions of this information are not sufficiently predictable or controllable as to permit the establishment of a unified and prescriptive legal model.

Many efforts have been made in the attempt to reach a common standard, or at least a harmonisation, among different ethical, social and legal issues, as well as common practices for the management of biobanks (World Health Organization 2011). International research projects, such as those related to cancer or molecular and translational medicine, need to take account of a global perspective (German National Ethics Council 2009).

One of the main challenges is that different countries deal with privacy in different ways, depending on their cultural characteristics. Individualism or collectivism is one of these characteristics (Hoffstede 1997). In countries with an individualistic perspective, persons take care of only themselves and their close family members. The collectivist approach refers to a society that maintains a high level of interactions between persons. The self-image of an individualistic society is based on “I” perspective, and in a collective society, a “we” perspective dominates. Using the individualism index, that varies from zero to 100 points, Latin American countries, such as Argentina (46), Brazil (38) and Uruguay (36) have lower levels than North American, such as the USA (91), and Northern European countries, such as the UK (89) and Germany (67) (Hoffstede 1997). Therefore, the boundaries of privacy vary in different countries, but confidentiality remains as a core professional duty in all of them, even after a patient or a research subject dies (Rosler 2008).

This paper aims to discuss the duties of biological resource centres and their administrators concerning the protection of the privacy of the research subjects. Our aim is to discuss the interfaces between biological and biographical issues, involving biological, social, ethical and legal dimensions related to biobanking activity from a Brazilian perspective.

The protection of privacy in storage of human biospecimens in biobanks

The storage of human biospecimens for research purposes is the main *raison d'être* of a human research biobank. This neologism, used by scientists and administrators of health-

related institutions, refers to an organized collection of human biospecimens and associated data, stored for research purposes, in observance of pre-established technical, ethical and operational recommendations or rules (Ashton-Prolla et al. 2009).

Since there is no international convention to regulate human research biobanks, we must look to national legal systems to find the principles and rules capable of forming the “bricks” in the “building” of a regulatory framework for the activities of biobanks, ensuring they work with efficiency, technical reliability and respect for ethical standards.

Since there is no specific law regulating biobank activities in Brazil, we may deduce the general duties from different legal sources, interpreted as a whole. Contemporary Brazilian law offers a wide set of normative procedures aiming to protect the human person and human personality. Beginning with the respect for fundamental rights, which includes privacy; this is expressed in the Brazilian Federal Constitution (Brasil 1988). In addition, there are many other infra-constitutional laws, such as the Organ Transplantation Law (Brasil 1997), the new Civil Code (Brasil 2002), and the Biosecurity Law (Brasil 2005), as well as other administrative guidelines and regulations (Fernandes et al. 2010).

In Brazilian Portuguese, there are two distinct but related terms for the private sphere: intimacy (*intimidade*) and private life (*vida privada*), which are commonly considered as synonyms, although some authors draw distinctions between them. Private life (*vida privada*) is a more general term, referring to the singularity of the individual that differentiates him or her from other individuals, society and the State, in order to guarantee a space of freedom, introspection and communication, i.e. a space for the individual to interact socially. On the other hand, intimacy (*intimidade*) refers to the sphere of exclusivity that an individual reserves for him- or herself. This is that part of life that bears no social repercussion, not even in the context of an individual's private social relations, which, private as it may be, is nonetheless a life with others, such as the members of one's family, coworkers or partners in leisure activities (Ferraz 1992; Dotti 1980a, b; Sampaio 1998).

Researchers must preserve the “dignity of the human person” included in the beginning of the Brazilian Federal Constitution (Brasil 1988). Many values and guarantees derived from this concept. Researches should not infringe the rules concerning personal rights, neither by actions nor by omissions, such as those that protect the right to privacy. In its broad sense, this includes personal information, intimacy and private life.

Privacy, as a value protected by law, has only been acknowledged in modern times. For the first time in history, the public and private spheres have been conceptually separated. The human person is to be considered as a root value (*valor-fonte*) and essential to the legal system (Reale 2004).

Such differentiation is vital for both spheres, public and private, because the principles governing them are not the same. Whereas the public sphere is ruled by the principles of equality and publicity, the private sphere is based on the principle of *exclusivity* (Arendt 2013). By this principle, the individual has the right to be alone, as well as the possibility of excluding from the knowledge of others that which concerns only him- or herself. Respect for the individual's privacy protects both lifestyle and private life. Such protection is granted to individuals in their relations with other individuals, as well as with the State (Ferraz 2002).

In Brazil, privacy is a personal right granted by the Federal Constitution (Article X, 5) that ensures the inviolability of individual privacy, private life, honour and personal image (Brasil 1988). The Federal Constitution protects the exclusive domain of subjects in those situations deriving from the choices they might make according to their own subjectivity, without the restraint of pre-established standards (Martins 2002).

In terms of confidentiality, just like the physician in clinical practice, the investigator in health research has the same duty to protect personally identifiable data from disclosure. The Brazilian Code of Medical Ethics (Resolution CFM 1931/2009) is conscientious in its specification of cases where confidentiality must be observed (Brasil 2009). Many other health professionals' codes of ethics have the same approach. Brazilian Penal Code Confidentiality also granted confidentiality as a duty (Brasil 1940). Trust is fundamental to an adequate relationship with patients and research subjects.

In a research project, all personal identifiable data is protected, unless the research subject allows its disclosure in the context of informed consent. Any research information that could have medical repercussions remains as private as any other medical information (Brasil 2009).

In the context of biobank research, the issue is raised of previously donated biological material. Donation should not entail the loss of the right to privacy even when the information "donated" reaches into the inner sphere of personal intimacy. That is precisely why the researcher has the duty to protect the privacy of the research subject, whether in terms of the data associated with certain biospecimens or any other information concerning the research process. It is the researcher's responsibility to manage the data, as well as the procedures used to obtain and maintain the data, in order to protect the research subject's right to privacy.

Data handling is one of the most important aspects in the activity of biobanks. One of the major priorities is to maintain safe and specific information systems. Personal data must be deidentified and stored using cryptography.

Privacy includes the right to anonymity concerning personal genetic information, since an individual's genetic structure is an element of their identity (Mathieu 2000). Violation of

confidentiality could result in a lawsuit for moral damage compensation by a research subject.

However, in the case of the research subject, one may say that, although personal rights cannot be waived or disposed of in Brazilian Law, a certain amount of flexibility ensues, concerning the object or information that has been donated. Thus, the researcher does not have to observe the duty of confidentiality toward the data obtained in research activities, if the research subject gives specific permission for disclosure. Therefore, there is no civil liability for violation of privacy if the research subject has expressly authorised the disclosure of data to others, under determined circumstances. In this case, there is no violation of trust or of any personal right (Martins-Costa 2011a, b).

In some cases, however, the disclosure of data—as long as it is done in a sincere, conscientious and responsible manner—may be inescapable, due to considerations of public order, even by force of the law, if the data concerns an endemic or highly contagious disease. In fact, concerning the duty to protect the privacy of research subjects, some exceptions apply, especially in cases related to genetic material. In these situations, it is sometimes necessary to share the information or to identify the data, to the extent that the detected problem is not limited only to one patient or research subject. Genetic data and genetic information exist in the space between biological and biographical aspects.

Genetic data and genetic information: between biological and biographical perspective

The adequate use of personal data, especially genetic information, is a priority. According to the EU Directive on the Protection of People concerning the Processing of Personal Data (1990), information related to an individual's health is considered as "sensitive data" and must be protected.

Informational systems must be able to harmonise, as much as possible, two situations that appear irreconcilable. Researchers must not know the identity of research subjects while the system must be able both to identify and to preserve their anonymity. This kind of paradox, strange as it may seem to non-specialists, is quite common in the realm of jurisprudence: after all, law is an attempt to regulate life through the establishment of criteria for the balancing of clashing interests or goods—in this case, public interest and the protection of privacy.

Researchers might be engaging with health information related to research participants that could be relevant to individuals, other family members or other persons that could be affected. Research participants may maintain the right to know personally relevant information, including information derived from projects that used stored biobank material. An investigator has the duty to protect this information from other

persons, but could inform research participants directly. A conflict emerges when this information could be useful to protect other persons. The balance between balancing the rights of the individual, understood as protecting private life or the boundaries of intimacy, and a collective perspective must be evaluated in order to understand the relationship that arises between duties and rights.

As a result, it is important that institutional rules concerning biobanks (or research projects themselves, in case those have not yet been established) define a priori criteria concerning the specific relevance given to one or other legal principle and, in each concrete case, how those principles may be deemed to relate to each other. Those previously defined rules must harmonise subjective liberties and the interests of society, because their function is to establish the *modus operandi* for *coexisting liberties*, which is a trait of societies ruled by law (Martins-Costa 2006).

In this vein, the German Constitutional Court, when dealing with the issue of data protection, has so far shown a tendency not to consider privacy as an absolute or unlimited right of the individual over his or her own data. The Court considers the individual as “a personality directed toward communication, which, within a social community, expands” and finds that the right to informational self-determination cannot be “an individual right to private defence, setting the subject apart from the rest of society”, but rather that it must “make it possible for all to engage in the processes of communication” (Ferraz 2002).

Consequently, the freedom protected by the right to privacy must not be based on a notion of egocentric expansion, but rather as the exercise of freedom in reciprocity (Ferraz 2002). In a real situation, the problem lies between private life and public interest. Either the issue concerns primarily an aspect of someone’s private life, in which case it must be kept within the private sphere, or it is something that deserves broad visibility, due to the acknowledged presence of a public interest (Cachapuz 2006). In such cases where the *legitimate interests* of a third party are negatively affected, confidentiality, as a *prima facie* duty, must be put to one side (Martins-Costa 2011a, b). In order to prevent a slippery slope approach to the interpretation of legitimate interest, this disclosure must be strongly justified. Using the same argument as in the Tarasoff case (Supreme Court of California 1976), a real-life or living risk to another person, or a group of persons, that could be minimised by this disclosure must be established.

The boundaries of private and public spheres are established by the balance between individual and social interests. This balance depends partially on the individualistic or collectivistic perspective of that society and on the national law concerning the protection of privacy.

Another important aspect of the management of information in the activity of biobanks, which affects the privacy of research subjects, is the sharing of information among

researchers and the creation of research networks which are increasingly connected globally. That is why an important objective must be the harmonisation of compatible information technologies and their systems, rules and guidelines related to these projects. The same rules must be applied to all investigators. The problem is to develop rules that can accommodate different cultural relations with research subjects. The cultural borders of the concept of privacy must be considered as a new challenge to research projects that involves the use of biological samples stored in biobanks.

Final considerations

In order to preserve justice, the answer to the challenge of privacy in the context of genetics research must be given according to the criteria established by the legal system, or whatever criteria may be deduced from it. The duty of confidentiality is thus submitted to the due consideration that must be given to the concretisation of everyone’s right to privacy, in both senses, of private life or intimacy. Those rights cannot be seen as mere “rights to egoism” (Oliveira Ascensão 1998) but rather as an instrument for self-development and to improve a collaborative relationship with other community co-participants (Leite de Campos 1993). Genetic information introduces a new perspective in privacy related neither to a single person nor to a time-specific period. Privacy, in this context, must be considered in a personal, social and historical perspective.

Acknowledgments The authors would like to thank Laís Bianchin da Costa (Undergraduate in Law at UniRitter - Laureate International Universities, Undergraduate trainee at Laboratório de Pesquisa de Bioética e Ética na Ciência (LAPEBEC) at Hospital de Clínicas de Porto Alegre (HCPA)) for their assistance in researching and organising some references.

Compliance with ethical standards

Conflict of interest The authors declare that they have no competing interests.

Ethical approval This article does not contain any studies with human participants or animals performed by the authors.

Funding This study was funded by FIPE/HCPA (grant number 2011/LAPEBEC).

References

- Agamben G (1998) *Homo Sacer: sovereign power and bare life*. Stanford University, Stanford
- Arendt H (2013) *The human condition*, 2nd edn. University of Chicago Press, Chicago

- Ashton-Prolla P, Clausell N, Santana-Fernandes M, Matte U, Bittelbrunn AC, Hemesath MP, Kuchenbecker R, Goldim JR (2009) Biobanco do Hospital de Clínicas de Porto Alegre: Aspectos Técnicos, Éticos, Jurídicos e Sociais [The Hospital de Clínicas de Porto Alegre Biobank: Technical, Ethical, Legal and Social Aspects] *Rev HCPA* 29(1): 74–79
- Brasil (1988) Constituição da República Federativa do Brasil de 1988. Brasília. Available at: http://www.senado.gov.br/legislacao/const/con1988/CON1988_04.02.2010/CON1988.pdf. Accessed 10/01/2015
- Brasil (1997) Lei de Transplante de Órgãos. Lei nº 10.211, de 23 de Março de 2001 e Lei nº 9.434. Available at: <http://www.saude.pr.gov.br/arquivos/File/centraldetransplantes/Lei9434.pdf>. Accessed 10/01/2015
- Brasil (2002) Código Civil: Lei 10. 406. Brasília. Available at: http://www.planalto.gov.br/ccivil_03/Leis/2002/L10406.htm. Accessed 10/01/2015
- Brasil (2005) Lei de Biossegurança: Lei nº 11.105. Brasília. Available at: http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/lei/111105.htm. Accessed 10/01/2015
- Brasil (2009) Conselho Federal de Medicina - Código de Ética Médica. Resolução [Resolution] 1931/2009,. Brasília. Available at: http://www.cremers.org.br/pdf/codigodeetica/codigo_etica.pdf. Accessed 10/01/2015
- Cachapuz M (2006) Intimidade e vida privada no novo código civil brasileiro: uma leitura orientada no discurso jurídico [Intimidade and vida privada according to the new Brazilian Civil Code: an interpretation based on legal discourse]. Fabris, Porto Alegre
- Dotti R (1980a) A Proteção da Vida Privada e Liberdade de Informação [The protection of private life and the freedom of information]. Editora Revista dos Tribunais, São Paulo
- Dotti R (1980b) A liberdade e o direito à intimidade [Freedom and the right to privacy]. *Rev Inf Legislativa* 17(66):24–33
- Fernandes MS, Ashton-Prolla P, Matte U, Meurer L, Osvaldt A, Bittelbrunn AC, Schlatter R, Pereira Da Silva FM, Clausell N, Goldim JR (2010) A normativa do Hospital de Clínicas de Porto Alegre para o armazenamento e utilização de materiais biológico-humanos e informações associadas em pesquisa: uma proposta interdisciplinar [Rules and standards used by the Hospital de Clínicas Biobank in Porto Alegre concerning the storage and use of human biospecimens and related research data: an interdisciplinary proposal]. *Rev HCPA* 30(2):169–179
- Ferraz T (1992) Sigilo de dados: o direito à privacidade e os limites à função fiscalizadora do Estado [Data confidentiality: the right to privacy and the limits of the State's invigilating function]. *Cadernos de direito tributário e finanças públicas*. N1. 1992
- Ferraz T (2002) A liberdade como autonomia recíproca de acesso à informação [Freedom as reciprocal autonomy to access information]. In: *Estudos de filosofia do direito: reflexões sobre o poder, a liberdade, a justiça e o direito* [Studies in Philosophy and Law: reflections on Power, Liberty, Justice and the Law]. São Paulo: Atlas
- Germany National Ethics Council (2009) Biobanks for Research. Opinion. 2 Mar. 2009. Available at: http://www.ethikrat.org/english/publications/Opinion_Biobanks-for-research.pdf. Accessed 15/01/2015
- Hofstede G (1997) *Cultures and organizations: software of the mind*. McGraw-Hill, New York
- Leite De Campos D (1993) O Direito e os Direitos da Personalidade [Law and personality rights]. *Rev Ordem Advogados* 1993(2):201–224
- Martins L (2002) O direito civil à privacidade e à intimidade [The civil right to privacy]. In: Martins-Costa J (ed) *A Reconstrução do Direito Privado – Reflexos dos Princípios, Diretrizes e Direitos Fundamentais Constitucionais no Direito Privado* [The reconstruction of Private Law]. São Paulo: RT
- Martins-Costa J (2006) Prefácio [Preface]. In: Cachapuz M (ed) *Intimidade e vida privada no novo código civil brasileiro: uma leitura orientada no discurso jurídico* [Intimidade and vida privada in Brazil's new Civil Code: an interpretation based on legal discourse]. Porto Alegre: Fabris
- Martins-Costa J (2011) O princípio do livre desenvolvimento da personalidade [The principle of the free development of personality]. In: Lobo Torres R, Kataoka E, Galdino F, Org. (eds) *Dicionário de Princípios Jurídicos* [Dictionary of legal principles]. Rio de Janeiro: Elsevier: 813–840
- Martins-Costa J (2011) Introdução à Responsabilidade Civil em Gineco-obstetrícia [Introduction to civil liability in the field of gynecology and obstetrics]. In: Freitas F (et al.) (ed) *Rotinas em Obstetrícia* [Routines in Obstetrics]. Porto Alegre: Artmed, 2011: 851–887
- Mathieu B (2000) *Génome Humain et Droits Fondamentaux* [Human genome and fundamental rights]. Paris: Economica: 59
- Oliveira Ascensão J (1998) Os Direitos de Personalidade no Código Civil Brasileiro [Personality rights in the Brazilian Civil Code]. *Rev Forense* 342:122
- Reale M (2004) Direitos de Personalidade. Available at: <http://www.miguelreale.com.br/artigos/dirpers.htm>. Accessed 15/01/2015
- Rosler H (2008) Dignitarian posthumous personality rights—an analysis of U.S. and German Constitutional and Tort Law. *Berkeley J Int Law* 26(1):153
- Ross WD (2002) *The right and the good*. Oxford: Oxford
- Sampaio JAL (1998) Direito à intimidade e à vida privada [Right to privacy]. Del Rey, Belo Horizonte
- Supreme Court of California (1976) *Tarasoff v. The Regents of the University of California* 131 Cal. Rptr. 14 (Sup. Ct. 1976)
- Taylor M (2012) *Genetic data and the law*. Cambridge: Cambridge
- Warren SD, Brandeis LD (1890) The right to privacy. *Harvard Law Rev* 4(5):193–220
- World Health Organization (2011) International Agency for Research on Cancer—IARC. Feedback on the operation of biobank activities. Available at: <http://www.iarc.fr/en/about/index.php>. Accessed 15/01/2015