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Ethical Issues of Consent for Genetic Research in Latin American Bio-banks

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Abstract

This article reviews ethical issues of consent for genetic research in relation to Latin American bio-banking practices and collaborative research projects with developed countries. There is need for ethical legal safeguards for informed consent procedures so that Bio-banks, bio-specimens and data will be used in accordance with Latin American cultural needs. The issue of national regulations for bio-banking in Latin America may help to clarify what can be done in the field of international and national research respecting subject donations.

Keywords: Bio-banks; Genetic research; Informed consent; Vulnerable populations

Introduction

A Bio-bank is a repository of biological tissue which may be associated or not to health data [1]. Samples may derive from clinical setting, research projects or judiciary mandate and may come from surgery, wastes, diagnostic tests, birth products (placenta and umbilical cord), body parts of deceased, donation of gametes or embryos or biological materials from genetic research population studies. Data associated to the samples may be individual (clinical, life style), familial (genealogy information or ethnic origin) or belong to a group (geographical location, language). Bio-banks store human biological materials (bio-specimens) for one or more research purposes, being helpful for health care decisions. In relation to genetic research it may produce new knowledge of clinical and public health relevance, [2] by providing novel insights into the genetic component of disease and therapy efficacy, leading to a personalized approach to healthcare, but the use of specimens and data stored in bio-banks raise ethical and legal issues [3].

Advances in biotechnology and bioinformatics have made possible to store in huge scale bio-specimens and data. Trans-national sharing of bio-bank resources has increased as more researchers seek to pursue cross-border collaborations with foreign bio-banks amplifying apprehensions between countries. On the other hand, the appropriateness of using stored specimens in ways not originally intended when they were collected has been questioned, such as the use of specimens stored for clinical reasons and subsequently used in research [4].

There are collaborative genetic research projects focusing on diseases prevalent in developing countries which require shipment of samples stored in bio-banks from developing to developed countries. Therefore, there is a growing need to harmonize bio-bank processes. Processes should be formulated in such a way that all areas of bio-banking are covered to improve the bridges between research and clinical application. The scope and purpose of transferring bio-specimens between countries is subject to major constraints, due to the legal, ethical and political framework differences [5]. Furthermore, bio-bank partners expect a certain level of quality of the bio-specimens they receive, which implies stringent quality control measures covering acquisition, transport, pre-analytical handling and bio-specimen storage [6]. In many Latin American countries, norms referring to international transfer of bio-specimens are subjected to international cooperation agreements which may need contractual warranties, not being regulated by national regulations. These agreements may not be sensitive to some specific ethnic groups, such as indigenous populations or may enter into conflict with some country national regulations.

Some developed countries have created international networks coordinating their bio-specimen collections by development of common standard operating procedures, compatible informatics systems and harmonized informed consent and material transfer policies and procedures [7], but there is a long way to be covered in Latin American bio-banking procedures.

Legal safeguards must assure that bio-banks will not be used in any way that may harm individuals providing samples, their genetic relatives or community. There are concerns with the possibility of invasion of privacy, difficulties in safeguarding confidentiality, ways to avoid discrimination and stigmatization and that bio-specimens may be used in international commercial trade [8]. Numerous international ethical guidance has been produced [9].

Research ethics has established the right of participants to be fully informed of objectives and procedures of research projects and the right to withdraw from a project at any time. However, bio-banks may have open-ended scientific goals; some logistic difficulties, such as re-contacting people whose biological material and related data are stored in bio-banks, should be addressed when planning research [10]. Also, the way, some bio-banks are established make it difficult to report individual data due to privacy protection [11]. Comprehension of disclosed information in informed consent processes may be complicated in low literacy groups and in elderly with lack of education in science; furthermore, religious and cultural beliefs must be respected.

There are different views of consent for use in research of materials and data stored in bio-banks, from broad (open to any kind of research), to restricted (specific informed consent for each research) or tiered consent (choosing among a potential use of secondary research list) [12]. Bio-banks tend to favor a broad model of consent, justifying

it by referring to the potential benefits research could produce combined with the presumed low level of risk when privacy and confidentiality measures are taken [13]. The broad model argues for a general or generic consent open to any kind of research given once the tissue is procured for health issues taking into account that many patients do not wish to be re contacted again. Scientists tend to favor broad consent while accepting that donors need some form of assurance that nothing unethical will be done with their samples and information [14]. Others consider that broad consent is not truly informed consent, but rather a generic authorization that sacrifices the right of the donor to self-determination in favor of research interests [15]. Brazil favors a consent form with two mutually exclusive options: an explanation about the use of the stored material in each research study, and the need for new consent or the waiver thereof when the material is used for a new study. On the other hand, the informed consent form for Bio-repositories must be exclusive and related to specific research [16].

Ethical Issues Related to Informed Consent for Genetic Research Using Bio-banks, Bio-specimens and Data

The ethical issues involved on the necessary content of informed consent for the use of bio-specimens in research are very complex. Although some of the issues may be related to biosafety, commercial use or bio-banking administration, these are argued that must be included in the information provided in informed consent. Most are worldwide concerns, but there is still need to assess specific issues for Latin American context. Some ethical concerns are:

Scope of the information

Researchers should provide potential participants with sufficient information on the nature, implications and foreseeable benefits and risks (stigmatization, discrimination, intra familial conflicts), so that they can realistically assess the implications of their participation and make informed decisions. Prior to consent, there is need for risk assessment. Another issue is the need to harmonize a common language for international bio-banking information procedures related to technical terms in order to avoid confusion [17]. Some English technical terms area translated into Spanish in different ways in Latin America countries, which may cause confusion.

Understandable communication

The information to be provided to potential participants needs to be in simple language, concise and explicit, considering the different needs. But, it is very doubtful that vulnerable populations with low level of education in science, such as Latin American indigenous populations, may be able to understand the complex issues exposed in informed consent content for the use of bio-specimens in research. Lack of understanding is the main barrier for a proper informed consent in this type of populations [18].

Ownership Issues and benefit sharing

There is need for clarification of ownership issues with respect to the bio-specimens, information and collection and who will be benefited. In transnational research often developed countries get the benefits, which are viewed with suspicion in Latin American countries and may hamper international collaboration [19]. There have been disputes over who has the right to control the use and distribution of bio-specimens and products derived [20]. Policies for potential commercialization and whether participants will derive benefit from any such commercialization must be established.

Source

The source of the bio-specimens that will be collected for research must be informed.

Intended purpose

The purposes for which the data will be used and/or disclosed must be clearly stated.

Secondary use of samples

Circumstances for new consent should be specified when there is secondary use of samples. If there is no new consent it should be assess the specificity of the first consent for secondary use. The secondary use may be difficult to ascertain when bio-specimens are stored in bio-banks, since it is difficult to control what will be done with them.

Data sharing

Whether bio-specimens and genetic information will be made available for proficiency testing, commercial entities, including those from other countries and publication of data; policies with regard to access to bio-specimens and data by third parties such as insurers, employers or law enforcement agencies must be established. The necessity for bio-banks to share their resources with third parties poses potential risks to public trust particularly if these may affect social stigmatization or discrimination. This is a sensible issue for Latin America as well. It may also affect the intention to participate in genetic research [21].

Consent of children

Ethical concerns arise related to consent for future use in children [22], such as whether child participants will be involved, whether, when and how a child's assent will be obtained and procedures for possible future consent.

Culture respect

The consent process should take into consideration the cultural and religious sensitivities of participant and the community in which the research is to be conducted. Except in a few cases, the views of donors of bio-specimens with respect to future genetic research have not been reported in Latin America. Consent to collect bio-specimens from indigenous groups is a sensible issue due to their vulnerability and the value they give to body parts, specially blood samples [23]. Also there is generally a requirement to ask consent previously to elderly leaders. Several declarations of indigenous populations in Latin America manifest opposition to the collection of blood samples used for DNA characterization [24]. In Chile research with blood samples taken from Mapuches caused a protest by ethnic leaders [25]. In a study carried out by our group it was shown that lack of understanding about the technology and implications of genetic research is associated with an increase in anxiety and hostility towards genetic experimentation in Latin America and that civil society relies on media coverage for their knowledge [26]. In Mexico, the National Institute of Genomic Medicine, first of its kind in Latin America, was created to map the genome of Mexicans in order to promote preventive medicine, but

since its inception provoked social controversies in misunderstanding its purpose [27].

Release of information

Whether the research may reveal information of potential importance to the future health of participants or their blood relatives and would be released to them, respecting the right to know the information and the right not to know it when there is no therapy. Researchers who oppose returning results to participants assert that the purpose of research is to generate knowledge rather than provide clinical care and that research laboratories do not necessarily operate in accordance with clinical laboratory standards [28]; in this sense there is only consensus that people should be offered results that could trigger interventions that are lifesaving or that could avert serious adverse health outcomes, but not for other situations. Some common principles such as analytical validity, importance to health, clinical applicability, and consent to receipt the information have been identified by multiple groups as required for return of individual research results. However, this issue has not been explored in Latin America. Also, it should be addressed whether information from or about family members, in addition to that provided by participants, is required for the research.

Data storage, transfer and disposal

The form in which the data will be stored, duration, transfer and disposal procedures, including the international transfer of data where applicable. The possibility of tracing the person from whom sample and data were derived varies according to how the samples are linked to their donor identity in the database. Samples and associated information can be [29]:

Identifiable: The identity (or personal and unique id number) of individuals is directly attached or linked to the samples or data.

Traceable or coded: A code is attached to them and the correspondence between code and identity is physically separated from sample and data. A limited number of people can connect the code to the identity.

Encrypted: There is a further level of protection through encryption (that is, the code is transformed into several characters that are linked to the code with the intervention of a third party). This third party intervention will then be required to trace individual identity.

Anonymized: The link has been irreversibly cut between sample/data and the individual identity.

Anonymous: There has never been any possibility to link the sample and the attached data to a given person.

Confidentiality and privacy

Procedures and safeguards used to protect confidentiality and privacy; details of data linkage, including which health and other records are to be accessed, who will be the custodian of the bio-specimens and what will be the custodian's role. Privacy concerns are raised by the difficulty of accepting that biological samples must be completely anonymous without incurring into the practical impossibility of exploiting their information potential. Confidentiality and privacy issues raise the need for protection of databases storing genetic and health information obtained from the samples. Confidentiality policies may include data encryption, coding of bio-specimens and data, establishing limited access or varying levels of access by bio-bank employees, use of nondisclosure or other agreements, as well as data security practices [30]. Most Latin American countries consider genetic data as private, subject to confidentiality agreements.

Right to withdraw

The available types of withdrawal and the implications of such withdrawal; in the case of clinical trials patients have the right to refuse bio-specimen donation, without affecting their treatment or eligibility to participate.

Death or incapacity of participant

Arrangements for the bio-specimens and data in the event of incapacity or death of the participant.

Waiver of consent

A human research ethics committee may waive the requirement for consent if there is minimal risk to human subjects; the waiver will not adversely affect the rights and welfare of the subjects; there is no known or likely reason for thinking that participants would not have consented if they had been asked; there is sufficient protection of their privacy; and there is an adequate plan to protect the confidentiality of data.

Ethical Issues Related to Regulation of Bio-banking

Developed countries have regulations to address the issues in bio-banking [31], but most Latin American countries lack specific national regulations for the use of stored human samples. Brazil has been pioneer in this sense with Resolution CNS 441/11, enacted by the National Health Council of Brazil in May 2011, and the National Guidelines for Bio-repositories and Bio-banks (Ordinance No. 2201) published by the Ministry of Health in September 2011. Most bio-banks in Latin America function with their own norms of consent and quality standards in the absence of specific country regulations. These norms may be too open or too restrictive for research subjects or researchers satisfaction. Colombia, for example, has regulations for research using biological samples in clinical trials, but has no regulation for bio-banks. In Chile, there are some regulations for research using human bio-specimens, but regulation of bio-banks is not specified. Chilean Law 20.120 about research involving human beings and genomic data qualifies genetic data as private, protected by law 19.628, except in case of criminal justice requirements. This law obliges the encryption of personal genetic data in storage and transfer, avoiding individual identification, except in cases of public utility; research with human individuals requires previous informed consent with sufficient information provided in order to participate, respecting cultural and ethnic factors. Ministry of Health has guidelines for the collection and storage of biological materials by health care institutions: "Guide for Surveillance Systems for Diseases Transmitted by Food and Research on Outbreaks [32]. Furthermore, the National Commission for Science and Technology requires the approval by scientific ethical review committees of any research with human biological materials. In the informed consent recommendations elaborated by this Commission, the following is pointed out: to inform potential subjects of type of biological sample to be extracted, quantity of fluids to be extracted, destiny of samples, risks involved, destiny of leftover tissue, measures to guaranty confidentiality and the

requirement of re consent for new research with the biological materials, when this is not possible the decision is taken by scientific ethical review committees [33]. Research subject protection is safeguarded by ethical review committees in research performed in the country, but donor provisions are not always fully incorporated in bio-bank consent, especially when there is transfer of bio-specimens to other countries.

There are numerous bioethical issues to take into account in order to satisfy research needs and guarantee data protection. Issues of privacy and safeguard of confidentially and differences in understanding and perception of risks are culturally determined [34]. Personal identifiers or community/population identifiers may cause problems in safeguarding confidentiality over sensible issues which risk the possibility of social stigmatization or discrimination. Anonymity of the samples may not preclude the possibility to trace the community or population origin if the location, language or name of the ethnic group is given. Moreover, depending on the type of research some health and environmental exposure data may be necessary to keep and archive samples may be used without previous consent on donor.

Another problem in Latin American is the regulation of safety procedures and quality assurance for keeping bio-specimens. Safety procedures are costly due to the need of personnel, equipment, processing methods and the need to monitor that frozen samples are kept in adequate temperature and liquid nitrogen levels.

Genetic counselors may play in ethically and legally appropriate bio-bank recruitment and management strategies for genetic research [35], but this specialty is very limited in Latin American countries.

There is need for international harmonization and oversight of best practices for improving bio-specimen quality and coordination in bio-banking networks in Latin America. While technical and management issues of use of bio-specimens stored in bio-banks are more straightforward, ethical and regulatory practices often involve issues that are controversial and difficult to standardize since they are developed within particular contexts [36]. Nevertheless, the issue of national regulations for bio-banking in Latin America may help to clarify what can be done in the field of international and national research respecting subject donations.

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