Council of Europe
Conseil de l'Europe

Ethics in biobanking the CoE perspective

Javier Arias Díaz

Consejo de Europa

Desde 1949. Unidad de los gobiernos en la defensa de:

- Derechos humanos
- Democracia parlamentaria
- Estado de derecho

Consejo de Europa

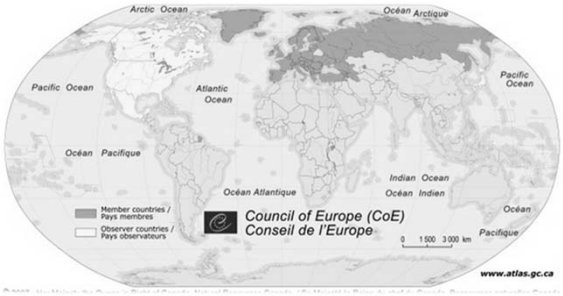
47 países *(todos los miembros de la UE son miembros del CoE)*

Status de «Observadores»

Canadá, Santa Sede, Japón, Méjico, Estados Unidos

Consejo de Europa

Estados Miembros y Observadores



Papel en la Bioética

Objetivo:

"Protección de la dignidad humana y los derechos fundamentales en el entorno de la biomedicina"

Comité intergubernamental responsable:

Comité « Director » de Bioética (DH-BIO)

International Documents

Non-binding	Binding
▪ Helsinki Declaration (1964 – 2013, AMM)	▪ Regulation (EU) 536/2014 on clinical trials on medicinal products for human use
▪ International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002, CIOMS)	▪ Convention on Human Rights and Biomedicine (Oviedo Convention), 1997
▪ Universal Declaration on Bioethics and Human Rights (2005, UNESCO)	▪ Additional Protocol concerning Biomedical Research, 2005

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

Recommendation Rec(2006)4
of the Committee of Ministers to member states
on research on biological materials of human origin

(Adopted by the Committee of Ministers on 15 March 2006
at the 958th meeting of the Ministers' Deputies)

Preamble

The Committee of Ministers, under the terms of Article 15.*b* of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Considering that one of the aims of the Convention for the Protection of Human Rights and Fundamental Freedoms (ETS No. 5) is the protection of private life;

Considering that the aim of the Convention on Human Rights and Biomedicine (ETS No. 164, hereinafter

Recommendation on Research on Biological Materials of Human Origin

Conseil de l'Europe, March 2006

- Protection of the donor
- Donor's interest prevail over Society and Science
- Particular protection for vulnerable subjets

- International research infrastructures that pool and share samples/data across borders
- Biological materials from persons who are not able to consent
- Developments resulting in the possible increased risk for participants

Council of Europe
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www.coe.int

Biomedical research

Research on biological materials / Biobanks

- Objective: Re-examination of Rec(2006)4
- **Symposium** organised in june 2012

Video available on www.coe.int/bioethics

Cooperation with the European Commission

⟶ Final draft to be discussed in May 2015

Preamble

Chapter I.- Object, scope and definitions

Chapter II.- General provisions

Chapter III.- Information and consent

Chapter IV.- Use in research project

Chapter V.- Governance

Human Samples

- Carriers of data that may reveal predisposition to certain diseases (risk for relatives remains after donor's death)
- Same principles applicable to personal data protection must be implemented

Identifiability of biological material and/or data

- Identifiable (coded)
- Non-identifiable (anonymised)

"Dynamic"

"Layered"

"Broad"

"Blank"

"Broad" consent
NOT
"Blank" consent

B**iological materials removed for storage for research**

- More emphasis on the content of the information to be provided at the time of consent
- Possibility to exercise choices with regard to the type of research use of their biological materials and associated data

Need to address the issue of **persons not able to consent**

- Including a provision requiring consent for continued storage and research use when the person concerned attains capacity to consent

More emphasis on:

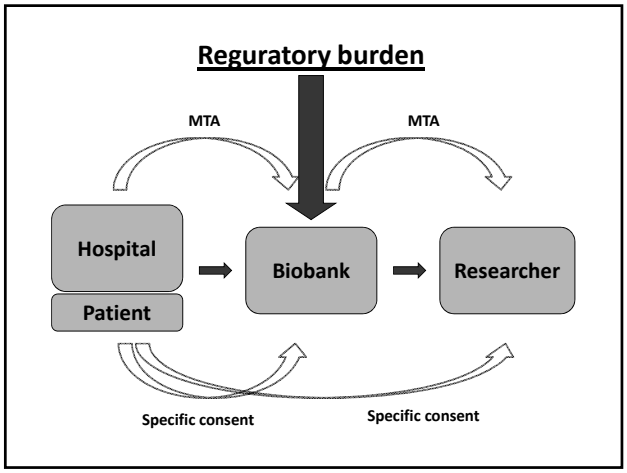
- The need to ask for new consent each time use of identifiable biological material is considered that is not within the scope of prior consent
- The exceptional character of situations in which research could be carried out without the consent of the persons concerned

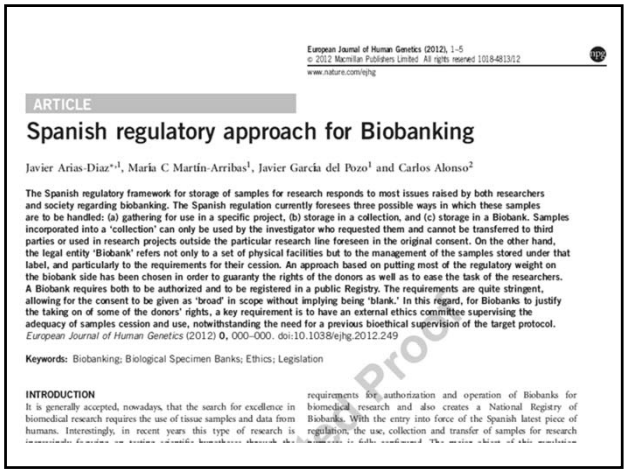
… only after independent evaluation of the fulfilment of several conditions.

The ones listed in the original Recommendation, plus:

- That sufficient efforts have been made to contact the person concerned
- That research will be carried out in accordance with the principle of proportionality

Governance of collections





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ARTICLE

Spanish regulatory approach for Biobanking

Javier Arias-Diaz*,1, María C Martín-Arribas1, Javier García del Pozo1 and Carlos Alonso2

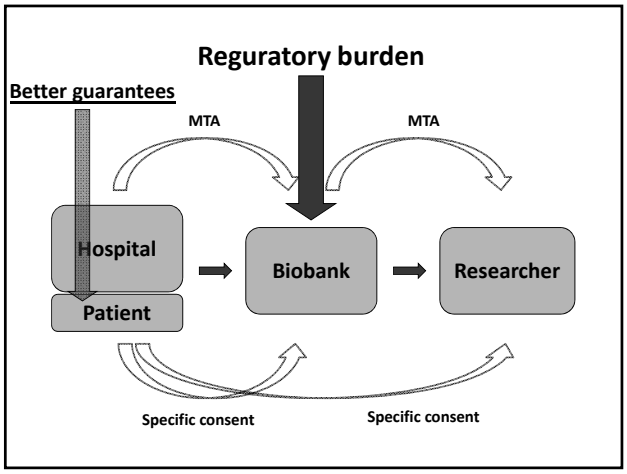
The Spanish regulatory framework for storage of samples for research responds to most issues raised by both researchers and society regarding biobanking. The Spanish regulation currently foresees three possible ways in which these samples are to be handled: (a) gathering for use in a specific project, (b) storage in a collection, and (c) storage in a Biobank. Samples incorporated into a 'collection' can only be used by the investigator who requested them and cannot be transferred to third parties or used in research projects outside the particular research line foreseen in the original consent. On the other hand, the legal entity 'Biobank' refers not only to a set of physical facilities but to the management of the samples stored under that label, and particularly to the requirements for their cession. An approach based on putting most of the regulatory weight on the biobank side has been chosen in order to guaranty the rights of the donors as well as to ease the task of the researchers. A Biobank requires both to be authorized and to be registered in a public Registry. The requirements are quite stringent, allowing for the consent to be given as 'broad' in scope without implying being 'blank.' In this regard, for Biobanks to justify the taking on of some of the donors' rights, a key requirement is to have an external ethics committee supervising the adequacy of samples cession and use, notwithstanding the need for a previous bioethical supervision of the target protocol.
European Journal of Human Genetics (2012) **0**, 000–000. doi:10.1038/ejhg.2012.249

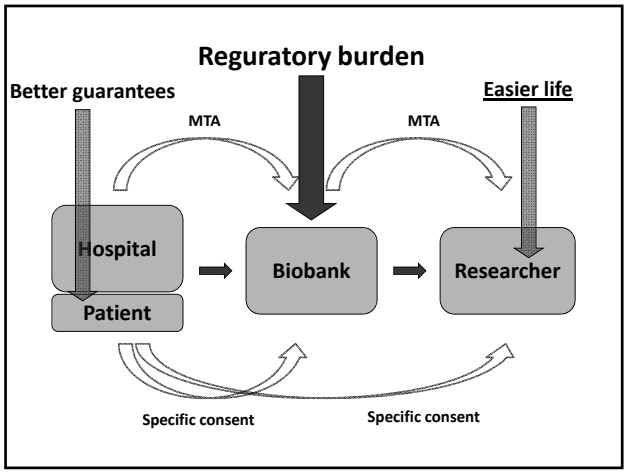
Keywords: Biobanking; Biological Specimen Banks; Ethics; Legislation

INTRODUCTION

It is generally accepted, nowadays, that the search for excellence in biomedical research requires the use of tissue samples and data from humans. Interestingly, in recent years this type of research is

requirements for authorization and operation of Biobanks for biomedical research and also creates a National Registry of Biobanks. With the entry into force of the Spanish latest piece of regulation, the use, collection and transfer of samples for research





Specific Project	Collection	Biobank
National Registry Not required	**National Registry** Required	
Ethical Assessment REC	**Ethical Assessment** REC	**Ethical Assessment** REC and Biobank ethical committee
Administrative authorization Not required	**Administrative authorization** Not required	**Administrative authorization** Required
Scope of the consent Particular project	**Scope of the consent** Particular project / research line	**Scope of the consent** Any research, with possible restrictions
Third party use No	**Third party use** No	**Third party use** Yes

General provisions

- Person/institution responsible to be designed
- Purpose to be specified
- Transparency, accountability
- Traceability, quality assurance
- Public availability of information

Individual feedback

- Clear policies
- Adequate framework
- Wishes of individuals should be observed

Transborder flows

- Only if comparable level of protection (or legally binding instrument)
- Proper MTA

Access & Oversight

- Transparent access polices
- Independent examination of its compliance
- Oversight proportionate to the risk

Oversight

Oversight mechanisms should cover, at a minimum:

i. the implementation of security measures and of procedures on access to, and use of, biological materials;
ii. the publication of reports on past and planned activities, including information about access by third parties, at least annually;
iii. the change in the risks to persons whose biological materials are stored in the collection and, where appropriate, revision of policies;
iv. appropriate information to the persons concerned of changes in the management of the collection in order to be able, where appropriate, to exercise the rights laid down in Article 16; and
v. the development and implementation of feedback policies, including regular review.

Oversight mechanisms should be able to adapt to possible evolutions of the collection and of its management.

Biobank ethics committee?

- Relevant findings/information to be returned to the donor
- Possible limits of research to be carried out in child samples
- Special cases when to seek additional consent from the donor

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Strasbourg, 2 October 2014

T-PD-BUR(2014)06

BUREAU OF THE CONSULTATIVE COMMITTEE OF THE CONVENTION FOR THE PROTECTION OF INDIVIDUALS WITH REGARD TO AUTOMATIC PROCESSING OF PERSONAL DATA (T-PD-BUR)

OPINION ON THE DRAFT RECOMMENDATION ON RESEARCH ON BIOLOGICAL MATERIALS OF HUMAN ORIGIN

…this article is ambiguous as it refers to the treatment of biological materials and the processing of data which are **two different aspects** although linked by a single set of rules.

Accordingly, they need to be differentiated. It is suggested that the wording be changed as follows:

"The collection, storage and use of biological materials of human origin may be accompanied by associated personal data. Where in this Recommendation provisions make reference to biological materials of human origin these extend, where relevant, also to associated data ***which in all cases should be adequately protected in accordance with the data protection principles****"*

The question of the **anonymisation of the data** is addressed in various sections…

…suggests that a specific part of the general provisions be devoted to this particularly important issue.

Accordingly, it is suggested that the following text be included: *"Regarding anonymised data, in light of the risks implied by the re-identification of the persons, all possible measures preventing such risks, both of a technical and organisational nature (regarding for instance the issue of access to anonymised data) have to be taken and be regularly reviewed".*

When data are made anonymous, necessary means, including technical ones, should be put in place to avoid re-identification of individuals and preserve anonymisation.

The anonymity of data should be regularly re-evaluated in time as in light of the fast pace of technological development, what could at a point in time be considered 'unreasonable' could after some time be considerably facilitated by technology and enable identification with reasonable ease.

On Transborder data flows

Acknowledging the general data protection principle that transborder flows of personal data can only occur if in the recipient state an appropriate level of protection is guaranteed…

…where an appropriate level of protection is not guaranteed by domestic law, the transfer of biological materials and/or associated data can still occur on the basis of safeguards provided in a **bilateral contract** between the sender and the recipient of the biological material and/or associated data (notion of **"enforceable instruments"**)

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