

**WMA DECLARATION ON ETHICAL CONSIDERATIONS REGARDING HEALTH  
DATABASES AND BIOBANKS**

**2015-03-18**

**A draft from the Work Group intended for open consultation after acceptance of the  
Executive Committee of the WMA**





# INSTITUT PASTEUR DE MONTEVIDEO

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Biobanks and databases had open a new field in research

Since WMA recommendations aim to promote the ethical conduct on research and to protect human subjects from it's associate risk



It's our duty to recommend an ethically correct informed consent process which takes into account the willingness and trust of those donating and sharing part of themselves, but also we must recommend high standards of protection

This is why we must reinforce in this draft some aspects that we already know as the weaker chains of this process:

- Type of consent
- The quality of the information given
- Accreditation process of Research Ethical Committees dealing with Biobanks or Databases

• Type of consent      Broad informed consent

- The quality of the information given



26. Governance arrangements must include:

26.1 The purpose of the Health Database or Biobank;

**Transparency: Real interest behind the project**

- Include a description of the purpose
- Avoiding simple referral as research or investigation
- Include financial source
- Include Institution that supports the investigation

Full information is the only way to achieve free consent

The information given should be fully evaluated by the Research Ethical Committee

- Accreditation process of Research Ethical Committees dealing with Biobanks or Databases

**Uruguay:** National Research Ethics Commission

Normatization  
Regulation  
Accreditation

Restrictive Ethical position towards research

vs

Ethical position which encourage research with appropriate protection

- Accreditation process of Research Ethical Committees dealing with Biobanks or Databases

Research Ethic Committees are highly variable around the world



Many so called  
*“Independant Ethic Committee”*  
*which are independant of an*  
*institution*  
*but are financially dependant of*  
*the promotor*

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In the draft we rely on REC as if they are all reliable worldwide

This declaration should strongly recommend:

- Accreditation process of Research Ethical Committees dealing with Biobanks or Databases





Wide range of diversity

This declaration should list  
which are the high standards of protection recommended



23 ORIENTALES



MIL GRACIAS

