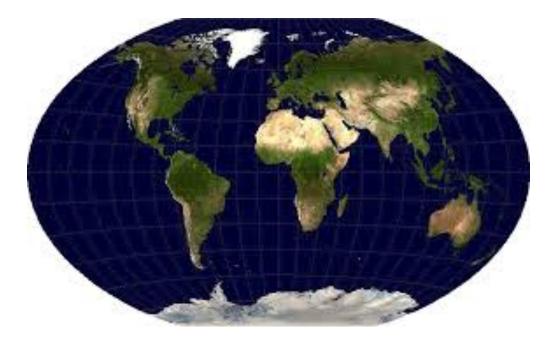
WMA DECLARATION ON ETHICAL CONSIDERATIONS REGARDING HEALTH DATABASES AND BIOBANKS

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 proyect

- 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 Acreditation

Restrictive Ethical position towards research

VS

Ethical position which encourage research with appropiate 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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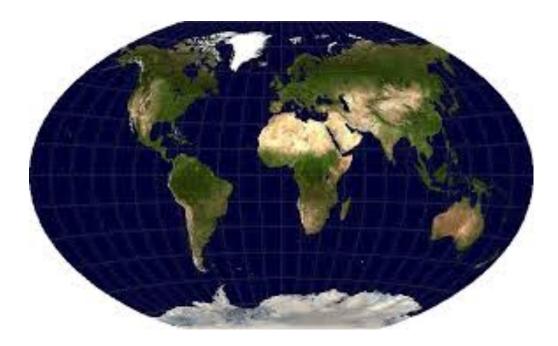
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In the draft we rely on REC as if they are all reliable worldwide

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

