

# ETHICS COMMITTEES

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# Presenter's Details

- I am a Nephrologist and Professor in Bioethics working in the Facultad de Medicina de la Universidad de la República (UDELAR)
- I represent the Uruguayan Medical Association the “Sindicato Médico del Uruguay (SMU)”

# The region I represent.

- I am representing Uruguay, a developing world country situated in South America.
- Latin America has the highest degree of inequality in the world.
- I am independent of all pharmaceutical and institutional interests.
- I have five years experience working in two ethics committees involving human research in Uruguay.



# Presentation Objective

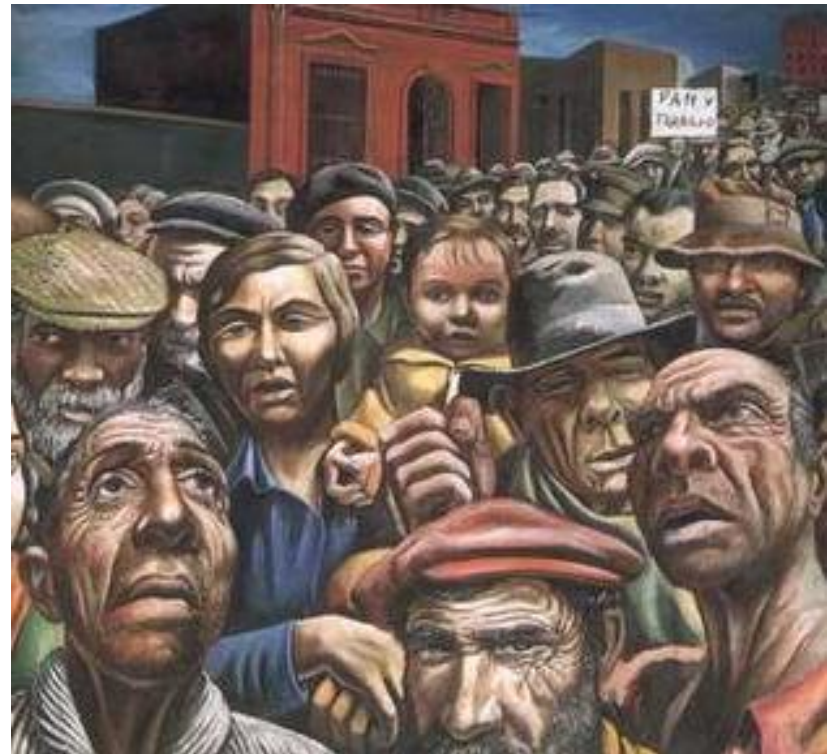


- My objective today, is to talk about the main functions that I consider an ethics committee must have.

# Functions of ethics committees

- The principle function is to protect human beings from biological, physical, emotional, mental, and social harm or damage from medical research that may infringe on their basic human rights.

Antonio Berni



# What are the most important skills and attributes required for ethics committee members?

- It is the member's **RESPONSABILITY** to be completely independent of all institutional, governmental, pharmaceutical, and vested financial interests.
- It is the member's **RESPONSABILITY** to develop the necessary skills for studying scientific issues: they must understand completely the human research that is being proposed (or they must consult with a specialist in these issues).
- They must be able to assess the social value of the research, identifying any possible harm that may occur to vulnerable research participants.

# Member skills and attributes continued...

- Committee members must check and ensure that all of the information given to the research participants is clear to read, and easy for them to understand. The information must not be deceptive, mis-leading or have a negative effect on the research participants individual autonomy.

# What are the key personal qualities needed for ethics committee members?

- They must possess a high level of honesty and personal integrity.
- They must be **STRONG** defenders of their findings and recommendations



# Procedures for assessing research protocols

- Assess how HUMAN DIGNITY is affected by the research project.
- Assess how the intrinsic value of all human beings will be affected.
- Assess possible research consequences and effects on the individual and on the society. Reviewing both the positive and negative possibilities of all aspects.

# Procedures for assessing research protocols continued...

- Assess the impact the research will have on the individuals autonomy.
- Assess if individuals have rights to legally redress any negative effects they may experience from the research.
- Only after reviewing the research project details and finding them acceptable, do you go ahead and review the Informed Consent document.

# Procedures for assessing research protocols continued...

- Assess the research information from the individual committee member's perspective.
- Assess the research information based on the Declaration of Helsinki 2002.
- (subsequent Declaration of Helsinki reviews have weakened the protections of human beings).
- Assess the research information based on the Universal Declaration on Bioethics and Human Rights (2005)
- Assess the research information based on the Universal Declaration of Human Rights signed 1948 .

## Framework and Levels of Accountability needed for implementing effective protection of Human Beings involved in medical research

- National governments must have a interest in protecting the basic social needs of their citizens.
- National political systems must become more active in protecting the welfare of their populations.
- National Health departments must be active in coordinating all national research projects and monitoring their outcomes
- National legal systems must become active in creating laws for the protection of their citizens from harmful research projects and practices.

# Framework and levels of accountability continued...

- Establishment of National Ethics Committees.
- Establishment of local institutional Ethics Committees in hospitals and medical institutions.
- Teaching of ethics committee courses in medical universities.

# In Conclusion:

- Ethics committees without a national support structure will not be able to protect humans beings and their rights in medical research projects.
- Blindly following of procedural rules or check lists is not the solution to protecting human from unethical research. More is needed!
- Signing a research project's Informed consent document without close consideration may not protect the human rights of participating individuals.