

# Importance of a Research Ethics Committee

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When is research ethical? Ethical evaluation must integrate a system whose objective contemplates the level that establishes the protection of individuals from risk and harm, in order to reach more distant goals, such as integral health, well-being and human development.

A Research Ethics Committee or Institutional Review Board (IRB) is an independent, multidisciplinary and multispectral group of health professionals, as well as professionals from other fields of knowledge, and members of the community, balanced in age and gender, whose objective is to contribute to safeguarding the dignity, rights, safety and well-being of current and potential research participants, ensuring that the benefits and drawbacks of research are equitably distributed among groups and classes of society, as well as safeguarding the scientific relevance and correctness of the research protocol under consideration (modified from the World Health Organization Operational Guidelines, 2000).

Its antecedents are recent, starting in the second half of the 20th century when the idea was introduced that ethical evaluation should be independent and external to the field of physicians and researchers. The need for evaluations of the ethical aspects involved in research to be carried out by people other than the researchers themselves was the consequence of various historical circumstances. Numerous events occurred during the late nineteenth and mid-twentieth centuries (particularly in research related to the search for vaccines for infections that killed thousands of people) that culminated in the atrocities committed by doctors in Nazi concentration camps and, as a result, the adoption of the Nuremberg Code. The contemporary history of health research ethics and IRBs dates back to the 20th century. It is marked by the crimes committed by the Nazis during World War II, whose leaders were tried in Nuremberg by the United Nations. These trials included crimes related to medical research that left countless victims and, from there, the Nuremberg Code was born. This code contemplates the basic ethical standards for medical research on human subjects and establishes that the participation of individuals in research must be voluntary and autonomous. All subjects should freely decide to participate, with prior knowledge of the risks of the study; the responsible investigators should explain to the subjects what their participation consists of and how the risks will be prevented or managed when they materialize. From the atrocities committed by the Nazis also emerges the Universal Declaration of Human Rights, adopted at the United Nations General Assembly in 1948 (Ghooi 2011; Shuster 1997; Unesco 2005a, 7-8).

The Nuremberg Code was followed in 1964 by the Declaration of Helsinki of the World Medical Association, which promulgates ethical principles for research on human subjects. The Declaration of Helsinki, in its 1975 version, includes an amendment from the 29th Assembly of Tokyo (Japan) that requires, in addition to the subjects' voluntary participation, that the research protocol be approved by an independent committee comprised of peers of the researchers and other community members who evaluate and verify that ethical aspects are included in the research to ensure the safety and protection of the volunteers, with due regard for the rights of the subjects; this refers precisely to the IRBs (World Medical Association 1964; 1975; Unesco 2006, 41).

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IRBs evaluate proposed human-participant studies to ensure that they comply with internationally and locally accepted ethical criteria, monitor the studies after they begin, and, if applicable, participate in follow-up and surveillance procedures after the research is concluded. IRBs have the authority to approve, reject or stop studies, or to require modifications to research protocols. They may also perform other functions, such as setting standards or offering opinions on current research ethics issues.

Evaluation is also essential if investigators intend to publish the findings of their research, as most medical journals will not publish the findings of research that has not been approved by an IRB.

The primary responsibility of an IRB is to protect potential research participants, but it must also take into account the potential risks and benefits to the community in which the research will be conducted. Its ultimate purpose is to promote high ethical standards in health research.

In international research, the IRB represents the interests of the local population. Therefore, it should ensure that participants and their communities receive fair benefits from the design. IRBs should evaluate what acceptable treatment and care will be offered to participants in studies with medical interventions.

The ethical and legal integrity of IRBs must be strongly protected, because corruption not only undermines citizens' trust in medicine and science, but it also fundamentally breaks the fine thread that allows vulnerable countries with low levels of development and precarious health conditions to participate in local or international health research that promotes the health and well-being of their communities while exposing them to the least amount of risk and enjoying the benefits of the results, within a universal framework of justice and equity. IRBs must ensure that these objectives are met in a way that ensures every individual is treated with equal dignity.

As final conclusions, we wondered what the role of an Ethics Committee in the Argentine Association of Orthopedics and Traumatology would be. We summarize it in the following lines: To help to understand and appreciate the bioethical policies and concepts that inspire them. To emphasize the issues that researchers should be aware of. To consider the scientific, bioethical and regulatory dimensions of research proposals. To review the scientific and ethical approaches of the protocols presented. To address the difference with Hospital Bioethics Committees. To monitor the search, methodology and participant screening. To promote bioethics training. To ensure that conflicts of interest do not arise within the group.

At this point, it is important to note that IRBs have an educational responsibility not only towards Committee members, but also towards the organizations' collaborators and the general public, in order to help them comprehend core bioethics policies and concepts.