

International Research Ethics



Yesterday

- In the Nuremberg Trials following World War II, Nazi scientists were prosecuted for conducting inhumane experiments. At the close of the Doctors' Trial, the US judges issued the Nuremberg Code—the first guidelines for the ethical conduct of medical research with humans. In 1964 the World Medical Association issued the Declaration of Helsinki to guide physicians conducting biomedical research.
- In 1979, the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued the “Belmont Report.” The principles articulated in the Belmont Report were the basis for the current US regulations for the protection of human subjects. These apply to most human subjects research funded by the federal government or regulated by the FDA anywhere in the world.
- Until recently, most ethical review of international research took place in the sponsoring developed country institutions.

Today

- In part due to shared disease burdens and efforts to conduct research in places where diseases are especially problematic, an increasing amount of health research is being conducted in low- and middle-income countries (LMICs).
- Global health, including research for global health, not only safeguards the health of US citizens, but builds good will in other countries. Building this good will requires that the research is conducted fairly and regarded as ethical by host countries and populations.
- The ability of LMIC institutions to conduct their own ethical review of research activities has grown stronger. Many LMICs have established national regulations governing research with human subjects. These usually require local ethical review of research, which helps to ensure that the research is conducted in a way that protects and respects the rights of local populations.

- The NIH provides grants to institutions to develop graduate curricula and training opportunities in ethics related to performing biomedical research in LMICs. Through these grants, NIH supports the advanced training of LMIC personnel who will assume responsibility for ethical review or clinical trial design in their home institutions. NIH programs have supported the training of over 450 trainees in this area, and thousands of ethics committee members, government officials, and scientists have attended NIH-funded workshops.

Tomorrow

- The scientific community and the public continue to be concerned about the social and ethical dimensions of medical research. Ethical challenges include:
 - Ensuring that research is relevant to local populations.
 - The obligations of research sponsors regarding the care provided to research participants and the local community after the research is completed.
 - Obtaining voluntary informed consent while remaining sensitive to cultural differences.
- The NIH will continue to strengthen expertise to help ensure the ethical conduct of international biomedical research. For example:
 - An NIH-funded program in South Africa is becoming a hub for ethics training and innovative research, attracting grants from other international funding bodies and the South African government.
 - NIH bioethics training programs continue to pioneer innovative web-based and distance learning strategies to connect researchers and ethicists across time zones and countries.
 - Researchers at the NIH are studying the effectiveness of different techniques to help research participants to have a better understanding of the research and make better and more well-informed decisions.

- Increased in-country expertise focused on research ethics will help to ensure that the growing numbers of international research projects supported by the NIH are conducted ethically and responsibly.

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