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## *Fact Sheet*

## *International Research Governance*

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### History

- In the past, ethical review of international research took place primarily in the sponsoring developed country institutions. There was little local review or involvement to ensure the ethical conduct of research on overseas populations. Following WWII, the Declaration of Helsinki was the first international guidance on the conduct of biomedical research involving human subjects.
- In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued the “Belmont report,” which set forth ethical principles and guidelines for the protection of human subjects of research. The principles articulated in the Belmont Report led to significant revision and expansion of U.S. human subject protection regulations.

### Today

- The global bioethics situation has improved considerably in recent years. Many developing countries established national guidelines for the ethical conduct of research. In such countries, professionals are training in research ethics, which is facilitating conduct of research that protects and respects the rights of local research populations. Numerous national or “representative” ethical review committees are now established globally.
- The NIH now supports the advanced training of developing country officials who will assume the responsibility of ethical review or clinical trial design in research and clinical investigations in their home institutions. The NIH provides grants that enable institutions to develop or expand graduate curricula and training opportunities in ethics related to performing biomedical research in developing countries.

- Diverse curricula were created related to research ethics in developing countries. NIH programs supported close to 200 long-term trainees from approximately 40 countries. Another 1500 individuals attended NIH funded workshops. Often, NIH programs are the only opportunity for training in bioethics or research ethics. For example, NIH trained every research ethicist working in India.

### The Future

- The NIH will continue to build on its success and strengthen expertise to help ensure the ethical conduct of international biomedical research. Future plans include efforts to Work in partnership with developing countries to resolve complex ethical issues in international research.
- The scientific community and the public are increasingly concerned with the social and ethical dimensions of research. Challenging ethical dilemmas include:
  - The need for research being relevant to local populations.
  - The standard of care provided to participants in the control group of a clinical trial.
  - The obligation of research sponsors regarding the care provided to research participants and the wider community after the research is completed.
  - The need to obtain voluntary informed consent while remaining sensitive to cultural differences.

- To effectively address these issues, NIH and other research funding agencies will need to draw upon the experience and perspective of developing country professionals with expertise in research ethics. NIH will therefore continue to support the training of developing country professionals who can provide such expertise to research partners, local institutions, national governments and international bodies.
- Increased in-country capacity focused on research ethics will help to ensure that the growing number of international research projects supported across the various NIH Institutes and Centers are conducted ethically and responsibly.