

EDITORIAL

INTERNATIONAL RESEARCH ETHICS EDUCATION

In 1999, the Fogarty International Center hosted the first Global Forum on Bioethics in Research and followed it in 2000 with the launch of the International Research Ethics Education and Curriculum Development program. Several other NIH institutes, who appreciated the value of this endeavor to their own programs, joined this initiative. The program recognized that no research on human subjects could be conducted without an effective local system in place to ensure the protection of human subjects. This would require trained people able to evaluate research funded from abroad and ensure that it addressed problems in their home country in an ethical and culturally sensitive way. Over the past decade, this program has grown to address the urgent need to train a cohort of bioethicists in low- and middle-income settings where research is conducted and encourage them to build academic programs and national structures for biomedical review and research ethics. The papers in this collection are written by the Principal Investigators of the research ethics training grants in collaboration with other experts in international research ethics.

This collection on international research ethics education comes at a critical time for the global health community. The past decade has witnessed a major increase in funding for biomedical research globally and a clear shift toward the conduct of more clinical trials in low- and middle-income countries. This shift recognizes that biomedical research anywhere can help people everywhere and that many health problems of global concern can best be addressed by conducting studies in countries where these problems are most prevalent. For example, much of our understanding of the treatment and prevention of HIV/AIDS has come from research in countries where this problem is most devastating, especially in Sub-Saharan Africa. The testing of new drugs and regimens, and the development of strategies to prevent transmission of the disease—PMTCT, circumcision, counseling of discordant couples, and treatment as prevention—have all benefited from extensive research conducted in areas where the disease has the greatest prevalence and the most devastating impact. Major funding for these studies has come from international donors, which raises additional concerns about who controls the research agenda, who benefits from the research, and whether the pressure to achieve expeditious results might trump concerns for the safety and well-being of the populations being studied. Researchers also face unique challenges in low-resource settings, for example, creating a meaningful informed consent process among low-literacy populations and providing ancillary care to study participants who lack access to adequate health care. NIH-supported research, no matter where it takes place, must adhere to the same high ethical standards. Our ability to address many critical health concerns can only advance by globalizing our research agenda and extending our ability to assess and understand the underlying ethical issues. International training and research in research ethics is essential.

The papers in this issue, and a subsequent special issue of *JERHRE*, review the state of research ethics capacity in low- and middle-income regions around the world, analyze lessons learned about ethics education, and outline priorities for the future. The timing could not be better: 2014 will mark the fiftieth anniversary of the publication by the World Medical Association of the Declaration of Helsinki, the document that first outlined many of the central principles for the ethical conduct of biomedical research.

While many other research sponsors have recognized and joined the global effort to support training and research in research ethics in LMICs, funding and support has not kept pace with the growth of global health research. Consequently, these efforts at training and research in research ethics remain a critical need but an orphan child.

Given the central importance of research ethics to the pursuit of global health research, one can only imagine what might happen if this endeavor did not grow and flourish. Unfortunately, research ethics is a field that has grown historically by perceived disasters, case studies of purported abuse, insensitivity, and misunderstanding, from the recently discovered STD studies in Guatemala, to the Tuskegee syphilis studies, to the controversial protocol for use of Nevarapine for the prevention of the vertical transmission of HIV in low-resource settings. Each controversy risks damaging the ability to advance meaningful and ethical research and undermines the trust of communities and their willingness to participate. At the same time, such cases have helped to stimulate improved standards that advanced research practice and improved our appreciation of the ethical principles that should govern global health research.

While this collection highlights some of the key features and findings of the Fogarty program, it also provides clear directions to advance research ethics education for the future. Unquestionably, as clinical research and trials increase in LMICs, the need for skilled local experts to independently assess and address thorny ethical issues will remain key. Fogarty, along with its many partners at NIH, is committed to being part of this continuing and essential process.

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