

AMA Code of Medical Ethics

7.3.3 International Research

Biomedical and health research in international settings often raises special ethical questions, particularly when research is carried out in resource-poor settings by sponsors or researchers from resource-rich countries. Physicians engaged in international research may encounter differing cultural traditions, economic conditions, health care systems, and ethical or regulatory standards and traditions than in the US.

While fundamental requirements to ensure scientifically sound research and to protect the welfare, safety, and comfort of human participants apply in any research setting, physicians who are involved in international research may need to address special concerns about selection of research topic and study design, informed consent, and the impact of the research on the participating community.

In addition to following general ethical guidelines for biomedical and health research, physicians who are involved in international research have obligations to:

Study design

- (a) Ensure that the research responds to a medical need in the region in which it is undertaken.
- (b) Ensure that the research does not exploit the populations and communities from which participants will be drawn.
- (c) Be sensitive to special considerations in assessing the risks and benefits of the research in the particular setting and employ a research design that minimizes risks to the participant population by:
 - (i) ascertaining that there is genuine uncertainty within the clinical community about the comparative merits of the experimental intervention and the intervention that will be offered as a control for the population to be enrolled;
 - (ii) obtaining relevant input from representatives of the host community and from the research population;
 - (iii) considering the harm that is likely to result for the host community or research population if the research is not carried out.
- (d) In some instances, a three-pronged protocol that offers the standard of care in the US, an intervention that meets a level of care that can be attained in and sustained by the host community, and a placebo may offer the most ethically desirable means for evaluating the safety and efficacy of an intervention in a given population.

Informed consent

- (e) Ensure that a suitable process for informed consent is in place. If consent is to be meaningful, physicians (or other health professionals) who obtain consent must communicate with sensitivity to local customs. Notwithstanding, they should always ensure that individual participants are informed and that their voluntary consent is sought.

Impact on the host community

- (f) Foster research with the potential for lasting benefits to the host community, especially when the research is carried out among populations that are severely deficient in health care resources. This can be achieved by:
 - (i) facilitating development of a health care infrastructure that will be of use during and after the research period itself;
 - (ii) encouraging sponsors to provide interventions that have been demonstrated to be beneficial to all study participants after the study concludes.

AMA Principles of Medical Ethics: I,IV,VII,VIII,IX