International Research and Cross Cultural Issues

Research involving human subjects conducted outside the United States or in other cross cultural communities creates additional areas of concern for both the Principal Investigator and the Institutional Review Board (IRB). Cultural, economic, or political conditions of the host country or other communities may alter the risk for participants

Ethical Standards

Children's Hospital is committed to upholding the standards for ethical research and informed consent articulated in the Belmont Report for all research that involves CHB investigators, regardless of whether this research is conducted within or outside the United States. Research conducted outside the United States by CHB investigators must conform to the same or equivalent ethical standards as described in the Belmont Report. Research conducted outside the United States by CHB investigators must also comply with the relevant laws of the host country. Researchers will need to collaborate whenever possible with a research or educational institution familiar with the local culture and research-related issues. It will be incumbent upon all researchers to ensure that the cultural considerations of the host country/community are respected and that the participants will not be subjected to retaliation from local authorities or the local community.

Local IRB review

Review by a local IRB or Ethics Board must be sought whenever possible even for research not supported by federal funding. The Local IRB or Ethics Board must be knowledgeable about and sensitive to, local community composition, mores and standards of conduct. A list of registered international IRB's may be found on the OHRP web site at: http://ohrp.osophs.dhhs.gov.
Where there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. In most circumstances the IRB requires documentation of this "local approval" before it gives approval.

An international institution or site considered engaged in research must obtain IRB approval from an institution that holds a Federalwide Assurance in the country where the research is taking place if the research is supported by federal funding. Copies of the local IRB approval should be submitted to the Children's Hospital IRB with other pertinent research documentation.

When determined appropriate Children's Hospital may rely on another local IRB or Ethics Committee. This decision will be made on a case by case basis taking

into consideration the activities conducted by the investigator and research team members, the subject population and IRB expertise

Informed consent

The requirements for obtaining and documenting informed consent vary among cultures. In some cultures an investigator may enter a community to conduct research or approach prospective subjects for their individual consent only after obtaining permission from a community leader, a council of elders, or another designated authority. Such customs must be respected; however, the permission of a community leader or other authority substitute for individual informed consent may not be permissible. Some cultures are unfamiliar with, or do not readily understand, scientific concepts such as those of placebo, randomization or even the concept of asking for informed consent Investigators should develop culturally appropriate ways to communicate information that is necessary for adherence to the ethical standard and those standards required in the informed consent process. Investigators should describe and justify in the research protocol the procedure they plan to use in communicating information to subjects. Special attention should be given to local customs and to local cultural and religious norms in the entire informed consent process including drafting written consent documents or proposing alternative consent formats.

In some instances it may be appropriate for the IRB to waive some or all requirements for written consent. Research proposals for which this may be reasonable should include explanations of cultural norms or conditions requiring such as waiver. (eg. societies where no written language is used, societies where signatures represent the surrender of spirit or soul to the researcher). The informed consent discussion, as well as all consent documents, must be in the subjects' native language.

IRB Responsibilities at Children's Hospital

In order to facilitate the review of protocols that involve human subjects in international/other cultural settings, the following will be considered when the protocol is submitted for IRB review:

- qualifications of the researcher and on site collaborators in relevant coursework, past experience, or training to justify his/her international/cross cultural research capabilities
- cultural sensitivities and the context of cultural norms or local laws and differences with U.S. culture with respect to research autonomy of individuals, or groups, consent procedures, recruitment techniques, age of majority, if parental consent is required, etc
- research that involves a population or community with limited resources should be responsive to the health needs and the priorities of the population or community; and as applicable any intervention or product developed, or knowledge generated, should be made available for the benefit of that population or community

- the primary language(s) spoken in the community and the researcher's ability to speak, read, or write the language of the potential participants including provisions for culturally appropriate recruitment and consent accommodations such as translations or involvement of native language speakers
- the local or state or national laws that may have an impact on this research and cultural or community attitudes
- how the researcher will have culturally appropriate access to the community.
- information about the ethics committee (IRB equivalent) or other regulatory entity with oversight responsibility for the research in the host country that will review the protocol/project
- aspects of the cultural, political or economic climate in the country where the research will be conducted which might increase the risks for participants and steps taken to minimize these risks.

All policies and procedures that are applied to research conducted domestically should be applied to research conducted in other countries, as appropriate. This includes oversight of the following activities: Initial review, continuing review, and review of modifications. post-approval monitoring, handling of complaints, non-compliance and unanticipated problems involving risk to subjects or others.

Community Based Participatory Research

Community –based participatory research is a collaborative approach to research that combines methods of inquiry with community capacity –building strategies to bridge the gap between knowledge produced through research and what is practices in communities to improve their health and well being. This type of approach is important to consider when conducting international research as well as research within the United States that involved different communities. As appropriate investigators should consider the following principles and integrate them into their protocol development. The Committee on Clinical Investigation may also ask that these principles be considered

- identify the additional considerations that the IRB must consider when reviewing community based participatory research. Some examples are as follows:

- A requirement that members of the community involved in recruitment or screening procedures receive adequate training to perform research-related functions.

- Whether community members will be both in the role of "investigator" and "subject" and if so, how risks will be minimized when in the subject role.

- The research should facilitate collaborative, equitable partnerships with the community at all stages. This includes, planning and implementing the research and disseminating research results

- The risks and benefits to individuals and the community must be considered. The community needs to be recognized as a unit of identity

- Investigators need to consider the methods used to be sure they are sensitive and appropriate to the various communities(literacy, language barriers, cultural sensitivities)

- Community members should be involved with the identifying the issues of concern and need for the research. In addition they need to be involved in designing, planning and implementing the research . This permits building on the community strength and resources and promotes co-learning and capacity building among all partners. This also helps emphasize the local relevance of the issues to be studied.

- The researchers and community need to consider long term commitments to the community form which the subjects are drawn.

- When possible the research should include capacity building opportunities

When reviewing a specific protocol that utilizes community based participatory methods the IRB will consider special issues such as

- The requirement that members of the community involved in recruitment or screening procedures are appropriately qualified and receive adequate training to perform research-related functions.

- Whether community members will be both in the role of "investigator" and "subject" and if so, how to minimize the risk when in the subject role

- The need to maintain trust with the community if one of its members partcipoates in conducting the research

Other Educational Resources for International and Cross Cultural Research

International Ethical Guidelines for Biomedical Research Involving Human Subjects
Oct. 2002
by the Council for International Organizations of Medical Sciences

OHRP International Issue Links

NIH Educational Resources on International Research Ethics

Policy Issues in International Research: Clinical Trials in Developing Countries
April 2001
Report and Recommendations of the National Bioethics Advisory Commission (NBAC)

Family Health International
Training Curricula for Research Ethics

Indiana University
Center for Bioethics
International Research Ethics Subject Guide

United Nations Educational, Scientific and Cultural Organization (UNESCO) - International Bioethics Committee

Related Content

Document Attributes

Title	**Committee on Clinical Investigation: Autonomy and Functions**		
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