# International and Cross-cultural Research

## Purpose

This policy describes the principles that Boston Children Hospital (BCH) investigators should observe in research conducted outside of the United States.

This includes the following principles and procedures:

1. Ethical Standards
2. Local IRB or Ethics Board/Committee Review
3. Local Experts or Community Leaders Approval
4. Informed Consent Considerations

## Policy

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 (PI) and the Institutional Review Board (IRB). Cultural, economic, and/or political conditions of the host country may alter the risk for participants.

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

Research conducted outside the United States by BCH investigators must:

1. Conform to the same or equivalent standards as described in the Belmont Report and federal regulations.
2. Comply with the relevant laws of the host country.
3. Obtain review by a local IRB or Ethics Board/Committee.
    a. Regardless of funding review applies to both, federal and not federally funded research.
    b. Local IRB or Ethics Board must be knowledgeable about and sensitive to local community composition, mores, and standards of conduct.
    c. If there is not a local IRB or ethics board, then the IRB may require permission from local experts or community leaders.

The BCH IRB will consult with appropriate experts as needed to assist then in these reviews.

## Procedure

### Ethical Standards

Boston Children's Hospital (BCH) is committed to upholding the standards for ethical research and informed consent articulated in the Belmont Report for all research that involves BCH

investigators, regardless of whether this research is conducted within or outside the United States.

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 or Ethics Board Review

BCH requires Local IRB or Ethics Board review for all international research, regardless of funding.

Copies of the local IRB approval should be submitted to the BCH IRB with other pertinent research documentation.

If the research is federally funded, then an international institution or site considered "engaged" in the research can obtain IRB approval from an institution that holds a Federalwide Assurance. To confirm that an institution holds a Federalwide Assurance (FWA) and a registered IRB go to the ***Office of Human Research Protection's website***.

If the IRB determines that the Local IRB or Ethics Board has greater expertise in an international or other cultural setting, then BCH may rely on that Local IRB or Ethics Board. 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. In most cases the BCH IRB will review the protocol but may request local, legal and cultural context from the local IRB/Ethics Board.

## Local Experts or Community Leaders Approval

If there is no equivalent board or group, investigators must rely on local experts or community leaders to provide "local approval." In most circumstances the IRB requires documentation of this "local approval" before it provides IRB approval.

## Informed Consent Considerations

The requirements for obtaining and documenting informed consent vary among cultures and international settings. Some cultures are unfamiliar with or do not readily understand scientific concepts such as placebo, randomization, or the concept of research informed consent in a medical situation.

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 may not substitute for individual informed consent.

Investigators should:

- Develop culturally appropriate ways to communicate information that is necessary for adherence to the ethical standard and those standards required by the informed consent process.
- Describe any customs, cultural, and religious context and how it impacts the informed consent process.
- Provide alternative consent formats, when applicable.

**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. (e.g. Societies where no written language is used, societies where signatures represent the surrender of spirit or soul to the researcher, etc.).

The informed consent process must be in the subjects' native language.

## Related Content

Federal and Educational Resources

*Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) – 2016:* ***International Ethical Guidelines for Health-related Research Involving Human Subjects***

*OHRP:* **International Guidance**

*NIH*: ***E-learning Resources for Global Health Researchers***

*National Bioethics Advisory Commission (NBAC):* ***Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries Volume I - 2001***

## Document Attributes

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