

Protecting people who participate in research

CITI Training Study Guide International Research*

* Note, this study guide combines the International Studies and the International Research – SBR modules in the CITI human subjects training program.

Variations in Research Ethics Across Countries

- The interpretation of “respect for persons,” “beneficence” and “justice” may differ from country to country.
 - For example, in some cultures, an individual cannot make a decision about medical care without the full engagement of relatives, friends, and/or those in authority in the community.
 - International debate about research ethics has resulted in several different attempts to codify international guidelines.
- In most cases, IRB review should take place in both the U.S. and in the host country.

Importance of Local Research Context

- **Researchers must have sufficient knowledge of the local research context to be able to design and carry out research in a way that protects subjects' rights and welfare.**
- The local research context includes socioeconomic, political, and cultural factors and influences every aspect of the research design.
 - For example, an effective child assent process requires understanding how relationships between parents and their children are defined, and when a person reaches the age of majority and is no longer considered a "child."

When does initial interaction within a social/cultural context become research?

Preliminary work may include:

- Informing prospective subjects about the existence of a research project;
- Providing potential subjects with written information about a specific study;
- Obtaining subjects' permission for researchers to contact them.

When interaction becomes research:

- Researcher obtains informed consent;
- Researcher begins to systematically record answers to questions (conduct interviews)