

Protecting people who participate in research

CITI Training Study Guide
Cultural Competence in Research

What is Cultural Competence?

- Recognizing the importance for research ideas, design and findings of participants' diverse social and cultural values, beliefs and behaviors.
- For health care professionals, providing high quality care by communicating effectively and tailoring care in a way that meets patients' social, cultural and linguistic needs and perspectives.

How is Cultural Competence Important in Human Subjects Protection?

- The three principles outlined in the Belmont Report [Respect for Persons, Beneficence and Justice], require culturally competent interactions with study participants.
- The federal guidelines provide a framework for resolving ethical problems arising from research that involves human subjects.

Policy Requirements

In 1994, the National Institutes of Health (NIH) began to require inclusion of women, children, and members of minority groups and their sub-populations in biomedical and behavioral clinical studies, to ensure that results are relevant in light of racial/ethnic (as well as gender and age) differences.

- Further, investigators must develop outreach efforts to recruit these groups into clinical trials.

Trust, Transparency & Impartiality

Researchers must:

- Build trust and understanding with the cultural groups or populations they are recruiting to participate in research.
- Develop skills for communicating effectively and learning about relevant customs, values and beliefs.
- Have a working knowledge of the important customs, values, beliefs, and communication styles, without stereotyping.

Trust, Transparency & Impartiality

- **Researchers generate trust with study subjects when they involve community members in decisions about key aspects of the research, promote feelings of ownership within the community, maintain public accountability and transparency, and assure appropriate ethics oversight.**
- **Researchers need to understand historical contexts for study populations before initiating research.**

What is the IRB's Responsibility?

- **Ask questions to evaluate the efforts the researcher has made to work with and understand the community.**
- **Encourage researchers to seek guidance from community representatives when developing research protocols or interpreting findings.**
- **Encourage researchers to add community members to the research team.**