

Policies and Procedures

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| CHAPTER: Institutional Review Board | ISSUED: 7/2010 | REVISED/REVIEWED: 3/2011; 11/2013 |
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1. PURPOSE

This policy defines the standards and parameters for the conduct of biomedical, behavioral, and social science research done by Creighton University researchers outside of the United States.

2. POLICY

- 2.1. Creighton University is committed to upholding the standards for ethical research and informed consent expectations articulated in the Belmont Report for all research conducted outside the United States. Research conducted outside the United States shall conform to the same ethical and regulatory standards to which domestic research is held and shall be conducted in accordance with U.S. Federal regulations for the protection of human research subjects (45 CFR 46) regardless of the funding source.
- 2.2. Research conducted outside the United States shall comply with the relevant laws of the host country. Researchers shall 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 norms of the host country are respected and that the participants will not be subjected to retaliation from local authorities or the local community. No research involving humans shall be initiated prior to obtaining appropriate IRB approval.
- 2.3. An IRB shall review and approve all international research involving human subjects. An international institution or site considered engaged in research shall obtain IRB approval from an institution that holds a Federal-wide Assurance in the country in which the research is taking place (if the research is supported by federal funding). Review by a local IRB or ethics board shall be sought whenever possible, even for research not supported by federal funding. The IRB or ethics board must be knowledgeable about and sensitive to local community composition, mores, and standards of conduct. See IRB Policy 115, "[External Studies](#)." IRB oversight for transnational research includes the following:
 - 2.3.1. Initial review, continuing review, review of modifications to previously approved research
 - 2.3.2. Post-approval monitoring

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- 2.3.3. Handling of complaints, noncompliance, and unanticipated problems involving risk to participants or others
- 2.4. In the event that no such local IRB or ethics board exists in the immediate locale in which the research is to take place, steps shall be taken either to identify such a review board within the general region or to identify a local institution that could serve in a comparable capacity (i.e., a tribal council, school board, town committee, hospital board, etc.). The Creighton University IRB shall also review these projects. The investigator shall include in the protocol specific information about the culture of the country in which the project will be conducted and the permission from the site where the research is to be conducted. The IRB may consult with outside personnel who have experience with the culture in the country in which the study is to be conducted.
- 2.5. The informed consent discussion, as well as all consent documents, shall be in the subjects' native language. A translator/interpreter may be employed to help with the consent process. Family members shall not be asked to provide such translation because they may not be able to fully explain the study's risks and benefits to the potential subjects. If subjects are likely to be unable to provide written consent, the researchers shall provide justification in the protocol submitted to the IRB for a waiver of written consent, as well as an acceptable alternative method of obtaining oral consent that is appropriate to both the subjects and their culture.