Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 129	
CHAPTER: Institutional Review Board	ISSUED: 7/2010	LATEST REVIEW/REVISION 4/2019
POLICY: International Research	PAGE 1 OF 3	

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.

1. POLICY

1.1. 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.

1.2. 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 the cultural norms of the host country are respected and the subjects 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.

1.3. 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, “External Studies.” IRB oversight for transnational research includes the following:

1.3.1. Initial review, continuing review, review of modifications to previously approved research

1.3.2. Post-approval monitoring

1.3.3. Handling of complaints, noncompliance, and unanticipated problems involving risk to subjects or others

1.4. The Role of the Principal Investigator (PI)

The IRB requires that all PIs involved in the conduct of international research adhere to ethical principles as outlined by federal regulations (See 45 Code of Federal Regulations 46). When conducting international research, the PI must:

1.4.1. Provide equivalent protections to human subjects in foreign countries. The protections need not be the same as provided in the U.S. but should be equal in function or effect (See Belmont Report).

1.4.2. Comply with any applicable regulations of the country in which the research will take place. (Refer to The International Compilation of Human Research Standards).

1.4.3. Have sufficient knowledge of the local context (laws, regulations, culture and political and socio-economic factors) to enable the design and conduct of the research in ways that protect the rights and welfare of subjects. The IRB recommends that a local collaborator be included on the research team to ensure that the design and conduct of the research conforms to local regulations/customs.

1.4.4. Be aware of and adhere to any additional international guidelines that may be applicable when conducting biomedical research, (e.g. Declaration of Helsinki, International Conference on Harmonization - Good Clinical Practice E6). It should be noted that the Health Insurance Portability and Accountability Act (HIPAA) regulations do not apply to countries outside the US. However, once identifiable health information is transferred to a HIPAA-covered entity all U.S. HIPAA regulations apply.

1.4.5. Arrange for the training of all members of the research team, including those involved in data collection at the local site.

1.4.6. Be aware of any special sponsor-specific requirements for funded projects involving international research.

1.4.7. Be familiar with export control regulations. Training in export control may

be required. See Export Control Regulations and Resources for information on export control and training requirements.

1.4.8. Be aware of travel warnings and restrictions before arranging travel to international countries. The U.S. Department of State informs the public of conditions in other countries that may threaten the safety and security of US citizens. Refer to U.S. Passports & International Travel for travel alerts, travel warnings and country specific information.

1.5. 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.

1.6. The informed consent discussion, as well as all consent documents, shall be in the language the subject can understand. 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 appropriate to both the subjects and their culture.