INTERNATIONAL RESEARCH

Description

Investigators conducting international research must be qualified by training and experience to conduct such research. Investigators must design scientifically sound and culturally appropriate research that is relevant to the needs and conditions of the population of study.

Research Regulations

The regulations applicable to human subject research differ based upon the country in which the research is conducted. The University of Utah IRB reviews international research to ensure adherence to local laws and that the conduct of research is according to ethical standards equivalent to those in the United States and expected by international codes of ethics and conduct, including Good Clinical Practices and the Declaration of Helsinki. If the research is sponsored by a U.S. federal agency, the regulations of that agency are applied.

For research that is conducted outside of the United States, the University of Utah IRB and the Office of General Counsel work with the investigators and local authorities to determine the laws applicable to the research. The IRB may also consult with the Office of Human Research Protections International Activities program (http://www.hhs.gov/ohrp/international/index.html). Investigators are expected to provide the University of Utah IRB with relevant information regarding local laws, customs, cultural norms, research conditions, and so on, such that the IRB can make appropriate determinations regarding the research. The investigator must act as a liaison between the University of Utah IRB and local authorities.

Investigators may be expected to secure approval from the local equivalent of an IRB or ethics committee (EC) that is responsible for the oversight of human subject research within the country or at a specific site within the country. Where there is no equivalent committee or group, it may be appropriate to rely on local authorities or community leaders to provide approval or permission for the research to be conducted. In cases where formal IRB/EC approval is necessary, the University of Utah IRB may choose to make determinations based upon the expert review of the local IRB/EC or may choose to defer review to the local IRB/EC in part or in full.

Additional Considerations

The University of Utah IRB follows the same policies and procedures when reviewing research conducted in the United States and research conducted internationally. However, there may be additional considerations in order to appropriately address the unique situations and populations relevant to specific international projects. The following items should be considered when designing and conducting international research projects.

Informed consent

- Does the consent document need to be translated into a language other than English?

- Do the consent discussion and participant interactions require the use of an interpreter?
- Are participants able to read and write?
- Is it culturally appropriate for participants to provide consent without consultation with family or other members of the community?
- Is it culturally appropriate to obtain a signature from the participants?
- What is the age of majority for giving legal consent versus needing parental permission?

Conducting study procedures

- Are interventions, questionnaires, surveys, and data collection tools culturally appropriate and valid for the population?
- What is the culturally appropriate method of providing compensation to participants?

Post-approval monitoring

- What is the most effective method for communicating with local collaborators and authorities over long distance?
- How will participant complaints, non-compliance, and other unanticipated problems be handled within the cultural context?
- Are local collaborators appropriately trained to identify and report participant complaints, non-compliance, and other unanticipated problems to the investigator?
- How will data be monitored over long distance for compliance, completeness, and validity?
- How will confidentiality of data be maintained over long distance?

VA Research: For VA research, additional requirements must be met for international research. International research includes VA-approved research conducted at international sites not within the United Sates, its territories, or Commonwealths; and includes research where human tissues are sent outside of the United States. The IRB will apply the requirements as outlined in the VHA Directive 1200.05(2) regarding International Research.

- All international research must also be approved by the VA medical facility director. Cooperative Studies Program activities must be approved by the Chief Research and Development Officer (CRADO).
- Before approving international research involving human subjects research, the IRB must ensure that human subjects outside of the U.S. who participate in research in which the VA is a collaborator receive equivalent protections as research participants in the United States. This includes research subject to limited IRB review.

Points to Address

New Study Application: 1. **Contacts and Title~~Study Introduction~~ page (1), question 8**: In the Background and Introduction, ~~D~~describe the cultural context, including laws, customs, cultural norms, etc., that may have an

	influence on the conduct of the research. In appropriate other sections of the application, describe this in context of a. Age of majority (Participants page, questions 1-3, 5) b. Recruitment methods (Study Information page, question 4) c. Consent process (Consent Process page, questions 2-5) 2. **Consent Process page, question 7:** Indicate how informed consent will be obtained if a language other than English will be used. 3. **Data Monitoring ~~Plan~~ page (5):** Address all post-approval monitoring methods that will be used. 4. **Resources and Responsibilities page (8), questions 1 and 2:** Describe the qualifications and training of the research team that justify their qualifications and training of the research team that demonstrate their knowledge of local laws and customs, as well as their ability to conduct international research with the population and in the country/sites described in the application. 5. **Resources and Responsibilities page (8), question 3:** Describe the U.S. and international facilities that will be used. You must ensure that you have appropriate permission to perform research procedures at this location. When possible, you should obtain written documentation of this permission; however, you may choose to document that you received verbal permission. Research procedures should not begin at the location until appropriate permissions are obtained. In this question on the application, please state these requirements and confirm that you will follow them.
Consent Document:	1. If appropriate, provide contact information for a local investigator or representative (in addition to contact information for the U.S. investigators), for participant questions, concerns, and complaints. 2. If appropriate, provide contact information for the local IRB/EC. It may also be appropriate to remove the contact information for the University of Utah IRB.
Documents and Attachments:	1. Attach all translated materials, including the English-versions. Also attach a Certificate of Translation that documents appropriate translation for all materials. 2. For VA research, attach a written approval from the facility director, or Chief Research and Development Officer (CRADO), as required.

References & Links

VHA Directive 1200.05, Section: International Research	*https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=8171*

IRB Forms: Short form and Certificate of Translation templates	*http://irb.utah.edu/forms/*
~~*Investigator Guidance Series: Investigator Responsibilities for Drug Studies*~~	~~*http://irb.utah.edu/guidelines/investigator.php*~~
~~*National Bioethics Advisory Commission. Ethical and policy issues in international research: Clinical trials in developing countries.*~~	~~*https://bioethicsarchive.georgetown.edu/nbac/clinical/execsum.html*~~