1. POLICY

A. Research conducted by University investigators in foreign countries must provide the same or equivalent protections to the rights and welfare of participants as research conducted in the United States (U.S.). Protections should encompass the ethical principles of respect for person, beneficence, and justice. The foreign participant protections need not be identical to those provided in the U.S. but must be equal in function or effect. Participant autonomy and dignity should be respected.

B. Both the U.S. and host country standards for protecting human participants must be respected within the research design and considered during the IRB approval process and during the conduct of the research. Where the two sets of standards present a conflict, the research must meet the higher standard.

C. The level of knowledge about the local context and laws required for research project approval is based on the degree of risk to potential research participants. Researchers must pay special attention to maintaining sensitivity to local cultural, political and socio-economic factors, religious norms, and applicable laws. Research methods that have minimal risk in the U.S. might have greater than minimal risk when conducted at international sites. For example: Questions considered innocuous in the U.S. could be offensive or more sensitive at the international location; assuring and maintaining confidentiality may be difficult in other countries; and a breach of confidentiality in the research locale could have potentially dangerous consequences. The IRB will confirm the qualifications of the researchers and research staff for conducting research in the country in question.

D. The research project should include details regarding issues such as the following: disclosure of scientific and/or medical facts to individuals who may be unfamiliar with and distrustful of the concepts to be studied; differences in cultural and societal norms; differences in the role of women in society; differences in the role of family and community in the consent process; multiple local languages; and participant literacy level.

Export Controls/Embargoed Countries

E. In some circumstances, the University may be required to obtain prior approval from a U.S. government agency before allowing foreign nationals to participate in research, collaborating with a foreign company, or sharing research results with foreign nationals. For example, the Treasury Department’s Office of Foreign Assets Control (OFAC) regulates trade embargoes, sanctions, and travel restrictions and restricts exportation of information and research articles to embargoed entities and persons. Researchers are encouraged to consult with the University’s Office of Export Control for further guidance.

1.1 Specific Policies
a) Local Research Approval:
The investigator may be required to provide some form of documentation of research project approval by an IRB with a foreign FWA, a local review body equivalent to the IRB, or an independent local community expert or leader, in this order. Documentation of local approval must include an attestation to the host country standards for human participant protection and the research project’s conformity to those standards. Details about this requirement are described in Section 1.2 of this SOP.

b) Research Resources and Facilities:
The investigator and research hosts at the international site are responsible for providing evidence ensuring that the resources and facilities are appropriate for research at each international site where the research will be conducted. The IRB may require the investigator to provide a letter of cooperation from each international site where the research will be conducted. Examples include NGOs, universities, schools, or other institutions. In some instances (such as anthropological research in smaller tribal communities), investigators will be asked to provide details about an established local contact. Investigators should provide the IRB with an explanation of how they will be invited into the community.

c) International Research Involving Children:
The legal and ethical standards for what is appropriate for informed consent, parental permission, and child assent may differ in international research settings. The research project involving children should document that consideration was given to:

1. In the locale of the research, when a child is considered an adult.
2. The relationship between parents and their children in the specific country
3. Acceptable and effective parental permission processes.
4. Whether child assent is acceptable/permitable by local custom.
5. Whether there are laws pertaining to orphans.

d) Cross-Cultural Issues and the Consent Process:
The research project must include an informed consent process and, if applicable, consent documents that are meaningful in terms of the local research setting and that comports with international standards of ethical research. Special attention must be given to language issues, local customs, cultural and religious norms in reviewing written consent documents or proposed alternative consent formats. The IRB does not exempt research projects conducted in foreign countries from the legally effective consent requirement, but it can waive the requirement for written documentation of consent.

e) HIPAA Applicability:
HIPAA regulations do not apply to health information obtained and held at international sites; however, researchers must comply with all applicable local privacy laws. If identifiable health information is collected at an international site by or on behalf of the University or is collected by a non-covered, non-contracted entity but is stored within a University HIPAA health care component, it is subject to HIPAA regulation.
1.2. IRB Criteria for Local Review and Approval

There are four ways for the IRB to demonstrate that the research project has been reviewed for conformance with local human research protections and research conduct standards for international research sites. When submitting local IRB or equivalent project approval, language barriers may need to be addressed through the submission of documents in their original form and with an English translation that includes an attestation from a translator who is not an investigator.

a) If the research project is approved by an IRB designated under an approved foreign Federal Wide Assurance (FWA) in the country where the work will be done, then no other review is needed other than that of the OU IRB. The investigator must submit the notice of approval and a copy of the research project that was reviewed.

b) For international research where it is not possible to have the work reviewed under a foreign FWA, then a local review body such as a local ethics committee or a tribal council that is equivalent to an IRB within the country of the research site can review the project. The investigator should describe in the application the qualifications of the local review body (e.g., source and scope of authority, location, membership).

c) If no local review body is available, the IRB may require the investigator to provide some documentation from an independent local community expert or leader (e.g., NGO director, university professor) indicating that the research project is in keeping with local social standards and expectations. This leader or expert should be familiar with the culture, mores, and attitudes of the community from which participants will be drawn and must not be associated with the conduct of the research. This local community leader or expert may not receive compensation of any kind from the investigator for the review of the research project. A local community leader or expert cannot provide approval if the country has promulgated human research standards and an IRB with a foreign FWA or a local review body.

d) On a case-by-case basis, the IRB may determine that no international review of research is possible. In this situation, the IRB must demonstrate that it has obtained necessary information about the local research context through written materials and at least one of the following at the discretion of the IRB: personal knowledge of the local research context on the part of one or more IRB members or discussions with appropriate consultants.

e) Written materials may include, for instance, peer-reviewed research publications that provide relevant information about the local research context that would assist the IRB in making its determinations. Written materials alone are not sufficient for a greater than minimal risk research project but may be submitted as supporting information.

f) Personal knowledge of the local research context on the part of one or more IRB members, such knowledge having been obtained through extended, direct experience with the subject population and their environment.
g) Appropriate consultant referrals to individuals with personal knowledge of the research site, such knowledge having been obtained through extended, direct experience with the subject population and their environment, and who are, in the estimation of the IRB qualified to provide an informed and independent review. It is not acceptable for the consultant to have a Conflict of Interest (SOP 104_B Conflict of Interest IRB Members) or a collaborator on research projects or grants of the investigator(s), anyone who has personal/professional ties with the investigator(s) that precludes him or her (in the opinion of the IRB) from speaking independently and objectively about the research project, or anyone who in the estimation of the IRB is not qualified to conduct the review.

h) The investigator will provide the consultant(s) with application materials for the research project to make a determination. The consultant will be asked to verify that, in his or her judgment, the research project design is appropriate to the social/political/cultural conditions of the research site and (as applicable):

i. the selection of subjects is equitable;
ii. informed consent is sought in a language understandable to the subject(s) and consent is obtained under conditions that minimize the possibility of coercion or undue influence;
iii. appropriate safeguards protect the rights and welfare of vulnerable subjects.

i) The consultant’s review is submitted to the IRB and the review will be held confidential to the IRB. The IRB will take under advisement any concerns the investigator may have about confidentiality, proprietary information, or other sensitive issues relating to his/her research. Final determination of whether to approve or not approve a research project remains with the IRB regardless of what a consultant may advise.

1.3 IRB Criteria for Informed Consent/Assent

Legally effective informed consent is required from each international human research participant, unless a waiver of the requirement is approved by the IRB. When approving international research projects (see SOP 701: Consent Process and Documentation) criteria must be followed; however, there are additional protections that will be required. The investigator should consult, if possible, with a local culture expert to determine an appropriate informed consent process and related documentation, or any issues related to language. Surrogate consent/permission may not be substituted for a subject’s informed consent unless the IRB has approved an alteration or waiver to the consent process.

If the investigator or local expert or leader has indicated that written informed consent is not standard or appropriate in the host country, alternate consent procedures (for example: use of pictures, video, or computers, or alternate forms of documentation such as thumbprints) should be considered. The researcher may also request a waiver of documentation of informed consent and use an oral consent process. Oral consent is appropriate when the local community uses no written language or considers the signing of documents problematic. If these alternatives are not possible, the investigator may request a waiver of informed consent. For both
waivers of documentation of consent and waivers of consent, the research protocol must include explanations of cultural norms or conditions requiring such a waiver.

1.4 Compensation to International Participants

In any human research project, every effort should be made to minimize opportunities for coercion and to ensure that participation is truly voluntary. If a person is to be paid in cash or goods at a value that far surpasses what would be commonly available in the local community, such payment could be coercive. The investigator must consider the appropriateness of any incentives or reimbursements to be paid to international participants and include a justification that describes the relative value of the compensation based on the local context. (Example: The investigator may report the prevailing hourly wage of the participants in the local research context. The compensation should be commensurate with other compensation the participant could receive for the same amount of time in wage-based employment.) Additional guidance on compensation is provided in SOP 410: Study Recruitment and Advertisements.

1.5 Sponsoring Organizations

Investigators seeking to conduct research outside the United States that is sponsored by a federal agency or external organization should be aware of additional special requirements that may apply (See VHA Handbook 1200.05 § 56 for additional guidance). The VA and DOD requirements are provided below. The investigator must consult with funding organizations to learn of any special requirements that may apply.

a) VA Research Requirements for International Research

VA international research is defined as any VA-approved research conducted at international sites (not within the U.S., its territories, or Commonwealths); any VA-approved research using either human biological specimens (identified, de-identified, or coded) or human data (identified, de-identified, or coded) originating from international sites; or any VA-approved research that entails sending such specimens or data out of the U.S. NOTE: This includes sending such specimens or data to individuals with VA appointments at international sites (e.g., a WOC appointment, a VA investigator on sabbatical at an international site). It also includes a VA's serving as a coordinating center for an international research project. Multi-site trials are covered under this definition if any of the following apply:

1. VA is a sponsor;
2. VA functions as the coordinating center;
3. VA subcontracts to a foreign site;
4. The PI for the total study is a VA investigator; or
5. The VA investigator is specifically collaborating with an international investigator and the VA investigator sends data or human biological specimens outside the U.S. or receives data from outside the U.S.
NOTE: This requirement does not apply if the VA is only one of the participating sites and the trial does not meet the preceding conditions.

i. All individuals who participate as subjects in VA Research at international sites must be provided appropriate protections that are in accord with those given to research subjects within the U.S., as well as protections considered appropriate by local authority and customs (38 CFR 16.101(g)). All VA international researchers must obtain permission from the Chief Research and Development Officer (CRADO), Office of Research and Development (ORD), or designee, prior to initiating research.

ii. This applies regardless of the funding source (funded or unfunded) and to research conducted through any mechanism of support including agreements, MOU, Cooperative Research and Development Agreements (CRADA), grants, or contracts. The CRADO, or designee, will not grant permission for an international research study involving prisoners as research subjects.

iii. All VA Research international sites must hold an international FWA, and the research must be approved by the IRB or Research Ethics Board of the participating site(s) that are listed on the international FWA. In addition to VA facility Director responsibilities delineated in VHA Handbook 1200.05, the facility Director is responsible for:

- Approving the request for permission to conduct international research prior to forwarding it to the CRADO for action.
- Ensuring permission has been obtained from the CRADO, or designee, for the international research prior to its initiation by an investigator at the facility.

NOTE: Information on how to request permission from the CRADO may be referenced at: http://www.research.va.gov/resources/policies/docs/instructions-intl-research.pdf.

iv. In addition to the PI responsibilities delineated in VHA Handbook 1200.05, the PI is responsible for:

- Obtaining approval from the facility Director.
- Obtaining permission from the CRADO, or designee, in writing before initiating an international research study.
- Conducting research in compliance with this VHA Handbook 1200.05, and all other applicable VA and other Federal requirements including those for protecting human subjects, tissue banking, use of databases, Federal criminal laws, and the Standards of Ethical Conduct for Employees of the Executive Branch.
1.6 Communication with Home Institution

The investigator must make adequate provisions for communication from the international site to the University. The research protocol must include descriptions of the following:

a) How communication by the investigator will occur with the IRB and the local site organization, host, or supervisor.
b) How ongoing review, modifications, or reporting of unanticipated problems/adverse events non-compliance or complaints will be handled by the investigator and communicated to the IRB.
c) Local contact information if the investigator cannot be reached.
d) For student researchers, the extent of the student’s knowledge of the country and how the student will communicate with the faculty sponsor.
e) The investigator shall provide the IRB the contact information for the local IRB or research counsel for communication and coordination purposes.

1.7 Monitoring of Approved International Research

In certain cases, the IRB may require the following documentation:

a) Continuing IRB/Ethics Committee approval from the international institution or site;
b) Continuing cooperation from the international institution or site if the institution or site is not engaged in the research;
c) Verification from sources other than the researcher that there have not been any substantial changes in the research since the last continuing review; and/or
d) Inclusion of an independent monitor/body as part of the data safety/monitoring plan.

2. SCOPE

This policy applies to all international human subject research conducted at the University.

3. RESPONSIBILITY

A. Training Programs:

The Investigator should submit as part of the application materials verification that all KSP (including all those recruited from the research site) who are participating in the international research project have received human research training. The training options are:

1. CITI online training
2. Local training program

If local research participants are not proficient in English, the assistance of a translator
may be required. If the locally recruited KSP elect to use a local training program, documentation from the provider of that training program must be provided to the IRB. This training is in addition to any specific research project instructions that the IRB may require the Investigator to provide to any KSP recruited from the research site.

B. Local Research Assistants/Translators:

In instances where the data to be collected has the potential to cause social stigmatization, investigators should use care in selecting an appropriate field assistant or translator to ensure that participant confidentiality is maintained. Graduate students from a regional University are sometimes hired in this role, provided that they are sufficiently external to the community of interest to assure confidentiality. In other cases, local customs require that the translator/field assistant be drawn from the community. In this case, the investigator should train the field assistant in the confidentiality requirements of the research project and train the assistant about not unduly influencing a participant to respond to questions that s/he may otherwise not wish to answer.

C. Location of Data Collection:

The collection of data must comply with local law relating to data privacy and security, as well as applicable U.S. law. Researchers should consider the appropriateness of locations where any interactions with participants will occur, considering whether or not there may be issues related to being seen speaking to the researchers or the possibility of being overheard.

1. Securing Data and Enhancing Participants’ Privacy.
   Depending on the nature of the data to be collected and its sensitivity in the local culture, the research protocol may need to include a range of suggested data protection measures, for example:

2. Paper files:
   Secure data in the research field by means of a lock box or locking file cabinets whenever possible. In some remote sites, physically securing records may be difficult so alternate approaches such as maintaining records in English in an area where English is not understood can be more effective. Use of notebooks interspersed with random travel notes may hinder unauthorized access to respondent data.

3. Electronic Data:
   The collection of data must comply with local law relating to data privacy and security, as well as applicable U.S. law. As a matter of best practices under U.S. law, researchers and other IRB-approved key study personnel should use only password-protected computers and encrypted files and devices and should limit access to necessary key study personnel. If the information to be collected is politically sensitive either in the country or in the U.S., researchers may wish to consider storing data by uploading encrypted data files to University servers and then securely deleting the files from the laptop on-site to avoid unlawful or unauthorized confiscation of data. Researchers should use caution in connecting through unsecure connections such as Internet cafes. U.S. export control laws may affect the
ability to travel outside the United States with laptops and other electronic storage devices. Similarly, U.S. Customs may control re-importation of these devices.

4. APPLICABLE REGULATIONS AND GUIDELINES


Biomedical research - international guidelines: e.g., The Declaration of Helsinki, the International Conference of Harmonization – Good Clinical Practice (E6) Guidelines, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects published by the Council for International Organizations for Medical Sciences (CIOMS).

Department of Defense: Instruction 3216.02 6 para. 3.a.(4); SECNAVINST 3900.39D, para. 6i

Veterans Administration: VHA Handbook 1200.05, 4, 5, 56

U.S. export controls and sanctions laws apply to international research activities. Contact the University Office of Export Control for information about legal, procedural, and practical matters related to international travel of faculty, staff, researchers, and students. Further information is available on ORIA’s export controls website.

5. REFERENCES TO OTHER APPLICABLE SOPs

SOP 104B Conflict of Interest IRB Members
SOP 403 Initial Review
SOP 404 Continuing Review
SOP 405 Modifications/Notification
SOP 410 Study Recruitment and Advertisements
SOP 701 Consent Process and Documentation
SOP 801 Investigator Responsibilities

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

A. The Investigator or Investigator’s staff submits a new study application and uploads all applicable documents into the IRB electronic information system.
B. The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403: Initial Review – Criteria for IRB Approval). The submission with all applicable documents made available to all IRB members.

C. The IRB Administrator conducts a pre-review of the submission and verifies that all necessary documentation is included in the submission regarding local research approval, research resources and facilities, research involving children, and the type of local review and approval.

D. The IRB Administrator assigns the submission either to (1) the appropriate Board agenda or (2) to the IRB Chair/IRB designee.

E. If assigned to an IRB agenda, the process follows SOP #403: Initial Review – Criteria for IRB Approval.

F. If assigned to IRB Chair / IRB Designee, the process follows SOP #402: Expedited Review.

G. Following review of the submission, the IRB Administrator updates the outcome of the IRB review and communicates the outcome and any stipulations to the Investigator. The IRB Administrator posts the final IRB approval to the next appropriate IRB agenda.

H. Enrollment into the research project may not commence until all required institutional committees have completed their review and the contract is signed, if applicable.

APPROVED BY: ___________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016