SOP: Global Human Subjects Research				
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1 PURPOSE

1.1 The purpose of this standard operating procedure is to establish the requirements and processes to obtain approval to conduct human subjects research (HSR) outside of the United States (U.S.).

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 These requirements apply to all HSR conducted outside of the U.S.

3.2 The requirements outlined in this document are in addition to the requirements for conducting HSR in the U.S.

3.3 The HSR regulations and requirements of the host country must be followed.

3.4 The norms and values of the host country should be honored and respected.

4 RESPONSIBILITIES

4.1 Researchers

4.1.1 The research team should be familiar with the regulatory requirements in the host country.

4.1.2 In addition to obtaining approval from the Virginia Tech Human Research Protection Program (HRPP) or Institutional Review Board (IRB), researchers must obtain the appropriate approvals from the host country before initiating any HSR activities.

4.2 HRPP and IRB

4.2.1 The HRPP and IRB will coordinate with local programs and committees to streamline the ethical review process.

4.2.2 The HRPP will identify consultants to provide the IRB with additional information to facilitate their review, as needed.

5 ADDITIONAL REQUIREMENTS AND CONSIDERATIONS

5.1 Local Documentation and Approvals

5.1.1 For HSR that is determined to be exempt or for countries that do not require approval by an IRB or ethics committee, researchers must obtain written documentation from a local authority that confirms that review and approval by an IRB or ethics committee is not required. This written documentation must include the name and title of the individual along with a brief statement that confirms local approval or authorization is not required and should reference the title of the protocol (and protocol number if available) and the Virginia Tech principal investigator (PI).

5.1.2 For all other HSR (exempt with limited IRB review, expedited, and full board studies) researchers must obtain:

5.1.2.1 Approval from a local IRB or ethics committee.

5.1.2.2 If approval is not required:

5.1.2.2.1 Researchers must obtain written documentation from a local authority as described in 5.1.1.; and

5.1.2.2.2 A memo of cultural appropriateness. This is written documentation from an expert who is familiar with the culture of the country/local community that will be the target of the research. This can be the same individual who provides confirmation that local IRB or ethics committee review and approval is not required, but must be a person independent from the research team who does not have a conflict of interest.

5.1.3 If local IRB or ethics committee approval or written documentation from a local authority and a memo of cultural appropriateness are available at the time of submission, the researcher should include them. If they are not available, conditional approval can be granted pending the receipt of these documents and completion of any other requirements.

5.1.4 In situations where the requirements in this section are unable to be met, the researcher should reach out to the HRPP at irb@vt.edu to discuss alternative options for local approval.

5.2 Informed Consent

5.2.1 Researchers should follow the informed consent requirements outlined in HRP-090.1 and any local requirements.

5.2.2 Researchers should involve local experts when designing their consent process to make sure it is consistent with national requirements and respectful of the host community's norms. Researchers should include in the protocol results of local expert involvement (along with a description of any resulting deviations from the standard consent process) if a waiver or alternation of the consent process is being requested or if documentation of consent will include something other than a signed consent form. .

5.3 Translations

5.3.1 If the research will be conducted in a language other than English, the researcher must arrange for the participant-facing materials to be translated. The following materials should be included with the protocol submission:

5.3.1.1 Copies of all the translated materials, in English and the translated language; and

5.3.1.2 A certification of translation by an individual who is independent of the research. The certification should include a list of all the translated documents, the name of the translator and credentials, and the date of the translation.

5.3.2 Translated documents can be provided for the final, IRB-approved forms (i.e., following revisions requested on the initial submission) to avoid multiple translations.

5.3.3 Any changes to participant facing material will require a new translation of the revised portions, which can be submitted after the review of the amendment.

5.4 Appropriate Resources and Facilities

5.4.1 The protocol should include details of any local resources that will be available to support the proposed research. For example, if local experts will be advising the research team, this should be described. If local staff will be engaged in the research, they need to be included as collaborators and will to obtain the appropriate approvals.

5.5 Export Controls/Embargoed Countries

5.5.1 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 HSR, collaborating with a foreign company, or sharing HSR results or data/specimens with foreign nationals. The Office of Export Controls and Secure Research Compliance (OESRC) personnel review areas of such sponsored research, international visitors, international travel, international shipping, procurement, foreign influence, and several other areas of international collaboration or controlled technology access. Researchers should contact OESRC at oesrc@vt.edu to determine if additional approvals are needed.

5.6 Data Storage and Protections

5.6.1 Data protection laws vary from country to country and some countries do not allow the export of their data. Researchers should be aware of local data protection requirements and restrictions.

5.6.2 General Data Protection Regulation (GDPR) and United Kingdom GDPR

5.6.2.1 GDPR is a European data privacy and security law that applies to any organization collecting data related to the people in the countries that are part of the European Union (EU). Researchers who are conducting research in an EU country will have to adhere to these requirements.

5.6.3 Researchers conducting HSR outside of the U.S. are strongly advised to consult with the Privacy and Research Data Protection (PRDP) program (prdp@vt.edu) before submitting a protocol.

5.7 Researchers with questions about this process or who are unsure which requirements apply to their research should contact the HRPP at irb@vt.edu to request a consultation.

6 PROCEDURE

6.1 The protocol and supporting documents should be submitted in protocol management following the standard procedures. The researcher should address the following points in the protocol or upload the appropriate documents.

6.1.1 A description of where the research will be conducted. An ethical justification for conducting the research in the setting. A description of the relevance and benefit of the research to the target community.

6.1.2 A description of the current socio-political environment and in the research setting that might alter or increase risk to research participants. If appropriate, describe the mitigation strategies to reduce these potential risks.

6.1.3 A description of the local dialect and norms for the consent process, including documentation, if they differ from the U.S.

6.1.4 All participant-facing materials must be translated into the local language. See section 5.3 for details.

6.1.5 Local approval documents:

6.1.5.1 Local IRB or ethics committee approval; or

6.1.5.2 Documentation from a local authority and a memo of cultural appropriateness (see section 5.0 for details).

6.1.6 The research team should have experience conducting research in the proposed setting. These qualifications should be outlined or described in the curricula vitae that is uploaded in protocol management.

6.2 If any requirements outlined in section 5 apply, they should be addressed in the protocol or supporting documents.

6.3 Upon receipt of the submission, the HRPP will review and work closely with the IRB and the PI to secure approval. The researchers should not initiate any HSR activities until all the appropriate approvals have been obtained.

7 MATERIALS

7.1 None

8 REFERENCES

8.1 International Compilation of Human Research Standards (Office for Human Research Protections)