SOP 1.3.2 International Research

General Description:

International human research refers to research conducted outside the United States using participants from the local community. Such research involving or conducted by Mason investigators remains subject to the review and approval authority of the Mason IRB and the obligations undertaken by Mason in its Federal Wide Assurance on file with the federal Office of Human Research Protections (OHRP). When international research is conducted, both the Mason IRB and the applicable foreign site's IRB/ethics committee must approve the research before the research is initiated.

In order to develop appropriate protocols, researchers need to be familiar with the host country's laws, as well as the local culture and norms. Without this knowledge, a PI may unintentionally put their subjects, the research team, or him/herself at risk.

Those aspects of the human subject research that are carried out at Mason or by Mason agents are under the purview of the Mason Institutional Review Board (IRB), and those aspects of the research that are carried out in the participating country are also under the purview of that country's IRB or ethics committee. Ethical guidelines and laws regarding human subject research in over 100 countries and from several international organizations can be found in the Office for Human Research Protections (OHRP) International Compilation of Human Subject Protections. In addition to consulting the ethical guidelines and laws, it is recommended for researchers to be knowledgeable of all relevant local contexts and norms, either through consultation with local entities or through academic experts.

The investigator must provide the IRB with information through use of the international study site addendum. This addendum requires the information from an individual with expertise in the location where the work will occur and provides the IRB information about potential risks to the subjects as well as relevant regulations. At the time of preliminary review of a new project application or modification, the IRB chair or primary reviewer may determine that the study requires further review by a consultant with expertise outside of the current IRB membership.

Procedures:

1. **Research planning.** Researchers planning to conduct human subjects research outside of the US should conduct the necessary planning and allow adequate time to comply with all requirements of international research.
    a. A researcher seeking to conduct research outside the United States which is sponsored by a federal agency should consult that agency to learn of any special requirements that may apply.
    b. The researchers should investigate and learn about cultural and political differences that may bear on the conduct and purpose of the proposed research and communicate these findings to the IRB in the protocol.

2. **IRB Review and Approval.** The PI must submit an IRB application for IRB review and approval through IRBNet.

a. The IRB shall review all aspects of the research that will be carried out in each country. The protocol should include information that shows the PI is familiar with the proposed research area and is qualified to do the study at the foreign site.
b. The PI should submit verification that all key personnel (including all those recruited from the research site) who are participating in the international research study have received human research training before the study is initiated.
c. Addendum I must be submitted with the application in IRBNet. This document must be completed by an expert on the local culture of the location where the research is to be conducted. The expert may be a current resident of the culture or may live outside the culture, but should have knowledge of the culture's customs, public policies, history, etc. This addendum should identify any risk, harm or offense introduced by the consent process or other aspects of the research protocol procedures.
d. Informed Consent procedures must be detailed and carried out in the subjects'native language or per OHRP guidelines. Generally, written or oral informed consent information must be presented in a language and at an educational and cultural level that will be understood by study participants. The PI should submit translated copies of any recruitment documents, consents, or instruments that will be used in a language other than English as part of the IRB application. The PI must also indicate whether a translator will be used, and if so, whether they will be part of the research team.

Related Forms, Guidance, and SOPs:

- Office for Human Research Protections (OHRP) International Compilation of Human Subject Protections
- Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English. Available at: http://www.hhs.gov/ohrp/policy/ic-non-e.html.
- 45 CFR 46.101(h)
- 45 CFR 46.107(a)
- 21 CFR 56.107(a)
- 21 CFR 312.120(c)(1)
- 21 CFR 814.15(a) and (b)
- OHRP Guidance "IRB Knowledge of Local Context"; available at: http://www.hhs.gov/ohrp/policy/local.html

Responsibility:

Execution of SOP:
Principal Investigator
Study Team Members
IRB Staff
IRB

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	February 19, 2015
Greg Guagnano	IRB Chairperson	February 19, 2015