UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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AAHRPP:	Standard I-3
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Updated By:	
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Procedure Title:	International Research

1.0 Objective

1.1. To describe the policies and procedures when research activities are partially or fully conducted outside of the United States (US) for the University of Southern Maine (USM) from the Office Research Protection and Outreach (ORIO).

2.0 General Description

2.1. International human research refers to research conducted outside the United States (US) using participants from the local community. Such research involving or conducted by USM Principal Investigators (PI) remains subject to review and approval by the USM Institutional Review Board (IRB) and the obligations undertaken by USM and the Federal Office of Human Research Protection (OHRP). When international research is conducted, both the IRB and the applicable foreign site's IRB/ethics committee (EC) if any, must approve the research before the research is initiated.

2.2. Ethical guidelines and laws regarding human subject research and from several international organizations can be found in OHRP International Compilation of Human Subject Protections. In addition to consulting the ethical guidelines and laws, it is recommended that the Principal Investigators be knowledgeable of all relevant local contexts and norms, either through consultation with local entities or through academic experts.

3.0 Definitions

3.1. **Ethics Committee (EC)** is a group who have knowledge about the local laws and/or traditions/customs who are also responsible for ensuring the safety of subjects in proposed research protections.

3.2. **Expert** is an individual who has extensive knowledge of the country's culture, customs, public policies, history, law, etc. where the research is to be conducted. The Principal Investigator, or research staff may be considered an expert depending on their experience.

4.0 Responsibility

4.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), Institutional Review Board (IRB), and Principal Investigators to execute this Standard Operating Procedure (SOP).

4.2. Principal Investigators planning to conduct human subject research outside the US should plan ahead to allow adequate time to comply with the additional requirements of this policy. The approval requirements can be time consuming such as translating consent forms, obtaining approval from the international research site, obtaining review and approval by a local Ethics Committee equivalent to an IRB, and obtaining approval from the IRB at USM.

4.3. A Principal Investigator 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.

4.4. In order to develop appropriate protocols, PIs need to be familiar with the host country's laws, political differences as well as the local culture and norms that may bear on the conduct and purpose of the proposed research. Without this knowledge, a PI may unintentionally put their subjects, the research team, or themselves at risk.

4.5. The PI should submit with the protocol application 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. The Collaborative Institute Training Initiative (CITI) is available to the University of Maine System and its affiliates. CITI Social and Behavioral course is available in both English and Spanish. www.citiprogram.org

5.0 Procedure

5.1. Research Planning

5.1.1. Principal Investigators planning to conduct human subject research outside of the US should conduct the necessary planning and allow adequate time to comply with all requirements of international research.

5.1.1.1. A Principal Investigator 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; and

5.1.1.2. The Principal Investigators 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.

5.2. IRB Criteria for Local Review and Approval

5.2.1. The PI must submit an IRB application for IRB review and approval.

5.2.1.1. 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, knowledgeable of local laws and is qualified to do the study at the foreign site.

5.2.1.2. 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 research is initiated.

5.2.1.3. An additional set of questions must be submitted with the protocol about the local culture of the location where the research is to be conducted. The protocol should include an expert who has extensive knowledge of the country's culture, customs, public policies, history, law, etc. This questionnaire form should identify any risk, harm, or offense introduced by the consent process or other aspects of the research protocol procedures.

5.2.1.4. Informed consent procedures must be detailed and carried out.

5.2.1.5. Expedited IRB review requires an annual review and reporting of research progress and/or results to date.

5.2.2. The IRB staff will refer to the OHRP International Compilation of Human Research Protections website for the applicable country or countries to determine local requirements. The IRB will also consider:

5.2.2.1. The experience of the PI in working in the area or region and the PI's knowledge of the area or region as it relates to the research;

5.2.2.2. The appropriateness of the provisions for the Principal Investigator to ensure ongoing review and approval from the IRB;

5.2.2.3. The appropriateness of the provisions for reporting unanticipated problems involving risks to subjects or others, complaints and non-compliance to the IRB;

5.2.2.4. A process for obtaining consent that is appropriate given the local laws, customs, and/or traditions; and

5.2.2.5. Documentation of local IRB or Ethics Committee review and approval. When applicable, there will be appropriate coordination and communication between the IRB and the local Research Ethics Committee.

5.3. IRB Criteria for Informed Consent/Assent

5.3.1. Written informed consent is required from each international human research participant, unless a waiver of the documentation is approved by USM IRB (*See HRPP-029 Informed Consent)*.

5.3.1.1. 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.

5.3.1.2. The consent form is translated into appropriate language, then translated back into English for accuracy of content.

6.0 References

6.1. 45 CFR 46.101(h);

6.2. 45 CFR 46.107(a);

6.3. OHRP http://www.hhs.gov/ohrp/international;

6.4. 21 CFR 56.107(a);

6.5. 21 CFR 312.120(c)(1);

6.6. 21 CFR 814.15(a) and (b);

6.7. Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English. Available at: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-infomed-consent-non-english-speakers/index.html.

6.8. CITI on-line training program www.citiprogram.org