INTERNATIONAL RESEARCH STUDIES

Unit: Human Research Protections Program (HRPP), Office of Research
Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE:
The MCW/FH IRB reviews international research using the same approval criteria, policies and procedures that are applied to research conducted domestically.

International research requires investigators to be aware of the additional requirements that accompany such research, including those of the country in which the research is to be conducted. Investigators are responsible for ensuring that research performed in other countries meets equivalent levels of protection that would be required in the investigator's principal location, taking into account local laws and cultural context.

DEFINITIONS:
Assurance: a statement by an institution of compliance with the US federal regulations for the protection of human subjects.

FWA: the assurance currently accepted and approved by OHRP. It is required whenever an institution becomes engaged in non-exempt human subjects research conducted or supported by a US federal department or agency.

PROCEDURE:
1. For new projects, investigators will complete the eBridge SmartForm in accordance with the IRB SOP: Submitting New Studies. For approved projects which will add an international location where research will be conducted, investigators must submit an eBridge Amendment SmartForm along with the identified documents noted below.
2. Regulations, policies and procedures that are applied to research conducted domestically will be applied to research conducted in other countries, as appropriate.
3. While local review that considers how the project may impact the country is required, it does not replace review by the MCW/FH IRB.
4. The PI must include in the eBridge SmartForm:
   - A description of the experience, expertise and knowledge of the country that the PI or a member of study team holds
   - Demonstration of knowledge of local laws and sensitivity to customs, for example who may sign a consent form or differing legal definition of “minor”
   - An appropriate plan for how subject complaints, non-compliance, and UPIRSOs will be handled
   - An appropriate plan for communication and coordination with local investigators
- The plan for post-approval monitoring of the study by the PI
- If subjects will be compensated for research participation, a description of the amount in both US and local currency and how the payment is relative in local terms, for example, comparable to a day's work or other local reference.

5. The following documentation must be provided in the eBridge SmartForm:
   - A translated consent form, approved by the local IRB (or equivalent other organization), encompassing all of the required elements of informed consent in the language appropriate to the location of the research and in accordance with IRB SOP: Recruitment and Enrollment of Non-English or Limited English-Proficient Subjects and IRB SOP: Informed Consent and Documentation for Human Subject Research.
   - For federally funded research, the study must be approved by a local IRB or Ethics Board/Committee from an institution that holds an Assurance with OHRP. The Federalwide Assurance (FWA) number must be provided. An approval letter from the local IRB or Ethics Board/Committee must be provided to the MCW/FH IRB before final approval can be granted.
   - For non-federally funded research, if a local IRB or Ethics Board is not available, equivalent protections must be in place. A letter from the local Ministry of Health or hospital representative is acceptable.

6. Research activities may not begin until approval has been obtained from the MCW/FH IRB.

7. The PI is responsible for maintaining continuing approval for the study and the consent form.

REFERENCES:
45 CFR 46.111
21 CFR 56.111
HHS International Compilation of Human Research Standards

SUPPORTING DOCUMENTS:
IRB SOP: Submitting New Studies
IRB SOP: Recruitment and Enrollment of Non-English or Limited English-Proficient Subjects
IRB SOP: Informed Consent and Documentation for Human Subject Research

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