MCW Office of Research
Standard Operating Procedure

INTERNATIONAL RESEARCH

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:
The MCW IRB reviews international research using the same approval criteria, policies and procedures that are applied to research conducted domestically. When the research is sponsored by a U.S. federal agency, the regulations of that agency apply.

International research refers to research conducted outside the United States using participants from the local community. Such research requires investigators to be aware of the additional requirements that accompany the 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: An assurance of compliance is a written document submitted by an institution (not an Institutional Review Board) that is engaged in non-exempt human subjects research conducted or supported by HHS. Through the assurance of compliance, an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46.

FWA: The Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by a US federal department or agency. Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance.

PROCEDURE:
1. For new projects, investigators will complete the eBridge SmartForm in accordance with the *IRB SOP: Submitting New Projects*.
    a. For approved projects which will add an international location where research will be conducted, investigators must submit an amendment 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 IRB.
4. The PI must include in the eBridge SmartForm:

a. A description of the experience, expertise and knowledge of the country that the PI or a member of the project team holds
b. Demonstration of knowledge of local laws and sensitivity to customs, for example who may sign a consent form or differing legal definition of "minor"
c. An appropriate plan for how subject complaints, non-compliance, and UPIRSOs will be handled
d. An appropriate plan for communication and coordination with local investigators
e. The plan for post-approval monitoring of the project by the PI
f. 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. 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*; *IRB SOP: Informed Consent for Human Subject Research and IRB SOP: Informed Consent Document for Human Subject Research.*
    b. For federally funded research, the project 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 IRB before final approval can be granted.
    c. 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 IRB.
7. The PI is responsible for maintaining continuing approval for the project and the consent form with both in-country IRB and MCW IRB.

Requirements of other Federal Agencies:
In the event of an unresolved conflict in research projects funded or otherwise supported by the Department of Defense the requirements most protective of the human subjects will be followed. When there is an unresolved conflict, DoD Components shall consult with legal counsel and seek guidance from the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)).

Continuing Progress Reports (CPR):
Investigators must submit a CPR in accordance with *IRB SOP: Submission of Continuing Progress Reports.* In addition, the Investigators must provide:

1. A summary of activity for the overall project, including enrollment at the international location
2. A copy of their most recent approval by the local IRB or Ethics Committee.

Amendments:
Prior to any change to a project Investigators must submit an amendment in accordance with *IRB SOP: Amendments.* In addition, the Investigators must provide a copy of approval by the local IRB or Ethics Committee for this change.

REFERENCES:
45 CFR 46

SUPPORTING DOCUMENTS:
IRB SOP: Submitting New Projects
IRB SOP: Recruitment and Enrollment of Non-English or Limited English-Proficient Subjects
IRB SOP: Informed Consent for Human Subject Research
IRB SOP: Informed Consent Document for Human Subject Research
IRB SOP: Submission of Continuing Progress Reports
IRB SOP: Amendments

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