INTERNATIONAL RESEARCH

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

Applies to: Institutional Review Board Committees

PURPOSE:
International research requires the IRB to be aware of the additional requirements that accompany such research, including those of the country in which the research is to be conducted. The IRB is 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.

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.

DEFINITIONS:
Assurance: An assurance of compliance is a written document submitted by an institution 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. The IRB will review the project in accordance with the *IRB Member SOP: Initial Review and Primary Reviewer Responsibilities* or *IRB Member SOP: Review of Exempt and Expedited Projects*.
2. IRB review will include appropriate expertise and knowledge of the international

6. The IRB must find that the necessary information about the following is described in the eBridge SmartForm:
    a. Adequate experience, expertise and knowledge of the country that the PI or project team holds. The level of local knowledge required is based on the degree of risk presented by the research.
    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. An appropriate plan for post-approval monitoring of the project by the PI and/or local PI

d. An ap-1.153D-.0002 Tw[d15318be plorm:)-t6.9(s,wledgea-1.639de5.5(p.9(s393 -1.0003 Tw153 TD.

Limited English-Proficient Subjects and *IRB SOP: Informed Consent 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.

Amendments:

1. The IRB will review amendments in accordance with *IRB Member SOP: Amendments.*
2. Investigators must provide a copy of approval by the local IRB or Ethics Committee for this change along with all revised documents.

Continuing Progress Reports (CPR):

1. The IRB will review the CPR in accordance with *IRB Member SOP: Review of Continuing Progress Reports.*
2. The IRB will review the summary of activity for the overall project, including enrollment at the international locations along with confirming on-going approval by the local IRB or Ethics Committee.
    a. An approval letter from the local IRB or Ethics Board/Committee must be provided to the MCW IRB before final approval can be granted.
    b. If the local IRB or Ethics committee does not require continuing review of a project, Investigators should upload documentation in support of this.

REFERENCES:

45 CFR 46

SUPPORTING DOCUMENTS:

IRB Member SOP: Initial Review and Primary Reviewer Responsibilities.
IRB Member SOP: Recruitment and Enrollment of Non-English or Limited English-Proficient Subjects
IRB Member SOP: Informed Consent for Human Subject Research
IRB Member SOP: Review of Continuing Progress Reports
IRB Member SOP: Amendments

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