MCW IRB Committee Procedures

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 locations either through IRB membership or use of consultants.
3. Regulations, policies and procedures that are applied to research conducted domestically will be applied to research conducted in other countries, as appropriate, during initial review, continuing review, and review of modifications to previously approved research.
4. While local review that considers how the project may impact the country is required, it does not replace review by the MCW IRB.
5. When MCW is the recipient of a governmental award for the research activities to be conducted at MCW and international locations, the MCW IRB is responsible for reviewing the entire project.

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
    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.
    g. The IRB Committee must assure that adequate provisions are outlined for data and safety monitoring keeping in mind that some foreign Ethics Committees may not require continuing review of approved research
    h. Conduct of research funded or supported by the Department of Defense complies with Department of Defense requirements and includes statement that the researcher will follow all local laws, regulations, customs and practices.
7. The IRB will consider the following elements of local research context when reviewing the project:
    a. Disclosure of scientific and medical facts to individuals who may be unfamiliar with and distrustful of the concepts
    b. Differences in cultural and societal norms
    c. Differences in the role of women in society
    d. Differences in the role of family and community in the consent process
    e. Multiple local languages
    f. Literacy level
    g. The influence of local officials on the population
    h. The relevance of the research to the area's health needs
    i. The nature of the procedures conducted
    j. The growth rate of sociology and medicine in that area
    k. The local legal rights of the population
8. When reviewing the consent process, the IRB will consider all consent elements as required by the federal regulations, and appropriate to the nature of the project are included in the consent form in addition to these considerations:
    a. Disclosure of scientific and medical facts to individuals who may be unfamiliar with and distrustful of the concepts
    b. Differences in cultural and societal norms
    c. Differences in the role of women in society
    d. Differences in the role of family and community in the consent process
    e. Multiple local languages
    f. Literacy level
9. 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 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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