MCW IRB Committee Procedures

MULTI-SITE PROJECTS AND COORDINATING CENTER RESPONSIBILITIES

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

Applies to: Institutional Review Board Committees

PURPOSE:
To outline the necessary information which the IRB Committee needs to review to provide oversight of the conduct of a multi-site project.

DEFINITIONS:
Engaged in Research: An institution becomes "engaged" in human subjects research when its employees or agents (all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility)

1. Intervene or interact with living individuals for research purposes.
2. Obtain individually identifiable private information for research purposes,
3. Obtain informed consent from human subjects; or
4. Receive HHS funds even when all activities are carried out at another institution or by employees of another institution. Determinations on MCW/FH/Versiti engagement are made by MCW's HRPP Director or designee.
    a. Determinations on Children's Wisconsin (CW) engagement in human subject research are made by the CW HRPP Director or designee.

IRB of Record: The IRB responsible for review and oversight of research involving a performance site. If the IRB of Record for non-MCW performance sites is the MCW IRB, an IRB Authorization Agreement or Master Agreement must be in place.

Multi-site Project: Projects that will be initiated at more than one location other than or in addition to MCW. Examples of multi-site projects include:

1. A project conducted at MCW, Children's Wisconsin, and Versiti.
2. A project conducted at MCW and Marquette University.
3. A project conducted both Froedtert Hospital and the University of Wisconsin-Madison.
4. A clinical trial conducted at 40 different sites in the United States, even though the non-MCW sites may pursue IRB review independently.
5. A project conducted at a social services agency in Milwaukee, or in a Milwaukee neighborhood.

Coordinating Site: The Coordinating Site will typically be the home site of the lead investigator for the entire project. For federally funded and/or FDA-regulated multi-site projects, the "primary awardee" or "grantee institution" will typically be designated as the Administrative or Coordinating Site. The MCW HRPP requires the project to identify a nominal lead investigator by name and site when a multi-site project is being led or directed by two or more lead investigators (e.g. a leadership committee). The

Coordinating Site is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.

Performance/Participating Site: A participating site is one at which staff are engaged in the conduct of research (see definition of 'engaged"). A participating site is the actual place where the research activity takes place (e.g., clinic, hospital, community center). The participating site's location may be different from the location where the IRB review takes place.

PROCEDURE

1. Investigators must complete and submit an eBridge PRO SmartForm in accordance with the *IRB SOP: Submitting New Projects*. For projects which will include multiple locations, the PRO SmartForm must include:
    a. A description of where research activities will take place
    b. A protocol that describes the entire project
    c. Operating or coordinating center procedure manuals to be used, if applicable
    d. If the same protocol is disseminated to all sites, a description of what parts of the protocol will not be conducted at MCW/FH/Versiti/CW, e.g. not enrolling minors when the project protocol includes adults and minors, not conducting a sub-project as described in the project protocol
    e. The plan for continuing oversight of subject safety, name of individual at MCW/FH/Versiti responsible for evaluating and responding to subject complaints, plan for how the coordinating center will disseminate information to sites regarding UPIRSOs, new information, and changes in the project protocol or consent form.
2. A CV is required for the lead investigator from each site in the following cases. In addition, a narrative in the protocol or protocol addendum that describes the resources available to the lead investigator at each site must be uploaded with eBridge PRO SmartForm:
    a. MCW IRB is the IRB of Record for another site.
        i. HRPP office may waive this requirement if the investigator is a faculty member of one of the institutions within the SEWIC CTSI partnership.
    b. The multi-site project is investigator-initiated and the MCW investigator is the lead PI for the entire project.
    c. The MCW investigator is the lead PI for the entire project and the project is federally funded and/or FDA regulated.

For non-exempt projects, when the MCW PI is the Principal Investigator for the entire project:

a. In addition to the above requirements described in step 1, the eBridge SmartForm and associated documents should describe the duties and activities of the MCW/FH/Versiti/CW PI as Principal Investigator of the entire project. The SmartForm should include the following:
    i. Description of the Principal Investigator's responsibilities
    ii. A list of all performance sites in the eBridge PRO SmartForm
    iii. Plan for communicating changes to the protocol, interim analysis results, etc. to all performance sites
    iv. Method for assuring all sites have and are using the most current version of the protocol and consent form
    v. Monitoring plan appropriate to the nature of the project for receiving and evaluating subject complaints and protocol events, unanticipated problems involving risks to subjects or others and protocol deviations from performance sites

vi. Process for reporting all UPIRSOs from any site to appropriate institutional and federal officials, as appropriate
vii. If federally funded, documentation that each performance site has an FWA with OHRP on file or documentation of IRB approval at each site.

For non-exempt projects, when MCW is the coordinating center or other sites are relying upon the MCW IRB for review:

a. In addition to the above requirements in step 1, the eBridge PRO SmartForm and associated documents should describe the duties and activities of MCW/FH/Versiti/CW as the coordinating center including:
   i. Description of coordinating center's leadership structure and responsibilities
   ii. A list of all performance sites
   iii. Plan for ensuring the protocol and consent form have been reviewed and approved at each site before the project begins at that site
   iv. Plan for assuring that informed consent is obtained in accordance with HHS regulations
   v. Plan for continuing oversight of the project including: maintaining confidentiality of data, evaluating and responding to subject complaints, ensuring protocol compliance and data accuracy, evaluating problems and adverse events that arise during the project, communicating changes to the protocol, interim analysis results, etc. to all performance sites
   vi. Plan for collection, management, and analysis of data from all sites

Community-based multi-site projects

1. For projects where the MCW/FH/Versiti/CW PI is the Principal Investigator for the entire project, the eBridge PRO application should include:
   a. List of all sites
   b. Description of research activities that will take place on the MCW campus and those that will take place at community-based sites
   c. Description of who will conduct research activities on the MCW campus and who will conduct those at community-based sites. These should be listed in the eBridge SmartForm as project personnel
   d. A protocol that describes the entire project
   e. Recruitment procedures at each site and who will be conducting these
   f. Procedure for obtaining informed consent at community-based sites, if applicable, and who will be conducting the process
   g. Name of individual at MCW/FH/Versiti/CW responsible for evaluating and responding to subject complaints and reporting UPIRSOs
   h. Plan for how new information and changes in the project protocol or consent form will be communicated to all sites
   i. If not federally funded, a letter of support from the community-based sites unless the site has already provided this document as part of an award application.
2. For federally funded projects for which MCW/FH/BCW is the awardee or Coordinating Site, the eBridge IRB application must include all information listed under "when MCW is the Coordinating Center".
3. For federally funded projects directed or initiated by an MCW/FH/Versiti/CW PI and for which a community-based organization receives federal funding via a sub-contract or other mechanism, the organization must have an FWA or contact the HRPP Office to discuss the possibility of an Individual Investigator Agreement.

Continuing Review
The MCW IRB will review the summary of activity for the overall project, including enrollment at the various performance sites.

Other Federal Agency Requirements
For projects which are supported by or receive funding from the Department of Defense (DoD) or a component of the DoD, a formal agreement (MOU or IAA) between organizations that specifies the roles and responsibilities of each party must be provided.

REFERENCES:
N/A

SUPPORTING DOCUMENTS:
IRB SOP: Submitting New Projects

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