



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 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) (i) intervene or interact with living individuals for research purposes; (ii) obtain individually identifiable private information for research purposes, or (iii) obtain informed consent from human subjects; or (iv) receive HHS funds even when all activities are carried out at another institution or by employees of another institution. Determinations on MCW/BCW/FH engagement are made by MCW's 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: A project involving more than one performance site (i.e. at MCW/FH and at non-MCW/FH sites). Examples of multi-site projects include:

1. Community-based project in which activities may or may not be different at each non-MCW location, and all activities are under the direction/supervision of the MCW PI
2. Project conducted at MCW/FH and other institutions for which the MCW PI oversees the conduct of research at all sites and serves as Principal Investigator for the entire project
3. Project conducted at various sites with non-MCW investigator serving as Principal Investigator for the entire project
4. Project conducted at MCW/FH and other institutions and MCW is the coordinating center
Sponsored clinical trial with a PI at each site

Coordinating Center: A Coordinating Center may consist of a group of individual investigators or a single investigator. The Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project. A Coordinating Center may be designated either by a sponsor or by mutual agreement of the participating sites.

Performance/Participating Site: A site whose staff, use of facilities or private records of identifiable individuals, or receipt of HHS funds make the site engaged in the conduct

of research. A performance site is the actual place where the research activity takes place (e.g. clinic, hospital, community center). The performance site's location may be different from the location where the IRB review takes place.

PROCEDURE

1. Multi-site projects must complete and submit an eBridge SmartForm in accordance with the *IRB SOP: Submitting New Projects*. The 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, 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. For more than minimal risk projects, an explanation of the plan for continuing oversight of subject safety, name of individual at MCW 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 SmartForm:
 - a. MCW IRB is the Reviewing IRB 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.
3. **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 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 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.
4. **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 SmartForm and associated documents should describe the duties and activities of MCW 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
5. For community-based multi-site projects where the MCW/FH/BCW PI is the Principal Investigator for the entire project, the IRB 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 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.

For federally funded projects for which MCW/FH/BCW is the awardee or Coordinating Site, the IRB application must include all information listed in step 3.

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

Effective Date: 06/15/2018
Version number: 4.0
Previous Version/date: 3.0; 06/01/2016
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