**MULTI-SITE PROJECTS AND INVESTIGATOR RESPONSIBILITIES**

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

Applies to: Faculty and Staff involved in human research

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**PURPOSE:**
To define the scope of MCW IRB oversight, to outline the responsibilities of investigators when participating in or leading multi-site research, and to describe information to be provided to the

A clinical trial conducted at forty different sites in the United States, even though the non-MCW sites may pursue IRB review independently.
A project conducted at a social services agency in Milwaukee, or in a Milwaukee neighborhood.

**Participating/Performance 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.

**Reviewing IRB/IRB of Record:** The IRB responsible for review of research involving a participating site. If the Reviewing IRB for non-MCW sites is the MCW IRB, a Reliance Agreement must be in place. See IRB SOP: *Reliance Agreements for Multi-site Projects.*

**Safety Monitoring Site:** Some projects designate a person, committee, or board (e.g. "Data Safety Monitoring Board") to specialize in monitoring, reviewing, and analyzing adverse events and unanticipated safety/rights/welfare problems for the entire project.

**MCW IRB Oversight:**
The MCW IRB defines its scope of oversight jurisdiction to include:

Human subject research activities conducted at MCW.
Human subject research activities conducted or initiated by MCW employees or agents at any other site.
Human subject research activities that make use of any MCW resources other than faculty or employee time commitment.

All projects meeting these criteria must be submitted to the MCW IRB for review and approval. If an investigator wishes MCW to rely upon a non-MCW IRB for review and approval of a project, consult the IRB SOP: *Reliance Agreements for Multi-Site Projects*.

Froedtert Health, Versiti and Children's Wisconsin have assigned the IRB review and approval of human subjects research to the MCW IRB. In addition, Froedtert Health and Versiti have assigned decisions to defer IRB review to an external IRB to the MCW HRPP. Children's Wisconsin HRPP maintains review and oversight of projects involving Children's Wisconsin resources, and makes their own decisions when deferring to an external IRB is required and for a limited number of other projects. Questions regarding MCW IRB oversight jurisdiction should come to the MCW HRPP Office.

**PROCEDURE:**
**Requesting reliance/deferral:** When requesting that MCW/FH/Versiti rely upon another IRB for review of a project or that an outside institution, agency, or other entity rely upon the MCW IRB, an investigator must follow the procedures outlined in the IRB SOP: *Reliance Agreements for Multi-Site Projects.*

**Sub-contracts or service agreements:** When different institutions are conducting portions of a single federally funded non-exempt human subjects research project, a portion of the project on the MCW campus that is sub-contracted or which has a service agreement cannot by considered exempt. The entire project must meet one or more of the exemptions in order for the exemptions to apply to a sub-contracted or service agreement portion of a project.

**IRB Submission**
For multi-site projects, the IRB must review information about what research activities will be conducted on this campus and information about the entire project in order to understand how the MCW/FH/Versiti/CW investigators' activities fit within the entire project. The breadth of information needed by the IRB is dependent upon the investigator's role and will increase as the investigator's responsibilities to the entire project increase. The list of required information below is <u>in addition</u> to that required for all new projects. See IRB SOP: *Submitting New Projects*.

In the following cases, the IRB application must pr

- Not under the jurisdiction of an IRB that has approved their project activities.

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a. The MCW/FH/Versiti/CW PI must submit study changes to the MCW IRB as outlined in the IRB SOP: *Amendments.*
b. The MCW/FH/Versiti/CW PI must provide a report on the progress of the project to both the MCW IRB and the Principal Investigator for the entire project.
c. The MCW/FH/Versiti/CW PI must report reportable events to the MCW IRB as outlined in the IRB SOP: *Requirements for Reporting to the IRB*.

<u>IRB review has been ceded to an outside IRB:</u>

a. The MCW/FH/Versiti PI must submit local changes as outlined in the IRB SOP: *Reliance Agreements for Multi-Site Projects.*
b. The MCW/FH/Versiti PI must report on the progress of the project to the Principal Investigator for the entire project and the reviewing IRB per their policies.
c. UPIRSOs, serious and/or continuing non-compliance, and protocol violations must be reported to the reviewing IRB per their policies. The MCW HRPP Office must also be notified as outlined in the IRB SOP: *Reliance Agreements for Multi-Site Projects.*