MCW Office of Research
Standard Operating Procedure

INSTITUTIONAL AUTHORIZATION AGREEMENTS AND OTHER REVIEW MECHANISMS FOR MULTI-CENTER STUDIES

Unit: Human Research Protections Program (HRPP), Office of Research
Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE:
Medical College of Wisconsin/Froedtert Hospital (MCW/FH) Institutional Review Boards (IRBs) provide oversight for all human subject research conducted by MCW faculty, fellows, residents, staff or students. This policy describes efficient review mechanisms available when research conducted by Medical College of Wisconsin or Froedtert Hospital personnel is subject to parallel oversight by the IRBs of other institutions.

DEFINITIONS:
IRB of Record: The IRB responsible for review and continuing oversight of a study.

Federalwide Assurance (FWA): The only type of assurance currently accepted and approved by OHRP. Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46

PROCEDURE:
1. MCW SOPs define when MCW faculty, fellows, residents, staff or students engaged in research activity must submit a written research plan to the MCW/Froedtert Hospital IRB for prior approval and oversight, summarized as follows:
   - Studies conducted anywhere on the premises of MCW or Froedtert Hospital (FH); or
   - Studies utilizing the resources of MCW or Froedtert Hospital; or
   - Studies conducted by MCW faculty, or by MCW or Froedtert Hospital employees or students anywhere in the world.

2. In situations where one or more other institutions (beyond MCW and Froedtert Hospital) has IRB jurisdiction over an MCW investigator's research study, there is the potential for several different IRBs to have parallel jurisdiction over the same study, or parts of the same study. Multiple IRB reviews of the same study may represent unnecessary duplication of effort. In the situation where one of the IRB limits its review to a small part of a larger study, that IRB review may be disadvantaged because of its partial understanding of the entire study.

3. Therefore, when more than one institution has IRB jurisdiction over an MCW investigator's research study, the MCW/FH IRB will be receptive to proposals to consolidate the IRB review process by executing Institutional Authorization Agreements with other involved institutions, so that a single IRB review might suffice on behalf of all. Agreements that encompass more than one research study may also be considered by the MCW/FH IRB.
4. The MCW/FH IRB recommends that investigators contact the IRB as soon as they’re aware of the involvement of other institutions. This will facilitate the IRB review process between all involved institutions.

5. When candidate studies have been identified, the Human Research Protections Program Director or designee will review the study in question and initiate discussions with their counterparts at the other involved IRBs. The questions to be decided are:
   - Are the other involved IRBs interested in the possibility of a deferral?
   - What research-related activities are occurring at which locations?
   - What subjects are involved and where will they be recruited from?
   - What is the source of funding?
   - Which site will serve as the coordinating site?
   - What is the role of the MCW investigator?
   - Which institution is in the best position, or has the most expertise, to deliver an optimal IRB review on behalf of all parties?
   - Which institutions are willing to defer IRB review to the selected institution by means of an Institutional Authorization Agreement?
   - Do all the institutions or organizations have a currently registered Federalwide Assurance (FWA)?

6. The final decision is an administrative judgment on the part of the Human Research Protections Program Director or designee, who will consult with the IRB Chairs for guidance as needed.

**Investigator Responsibilities under an IRB Authorization Agreement:**

1. The PI is responsible for initiating the IAA process by submitting a completed *IRB Form: Coordinated IRB Review Request Form* to the IRB Office. The IAA must be executed and appropriate IRB approval must be documented before study activities can begin.

2. When conducting research at another institution when MCW/FH serves as the IRB of record, PIs are required to comply with MCW corporate policies and MCW HRPP policies as well as the policies of the institution at which the research is conducted. Random audits may be conducted by the Quality Improvement unit of the MCW HRPP to assist the IRB in its determinations regarding compliance.

3. When conducting research at another institution when MCW IRB is not the IRB of record, PIs are required to comply with the policies of the institution at which the research is conducted as well as MCW corporate policies and MCW HRPP policies. Random audits may be conducted by the Quality Improvement unit of the MCW HRPP to assist the IRB in its determinations regarding compliance.

4. When conducting research at FH, investigators must follow all FH corporate policies.

5. Investigators are responsible for assuring that institutional requirements are met in regard to human subjects protections training, Safety Committee reviews, FH OCRICC review (Office of Clinical Research and Innovative Care Compliance) and any other MCW or FH institutional requirement.

6. Unanticipated problems involving risks to subjects or others (UPIRSoS) must be reported to the IRB of Record and the MCW/FH IRB according to the *IRB SOP: Requirements for Report to the IRB*. 

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7. If the IRB of Record is not MCW/FH IRB, initial and continuing review IRB approval letters from the IRB of Record must be provided to the MCW/FH IRB Office.

IAA Procedures when MCW/FH IRB is the IRB of Record:

1. The Principal Investigator (PI) may request that MCW/FH serve as the IRB of Record. To begin this process the PI may apply for an IAA using the IRB Form: Coordinated IRB Review Request Form and submit it to the MCW/FH IRB. The request will be initially reviewed by the Director of the Human Research Protection Program (HRPP) or designee to determine if the IAA request is appropriate.

2. The Coordinated IRB Review Request Form will include information about the protocol and location of all research-related activities. Funding sources, subject pool, local context, institutional liability, study-related activities, and relationship with the involved IRB(s) will be evaluated in considering which institution will serve as the IRB of Record.

3. The HRPP Director or designee will be the responsible party at MCW for approving an investigator’s request for an IAA.

4. Once MCW and other identified Institutions engaged in the research have agreed upon MCW/FH serving as the IRB of Record, the MCW HRPP office will draft a formal IAA. The IAA may include any additional conditions regarding oversight including:
   - documenting whether collaborating IRBs require a facilitated review,
   - provision of IRB specific documents (i.e. IRB Approval letters, IRB meeting minutes, Continuing Review Reports, Unanticipated problems or Serious or Continuing Noncompliance),
   - documenting that MCW/FH HRPP may conduct on-site reviews and
   - identifying any limitations of oversight

5. The completed IAA will then be forwarded to the Institutional Official for all sites involved in the deferral process for review and signature. The original will be kept by the MCW HRPP office and copies will be forwarded to the identified Institutions.

6. A spreadsheet of executed IAAs will be maintained by the IRB Office.

IAA Procedures for when a Another Institution’s IRB will serve as the IRB of Record:

1. A Principal Investigator (PI) may request that another institution’s IRB serve as the IRB of Record. To begin this process the PI may apply for an IAA using the IRB Form: Coordinated IRB Review Request Form and submit it to the MCW/FH IRB Office. The request will be initially reviewed by the HRPP Director or designee to determine if the IAA request is appropriate.

2. The HRPP Director or designee will be the responsible party at MCW for approving an investigator’s request for an IAA in which another institution’s IRB will serve as the IRB of Record for a protocol.

3. Once the HRPP Director or designee and other identified Institutions engaged in the research have agreed upon the IRB of Record, the MCW HRPP office will review a formal IAA as drafted by the IRB of Record’s Institution or the MCW/Froedtert IRB. With agreement by the HRPP Director or designee, the IAA may include additional conditions regarding oversight such as:
documenting whether MCW/FH IRB requires a facilitated review,
provision of IRB specific documents (i.e. IRB Approval letters, IRB meeting minutes, Continuing Review Reports, Unanticipated problems or Serious or Continuing Noncompliance),
documenting that the IRB of Record may conduct site reviews at MCW/FH HRPP, or
identifying any limitations of oversight.

4. Although MCW IRB may not be the IRB of record, MCW HRPP office maintains responsibility for some oversight for any human subject research initiated by MCW faculty, fellows, residents, staff or students. The HRPP office will track all IIAAs to assure initial and continuing approval and to ascertain if any unanticipated problems or activities involving noncompliance have occurred. Unanticipated problems (UP) must be reported to the MCW/FH IRB immediately by the PI and IRB of record. If a UP is reported, the HRPP Director will work with the involved IRB(s) to address the issues raised as appropriate.

**Individual Investigator Agreements (IIA):**

1. An Individual Investigator Agreement is an agreement used by investigators who are collaborating with an MCW investigator on research overseen by the MCW/FH IRB and who
   - are not affiliated with MCW or FH;
   - will be conducting collaborative research activities outside of MCW or FH; and
   - are employed by an institution that does not have an FWA (Federal Wide Assurance) OR are not acting as an employee of any institution with respect to his or her involvement in the research.

This mechanism does not apply if the collaborating investigator's institution is the primary awardee of federally-funded human subject research or is awarded a federal subcontract.

**Principal Investigator Responsibilities Under an Individual Investigator Agreement**

The PI is responsible for assuring that the collaborating investigator has complied with all stipulations in the IIA for reviewing *The Belmont Report*, the HHS regulations for the protection of human subjects, and relevant institutional policies and procedures for protection of human subjects. The PI must also assure that the collaborating investigator has completed CITI training as required by MCW, has provided evidence of completion, and understands all requirements in the document.

**Procedures:**

1. An IIA may be submitted with a new MCW/FH IRB application or with an amendment to an existing MCW/FH IRB approved study.

2. The PI should describe the collaborating investigator's involvement in the research study and where these activities will take place in the eBridge application.
   - The following must be submitted when requesting an IIA:
     - the completed Individual Investigator Agreement Form
     - evidence of the collaborating investigator's human subject training
     - a letter of support from the collaborating investigator's institution if the collaborating investigator is an employee or agent of that institution. This letter of support must state that the institution is aware and supports the research activity taking place at their site.
3. The HRPP Director or designee will be the responsible party at MCW for approving an investigator's request for an Individual Investigator Agreement.

4. Individual Investigator Agreements when reviewed and approved by the HRPP are approved for a period of three (3) years. Prior to expiration of the IIA, the HRPP office will contact the PI to determine if the collaborating investigator is still involved in the study. If the collaborating investigator is still involved in the research activity, a new Individual Investigator Agreement will be required.

5. If a collaborating Investigator's role ends with a study the MCW/FH PI will submit an amendment to the study via eBridge stating that the collaborating investigator is no longer involved with the study. This amendment should include any revisions to study documents if applicable.

REFERENCES:
45 CFR 46.114
21 CFR 56.114
FDA Information Sheets: Non-Local IRB Review

SUPPORTING DOCUMENTS:
IRB Form: Coordinated IRB Review Request Form
IRB Form: Individual Investigator Agreement

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