



MCW Office of Research Standard Operating Procedure

PROJECTS DEFERRED TO NATIONAL CANCER INSTITUTE CENTRAL IRB (NCI CIRB)

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

Applies to: Faculty and Staff involved in human research

PURPOSE:

An institution participating in a cooperative project may enter into a joint review arrangement to avoid duplication of effort. To this end, MCW has entered into an Agreement with NCI CIRB that allows NCI CIRB to provide IRB review and oversight for cooperative group projects.

This policy pertains to MCW faculty who wish to conduct NCI CIRB approved protocols with NCI CIRB as the IRB of record. Appropriate information must be submitted to the MCW HRPP Office for deferral notification.

DEFINITIONS:

Local context: state and local laws, policies and conventions, community and/or cultural differences, institutional requirements, consent form template language

Internal Event: an event that occurs at and is limited to the Medical College of Wisconsin, Froedtert Hospital, Froedtert and Medical College of Wisconsin Community Physicians Health Centers and Clinics, Community Memorial Hospital, and St. Joseph's Hospital in West Bend.

Internal Adverse Event (AE): any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of any project procedure or treatment, regardless of whether it is considered related to the project procedure or treatment.

Internal Serious Adverse Event (SAE): an adverse event that (1) results in death, (2) is life-threatening, (3) requires inpatient hospitalization or prolongation of existing hospitalization, (4) results in persistent or significant disability/incapacity, (5) results in a congenital anomaly/birth defect, or (6) is an important medical event that jeopardizes the subject or requires medical intervention to prevent one of outcomes listed above.

Internal Unanticipated Problem Involving Risks to Subjects or Others (UPIRSOs): any incident, experience, or outcome that meets **all** of the following criteria:

1. Unanticipated (in terms of nature, severity, or frequency) given (a) the research procedures described in the protocol-related documents, such as the IRB-approved research protocol and informed consent, Instructions of Use/Device Manual and/or Investigator's Brochure; and (b) the characteristics of the subject population being studied;
2. Related or possibly related to participation in the research or test article (in this guidance document, *possibly related* means there is a reasonable possibility that

- the incident, experience, or outcome may have been caused by the procedures involving in the research);
3. Suggests that the research places subjects or others at a greater risk of harm (including *physical, psychological, economic, or social harm*) than was previously known.

PROCEDURE:

Guidelines for submitting new projects to the MCW HRPP Office

1. Check NCI CIRB website to ensure project has NCI CIRB approval and is Group Activated.
2. Assure that the *Annual Principal Investigator Worksheet About Local Context* has been submitted to CIRB.
3. Complete the SmartForm in eBridge for CIRB projects.
 - a. In section 3.1, choose “Deferral to NCI CIRB”
4. Upload the following documents in section 52.1.
 - a. Most current following documents from the NCI CIRB website:
 - i. Approval letter
 - ii. NCI CIRB approved full Protocol
 - iii. NCI CIRB approved consent form
 - b. MCW Safety Committee approval(s)
 - c. Local Advertising or other recruitment materials, if applicable
 - d. Local Consent Form that incorporates the CIRB approved consent form with the MCW-NCI CIRB boilerplate language

Guidelines for opening new projects with CIRB

1. Receive the acknowledgment letter from the MCW HRPP Office indicating that a new CIRB project will be opened at MCW/FH
2. Complete and submit the *Study-Specific Worksheet About Local Context* using the IRBManager program on the CIRB website.
3. When CIRB approves the *Study-Specific Worksheet About Local Context*, CIRB is the IRB of Record for this project and project-related activities can be initiated.

Guidelines for submitting local updates to the MCW HRPP Office

Submit through eBridge to the MCW HRPP Office local changes for:

1. PI changes
 - Also submit a signed MCW *Agreement of Investigator Responsibilities* form
2. Project staff changes
3. Additional Safety Committee review

Guidelines for submitting local Reportable Events

1. Report the following to CIRB using the *Potential Unanticipated Problem and/or Noncompliance* form using IRB Manager on the CIRB website:
 - a. Internal suspected UPIRSOs that are also AEs or SAEs
 - b. Internal suspected UPIRSOs that are **not** also AEs or SAEs
 - c. Internal potential serious or continuing noncompliance
2. Report the following to the MCW HRPP Office through eBridge:
 - a. Internal UPIRSOs that are **not** also AEs or SAEs, for example stolen laptop, security breach
 - b. Internal events that CIRB determines are UPIRSOs
 - c. Internal potential serious or continuing noncompliance
 - d. Internal subject complaints
 - e. All audit reports from the local site, including those from CIRB, cooperative groups, or the FDA

Audits

1. The MCW Human Research Protection Program QA/QI team will include CIRB projects in the routine review program.
2. Per the IRB *Authorization Agreement/Division of Responsibilities*, CIRB may conduct audits or consent observations of projects deferred by MCW to CIRB.

Requirements for closing a project

1. Notify the MCW HRPP Office of project closure at this site using eBridge.
2. Upload the letter from CIRB or the cooperative group indicating that the project is closing at this site. The CIRB closure letter must be provided when submitting the closure notification.

Investigator Responsibilities

1. Initiate research or enroll any subject only after receiving notification from NCI CIRB that the *Study Specific Worksheet about Local Context* has been approved.
2. Initiate amendments or changes to an approved protocol only after NCI CIRB review and approval, except where necessary to eliminate apparent immediate hazard to the subject. Changes in PI, project staff, or other changes that require Safety Committee review must be submitted to the MCW HRPP Office prior to implementation.
3. Follow MCW and FH corporate policies and requirements for conducting research.
4. Contact the FH Office of Clinical Research and Innovative Care Compliance (OCRICC) before initiating project activities.
5. Conduct the project in accordance with MCW IRB and NCI CIRB policies, federal and state regulations, and cooperative group policies.
6. Notify CIRB and the MCW HRPP Office of reportable events as described in this policy.
7. Submit the *Annual Principal Investigator Worksheet About Local Context* annually for each PI conducting research that is, or will be, deferred to NCI CIRB.
8. Maintain project and regulatory files according to NCI CIRB, federal, and institutional policies.
9. Notify the MCW HRPP Office of amendments as described in this policy.
10. Notify MCW IRB of project termination or completion.

REFERENCES:

N/A

SUPPORTING DOCUMENTS:

MCW Informed Consent Templates

MCW Agreement of Investigator Responsibilities

NCI CIRB Authorization Agreement/Division of Responsibilities

NCI CIRB Annual Principal Investigator Worksheet About Local Context Form

NCI CIRB Study-Specific Worksheet About Local Context Form

NCI CIRB Potential Unanticipated Problem and/or Noncompliance Form

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