

- 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 NCI CIRB.
3. Complete the NCI CIRB reliance SmartForm in eBridge.
 - a. In SmartForm section for Project Category, choose "Research Project requesting reliance on another IRB".
 - b. Choose "NCI CIRB" as the proposed reviewing IRB.
4. Answer all the questions and upload all documents prompted by the SmartForm.

Guidelines for opening new projects with NCI CIRB

1. Receive the acknowledgment letter from the MCW HRPP Office indicating that a new NCI 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 NCI CIRB website.
3. When NCI CIRB approves the *Study-Specific Worksheet About Local Context*, NCI CIRB is the IRB of Record for this project and project-related activities can be initiated.

Guidelines for submitting local changes to the MCW HRPP Office

Submit the following through eBridge using the 'Request Local Change' activity of the processed PRO SmartForm:

1. Change in PI
2. Significant updates intended to keep the SmartForm current
3. Requesting review of a new consent form
4. Requesting review of a revised consent form that has updates to the MCW templated sections
5. Requesting changes to the method of consenting
6. Significant change to the involvement of MCW/FH/Versiti
7. Changes related to access of Protected Health Information (PHI), such as adding screening medical records for recruitment or adding the use of medical records.

The MCW IRB does NOT need or want every protocol amendment for the project. These should only be submitted to the IRB of record for approval.

Updates to project team members should be made in eBridge using the 'Update My Project' activity in the processed PRO SmartForm.

Guidelines for submitting local Reportable Events

1. Report the following to NCI CIRB using the *Potential Unanticipated Problem and/or Noncompliance* form using IRB Manager on the NCI 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 using the 'Open New Reportable Event' activity in the processed PRO SmartForm. ONLY events which meet the prompt reporting criteria must be reported to MCW within 5 calendar days per *MCW IRB SOP: Requirements for Reporting to the IRB*. This generally includes:
 - a. Unanticipated problem involving risks to subjects or others (UPIRSO) that occur locally.
 - b. Notice from the sponsor or DSMB/Safety Committee that describes new information regarding risks or unanticipated problems involving risks to subjects or others (UPISRO)
 - c. Serious or continuing noncompliance
 - d. Suspension or termination of research

Other events do not need to be reported to the MCW IRB such as anticipated adverse events, minor deviations or miscellaneous reports. These only need to be reported to the IRB of record per their policies.

Audits

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

Requirements for closing a project

1. Notify the MCW HRPP Office of project closure at this site using eBridge via the 'Request to Close Project' activity.
2. Upload the letter from NCI CIRB or the cooperative group indicating that the project is closing at this site. The NCI 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. Submit the *Annual Principal Investigator Worksheet About Local Context* annually for each PI conducting research that is, or will be, deferred to NCI CIRB.
4. Follow all other Investigator responsibilities as outlined in *MCW IRB SOP: Reliance Agreements for Multi-site Projects*.

REFERENCES:

N/A

SUPPORTING DOCUMENTS:

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

IRB SOP: Reliance Agreements for Multi-site Projects

IRB SOP: Requirements for Reporting to the IRB.

Effective Date: 04/28/2023
Version number: 6.0
Previous Version/date: 5.0, 06/15/2018
Responsible office: HRPP Office
Approval Date: 04/14/2023

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