



MCW IRB Committee Procedures

REVIEW OF REPORTABLE EVENTS

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

Applies to: Institutional Review Board Committees

PURPOSE:

This procedure outlines the steps taken when a reportable event submission will be reviewed by the Medical College of Wisconsin (MCW) Institutional Review Board (IRB) either by expedited review or convened Committee and the expectations of the IRB members assigned as primary and/or secondary reviewers.

DEFINITIONS:

N/A

PROCEDURE:

Review of Reportable Events by the Convened IRB

1. At the time of review, the IRB Chair and/or IRB Committee considers the reportable event submission as a description of an event which met the prompt reporting requirements as described in *IRB SOP: Requirements for Reporting to the IRB* and will be reviewed in accordance with regulatory and institutional requirements.
2. The IRB Coordinator II (C2) assigns the eBridge reportable event submission to one or two IRB member(s) who are responsible for leading the discussion when the Committee reviews the submission in accordance with *Staff: Assigning Primary Reviewers and the Use of Consultants*.
3. The IRB C2 will provide to the Primary Reviewer and the other Committee Members access to the following documents:
 - a. The Protocol, if applicable
 - b. The Consent Form, if applicable
 - c. Safety Reports, Data Safety Monitoring Board/Data Monitoring Committee (DSMB/DMC) reports, Investigator Brochures (IBs), notifications from Sponsors (if applicable)
4. The Primary Reviewer performs an in-depth review of all the information included in the eBridge SmartForm and documents their review using the *IRB Member Form: Reportable Events Checklist*.
5. All other IRB Committee members are expected to review key documentation from the information submitted to the IRB Committee in the reportable event submission to the extent necessary to be prepared to participate in the discussion of the regulatory criteria for monitoring approved human subject research.
6. If the assigned Primary Reviewer, the IRB Chair or HRPP director determines that additional expertise is needed for review of the event, an appropriate consultant will be invited to assist in the review of the research in accordance with *Staff: Assigning Primary Reviewers and the Use of Consultants*.
7. Following the presentation, the Primary Reviewer makes a motion for the IRB Committee's vote as outlined in *IRB Member SOP: IRB Actions* and opens the floor for discussion among the members. At the end of the discussion the IRB Chair will call for a vote.

- a. If additional information, or a modification is required, the project team should respond within the identified timeframe or no later than 30 days to the IRB's request.
8. The IRB Committee must determine if the event represents or does not represent either an unanticipated problem involving risk to subjects or others or serious and/or continuing noncompliance. The IRB will use the following criteria in its determination:
 - a. **Unanticipated problems involving risk to participants or others (UPIRSO):**
 - i. Any incident, experience, or outcome that meets all of the following criteria:
 - 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 document, Instructions for Use/Device Manual and/or Investigator's Brochure; and (b) the characteristics of the subject population being studied;
 - related or possibly related to participation in the research (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 involved in the research) or test article; and
 - 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 or recognized.
 - b. **Serious non-compliance.** Serious non-compliance is defined as failure to follow any of the regulations and policies described in this document or failure to follow the determinations of the IRB and which, in the judgment of either the IRB Chair or the convened IRB, increases risks to subjects, decreases potential benefits, or compromises the integrity of the human research protection program.
 - c. **Continuing non-compliance.** Continuing non-compliance is defined as a pattern of non-compliance that, in the judgment of the IRB Chair or convened IRB, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.
9. If the IRB Committee determines that the reportable event submission constitutes an UPIRSO or Serious and/or Continuing Noncompliance, the IRB Chair and the IRB C2 will notify the HRPP Director of this determination. The HRPP Director will notify the Institutional Official and report the event to the required regulatory agencies in accordance with *Staff: Correspondence with and Reports to Federal Agencies*

Expedited Review of Reportable Events

1. The IRB C2 will identify if a reportable event submission may qualify for expedited review by either the IRB Chairperson or a designated IRB reviewer based upon *IRB SOP: Requirements for Reporting to the IRB*.
2. The IRB C2 will complete his/her review and upload the *C2 Review Checklist for Reportable Events (RE)* with his/her notes.
3. The IRB C2 will assign the reportable event to the IRB Chairperson or designated reviewer to complete the review.
4. The IRB Chair or designated reviewer will review the *C2 Review Checklist for Reportable Events (RE)* and the reportable event submission along with any additional documents submitted for the event.

5. The IRB Chair or designated reviewer will make a determination if the event appears to meet the criteria for either an UPIRSO or serious and/or continuing noncompliance.
 - a. If the event represents an external UPIRSO or external serious and/or continuing noncompliance, the IRB Chair or designated reviewer may choose to either acknowledge the event or forward the event to the convened Committee for review.
6. The IRB Chair or designated reviewer will complete the IRB Reviewer section of the *C2 Review Checklist for Reportable Events (RE)* and indicate their decision via eBridge:
 - a. to acknowledge the event, or
 - b. require modifications, or
 - c. forward the event for review by the convened Committee, as the event represents to be an internal UPIRSO or internal Serious and/or Continuing Noncompliance.
7. The C2 based upon the IRB Chair or designated reviewer's determination will either:
 - a. Forward the event for the convened Committee to review
 - b. Issue an acknowledgement letter
 - c. Request the identified modifications

REFERENCES:

N/A

SUPPORTING DOCUMENTS:

IRB SOP: Requirements for Reporting to the IRB
Staff: Assigning Primary Reviewers and Use of Consultants.
IRB Member Form: Reportable Events Checklist
IRB Member SOP: IRB Actions
Staff: Correspondence with and Reports to Federal Agencies
C2 Review Checklist for Reportable Events

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