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 (RE) submission to one or two IRB member(s) who are responsible for leading the discussion when the Committee reviews the submission in accordance with *IRB Member SOP: Assigning Reviewers and the Use of Consultants*.
3. The Primary Reviewer and the other Committee Members access to the following documents within eBridge:
    a. The Protocol, if applicable
    b. The IRB approved 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 eBridge RE 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 *IRB Member SOP: Assigning 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.
8. 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.

9. 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. When there is an action or omission taken by an investigator that shows disregard or violation of federal regulations or institutional policies applicable to human subject research that demonstrably increases risks to human subjects, adversely affects the rights and welfare of human subjects, or compromises the integrity/validity of the research.

- The IRB does not have to find that harm has occurred, or was likely to occur, to make a determination of serious noncompliance
- Failure to obtain IRB approval of human subjects research when required under HRPP or applicable laws and regulations constitutes serious noncompliance.
- Multiple instances of noncompliance that are deemed not-serious individually may constitute serious noncompliance when considered collectively.
- The IRB may consider mitigating factors such as corrective action, that play a role in the determination of whether the event increased risk, decreased potential benefits or negatively affected the integrity/validity of the research. If despite these factors, the event's occurrence meets the definition of serious noncompliance, then the event should be categorized as such.

c. Continuing non-compliance. When there is a pattern of repeated noncompliance that continues after initial discovery, including inadequate efforts to take corrective actions within a reasonable timeframe. Examples include a pattern of behavior that evidences a lack of attention to research or knowledge of the regulations or institutional policies HRPP, or the protection of research participants or that is likely to continue without intervention.

- Continuing noncompliance also includes failure to respond to a request to resolve an episode of noncompliance

10. If the IRB Committee determines that the eBridge RE 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.
11. 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 an eBridge RE submission may qualify for expedited review by either the IRB Chair or a designated reviewer based upon *IRB SOP: Requirements for Reporting to the IRB*.
2. The IRB C2 will complete their review and upload the *C2 Review Checklist for Reportable Events (RE)* with their notes.
3. The IRB C2 will assign the reportable event to the IRB Chair 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 eBridge RE 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 Full Committee for review.
    b. If the event represents an internal UPIRSO or serious and/or continuing noncompliance, the IRB Chair or designated reviewer should forward the event to the convened Full 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. Acknowledge the event, or
    b. Require modifications, or
    c. Forward the event for review by the convened Full 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
IRB Member SOP: Assigning 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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