

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

a. If additional information, or a modification is required, the project team

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: