USE AND REQUESTS TO QUALITY ASSURANCE/QUALITY IMPROVEMENT

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

Applies to: Institutional Review Board Committees

PURPOSE:
To outline and define the various activities and actions the IRB committees have in

1. The QI Specialist conducts routine reviews of approved projects under the oversight of MCW IRB, in accordance with *Staff: Routine Review: The Process of Routine Reviews*
2. The QI Specialist in the course of the Routine Review evaluates the following areas as applicable:
    a. Regulatory file
    b. Documentation of research related events
    c. Observation of the consenting process, if applicable
    d. Compliance with MCW policies and procedures regarding human subject research
3. Upon completion of the review, QI Specialist will create a final summary in accordance with *Staff: Routine Review: The Process of Routine Reviews* and submit the information to the Investigator and project team.
4. A copy of the final summary and, if applicable, the Investigator's Corrective Action Plan is uploaded in eBridge.
5. In the event there are findings from the review that require corrective actions, the final summary and corrective action plan will be sent to the IRB Chair for their review and determination.
    a. If the findings from the review that may represent serious noncompliance and/or unanticipated problems involving risks to subjects or others (UPIRSO) the QA/QI team will notify the HRPP Director and IRB Chair.
6. The IRB Chair will review the final summary and corrective action plan and decide upon one of the following actions based upon the report:
    a. Acknowledge
    b. Request changes
    c. Forward to Convened Committee
7. Investigators will report to the IRB whether a Routine Review occurred during the reporting period with the next Continuing Progress Report (CPR).
8. The IRB Committee or designated reviewer will review the final summary, and if applicable the Investigator's Corrective Action Plan (CAP), in conjunction with the progress report review and determine if the criteria for approval are still being met.

Observation of Research Activities, Consenting Process

1. Upon initial approval or over the course of a project, the IRB Committee may request observation of a research related activity, including the consenting process to ensure that it is being conducted in accordance with MCW policies and procedures.
2. The IRB Committee will determine this as a course of action and will notify the Investigator of this decision via the IRB decision letter. The HRPP Director and QI Manager will be copied on this letter regarding the IRB Committee's decision and notification will be sent to the QI Manager.
3. Upon receipt of notification, the QA/QI team will contact the Investigator and project team to schedule this activity.
4. Upon completion of the observation, the QI Specialist will submit a report to the requesting IRB Committee and provide a copy of the summary to Investigators.
5. The IRB Committee will review the summary and determine if further actions are required.

For-Cause Audits

1. Upon review of a CPR, a reportable event, an amendment or other notification, the IRB Committee may identify issues which require further evaluation. In these instances, the IRB Chair or IRB Committee may determine a need for a review specific activities and request a For-Cause Audit for an approved project.
2. The IRB Chair or Committee will notify the Investigator of the decision via an IRB decision letter. The HRPP Director and QI Manager will be copied on this decision letter.

3. The IRB Chair or Committee will provide information to the QI Manager regarding the concerns, need for verification, and/or questions to be addressed by the For-Cause Audit.
4. The QI Manager will work with the IRB Chair and HRPP Director to outline and identify the necessary audit activities, scope and timeframe for completion, and outline the proposed For-Cause Audit activities.
5. Upon the HRPP Director's authorization to proceed, the QI Manager will contact the Investigator regarding the upcoming audit activities. .
6. The QI Manager or Specialist will contact the Investigator and project team to begin the For-Cause Audit process.
7. When the For-Cause Audit is complete, the QI Manager or Specialist will submit the draft report to the Investigator and the project team for review and comment. A final report will incorporate feedback from the Investigator and project team and be sent to the requesting IRB Chair or Committee.
8. The IRB Committee will review the For-Cause Audit report to determine if further actions are required and provide a written determination letter to the Investigator and project team.

REFERENCES:
45 CFR 46.109(e)
21 CFR 56.109(f)

SUPPORTING DOCUMENTS:
Staff: Routine Review: The Process of Routine Reviews
Staff: Observation of Research Activity Including Informed Consent
Staff: Audit: The Process of a For-Cause Audit

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Approved By