USE AND REQUESTS TO QUALITY ASSURANCE/QUALITY IMPROVEMENT

Unit: Human Research Protections Program (HRPP), Office of Research
Applies to: MCW/FH Institutional Review Board Committees

PURPOSE:
To outline and define the various activities and actions the IRB committees have in requesting or utilizing the HRPP Quality Assurance/Quality Improvement (QA/QI) team to carry out review of project activities and/or audits.

DEFINITIONS:
Routine Review: A Routine Review is a component of the Quality Improvement Program utilized to ensure optimal conduct of human subject research within the framework of institutional policy and regulatory requirements and to provide educational resources to Investigators and members of the study team.

Routine review activities may include: interview with member(s) of the study team, review of project related documentation, feedback regarding review findings, and if applicable, recommendations and corrective actions.

For Cause Audit: Audit activity is initiated in response to a directive received from a MCW/FH IRB Committee, MCW/FH IRB Chair or Director of Human Research Protection Program. Audit activities are reviewed and authorized by the HRPP Director prior to initiation of audit activities.

Audit activity is based upon the question(s) or concern(s) associated with the request for audit. Audit activities may include interviews with member(s) of study team, review of project related documentation and written report to requestor of audit.

PROCEDURE:
Per federal regulations (45 CFR 46.109(e), 21 CFR 56.109(f)) An IRB shall ... have authority to observe or have a third party observe the consent process and the research

1. Under the MCW Human Research Protections Program (HRPP), the Quality Assurance/Quality Improvement (QA/QI) team provides a variety of activities to serve the needs of the research community, IRB Committees and IRB office staff. These include the following:
   • Routine Reviews of approved projects
   • Observation of Consent Process
   • For-Cause Audits

2. During the course of reviewing a submission, the IRB Committee may receive new information regarding the conduct of the project, or may determine the need of a report from QA/QI to determine the extent of an issue identified during review, and how best to address it.
Routine Reviews of approved projects

1. The QA/QI team conducts routine reviews of approved projects conducted by MCW Faculty, in accordance with QI Staff: Routine Review: The Process of Routine Reviews.

2. The QA/QI team in the course of their review evaluates the following areas as applicable:
   - Regulatory file, and documents
   - Subject Files
   - Compliance with MCW policies and procedures regarding human subject research

3. Upon completion of the review, QA/QI will create a final report in accordance with QI Staff: Routine Review Summary.

4. and submit the information to the Investigator and study team.

5. The final report and corrective action plan (if applicable) will be sent to the IRB Committee Chair for their review and acknowledgement of the activities.
   - If the final report identifies a serious and immediate problem or noncompliance with MCW policies and procedures, the QA/QI team will notify the HRPP Director and IRB Chair.

The IRB Committee Chair will review the final report and corrective action plan (if applicable) and will decide upon one of the following actions based upon the report:
   - Acknowledge
   - Request changes
   - Forward to Full Committee

6. Investigators will upload and include any routine review final reports with the next Continuing Progress Report (CPR) if a review occurred during the approval period. The IRB Committee or designated reviewer will review the report and corrective action plan as a part of the CPR submission to confirm the criteria for approval are still being met.

Observation of Consenting Process

1. Upon initial approval or during the course of a project, the IRB Committee may request observation of the consenting process to ensure that it is being conducted in accordance 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 Specialist Manager will be copied on this letter as notification of the IRB Committee's decision.

3. Upon this request, the QA/QI team will contact the Investigator and study team in accordance with QI Staff: Observation of Research Activity Including Informed Consent to begin this activity.

4. Upon completion of the observation, the QA/QI team will submit a report to the Investigator of their findings as described in QI Staff: Observation of Research Activity Including Informed Consent.

5. The QA/QI team will submit a copy of the report to the IRB Committee for their review and deliberation.

For-Cause Audits

1. Upon review of a continuing progress report, a reportable event, an amendment or other notification, the IRB Committee may identify issues which require further evaluation. In these instances, the IRB Committee, or IRB Chair may determine and authorize a For-Cause Audit for an approved project.

2. The IRB Chair and/or IRB Committee should review and specify the exact nature and questions to be addressed by the For-Cause Audit to determine the activities to be...
included in the audit and to identify if additional MCW or FH compliance departments 
may need to be involved.

3. The IRB Chair should provide this information to the HRPP Director.

4. The Investigator will be notified of the IRB committee’s or IRB Chair’s decision via an 
IRB decision letter, with the HRPP Director and QI Specialist Manager copied.

5. The QI Specialist Manager will work with the IRB Chair and HRPP Director to outline 
and identify the necessary audit activities, scope and timeframe for completion.

6. The QA/QI team will contact the Investigator and study team to begin the For-Cause 
Audit process in accordance with QI Staff: Audit: The Process of a For-Cause Audit

7. When the For-Cause Audit is complete, the QA/QI team will draft and submit their 
report to the Investigator and the study team along with the IRB Chair and HRPP 
Director as outlined in QI Staff: Audit: The Process of a For-Cause Audit

8. The IRB Committee will review the For-Cause Audit report to determine if any 
additional actions may be required or if they accept the findings and any identified 
corrective action.

9. The IRB Committee will issue an IRB decision letter indicating additional actions to 
be taken or acknowledging the For-Cause Audit report thus requiring no further 
action at this time.
   - The IRB decision letter will include copies to the QI Specialist Manager and 
   the HRPP Director

REFERENCES:
N/A

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

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