MCW Office of Research
Standard Operating Procedure

QA/QI ROUTINE REVIEW PROCESS

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

Applies to: Faculty and Staff involved in human research

PURPOSE:
The purpose of the Routine Review process at Medical College of Wisconsin (MCW) is to:

1. Verify the conduct, documentation and reporting of research related activities is in accordance with the IRB approved protocol, and applicable federal regulations, tribal laws and other state and institutional policies in addition to the protection of the rights, safety, and welfare of the subjects, and
2. Provide feedback to Investigators, the project team and IRB regarding the conduct, documentation and reporting of the research.

Routine Reviews are conducted on a sample of research projects approved by the MCW IRB, this includes research reviewed by a convened IRB committee, expedited review, and registered projects.

DEFINITIONS:
Corrective Action Plan (CAP): The CAP is developed in response to findings and recommendations provided in the QI Specialist's final summary. The CAP should include action items implemented within 5 calendar days of the filed final summary as well as action items for implemented at other times in response to the final summary findings. The CAP is submitted to the QI Specialist in response to the findings listed in the final summary.

Debriefing: The process of reviewing findings, commending good practices, requesting clarification, identify activities not consistent with policy, protocol, and regulations and outlining follow up activities.

QA Summary : A summation of findings and recommendations documented upon completion of the QI Specialist's onsite routine review activities. The document includes information regarding the review activities, and the subsequent findings.

Routine Review: A Routine Review is a Quality Improvement Program effort to review and verify the conduct and documentation and reporting of human subject research within the framework of institutional policy and regulatory requirements and to identify educational resources for Investigators and members of the project team and provide feedback specific to the research project.

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

    a. No observation of the consenting process will take place if the (prospective) subjects declines.
2. The QI Specialist will meet with the designated member(s) of the project team and will provide the following information at the beginning of the review.
    a. The purpose of the routine review
    b. The activities associated with the routine review
3. The QI Specialist will conduct an initial interview
    a. Review the roles and responsibilities of the members of the project team
    b. Review the conduct, documentation and reporting practices and other activities related to the research project.
    c. Review required HSRP training status for members of the research team
4. The QI Specialist will review the project related documents and document findings of the review on QI worksheets.
    a. The designated member(s) of the project team may be asked to provide clarification or additional information regarding process or documentation.
5. The QI Specialist will meet with the designated member of the project team to discuss initial findings of the review, and if applicable provide recommendations, describe the next set of steps in the Routine Review process and provide an opportunity for research team's questions in the debriefing.
    a. The debriefing meeting occurs upon completion of the Routine Review activities but may be deferred if there is a conflict in scheduling.
6. The QI Specialist will notify the IRB Chair and HRPP Director of findings that may represent serious noncompliance or unanticipated problems involving risk to participants or others (UPIRSO).

Post Review Activities

1. The QI Specialist will provide a written summary of the Routine Review activities and findings to the PI and Primary Contact within one week of completing the Routine Review activities.
    a. The QI Specialist does not provide the project team with a written summary of the review of Registered projects.
2. In the event there were no findings requiring a Corrective Action Plan (CAP), the QI Specialist will forward a final summary to the PI and Primary Contact within one week of completing the Routine Review activities.
3. If the QI Specialist identified findings that require a CAP, the QI Specialist will forward a draft summary to the PI and Primary Contact with a request for the team to review and provide feedback.
    a. The QI Specialist will issue a final summary to the PI and Primary Contact one week after providing the draft summary. The final summary will include the Routine Review findings and recommended corrective actions.
        i. The final summary will include research team's comments and clarifications.
    b. The QI specialist will honor requests for additional review time.
4. The research team will provide the requested CAP to the QI Specialist within 30 days of the final summary.
    a. A reminder will be sent via eBridge if no CAP received in 30 days.
    b. If CAP is not received within 14 days of emailed reminder, the QI Manager will contact the PI and Primary Contact requesting the CAP.
5. Upon receipt of the research team's CAP, the QI Specialist will submit the final summary to the IRB Chair for review and determination.
    a. If no CAP is received after eBridge reminder and QI Manager's request for CAP, the QI Specialist will forward the final summary to the IRB Chair for review and potential follow-up.

6. If applicable, the following parties will be copied on final summaries
    a. TRU Research Subject Advocate, if research is supported by the CTSI (resources or funding)
    b. CW HRPP, if research project involves CW resources, staff and/or patients.
    c. Versiti POC, if researcher is identified as a Versiti researcher by Versiti.
    d. MCW POC and HRPP Office of the relying institution(s) if there is a Reliance Agreements/IRB review in place and MCW IRB is the IRB of record.
    e. The external institutions HRPP Office if the selected research project takes place at more than 1 external location and has separate institution specific IRB review.

Continuing Progress Report