QA/QI ROUTINE REVIEW PROCESS

Unit: Human Research Protections Program (HRPP), Office of Research
Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE: The purpose of the Routine Review is to randomly select a MCW/FH IRB approved project and provide a mechanism to evaluate the conduct of research and ensure that the project is conducted in accordance with the MCW/FH IRB approved protocol, federal regulations and other state and institutional policies in addition to the protection of the subjects’ safety, rights, and welfare and provide feedback regarding the evaluation findings.

DEFINITIONS:
Corrective Action Plan (CAP): The CAP is designed and documented by the Principal Investigator (PI) in response to findings and recommendations provided in QA/QI Routine Review Summary. The CAP should include action items implemented within 5 calendar days of the filed QA/QI Routine Review Summary as well as action items for implementation at the time of the next continuing progress report.

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/QI Routine Review Summary: A summation of findings and recommendations developed upon completion of QA/QI staff’s onsite routine review activities. The document includes information regarding the review findings which are noncompliant with IRB approved protocol, federal regulatory requirements, institutional policy and SOP, and if applicable, GCP and includes as an attachment, a copy of the completed regulatory checklist used in the routine review.

Routine Review: A Routine Review is a Quality Improvement Program effort 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.
PROCEDURE:

Pre review

1. The QI Specialist will notify the Principal Investigator (PI) and Coordinator and the key contact person for that department/division that a project was randomly selected for routine review.
   a. The notification is emailed using the Initial Notification Routine Review one month prior to potential review period.
2. If the QI Specialist does not receive PI’s response within 3 business days of the initial notification, the QI Specialist will issue the Follow up to Routine Review Notification email, to schedule a date/time for the routine review.
3. PI or Coordinator to confirm availability for routine review, (date, time, location, pertinent personnel are available).
4. PI or Coordinator to forward information to QI Specialist concerning the number of subjects consented and the number of research subjects that participated in the project.
5. The QI Specialist will review information received regarding number of individuals consented and participating in the project and identify which consent forms and subject records are required for review in addition to the other documents listed in the Initial Notification Routine Review.
6. The QI Specialist will notify the PI and Coordinator that all records will be required for review.
   a. The QI Specialist will choose which subject files to review based upon the Subject File Selection Decision Tree.
7. The QI Specialist will provide the PI and Coordinator with the Reminder Confirmation email 2 business days prior to the routine review.

Onsite Review Activities

1. The QI Specialist will meet with the member(s) of the study team.
2. The QI Specialist will review with the member(s) of the study team.
   a. The purpose of the routine review
   b. The activities associated with the routine review
   c. Roles and responsibilities of the members of the study team, and the conduct, documentation practices and other activities related to the project related activities using the Routine Review Interview Questions
3. The QI Specialist will review the project related documents using the worksheets created during pre review of the project and document findings of the review on those worksheets.
   a. The QI Specialist will meet with the member(s) of the study team to discuss any questions or concerns regarding the reviewed documentation.
4. The QI Specialist will discuss findings of the review, provide applicable recommendations and describe the next set of steps in the process 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.

Post Review Activities

1. The QI Specialist will email the draft QI Routine Review Summary and a copy of the regulatory checklist used in the routine review activities to the PI and Coordinator within one week of the onsite review.
2. The PI and Coordinator will review the findings and forward comments to the QI Specialist within one week of receiving the draft summary.
3. Upon review of PI's comments, the QI Specialist will incorporate PI's comments into the QI Routine Review Summary and prepare the final version of the summary.
   a. If PI and QI Specialist are unable to agree upon findings, the QA/QI Manager and/or Director HRPP will be included in discussion and resolution.
4. The QI Specialist will email the final QI Routine Review Summary and a copy of the regulatory checklist used in the routine review activities to the PI and Coordinator within one week of issuing the draft summary for PI and Coordinator review.
   a. In addition, a hard copy of the final summary and attachments will be sent to the PI via interdepartment mail.
   b. A copy of the final QI Routine Review Summary will be emailed to the IRB Chair and IRB Coordinator of the overseeing IRB committee, and in the case of findings which require immediate IRB review and action, to the Director of the Human Research Protection Program (HRPP).
      i. For studies that do not require a CAP or studies which require immediate IRB review and action, copies are forwarded to the IRB Chair and IRB Coordinator of the overseeing IRB Committee at the time the final summaries are issued to the PI.
      ii. For routine reviews of studies which require a CAP, copies of the final summary are forwarded to the IRB Chair and IRB Coordinator of the overseeing IRB Committee 30 days after the final summary was issued to the PI.

STUDY TEAM’S FOLLOW-UP ACTIVITIES POST FINAL SUMMARY
Based upon the findings from the routine review, the study team's follow up activities may differ. The QI Routine Review Summary will contain an overall statement which will include information for the study team regarding the routine review findings and include the following:
  1. Routine review results in findings which do not require a corrective action plan;
  2. Routine review results in findings which require a corrective action plan;
  or
  3. Routine review results in findings which require immediate review and action by the IRB.

Routine Review Finding - No Corrective Action Plan Required
For routine review results in which there are no findings that require a CAP, the follow up activity includes the following steps.
  1. Review and file the final QI Routine Review Summary and the attached regulatory checklist with the research related records for that research project.
  2. Include information regarding the routine review in the next progress report to the IRB.

Routine Review Finding – Corrective Action Plan Required for Findings
For routine review results in which there are findings that require the PI to develop a corrective action plan, the follow up activity should include the following steps.
  1. Upon receipt of the final QI Routine Review Summary, the PI and Coordinator should review the document, noting the findings which require a corrective action and the QI Specialist's recommendation for corrective actions.
     a. Any corrective actions recommended by the QI Specialist for implementation within 5 days must be take place within 5 calendar days.
b. Corrective actions which do not require prompt implementation must take place in a timely manner and occur within current approval period.

2. Upon review of the final QI Routine Review Summary, the PI and study team develop a CAP which includes the corrective actions as recommended by the QI specialist, other corrective actions as identified by the PI and members of the study team, and the timeframe for completion of the activities.
   a. Any corrective actions implemented or planned for in response to the QI Routine Review Summary must be represented in the CAP.
   b. The QI Specialist is available to provide assistance to the PI and study team in the development of the CAP.

3. The PI must submit the completed CAP to the QI Specialist within 30 days of the date the final QI Routine Review Summary was issued.
   a. In the event the PI requires more than 30 days to develop, document and submit the CAP, or has questions or concerns regarding the process; the PI or Coordinator must contact the QI Specialist who conducted the onsite review and issued the QI Routine Review Summary.
   b. In the event the PI addressed the finding prior to the release of the Final Summary, this will be considered the CAP and no other documents will be required. A notation will be made in the Final Summary noting the corrective action and the date of the action.

4. The QI Specialist will email a reminder, CAP not Received and Deadline Approaching, to the PI and Coordinator at no later than 3060 days after the final QI Routine Review Summary was issued if the QI Specialist has not received the CAP or been contacted by a member of the study team.

5. Upon the receipt of the CAP, the QI Specialist will review the CAP.
   a. If in agreement with the CAP, the specialist will notify the IRB as outlined below.
   b. If the QI Specialist is not in agreement and changes are needed, the QI Specialist will discuss the CAP with the QI Manager. If changes are needed to the final report, the QI Specialist will make the appropriate changes and return the CAP and edited report to the PI.
   c. The PI will then have 1 week to revise their CAP to address the changes made by the QI Specialist in the final report.
   d. If no response is received within 1 week, the QI Specialist will notify the IRB as outlined below and include the originally submitted CAP.

6. The QI Specialist will forward a copy of the QI Routine Review Summary and the attached regulatory checklist to the IRB Chair and IRB Coordinator of the overseeing IRB committee within 60 days after the final summary was issued to the PI and Coordinator.
   a. A copy of the received PI’s CAP will be included with the documents submitted to the IRB.
   b. In the event the QI Specialist has agreed to the PI’s request for additional time for the development, documentation and submission of the CAP. The QI Specialist may delay the submission of the final summary and the attached regulatory checklist to the IRB up to 14 calendar days.
   c. In the event the QI Specialist has not received the PI’s CAP and has not been contacted by the PI or Coordinator, the QI Specialist will submit the final summary and the attached regulatory checklist to the IRB and indicate the requested CAP was not provided.

7. Upon completion and submission of the CAP the PI must file the CAP and final QI Routine Review Summary and the attached regulatory checklist with the research related records for that research project.

8. The PI must include information regarding routine review and status of the corrective actions listed in the CAP in the next progress report to the IRB.
Routine Review Findings Which Require IRB’s Immediate Review and Action

Any routine reviews of studies with findings which require immediate review and action by the IRB will include the following actions.

1. The QI Specialist will at earliest opportunity notify the Director, HRPP, PI and Coordinator of issue/concern noted during routine review.
2. The QI Specialist will complete the routine review activities including the debriefing meeting.
3. The QI Specialist will email the final QI Routine Review Summary and the attached regulatory checklist to PI, Coordinator, IRB Coordinator and IRB Chair of the overseeing IRB and Director HRPP.
4. The PI must review and file the QI Routine Review Summary and the attached regulatory checklist with the research related records for that research project.
5. The IRB Chair and IRB Coordinator of the overseeing IRB will contact the PI to inform him/her of additional required actions or request a response to QI Routine Review Summary.
6. PI and study team will work with the overseeing IRB regarding the request for additional required actions or response.
7. PI must include information regarding routine review in the next progress report to the IRB

REFERENCES:
45 CFR 46.108
21 CFR 56.108

SUPPORTING DOCUMENTS:
QA/QI Initial Notification to PI
QA/QI Follow up to Routine Review Notification
QA/QI Reminder Confirmation
QA/QI Routine Review Interview Questions
QI Routine Review Summary
QI Regulatory Review Checklist

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