SOP: Human Research Protection Program Quality Assurance/Quality Improvement Program

NUMBER	DATE	AUTHOR	APPROVED BY
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1. PURPOSE

1.1 This Standard Operating Procedure defines the Human Research Protection Program (HRPP) Quality Assurance/Quality Improvement function at the University of Massachusetts Medical School.

2. REVISIONS FROM PREVIOUS VERSION

2.1 None

3. AUTHORITY AND SCOPE

3.1 Under the general authority of the University of Massachusetts Medical School Human Research Protection Program (HRPP) [HRP-010], the Quality Assurance/Quality Improvement (QA/QI) Program is overseen by the Director, Office of Clinical Research and the Quality Improvement Manager, Center for Clinical and Translational Science (CCTS). The HRPP QA/QI Program includes the following:

3.1.1 **Post Approval Monitoring:** Conducted based upon selection of the Quality Improvement Manager or at the request of the IRB, Organizational Official, Institutional Official or Director, Office of Clinical Research. Circumstances where Post Approval Monitoring may occur include, but are not limited to;

- Monthly selection of active human research studies with enrolled participants;
- Investigator Initiated Studies;
- Investigator/Sponsor Investigational New Drug (IND)/Investigational Device Exemption (IDE) studies;
- Re-assessment of studies previously reviewed to evaluate adherence to corrective action plans and ongoing compliance; or
- Studies assessed by the IRB to include a high degree of risk (adverse events, type of study, or vulnerable populations);

3.1.2 **Directed or For-Cause Review:** Conducted at the request of the Institutional Review Board (IRB), Organizational Official or designee. Circumstances where a For-Cause Review may occur include, but are not limited to:

- As part of an ongoing corrective action;
- To support a review associated with an RNI or IRB's assessment of potential noncompliance, and/or;
- When there are concerns regarding whether the rights and welfare of participants enrolled in research are adequately protected.

3.1.3 **Voluntary Reviews:** Conducted upon request of Principal Investigator to support self-assessment and improvement efforts by Investigator and Study Team.

3.1.4 **IRB Minutes Review:** Conducted quarterly to assure compliance and support the operations of the IRB.

3.1.5 **Human Research Protection Program Quality Improvement:** Conducted quarterly to track and improve overall satisfaction and institutional compliance with human research protection program requirements.

4. RESPONSIBILITIES

4.1 The Quality Improvement Manager, CCTS (QIM) is responsible for ensuring these procedures are carried out.

5. PROCEDURE

5.1 Post Approval Monitoring:

5.1.1 Selection and Scheduling:

5.1.1.1 The Quality Improvement Manager, CCTS (QIM) selects studies as follows:

5.1.1.1.1 Through QIM selection via review of a report from the IRB of 1) active studies (exempt, expedited/non-committee and full committee review) 2) with a consent form (not waiver of consent) and 3) with reported enrollment, and selects 6-10 studies to review for the upcoming month; or

5.1.1.1.2 Through request by the IRB, Organizational Official, Institutional Official or Director, Office of Clinical Research to assess general programmatic compliance with regulatory and institutional requirements based upon specified study characteristics.

5.1.1.2 The QIM contacts the Principal Investigator and Study Coordinator (by phone or email) to:

5.1.1.3 Schedule the review in a timely manner;

5.1.1.4 Provide an overview of the scope, process and required workspace needed for the review; and

5.1.1.5 Provide a copy of the Quality Improvement Review Checklist to be used for review to the Investigator and Study Coordinator.

5.1.2 Review Procedures:

5.1.2.1 In advance of the review visit, the QIM reviews the protocol information on file with the IRB;

5.1.2.2 On the day of the review, the QIM will meet with the Investigator and designated study staff at the open and close of the review if possible. The investigator will arrange for a private work area for the conduct of the review. At a minimum, designated study staff should make themselves available for documentation retrieval, answer any questions or provide clarification as may be needed;

5.1.2.3 The investigator will provide the following study files (as applicable) for the QIM's review:

5.1.2.3.1 All study related regulatory documents;

5.1.2.3.2 Subject screening/enrollment log;

5.1.2.3.3 Case report forms;

5.1.2.3.4 Source documents;

5.1.2.3.5 Informed consents, assents and HIPAA for all enrolled and screened participants

5.1.2.3.6 Study drug accountability logs (to be reviewed in the Investigational Pharmacy, as applicable);

5.1.2.3.7 Device accountability logs (as applicable);

5.1.2.3.8 Lab logs (as applicable);

5.1.2.3.9 Other documents/files as requested that support the study administration;

5.1.2.4 Research records are expected to be maintained by study team in a review-ready state at all times. Study team will have an opportunity to locate and provide materials or documentation not present in the files at time of review, but the initial absence of material or documentation will be noted in the findings.

5.1.3 Findings

5.1.3.1 Finding types may include, but are not limited to:

5.1.3.1.1 No further action necessary;

5.1.3.1.2 Minor administrative issue (non-Reportable New Information) with best practice recommendation for corrective action;

5.1.3.1.3 Reportable New Information finding with best practice recommendation for corrective action.

5.1.3.1.4 Major finding indicating potential scientific misconduct and/or harm or imminent risk of harm to participants' safety and well-being. These findings will be reported immediately by QI Manager to the Director of Clinical Research, Organizational Official, Institutional Official, IRB Chair and IRB Manager.

5.1.3.1.5 Potential misconduct will also be reported to the Research Integrity Officer for UMass Medical School in accordance with the University of Massachusetts Medical Center Policy for Responding to Allegations of Scientific Misconduct.

5.1.4 Documentation and Distribution of Findings

5.1.4.1 QIM uses the Quality Improvement Review Checklist to document observations, findings and any concerns.

5.1.4.2 At the conclusion of the review, the QIM verbally debriefs the investigator and/or designated study team members regarding findings, applicable recommendations and next steps.

5.1.4.3 The QIM generates a written report of findings and recommendations. The written report of findings is shared with the PI, designated study team and Director, Office of Clinical Research.

5.1.4.4 In the event the Investigator disagrees with the findings of fact or wishes to provide clarification, the Investigator may provide the rebuttal and/or clarifications, in writing, to the QIM. The QIM will add the provided information as an appendix to the report.

5.1.4.5 The QIM may monitor submission of Reportable New Information reports as recommended in the review findings. If a Reportable New Information is not submitted as recommended, the QIM may send reminder and timeframe for completion to study team. If the study team has not completed follow up with in timeframe specified for Reportable New Information in (HRP-214) and Investigator Guide HRP-801 Section 2.1, QIM may directly report findings to IRB Chair and IRB Manager;

5.1.4.6 Follow-up reviews may be scheduled to confirm ongoing adherence to corrective action recommendation and continued compliance.

5.2 Directed or For Cause Review

5.2.1 Selection and Scheduling

5.2.1.1 The IRB Chair, Organizational Official or the Institutional Official ("Requestor") may request a directed or for-cause review.

5.2.1.2 The Requestor will notify the investigator of a directed or for-cause review by official notification to the investigator with a cc to the QI Manager. This request will include the scope, timing, scheduling process and next steps including distribution of audit findings.

5.2.1.2.1 The QIM may contact Requestor to seek additional clarification from the Requestor to ensure the requested audit is appropriately responsive.

5.2.1.3 Unless directed to contact investigator sooner, the QIM will contact investigator by the next business day following receipt of the audit request to schedule the review and will work with investigator and study team to schedule review within the timeline established by the requestor.

5.2.1.3.1 If scheduling and/or completion of audit will not be possible within the established timeframe due to circumstances beyond the investigator's control, the QIM will notify the Requestor and request additional guidance.

5.2.1.3.2 As research records are expected to be maintained in an audit-ready state at all times, time needed for record preparation is not an acceptable reason to request delay.

5.2.2 Review Procedures

5.2.2.1 Review procedures will follow those outlined in 5.1.2, above

5.2.2.2 In circumstances where there is concern over integrity of records, the HRPP QA/QI staff will seek guidance from the Research Integrity Office

5.2.3 Documentation and Distribution of Findings

5.2.3.1 The report and associated findings are shared with the Requestor and the Director, Office of Clinical Research. The findings are also cc'd to the Investigator.

5.2.3.2 In the event the Investigator disagrees with the findings of fact or wishes to provide clarification, the Investigator may provide the rebuttal and/or clarifications, in writing, to the QIM. The QIM will add the provided information as an appendix to the report and re-distribute.

5.3 Voluntary Reviews

5.3.1 The QIM makes the "Investigator Self-Assessment (HRP-901)" and "Investigator Self-Assessment Instructions (HRP-902)" available to investigators and study teams;

5.3.2 The Principal Investigator, or study team member with Principal Investigator's support, may ask for a voluntary review/assistive review by the QIM.

5.3.2.1 The review procedures will follow those outlined in 5.1.2, above.

5.4 IRB Minutes Reviews

5.4.1 Within [5] business days of meeting minutes completion by IRB staff, the QIM or designee reviews the IRB minutes for compliance with HRP-043 [IRB Meeting Minutes] or HRP-108 [Minutes];

5.4.2 The QIM uses the IRB Minutes Review Checklist to guide and document the review;

5.4.3 The QIM prepares a report of findings, if any, and meets with the IRB Manager or designee to debrief on findings;

5.4.4 The IRB Manager or designee develops a corrective action plan based on the findings or provides clarification to findings, and communicates the findings and corrective action plan as appropriate.

5.5 Human Research Protection Program Quality Improvement

5.5.1 Routine Monitoring Trends Assessment

5.5.1.1 On a Quarterly basis or as requested by the Organization Official or designees, the QIM will provide a report of general trends and findings from the Routine or Not for Cause reviews to the Director, Office of Clinical Research, Organizational Official, IRB Manager, IRB Chair and others as necessary.

5.5.1.2 The QIM and individuals listed in 5.5.1.1 will review the findings and develop corrective and education action plans as necessary.

5.5.1.3 The QIM will monitor the impact of the corrective and education plans on findings and will report outcomes to the individuals listed in 5.5.1.1.

6. MATERIALS

Clinical Trials Quality Improvement Inspection Checklist
HRP-043 [IRB Meeting Minutes]/ HRP-108 [Minutes]
IRB Minutes Review Checklist
HRP-901 [Investigator Self-Assessment]
HRP-902 [Investigator Self-Assessment Instructions]

7. REFERENCES

45 CFR 46.103(b)(5); 45CFR46.109(e); 21CFR56.108(b); 21CFR56.109(f), AAHRPP I.5.A, I.5.B