1. PURPOSE
   1. This SOP defines the Human Research Protection Program (HRPP) Post Approval Monitoring (PAM), Research Education Sessions, and Quality Assurance function within the Carilion Clinic HRPP.
2. AUTHORITY AND SCOPE
   1. The Carilion HRPP Post Approval Monitoring Program (PAM) is under the general direction of the HRPO Director. The HRPO PAM Program includes the following:
      1. Post Approval Monitoring: Routinely conducted based upon risk, category or type of study. Circumstances where Post Approval Monitoring may occur include, but are not limited to:
         1. Monthly selection of active human research studies;
         2. Investigator Initiated Studies (minimal risk and greater than minimal risk);
         3. Investigator/Sponsor Investigational New Drug (IND)/Investigational Device Exemption (IDE) studies;
         4. Studies assessed by the IRB to include a high degree of risk (adverse events, protocol deviations, type of study, or vulnerable populations); or
         5. New, or inexperienced investigator or research staff.
      2. Directed or For-Cause Review: Conducted at the request of the Institutional Review Board (IRB), IRB Chair, HRPP Director, Associate VPR, Institutional Official or designee. Circumstances where a For-Cause Review may occur include, but are not limited to:
         1. As part of an ongoing corrective action;
         2. To support a review associated with Reportable New Information or the IRB’s assessment of potential non-compliance including failure to follow the approved protocol, and/or;
         3. When there are concerns regarding whether the rights and welfare of participants enrolled in research are adequately protected.
         4. When there are concerns about the validity or integrity of the data collected.
      3. Voluntary Reviews: Conducted upon request of Principal Investigator to support self- assessment and improvement efforts by Investigator and Study Team.
         1. The investigator may also use Worksheet: Investigator Quality Improvement Assessment (HRP-430) to conduct a voluntary self-assessment.
      4. IRB Minutes Review: Conducted quarterly to assure compliance and support the operations of the IRB.
      5. Human Research Protection Program Quality Assurance: Conducted at least annually to track and improve overall satisfaction and institutional compliance with human research protection program requirements.
3. RESPONSIBILITIES
   1. HRPO staff members are responsible for ensuring these procedures are carried out.
4. PROCEDURE
   1. Post Approval Monitoring:
      1. Selection and Scheduling:
         1. The PAM selects studies as follows:
            1. From a list of active studies selects a sampling each month.
            2. Through request by the IRB, IRB Chair, HRPO Director, Associate VPR or Institutional Official or designee, to assess general programmatic compliance with regulatory and institutional requirements based upon specified study characteristics.
         2. The PAM contacts the Principal Investigator and Study Coordinator in writing (email) to:
            1. Schedule the review in a timely manner;
            2. Provide an overview of the scope, process and required workspace needed for the review; and
            3. Provide a copy of the Worksheet that will be used as a general guide for review to the Investigator and Study Coordinator.
      2. Review Procedures:
         1. In advance of the review visit, the PAM reviews the protocol information on file with the IRB;
         2. On the day of the review, the PAM 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;
         3. The investigator will provide the following study files (as applicable) for the PAM’s review:
            1. All study related regulatory documents;
            2. Subject screening/enrollment log;
            3. Case report forms;
            4. Source documents;
            5. Informed consents, assents and HIPAA for all enrolled and screened participants
            6. Study drug/product accountability logs, as applicable;
            7. Device accountability logs, as applicable;
            8. Lab logs. as applicable;
            9. Other documents/files as requested that support the study administration;
         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.
      3. Findings
         1. Finding types may include, but are not limited to:
            1. No further action necessary;
            2. Minor administrative issue(s) with best practice or additional education recommendation for corrective action;
            3. Finding that meets the definition of ‘Reportable New Information’ with best practice or other recommendation for corrective action.
            4. Major finding indicating potential harm or imminent risk of harm to participants’ safety and well-being. These findings will be reported immediately by the staff member conducting the PAM to the HRPO Director and IRB Chair, and when necessary to Institutional Official or designee.
            5. Potential misconduct will also be reported to the Office of Integrity and Compliance
      4. Documentation and Distribution of Findings
         1. The PAM will document observations, findings and any concerns.
         2. At the conclusion of the review, the PAM verbally debriefs the investigator and/or designated study team members regarding findings, applicable recommendations and next steps.
         3. The PAM generates a written report of findings and recommendations. The written report of findings is shared with the principal investigator, HRPP and IRB.
         4. The PAM submits a copy of the written report into the electronic IRB submission system PRIS3M, and references all applicable research through the Reportable New Information activity.
         5. The investigator is asked to review the written report and provide a response and a corrective action when necessary.
         6. 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. The provided information and any corrective action plan will be submitted into the electronic IRB submission system, PRIS3M.
         7. The investigator is also asked to submit each incident of Reportable New Information found through the review that has not already been reported to the IRB.
         8. Follow-up reviews may be scheduled to confirm ongoing adherence to corrective action recommendation and continued compliance.
      5. Directed or For Cause Review
         1. Selection and Scheduling
            1. The IRB Chair, HRPP Director, Associate VPR, Institutional Official or designee (“Requestor”) may request a directed or for-cause review
            2. The Requestor will notify the PAM of the investigator whose study will be subject to a directed or for-cause review. An official notification will be sent to the investigator with a copy to their department head. This notice will include the scope, timing, scheduling process and next steps.
            3. Unless directed to contact the investigator sooner, the PAM will contact the investigator by the next business day following receipt of the review request to schedule the review and will work with investigator and study team to schedule the review within the timeline established by the requestor.
            4. If scheduling and/or completion of review will not be possible within the established timeframe due to circumstances beyond the investigator’s control, the PAM will notify the Requestor and request additional guidance.
            5. 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.
         2. Review Procedures
            1. Review procedures will follow those outlined in 5.1.2, above.
         3. Documentation and Distribution of Findings
            1. The report and associated findings are shared with the Requestor, HRPP Director, IRB Chair and the IO as needed. The findings are also provided to the Investigator and their department head.
            2. The Remainder of Documentation and Distribution of Findings procedures will follow those as outlined in 5.2.1, above.
      6. Voluntary Review
         1. The HRPP makes the Investigator Self-Assessment (HRP-430) available to investigators and study teams;
         2. The Principal Investigator, or study team member with Principal Investigator’s support, may conduct a self-assessment or ask for a voluntary review/assistive review by the PAM team.
         3. The review procedures will follow those outlined in 5.1.2, above.
      7. IRB Minutes Reviews
         1. The PAM or designee reviews the IRB minutes for compliance with HRP-043 IRB Meeting Minutes.
         2. The PAM or designee uses the Worksheet: Minutes Quality Improvement Assessment (HRP-431) to guide and document the review;
         3. The PAM or designee prepares a report of findings, if any, and forwards to the IRB Staff and HRPP Director with a copy to the VPR’s office.
         4. The HRPP Director or designee develops a corrective action plan if necessary or provides clarification to findings, and communicates the findings and any corrective action plan to the PAM as appropriate.
      8. Human Research Protection Program Quality Improvement
         1. On an annual basis or more often if requested by the HRPP Director, Institutional Official or designee, the PAM will provide a report of general trends and findings from the audits and reviews to the Institutional Official, HRPP Director, IRB Chair and others as necessary.
         2. The PAM and individuals listed in 5.6.1.1 will review the findings and develop corrective and education action plans as necessary.
         3. The PAM team will monitor the impact of the corrective and education plans on findings and will report outcomes to the individuals listed in 5.6.1.1.
5. MATERIALS
   1. Checklist: Investigator Quality Improvement Assessment (HRP-430)
   2. Checklist: Minutes Quality Improvement Assessment (HRP-431)
   3. HRP-043 IRB Meeting Minutes
6. APPROVAL AND REVISIONS
   1. 07 APR 21: HRPO Director, Carley Emerson, originally created and approved
7. REFERENCES
   1. OHRP 45 CFR 46.103(b)(5); 45CFR46.109(e);
   2. FDA 21CFR56.108(b); 21CFR56.109(f),