1. PURPOSE
   1. This procedure establishes the process to conduct Post Approval Monitoring (PAM).
   2. This procedure begins when a committee member selects a study for PAM during initial review or when HRPP staff select a study for PAM.
   3. This procedure ends when the PAM is complete and corrective actions, if applicable, are completed by the Principal Investigator.
2. POLICY
   1. The goal of PAM is to achieve and maintain compliance and to achieve targeted levels of quality, efficiency, and effectiveness of the HRPP.
   2. Objectives of PAM are to:
      1. Improve compliance of investigators with their responsibilities.
      2. Ensure researchers are conducting the research in accordance with the relevant current protocol approved by the IRB.
      3. Identify which departments/faculty require more education on IRB policies and procedures.
3. RESPONSIBILITY
   1. HRPP staff members carry out these procedures.
4. PROCEDURE
   1. During initial review, a board member or HRPP staff may select a study for PAM. At the one year anniversary of approval, HRPP staff will contact the PI and inform them that their study has been selected for one of the following PAM activities:
      1. **Investigator Self-Assessment** – studies identified as low risk or first time researchers.
         1. For Investigator Self-Assessment, HRPP staff will notify the PI during their one year anniversary, that their study has been chosen for self-assessment.
         2. HRPP staff will send the PI the HRP- 901: Investigator Self-Assessment form and the PI Self-Assessment form.
         3. PI will be informed that the self-assessment is to be completed within a specified time frame. PI is informed that all new IRB submissions will put on a “process hold” if the self-assessment is not submitted on time.
            1. If not submitted on time, make Investigator <Restricted>.
            2. Process as <Noncompliance> using “SOP: New Information (HRP-212).”
         4. The completed assessment is returned to and reviewed by HRPP staff.
      2. **Full on-site assessment** – for studies that are complex, more than minimal risk or federally funded studies.
         1. For Full on-site assessment, HRPP staff will notify the PI that their study has been selected for PAM.
         2. HRPP staff will send the PI the Post Approval Monitoring Checklist.
         3. HRPP staff will arrange a time and place to meet that is convenient for the PI/study staff.
         4. HRPP staff will conduct a full review of all records and processes.
      3. **Consent document review** – for studies that collect a large number of signed consent/assent forms.
         1. For consent document review, HRPP staff will notify the PI that their study has been selected for a consent document review. HRPP staff will send the PI the Consent Document Review form that will be used by HRPP staff.
         2. HRPP staff will arrange a time and place to meet that is convenient for the PI/study staff.
         3. HRPP staff will review all signed consent/assent forms within a specified time frame.
   2. After each PAM activity, the findings will be documented and saved to the “I” drive.
   3. If HRPP staff find deviances from the approved protocol, investigators will be notified to submit an HRP-214: Reportable New Information form.
      1. Consider whether any immediate actions might be necessary to protect the rights and welfare of current or future subjects while additional information is gathered.
         1. If so, take those actions, notify the institution, sponsor, CRO, or SMO, as applicable, and notify the [Chief Compliance Officer].
      2. Consider whether immediate notification of the institution, sponsor, CRO, or SMO might be appropriate.
         1. If so, notify the institution, sponsor, CRO, or SMO, as applicable, and notify the [Chief Compliance Officer].
      3. If more information is needed, contact the submitter to gather new information.
      4. If the information represents <Noncompliance> that is neither <Serious Noncompliance>, nor <Continuing Noncompliance>, evaluate any submitted corrective action.
         1. If the corrective action plan is insufficient, contact the research team to develop a sufficient correction action plan.
         2. If the research team is unable to develop a sufficient corrective action, consider the <Noncompliance> to be <Continuing Noncompliance>.
      5. If the research team develops a sufficient corrective action, follow “SOP: Post Review (HRP-111)” to notify the submitter.
   4. If the information represents <Serious Noncompliance>, <Continuing Noncompliance>, an <Unanticipated Problem Involving Risks to Subjects or Others>, a <Suspension of IRB Approval>, or a <Termination of IRB Approval>:
      1. Notify the [Chief Compliance Officer].
      2. Bring the information to the attention of an IRB chair or IRB vice-chair for consideration of whether any immediate actions are necessary to protect the rights and welfare of subjects in advance of the meeting.
      3. Send for <Committee Review>.