1. PURPOSE

1.1. This procedure establishes the process for the Human Research Protection Program (HRPP) to conduct post-approval monitoring of <Human Research> functions at the [Organization].
1.2. This process begins when the human subjects research protocols are identified for post-approval monitoring.
1.3. This process ends when the post-approval monitoring process and corrective actions are completed.

2. POLICY

2.1. The goal of post-approval monitoring is to achieve and maintain ethical human research conduct and compliance with state and federal regulations, federal guidance, institutional policies, and best practices.
2.2. Objectives of the post-approval monitoring program is to:

2.2.1. Improve investigator compliance with currently approved protocols/amendments, applicable regulations, and best practices (e.g., Good Clinical Practice (GCP)).
2.2.2. Ensure that the rights and well-being of human subjects are protected.

2.3. Post-approval monitoring includes:

2.3.1. Routine compliance reviews
2.3.2. Directed or for-cause audits
2.3.3. Investigator Self-Assessments.

3. RESPONSIBILITY

3.1. HRPP staff members carry out these procedures.

4. PROCEDURE

4.1. Elements of the post-approval monitoring program will be scheduled as follows:

4.1.1. Routine compliance reviews are scheduled quarterly. Protocols to be reviewed are pseudorandomly selected from a list of currently approved studies that are under the purview of the HRPP, based upon specified study characteristics (e.g., study risk, research type, review category, etc.). Once a protocol is identified, contact the Principal Investigator (PI) to schedule the monitoring visit.

4.1.1.1. If the Investigators are not responsive to scheduling attempts, the HRPP may escalate the request up the organizational hierarchy and may result in a for-cause audit.

4.1.2. Directed or for-cause audits are scheduled after identification of a potential problem by the Institutional Review Board (IRB), [IRB Executive Chair], [Chief Research Compliance Officer], or [Organizational Official]. Once identified, contact the PI to schedule the audit.

4.1.2.1. If the PIs are not responsive to scheduling attempts, the HRPP may escalate the request up the organizational hierarchy.

4.1.3. The “Investigator Self-Assessment (HRP-901)” and “Investigator Self-Assessment Instructions (HRP-902)” will be sent, at least quarterly, to 10 PIs.

4.1.3.1. If the PIs are not responsive to scheduling attempts, the HRPP may escalate the request up the organizational hierarchy and may result in a for-cause audit.

4.2. Routine compliance reviews and directed or for-cause audits will occur as follows:

4.2.1. Prior to the visit, review the protocol information on file with the IRB

4.2.2. On the day of the visit, meet the PI and/or the designated study staff. The PI will arrange for a private work area for the conduct of the review. Designated study staff should be available for documentation retrieval, answer any questions or provide clarification as needed throughout the course of the visit.

4.2.3. The PI and/or the designated study staff will provide the following study files (as applicable) for review:

4.2.3.1. All study-related regulatory documents
4.2.3.2. Subject screening/enrollment logs
4.2.3.3. Case Report forms
4.2.3.4. Source documents
4.2.3.5. Signed informed consent, assent, and HIPAA Authorization forms for all subjects
4.2.3.6. Study drug/product accountability logs
4.2.3.7. Device accountability logs
4.2.3.8. Lab logs
4.2.3.9. Other documents/files as requested that support the study administration

4.2.4. Research records are expected to be audit-ready at all times. The PI or designee will have an opportunity to locate and provide materials or documentation that is not present in the files at time of review, but the initial absence of material or documentation will be noted in the findings.

4.2.5. Observations, findings, and concerns will be documented during the visit and can include, but are not limited to:

4.2.5.1. Acceptable:

4.2.5.1.1. No deviations/deficiencies identified - no further action necessary
4.2.5.1.2. Few lesser deviations/deficiencies identified
4.2.5.1.3. Major deviations/deficiencies identified during the review that were addressed and/or corrected prior to the review for which documentation exists and no further action is required.

4.2.5.2. Needs Follow-up:

4.2.5.2.1. Any major deviation/deficiency identified during the review but not corrected, addressed, and/or reported prior to the review
4.2.5.2.2. Multiple lesser deficiencies identified.

4.2.5.3. Unacceptable

4.2.5.3.1. Multiple major deviations/deficiencies identified
4.2.5.3.2. A single major, flagrant deviation/deficiency found
4.2.5.3.3. Excessive number of lesser deficiencies identified
4.2.5.3.4. Major finding indicating potential harm or imminent risk of harm to participants' safety and well-being. These findings will be reported immediately by the monitor to the [Chief Research Compliance Officer], [IRB Executive Chair], and when necessary the [Organizational Official] or designee.

4.2.6. At the conclusion of the visit, briefly debrief the PI and/or designee regarding the findings, recommendations, and next steps.

4.2.7. Generate a written report of findings that is shared with the PI.

4.2.7.1. If information represents potential misconduct, as defined in Policy on Misconduct in Research and Creative Work (Policy Number 02.54.01), the [Chief Research Compliance Officer] will liaise with appropriate entities within the Office for the Vice President for Research in accordance with the policy.

4.2.8. The Investigator will review the written report, provide a response and corrective and preventable action (CAPA) plan, as necessary.

4.2.8.1. The investigator will submit a copy of the written report, the response, and CAPA to the IRB via a Reportable New Information submission.

4.2.8.1.1. The Reportable New Information submission should include each incident of reportable new information found via the post-approval monitoring process that was not previously reported to the IRB.

4.3. Investigator Self Assessments:

4.3.1. The Principal Investigator or designee completes the “Self-Assessment Checklist (HRP-901)” by reviewing documents in the study file

4.3.2. Must be returned within 14 business days of receipt, unless an exception is made by the HRPP

4.3.3. HRPP staff will review and examine the self-assessment responses. The investigator and/or designee will be contacted if follow-up, clarification, or Reportable New Information submission is needed.

4.4. Results of the post-approval monitoring program will be reviewed quarterly.

4.4.1. Track the results.

4.4.2. Examine for significant trends.

4.4.3. Design interventions for adverse trends.

5. REFERENCES

5.1. Temple University Policy 02.54.01 Misconduct in Research and Creative Work