PURPOSE

1.1 This SOP defines the Human Research Protection Program (HRPP) Post Approval Monitoring and Quality Assurance function at Texas A&M University (TAMU).

2 REVISIONS FROM PREVIOUS VERSION

2.1 Revised from the 5/30/2017 version.

3 AUTHORITY AND SCOPE

3.1 The TAMU HRPP Post Approval Monitoring Program (PAM) is under the general direction of the HRPP Director. The HRPP PAM Program includes the following:

3.1.1 **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:

- Monthly selection of active human research studies;
- Investigator Initiated Studies (minimal risk and greater than minimal risk);
- Investigator/Sponsor Investigational New Drug (IND)/Investigational Device Exemption (IDE) studies;
- Studies assessed by the IRB to include a high degree of risk (adverse events, protocol deviations, type of study, or vulnerable populations); or
- New, or inexperienced investigator or research staff.

3.1.2 **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:

- As part of an ongoing corrective action;
- 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;
- When there are concerns or complaints regarding whether the rights and welfare of participants enrolled in research are adequately protected.
- When there are concerns or complaints about the validity or integrity of the data collected.

3.1.3 **Investigator QI Assessments**: As needed, complete HRP-534 - LETTER - Investigator QI Assessment or equivalent correspondence and send HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment to 10 investigators.

- Review the results of HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment sent out previously, track the results, and examine for significant trends.
- Conduct HRPP Quality Improvement Assessment:
- Review the results of all Investigator QI Assessments sent out previously and examine for significant trends.

3.1.4 **Minutes Quality Improvement Assessments**: Complete HRP-431 – CHECKLIST - on the minutes of a previous month. Track compliance and the days required to complete minutes and examine for significant trends.

- Send the results to the HRPP Director/IRB Manager or IRB Chair.
- If the results of any evaluations demonstrate inconsistency, recurring noncompliance or misinterpretation of HRPP requirements, high variability, or are outside performance targets, work with the HRPP Director or IRB Chair to implement an intervention.
- Interventions may include policy and procedure modifications, education and training efforts, system modifications, or other corrective actions.

3.1.5 **Human Research Protection Program Quality Assurance:** Assess at least annually to track and improve overall satisfaction and institutional compliance with human research protection program requirements.

4 RESPONSIBILITIES

4.1 The PAM team 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 PAM selects studies as follows:

5.1.1.1.1 From a list of active studies selects a sampling.

5.1.1.1.2 Through request by the IRB, IRB Chair, HRPP Director, Associate VPR or Institutional Official or designee, to assess general programmatic compliance with regulatory and institutional requirements based upon specified study characteristics.

5.1.1.2 The PAM contacts the Principal Investigator and Study Coordinator in writing (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 an overview of the process that will be used as a general guide for review to the Investigator and Study Coordinator.

5.1.2 ***Review Procedures:***

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

5.1.2.2 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;

5.1.2.3 The investigator will provide the following study files (as applicable) for the PAM'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/product accountability logs, 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(s) with best practice or additional education recommendation for corrective action;

5.1.3.1.3 Finding that meets the definition of 'Reportable New Information' with best practice or other recommendation for corrective action.

5.1.3.1.4 Major finding indicating potential harm or imminent risk of harm to participants' safety and well-being. These findings will be reported immediately by PAM to the HRPP Director and IRB Chair and when necessary to Institutional Official or designee.

5.2 Potential misconduct will also be reported to the Designated Officer in accordance with TAMU SAP 15.99.03.M1.01 Guidelines for Scientific Misconduct Investigation and Inquiry

5.2.1 ***Documentation and Distribution of Findings***

5.2.1.1 The PAM will document observations, findings and any concerns.

5.2.1.2 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.

5.2.1.3 The PAM generates a written report of findings and recommendations. The written report of findings is shared with the principal investigator and HRPP.

5.2.1.4 A copy of the written report will be submitted into the IRB submission system, and references all applicable research through the Reportable New Information activity.

5.2.1.5 The investigator is asked to review the written report and provide a response and a corrective action when necessary.

5.2.1.6 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 IRB submission system.

5.2.1.7 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.

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

5.3 **Directed or For Cause Review**

5.3.1 ***Selection and Scheduling***

5.3.1.1 The IRB Chair, HRPP Director, Associate VPR, Institutional Official or designee ("Requestor") may request a directed or for-cause review.

5.3.1.2 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.

5.3.1.3 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.

5.3.1.3.1 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.

5.3.1.3.2 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.

5.3.2 ***Review Procedures***

5.3.2.1 Review procedures will follow those outlined in 5.1.2, above.

5.3.3 ***5.2.3 Documentation and Distribution of Findings***

5.3.3.1 The report and associated findings are shared with the Requestor, HRPP Director, IRB Chair and the IO/OO as needed. The findings are also provided to the Investigator and their department head.

5.3.3.2 The Remainder of Documentation and Distribution of Findings procedures will follow those as outlined in 5.2.1, above.

5.4 **Investigator QI Assessments**

5.4.1 The HRPP makes the *Investigator Self-Assessment (HRP-430*) available to investigators and study teams;

5.4.2 The Principal Investigator, or study team member with Principal Investigator's support, conducts a QI assessment or asks for a voluntary review/assistive review by the PAM team.

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

5.5 **IRB Minutes Reviews**

5.5.1 5.4.1 The PAM or designee reviews the IRB minutes for compliance with *HRP-043 IRB Meeting Minutes.*

5.5.2 The PAM or designee uses the *Worksheet: Minutes Quality Improvement Assessment (HRP-431) to* guide and document the review;

5.5.3 The PAM or designee prepares a report of findings, if any, and forwards to the IRB Staff and HRPP Director.

5.5.4 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.

5.6 **Human Research Protection Program Quality Improvement**

5.6.1 ***Routine Monitoring Trends Assessment***

5.6.1.1 The PAM will periodically provide a report of general trends and findings from the audits and reviews to the IO/OO or designee, HRPP Director, IRB Chair and others as necessary.

5.6.1.2 The PAM and individuals listed in 5.6.1.1 will review the findings and develop corrective and education action plans as necessary.

5.6.1.3 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.

6 6. MATERIALS

6.1 Checklist: Investigator Quality Improvement Assessment (HRP-430)

6.2 Checklist: Minutes Quality Improvement Assessment (HRP-431)

6.3 HRP-043 IRB Meeting Minutes

6.4 SAP 15.99.03.M1.01 Guidelines for Scientific Misconduct Investigation and Inquiry

7 REFERENCES

7.1 OHRP 45 CFR 46.103(b)(5); 45CFR46.109(e);

7.2 FDA 21CFR56.108(b); 21CFR56.109(f),

7.3 AAHRPP I.5.A, I.5.B, I.5.D, 1-9