# PURPOSE

# This procedure establishes the process to conduct IRB post-approval monitoring (PAM).

# The process begins when the Human Subjects Protection Program (HSPP) Analyst identifies IRB-approved Human Subjects Research protocols for PAM.

# The process ends when the PAM has been completed and reported to the Institutional Review Board (IRB).

# PREVIOUS VERSION

# None.

# POLICY

# The HSPP has the responsibility to maintain a review program to monitor and improve compliance in identified problem areas.

# The HSPP investigates concerns, allegations, complaints on non-compliance, and systematic problem areas in Human Subjects Research. In addition to For Cause Reviews, conducted in response to reports of alleged noncompliance, the HSPP also conducts routine post-approval monitoring of Human Subjects Research protocols in order to review and ensure compliance in the conduct of Human Subjects Research at the University.

# RESPONSIBILITIES

# The HSPP Analysts carry out the activities related to post-approval monitoring.

# The HSPP Analysts report the post-approval monitoring activities at the IRB.

# PROCEDURE

# The HSPP Analyst will conduct a post-approval monitoring review on active and non-active exempt and non-exempt Human Subjects Research studies, regardless of the IRB of record.

# The HSPP Analyst will generate a list of IRB-approved protocols.

# The HSPP Analyst will select the appropriate number of studies (according to the sampling level) from the list.

# Studies may be selected based on one or more of the following factors: vulnerable population, subject enrollment, department, prior findings, sponsors/funding agency, study category/type, etc.

# Studies may be selected with input from IRB Directors.

# The HSPP Analyst will make an effort to not select multiple studies from the same Principal Investigator (PI) within the same calendar year for PAM review.

# The HSPP Analyst will send the proposed study selections to the Director, Human Subjects Protections Analysts to get feedback and verify selections.

# For each selected study, the HSPP Analyst will email the PI the appropriate documents from Section 6. Materials below.

# For the in-person PAM Visit, the HSPP Analyst will do the following:

# Conduct a pre-review of the protocol and save copies of relevant study files in the corresponding electronic folder.

# Schedule the visit.

# Conduct an assessment, including but not limited to:

# Review consent forms, as appropriate.

# Review participant files, as appropriate.

# Review regulatory documentation, as appropriate.

# Conduct an exit interview to share any findings and share good practices.

# When the assessment is complete, the HSPP Analyst will send a report of the review to the IRB.

# Any serious or continuing noncompliance discovered during a PAM will be promptly reported to the IRB Chair of the designated IRB and the Director, HSPP.

# Record the PAM activity in the HSPP PAM Log and include the report in the IRB Meeting Agenda.

# MATERIALS

* 1. HRP-061 - SOP - Ongoing HRPP Evaluations
  2. HRP-101 - SOP - Human Subject Protection Program Plan
  3. HRP-430a - CHECKLIST - Investigator Quality Improvement Assessment - Drug, Devices, Clinical Trial
  4. HRP-430b - CHECKLIST - Investigator Quality Improvement Assessment - Participant File
  5. HRP-430c - CHECKLIST - Investigator Quality Improvement Assessment - Biomedical Research
  6. HRP-430d - CHECKLIST - Investigator Quality Improvement Assessment - Social Behavioral Research
  7. HRP-430e - CHECKLIST - Investigator Quality Improvement Assessment - Humanitarian Use Device
  8. HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment
  9. HRP-534 - LETTER - Post-Approval Monitoring Self-Assessment Notification

1. **REFERENCES**
   1. None.