



## SOP: Post-Approval Monitoring Assessment

NUMBER	EFFECTIVE DATE	PAGE
12.001 (HRP-028)	11/21/2024	Page 1 of 2

### 1. PURPOSE

- 1.1. This procedure establishes the process to conduct the Human Research Protection Program (HRPP) post-approval monitoring (PAM).
- 1.2. The process begins when the HRPP Quality Assurance & Evaluation (QA&E) Team identifies IRB-approved Human Research protocols for PAM.
- 1.3. The process ends when the PAM has been completed and reported to the Institutional Review Board (IRB).

### 2. PREVIOUS VERSION

- 2.1 This is the first version of this Standard Operating Procedure (SOP). There are no previous versions or references.

### 3. POLICY

- 3.1. The HRPP QA&E Team has the responsibility to monitor and improve compliance in identified problem areas.
- 3.2. The HRPP Quality Assurance & Evaluation (QA&E) Team is responsible for investigating concerns, allegations, and complaints regarding non-compliance and systematic problems in Human Research. In addition to conducting Directed (For Cause) Reviews – which are done in response to reports of alleged non-compliance – the HRPP also carries out routine post-approval monitoring of Human Research protocols. This monitoring ensures that all aspects of Human Research at the University are conducted in compliance with established guidelines.

### 4. RESPONSIBILITIES

- 4.1. The HRPP QA&E Team carries out the activities related to post-approval monitoring.
- 4.2. The HRPP QA&E Team reports the post-approval monitoring activities at the IRB.

### 5. PROCEDURE

- 5.1. The HRPP QA&E Team conducts post-approval monitoring reviews on active and non-active exempt and non-exempt Human Research studies, regardless of the IRB of record.
- 5.2. The HRPP QA&E Team will generate a list of IRB-approved protocols.
- 5.3. The HRPP QA&E Team will select the appropriate number of studies (according to the sampling level) from the list.
  - 5.3.1. 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.
  - 5.3.2. Studies may be selected with input from IRB Directors.
  - 5.3.3. The HRPP QA&E Team will make an effort to not select multiple studies from the same Principal Investigator (PI) within the same calendar year for PAM review.
  - 5.3.4. The HRPP QA&E Team will send the proposed study selections to the HRPP QA&E Director to get feedback and verify selections.
- 5.4. For each selected study, the HRPP QA&E Team will email the PI the appropriate documents from Section 6. Materials below.
- 5.5. For the in-person PAM Visit, the HRPP QA&E Team will do the following:
  - 5.5.1. Conduct a pre-review of the protocol and save copies of relevant study files in the corresponding electronic folder.
  - 5.5.2. Schedule the visit.



SOP: Post-Approval Monitoring Assessment		
NUMBER	EFFECTIVE DATE	PAGE
12.001 (HRP-028)	11/21/2024	Page 2 of 2

- 5.5.3. Conduct an assessment, including but not limited to:
  - 5.5.3.1. Review consent forms, as appropriate.
  - 5.5.3.2. Review participant files, as appropriate.
  - 5.5.3.3. Review regulatory documentation, as appropriate.
- 5.5.4. Conduct an exit interview to share any findings and share good practices.
- 5.5.5. When the assessment is complete, the QA&E Team member will send a report of the review to the IRB.
- 5.5.6. Any serious or continuing noncompliance discovered during a PAM will be promptly reported to the IRB Chair of the designated IRB and the HRPP IRB Director.

## 6. MATERIALS

- 6.1. 1.001 (HRP-101) - SOP - Human Research Protection Program Plan.
- 6.2. 12.009 (HRP-061) - SOP – Evaluations of the HRPP.
- 6.3. 12.102 (HRP-430a) - CHECKLIST - Investigator Quality Improvement Assessment - Drug, Devices, Clinical Trial.
- 6.4. 12.103 (HRP-430b) - CHECKLIST - Investigator Quality Improvement Assessment - Participant File.
- 6.5. 12.104 (HRP-430c) - CHECKLIST - Investigator Quality Improvement Assessment - Biomedical Research.
- 6.6. 12.105 (HRP-430d) - CHECKLIST - Investigator Quality Improvement Assessment - Social Behavioral Research.
- 6.7. 12.106 (HRP-430e) - CHECKLIST - Investigator Quality Improvement Assessment - Humanitarian Use Device.
- 6.8. 12.107 (HRP-431) - CHECKLIST - Minutes Quality Improvement Assessment.
- 6.9. 12.301 (HRP-534) - LETTER – Investigator QI Assessment.

## 7. REFERENCES

- 7.1. None.