RUTGERS UNIVERSITY Office for Research

**SOP:** Post Approval Monitoring (PAM) Exit Interview for Routine and Directed (For-Cause) Review

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| 12.006 (HRP-025d) | 11/26/24 | 1 of 2 |

## 1 PURPOSE

1.1 This SOP ensures that the HRPP Quality Assurance & Evaluation (QA&E) Team provides a summary of their visit and allows the Principal Investigator to ask questions, clarify, and provide missing information. This meeting may be held in-person or via a virtual invitation. This assures the Principal Investigator that accurate information is communicated to the IRB Executive Committee representing how the IRB approved study, was reviewed and is being conducted.

## 2 REVISIONS FROM PREVIOUS VERSION

2.1 Version 1, 1/1/21

## 3 POLICY

3.1 This SOP applies to the HRPP QA&E team and pertains to providing clear and concise communication regarding their findings at the time of the Post Approval Monitoring (PAM) Review. It also pertains to the Principal Investigator and the study team allowing time to hear the concerns and observations and allowing time for discussion and comments.

## 4 RESPONSIBILITIES

4.1 HRPP QA&E Team is responsible for a thorough Exit Interview and that findings are discussed in a transparent manner with the PI and study team.

## 5 PROCEDURE

5.1 Exit Interview

- 5.1.1 The exit interview will ideally occur within 72 working hours of the completion of the initial data collection and analysis or upon receipt of all pertinent study documents. The exit interview may be held virtually or in-person depending upon specific circumstances.
- 5.1.2 The Principal Investigator or his/her designee is required to be present during the exit interview.
  - 5.1.2.1 The co-investigator and/or study team members are also strongly encouraged to attend.
- 5.1.3 The HRPP team member discusses the PAM review and responds to any questions from the Principal Investigator and study team.
- 5.1.4 It is important at this point to discuss all questionable issues and provide opportunities for clarification which will then be placed in the PAM report as information provided by the PI and/or study team.
  - 5.1.4.1 After the Exit Interview, the QA&E team member will provide a summary of the discussion to the PI and request clarifications if needed.
  - 5.1.4.2 Any missing, incomplete, or incorrect data should be provided by the PI within three (5) business days of the exit interview summary email, unless the finding(s) may impact the safety of subjects or otherwise affect the integrity of the research.
  - 5.1.4.3 If no communication is received regarding the missing, incomplete, or incorrect data, after two reminder emails, then the finding/deviation will be cited in the final report without the PI/Study team response.

## 6 MATERIALS

6.1 1.001 (HRP-101) – Human Research Protection Program Plan.

6.2 12.003 (HRP-025a) – SOP - PAM Initial Interview for Routine and Directed (For-Cause) Reviews.

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.

## 7 REFERENCES

7.1 Rutgers University

7.1.1 1.001 (HRP-101) - Human Research Protection Program Plan.

7.1.2 Rutgers HRPP Toolkit and Guidance.

7.2 Federal Regulations:

7.2.1 21 CFR Part 11 – Electronic Records; Electronic Signatures.

7.2.2 21 CFR Part 50 – Protection of Human Subjects.

7.2.3 21 CFR Part 54 – Financial Disclosures by Clinical Investigators.

7.2.4 21 CFR Part 56 – Institutional Review Boards.

7.2.5 21 CFR Part 312 Investigational New Drug Application.

7.2.6 21 CFR 314 Applications for FDA Approval to Market a New Drug.

7.2.7 21 Part 600 – Biological Products: General.

7.2.8 21 CFR 601 – Applications for FDA Approval of a Biologic License.

7.2.9 21 CFR 812 – Investigational Device Exemptions.

7.2.10 21 CFR Part 814 – Premarket Approval of Medical Devices.

7.2.11 45 CFR Part 46 HHS – Protection of Human Subjects.

7.2.12 45 CFR Parts 160 and 164 HIPAA Privacy Rule.

7.3 New Jersey State Law:

7.3.1 NJ Title 26 Chapter 316 - Access to Medical Research Act.