RUTGERS UNIVERSITY
Office for Research

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

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1 PURPOSE

1.1 The purpose of the Human Research Protection Program's Quality Assurance and Evaluation Team (QA&E) is to provide post-approval monitoring to protect the rights and welfare of research participants. This ensures that the investigator has the opportunity to provide an overview of how the IRB-approved protocol is being conducted. This allows the HRPP Quality Assurance and Evaluation (QA&E) Team to listen and observe to see if the description of how the study is being conducted mirrors the IRB-approved protocol.

2 REVISIONS FROM PREVIOUS VERSION

2.1 1/31/22

3 POLICY

3.1 This applies to the Principal Investigator (PI) who has the overall responsibility on conducting the study as approved by the IRB of Record. At the initial interview, the HRPP QA&E Team may make the inquiries as needed to conduct the PAM review listed in this SOP, or similar ones. This is not a comprehensive list, as the questions may vary according to specific protocol details.

4 RESPONSIBILITIES

4.1 The HRPP QA&E Team members review the submission in eIRB+, evaluate the conduct of HRPP, and conduct a thorough interview and site visit/virtual visit to review related study source documents. When this is complete the QA&E team member will write a report of any findings and present it to IRB Executive Committee.

4.2 A QA&E Team member will ensure that PAM activities are recorded in the eIRB+ System.

5 PROCEDURES

5.1 A Routine PAM Review is conducted as a quality assurance activity and randomly chosen, to ensure that human research studies are conducted according to regulatory requirements and the IRB-approved protocol.

5.2 A Direct (For-Cause) PAM Review is based on a complaint or a concern. This type of review is required review to ensure that the study is being conducted according to regulatory requirements and the IRB-approved protocol.

5.3 The process for both Routine and Directed (For Cause) Reviews are the same. The on-site review of the requested protocol begins with an initial interview whether on-site or virtual.

5.3.1 The PI is encouraged to invite his/her Co-investigator(s), study coordinator(s), and any other personnel named on the protocol.

5.4 HRPP QA&E Team may ask the following questions or similar ones:

5.4.1 How is your study conducted?

5.4.2 How are subjects recruited?

5.4.3 What is the informed consent process?

5.4.4 Where and how do you document the consent process?

5.4.5 What staff is involved in study activities, and what are their roles and qualifications?

5.4.6 How many subjects were approved by the IRB?

5.4.7 How many subjects are currently enrolled?

5.4.8 What source documents are available to support the conduct of the study?

5.4.9 Is this the only performance site?

5.4.10 Where are the original signed and dated consent forms stored?

5.4.11 Who and how do you determine whether subjects were eligible for the study?

5.4.12 Who evaluated research data for the safety of the subjects?

5.4.13 How frequently is the research data reviewed for safety?

5.4.14 Have there been any serious adverse events or unanticipated events, and have they been reported to the local IRB and sponsor (if applicable)?

5.4.15 Where are study medications/investigational drugs/investigational devices stored and dispensed (if applicable)?

5.4.16 Has there been a lapse in IRB approval? If so, why?

5.4.17 If there was a lapse in IRB approval, what study procedures were conducted?

5.5 Arrangements are made to conduct the document review whether after this interview or at another time and location.

6 MATERIALS

6.1 1.001 – Human Research Protection Plan

6.2 10.004 (HRP-026) – SOP – Suspension and Termination Issues Outside a Convened IRB

6.3 12.002 (HRP-025) – SOP – Post Approval Monitoring (PAM) Routine and Directed (For Cause) Reviews

6.4 12.102 (HRP-430a) - CHECKLIST - Investigator Quality Improvement Assessment - Drug, Devices, Clinical Trial

6.5 12.103 (HRP-430b) – CHECKLIST – Investigator Quality Improvement Assessment – Participant File

6.6 12.104 (HRP-430c) – CHECKLIST – Investigator Quality Improvement Assessment – Biomedical Research

6.7 12.105 (HRP-430d) – CHECKLIST – Investigator Quality Improvement Assessment – Social Behavioral Research

6.8 12.106 (HRP-430e) – CHECKLIST – Investigator Quality Improvement Assessment – Humanitarian Use Device

7 REFERENCES

7.1 Rutgers University

7.1.1 HRP-101 Rutgers Human Research Protection Program

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 Title 26 Chapter 316 - Access to Medical Research Act