1 PURPOSE

1.1 This SOP guides the investigator and the Quality Assurance and Evaluation (QA&E) Team in what documents must be maintained and be provided during Post Approval Monitoring (PAM). The Principal Investigator (PI) is responsible for the study records to contain the IRB regulatory documents submitted and approved by the IRB of Record, as well as signed and dated consent forms and study documents that related to the conduct of the study as approved by the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 4/2/22

3 POLICY

3.1 The scope applies to the PI and his/her/their study team that will prepare for a routine or for-cause review. The study team consists of those individuals named on the IRB approved protocol.

4 RESPONSIBILITIES

4.1 HRPP QA&E Team are responsible to assess via the study documents and meetings with the PI and study staff whether the conduct of the study was IRB Approved. Appropriate self-assessment checklists 12.102-12.106 (HRP-430a-e) will be provided to the PI and study team prior to the review of documents.

5 PROCEDURE

5.1 Work Space

5.1.1 The PI shall be asked to provide a space for the QA&E Team to review research records and arrange for research staff to be available during the routine or for cause review to assist with access to records/documents and provide answers to questions regarding the conduct of the selected study.

5.2 Study Documents to be Reviewed

5.2.1 Regulatory Files (where applicable to the study)

- 5.2.1.1 Initial submission, with IRB approval letter
- 5.2.1.2 All FDA documents for IND/IDE/protocols including single use and HUD (i.e. 1572/1571 correspondence)
- 5.2.1.3 Protocol and amendments/modifications, with IRB approval letters
- 5.2.1.4 Consents and amendments/modifications, with IRB approval letters
- 5.2.1.5 Advertisements, with IRB approval letters
- 5.2.1.6 Continuing reviews, with IRB approval letters
- 5.2.1.7 Reported adverse events
- 5.2.1.8 Correspondence (e.g., IRB debriefing letters, investigator responses to the IRB, emails)
- 5.2.1.9 Training and education of staff related to the study
- 5.2.1.10 Subject Recruitment and Enrollment records (i.e. CRF, screening, eligibility)
- 5.2.1.11 Reportable Events (ie. Protocol Deviations/Violations, Serious Adverse Events, Unanticipated Problems
- 5.2.1.12 Drug accountability and dispensing logs, as appropriate
- 5.2.1.13 Location where the study was conducted and where study documents, consents, are stored (i.e., confidentiality, limited access, separate from study data)

5.2.2 Appropriate recruitment of subjects with respect to protocol specific inclusion/exclusion criteria (i.e., enrollment and screening logs) Informed Consent Forms
- 5.2.2.1 Signed consents, by subject, investigator and surrogate are equal to the number of enrolled subjects
- 5.2.2.2 Content of signed consents are the IRB-approved versions
- 5.2.2.3 Proper execution of each informed consent (i.e., signed before study activities)
- 5.2.2.4 Documentation of the consent process
- 5.2.2.5 Determination of any enrollment during lapse in IRB approval and assessment if study activities took place

5.2.3 Data
- 5.2.3.1 Location (i.e., confidentiality, limited access)
- 5.2.3.2 Compliant with HIPAA
- 5.2.3.3 Source documentation of protocol-specific study procedures, interventions, study visits, follow-up, adverse events, and unanticipated problems (e.g., CRFs, computer generated study visit forms)

5.3 Institutional Review Board (IRB) Documents to be Reviewed via eIRB+ or paper files
- 5.3.1 IRB meeting minutes
- 5.3.2 IRB reviewer materials
- 5.3.3 Timeline for submissions and review

5.4 Subject Safety
- 5.4.1 In the event of suspected harm to subjects (i.e. increase in or non-reporting of SAE/AE), serious non-compliance and/or increased risk to subjects, the HRPP QA&E Director would be immediately notified in order to inform the Institutional Official and Designee to take appropriate action.

5.5 Findings of the PAM review will be itemized in the report to the Executive IRB Committee
- 5.5.1 The PAM report will be presented at the next available Executive IRB Committee meeting.

6 MATERIALS

6.1 1.001 (HRP-101) – Human Research Protection Program Plan
6.2 10.004 (HRP-026) – SOP – Suspension or Termination Issued Outside of Convened IRB
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) - 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 T itle 26 Chapter 316 - Access to Medical Research Act