1. PURPOSE

1.1. This procedure establishes the process to conduct Post Approval Monitoring (PAM) Routine and Directed (for-cause) Reviews.

1.2. The process begins when a study is chosen or assigned for review.

1.2.1. A Directed Review (for-cause) related to a question relating to non-compliance (perceived or confirmed) is raised, may be required because of:

1.2.1.1. Reportable events.

1.2.1.2. Any review of submitted materials via eIRB+.

1.2.1.3. Any allegation of non-compliance (perceived or confirmed).

1.2.1.4. A suspension or termination of IRB approval (see 10.004 (HRP-026)).

1.2.1.5. Request by an IRB Chair convened IRB Committee, IRB Directors, or Institutional Official.

1.2.2 A routine review is chosen by a random sampling of about 3% of active studies approved by the IRB.

1.2.2.1 Sampling of minimal risk studies

1.2.2.2 Sampling of greater than minimal risk studies

1.2.2.3 Sampling of device studies

1.2.2.4 Sampling of clinical trials with an IND

1.2.2.5 Sampling of social and behavioral studies

1.3. The process ends when:

1.3.1. The review is complete, and a report is written

1.3.2. The report is submitted to the Institutional Review Board (IRB).

2. PREVIOUS VERSION

2.1. 01.20.22

3. POLICY

3.1. The HRPP (Human Research Protection Program) maintains a review program to monitor and improve compliance for human research studies, supported or conducted by Rutgers University.

3.2. The HRPP investigators concerns, allegations, complaints for non-compliance, and systematic problem areas in Human Research.

4. RESPONSIBILITIES

4.1. Institutional Official or designee:

4.1.1. Requests that the HRPP QA&E Team conduct a review of the Investigator and/or study materials as needed to answer the questions raised by the review of non-compliance or other questions raised by an eIRB+ submission(s).

4.1.2. Provides the HRPP QA&E Team with the scope of the review.

4.2. Upon notification of the PAM Directed (for-cause) review or choosing a study for routine review, the HRPP QA&E Team members create a review plan and carry out these procedures.

4.3. The HRPP QA&E Team members make their findings based on the available materials, interviews, and/or information obtained during a PAM Routing or Directed (For-Cause) Review.

4.4. The HRPP QA&E Team members will document their findings in writing in the form of a report which will be submitted to the IRB for review and action.

5. PROCEDURE

5.1. Notification of Review will be provided to the PI

5.1.1. The HRPP QA&E Director will notify the investigator in writing that a PAM Directed (For-Cause) Review will be conducted.
5.1.2. The HRPP QA&E Team member will notify the investigator in writing that a Routine Review will be conducted.
5.1.3. The PI will be sent a 2nd notice of impending QA&E review five (5) days after the first notice is sent.
5.1.4. In the event that there is no response a third (3) notice will be sent by the Director of QA&E to the PI.
5.1.5. In the event that the PI does not respond to the third (3) notice, the School Dean and/or Department Head will be notified to ensure that the review can be completed.

5.2. The HRPP QA&E Team members schedule an on-site review of the protocol identified in 5.1.
5.3. Determine what information to gather and what individuals to interview.
5.3.1. The HRPP QA&E Team members will prepare and maintain the review file, which typically consists of the following elements (but may vary depending on the circumstances of a particular Study Review):
5.3.1.1. IRB Submission
5.3.1.2. Consent Document(s)
5.3.1.3. Protocol(s)
5.3.1.4. Investigators Brochure(s)
5.3.1.5. Protocol Modification(s)
5.3.1.6. Continuing Reviews
5.3.1.7. Post Approval Monitoring Checklists (12.101-12.105 (HRP-430a-d))
5.3.1.8. Report (Routine or For-Cause Review report)
5.3.1.9. Significant Findings/Determinations
5.4. Gather information and interview individuals.
5.4.1. Based on the nature of the concerns, this might involve one or more of the following activities:
5.4.1.1. Interviewing the PI, co-investigators and research staff
5.4.1.2. Reviewing source regulatory and all applicable documentation
5.4.1.3. Reviewing each consent form or a sample or of the consent forms
5.4.1.4. Reviewing each case report form or sample or all participant data or case report forms
5.4.1.5. Collect information from a tour of the research site(s)
5.5. The HRPP QA&E Team members complete 12.101 (HRP- 430a) for Drug or Device Clinical Trials
5.6. The HRPP QA&E Team members complete 12.102 (HRP- 430b) for each participant file
5.7. The HRPP QA&E Team members complete 12.103 (HRP- 430c) for biomedical research studies
5.8. The HRPP QA&E Team members complete 12.104 (HRP- 430d) for Social and Behavioral studies
5.9. The HRPP QA&E Team members completes 12.012 (HRP-430f) for Routine/Directed exit interview
5.9.1. The HRPP QA&E Team members will document their findings in writing and submit them to the IRB in the form of a report.
5.9.2. This documentation will include the following:
5.9.2.1. Background and Summary
5.9.2.2. Findings and/or observations and recommendations
5.9.2.3. Supporting documentation of findings

6. MATERIALS

6.1. 12.012 HRP-430f) – SOP - Post-Approval Monitoring Routine/Directed exit interview
6.2. 12.102 (HRP-430a) - CHECKLIST Post-Approval Monitoring Drug or Device Clinical Trial
6.3. 12.103 (HRP-430b) - CHECKLIST Post-Approval Monitoring Participant File
6.4. 12.104 (HRP-430c) - CHECKLIST Post-Approval Monitoring Biomedical Research
6.5. 12.105 (HRP-430d) - CHECKLIST Post-Approval Monitoring Social and Behavioral Research

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 Title 26 Chapter 316 - Access to Medical Research Act