1 PURPOSE

1.1 This Standard Operating Procedure (SOP) outlines the process for the IRB Executive Committee to determine the appropriate actions when a Post Approval Monitoring (PAM) review identifies non-compliance, serious non-compliance, or continuing non-compliance in the conduct of human research (HR) studies that are covered under Rutgers University's Federal Wide Assurance (FWA), as detailed in the PAM report.

2 REVISIONS FROM PREVIOUS VERSION

2.1 5.5.22

3 POLICY

3.1 This Standard Operating Procedure (SOP) pertains to the Rutgers Institutional Review Board (IRB) Executive Committee, which evaluates the findings of a PAM routine, or a directed for-cause report presented during a convened meeting. The IRB Executive Committee is obligated to make determinations based on the findings for all Human Research (HR) studies reviewed, as well as those covered under Rutgers University (FWA).

4 RESPONSIBILITIES

4.1 The Rutgers IRB Executive Committee is responsible for reviewing the findings of PAM Reports. They have the authority to make appropriate decisions, implement corrective actions, halt recruitment, request protocol amendments, increase monitoring, and enforce suspensions or the closure of Human Research (HR) under review for studies overseen by a Rutgers University IRB.

4.2 For studies reviewed by a non-Rutgers IRB, the Rutgers IRB Executive Committee will provide recommendations to the Rutgers Institutional Official (IO) and the Human Research Protection Program (HRPP) Quality Assurance & Evaluation (QA&E) Director.

4.3 For HR studies under PAM Review reviewed by a non-Rutgers IRB, the Rutgers IRB Executive Committee acts on behalf of the Rutgers Institutional Official.

5 PROCEDURE

5.1 Response to the PAM Review Report by the IRB Executive Committee

5.2 When there are no findings of non-compliance, the PAM review is sent to the HRPP QA&E Director.

5.2.1 The PAM Report will be presented by a QA&E team member at the next scheduled meeting. The IRB Executive Committee will review, discuss, and acknowledge the Report, which will be documented in the meeting minutes.

5.2.2 For findings of non-compliance, the Quality Assurance & Evaluation (QA&E) Team attaches the PAM review to the agenda of the IRB Executive Committee meeting and presents it during the next convened session. A member of the QA&E Team will outline the findings and specify the areas of non-compliance to the IRB Executive Committee. The committee will then review and discuss the information and make appropriate determinations regarding non-compliance, serious non-compliance, or continuing non-compliance. The decisions and details will be recorded in the meeting minutes.

5.2.3 No formal written response from the PI is required if the audit findings are considered "accepted with no further action" by the IRB Executive Committee.

5.2.4 A formal written response from the Principal Investigator is necessary if the PAM Review findings necessitate a corrective action plan or require clarification from the IRB Executive Committee. The HRPP QA&E Director will be notified if a non-Rutgers IRB serves as the IRB of record.

5.2.5 The IRB Executive Committee can take immediate action on a research protocol that has been reviewed by a Rutgers IRB. Additionally, they can provide recommendations to the Institutional Official (IO) or their designee regarding research protocols reviewed by non-Rutgers IRBs.

5.2.6 Actions in the event of serious or continuing noncompliance include, but are not limited to:

5.2.6.1 Require/Recommend administrative hold on the research.

5.2.6.2 Require/Recommend suspension of the protocol or suspend any of the components of the research (i.e. new enrollment, study treatment, follow-up, and data analysis) until a corrective Action Plan/Prevention Plan (CAPA) can be developed and implemented and approved by the Executive IRB Committee.

5.2.6.3 Require/Recommend closure of the protocol.

5.2.6.4 Require/Recommend Initiate audits of all or some of the investigator's active protocols.

5.2.6.5 Require/Recommend that the PI modify the protocol to minimize risk.

5.2.6.6 Require/Recommend the interval at which continuing review is conducted to be modified to less than one year as appropriate to the degree of risk.

5.2.6.7 Require/Recommend that the PI modify the informed consent process and/or document.

5.2.6.8 Require/Recommend observation of the research or the consent process and modify the information disclosed during the consent process.

5.2.6.9 Require/Recommend notification of current and previously enrolled subjects of new information that may relate to a subject's willingness to continue participation in the research.

5.2.6.10 Require/Recommend submission of status reports on a defined set schedule to the IRB

5.2.6.11 Require/Recommend additional education and training for the investigators and support staff.

5.2.6.12 Require/Recommend acceptance and approval of the PI's proposed CAPA or changes.

5.2.6.13 Require/Recommend a directed for-cause investigation by an outside consultant.

5.2.6.14 Require/Recommend Termination of the Research.

5.2.6.15 Require/Recommend other actions as necessary.

5.2.7 In cases where there are suspected risks to participant safety, potential research misconduct, or significant ongoing non-compliance identified during the PAM review process, the HRPP QA&E Director will take immediate action and notify the Institutional Official (IO).

6 MATERIALS

6.1 PAM Report Template.

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 Title 26 Chapter 316 - Access to Medical Research Act.