## 1 PURPOSE

1.1 This policy guides the HRPP Quality Assurance and Evaluation (QA&E) Team in the tasks of requesting and touring the facility to observe where the research is being conducted.

## 2 REVISIONS FROM PREVIOUS VERSION

2.1 Tour of the Facility for On-site Routine or For Cause Review

## 3 POLICY

3.1 This policy applies to the Principal Investigator (PI), Co-investigator(s), or study coordinator(s) that conduct the study activities to demonstrate that appropriate facilities and sufficient resources are available to conduct study activities and to determine where subjects are seen, documentation is stored, and where samples are obtained processed and stored. These tours will vary according to the description of study activities provided in the IRB approved protocol.

## 4 RESPONSIBILITIES

4.1 The HRPP QA&E team member may tour any study space listed in an IRB approved protocol including, but not limited to, a laboratory, clinical space, surgery areas, and procedure sites. The QA&E team member may observe and compare procedures conducted in these areas with those listed in the approved protocol(s).

## 5 PROCEDURE

5.1 Tour of facility

- 5.1.1 The HRPP QA&E Team may ask the PI, Co-investigator(s), and/or study coordinator(s) the following questions:
  - 5.1.1.1 Where are the Informed Consent Forms locked and stored?
  - 5.1.1.2 Where does the Informed Consent process take place?
  - 5.1.1.3 Where are the regulatory documents for the study kept and maintained?
  - 5.1.1.4 Where are physical exams and/or study procedures conducted (if applicable)?
  - 5.1.1.5 Where are samples obtained, processed, and stored?
  - 5.1.1.6 Are samples stored with identifiable information? If yes, how is confidentiality maintained?
  - 5.1.1.7 Is the area where samples are obtained kept clean?
  - 5.1.1.8 Where are study medications/investigational drugs/investigational devices stored and dispensed (if applicable)?
  - 5.1.1.9 Are there any temperature logs regarding storage of the study medications/investigational drugs/investigational devices?
  - 5.1.1.10 Are there calibration and/or maintenance logs available for any equipment requiring calibration/maintenance?
  - 5.1.1.11 Where is the study equipment located?
  - 5.1.1.12 Where are the computer stations located? Is the area private and secure?
  - 5.1.1.13 Are study records maintained in a secure manner to protect confidentiality of subjects?
  - 5.1.1.14 Where are the source documents stored?

## 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) - 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