1 PURPOSE

1.1 This procedure establishes the process to manage Reportable New Information that includes Allegations of Non-Compliance, Protocol Deviations, Protocol Violations, and Subject Complaints or other concerns received by the Human Research Protection Program (HRPP) involving human subjects.
1.2 The process begins when a staff member receives a written or verbal allegation of noncompliance or concern or complaint from research subjects and others.
1.3 The process ends when the information is determined not to represent a problem that requires management, is managed administratively, or referred to the convened IRB for review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 HRPP reviews all Allegations of Non-Compliance, Protocol Deviations, Protocol Violations, and Subject Complaints and takes any necessary action to ensure the ethical and compliant conduct of research.
3.2 HRPP reviews and investigates, as appropriate, concerns or complaints received from research subjects or anyone with a concern or complaint regarding a research study involving human subjects. Concerns or complaints may be submitted anonymously.

4 RESPONSIBILITIES

4.1 Investigators must report to the IRB Allegations of Non-Compliance, Protocol Deviations, Protocol Violations, and Subject Complaints regarding research studies they conduct [See 1.002 (HRP-103) – Investigator Manual; 1.005 (HRP-103p) – pSite Investigator Manual]:
4.1.1 When a concern or complaint rises to the level of a Reportable Event;
4.2 Complaint of a subject other than concerns regarding minor payments for study participation that cannot be resolved by the research team.
4.2.1 and
4.2.2 Potential Non-Compliance or Subject Complaints according to the requirements specified in a reliance agreement.
4.3 The HRPP, IRB Chair, members, and staff follow the procedures outlined at Sections 5 and 6.
4.4 The IRB Chair, Executive Committee in consultation with the HRPP Director or the Quality Assurance & Evaluation (QA&E) Director or the Institutional Official (IO) or designee promptly delegates the investigation of received concerns and complaints to QA&E staff or others, as appropriate.
4.5 When delegated to them, QA&E staff create an investigative plan, make their findings based on the results of the investigative plan, document their findings in writing in the form of a report, and submit their report to the IRB.

5 PROCEDURES

5.1 Allegations of Non-Compliance: The HRPP Director and/or the QA&E Director, will conduct a preliminary brief inquiry to determine whether each Allegation of Non-Compliance involves a current approved study, whether the study is sponsored and if yes, by whom, whether the study involves other research oversight committees/units and whether the allegation or report is reasonably supported. If yes, follow the procedures under Finding of Non-Compliance.

5.2 The IRB Chair, Executive Committee will be notified of all reported, potentially serious noncompliance promptly upon receipt.

5.3 The IRB Chair, Executive Committee, the HRPP Director and the QA&E Director will make the determination of whether an allegation of non-compliance has enough information to make findings, whether additional information is needed, or whether to open an investigation.

5.3.1 Self-reported noncompliance with details of the noncompliance may not need investigation to conclude the accuracy of the noncompliance (e.g., informed consent was obtained after research was initiated with submission of a copy of the signed consent form and a copy of research datum/data on a subsequent date).

5.3.2 When additional information is needed to determine that a protocol violation or noncompliance with regulations or policies occurred, the Chair, or designee, will determine what information is needed, who should obtain the information, and from what source(s) the information should be obtained.

5.3.3 When the IRB Chair in consultation with the QA&E Director and/or HRPP Director, or designee, determines that an investigation should be opened, the IRB Chair or designee will determine whether the investigation would be conducted by the QA&E team and/or designee, or an ad-hoc committee because special expertise is needed. .

5.3.3.1 A target date for completion of the audit will be determined by the IRB Chair, HRPP Director and the QA&E Director or designee.

5.3.3.2 If an ad-hoc committee is needed, the IRB Chair or designee, will determine in writing who shall serve on the ad-hoc committee.

5.3.3.3 All members serving on the ad-hoc committee must sign the IRB's Conflict of Interest and Confidentiality agreement.

5.3.3.4 Whenever an investigation for an allegation of noncompliance is initiated, the allegation and the method for investigating the allegation will be reported to the Executive Committee at the next available meeting.

5.4 **Reviewing Findings of Noncompliance – Investigation of Allegations of Noncompliance**: The QA&E Director, and the QA&E Staff (unless the Executive Committee Chair designates another individual or ad-hoc committee designated to review an allegation of noncompliance due to special required expertise) will conduct the for-cause investigation in accordance with 12.002 (HRP-025), 12.003 (HRP-025a), 12.004 (HRP-025b), and 12.005 (HRP-025c). A written report/summary of their review or investigation with conclusions will be provided to the Executive Committee who will make a determination of whether the allegation of noncompliance is clearly "No Noncompliance" or Minor Noncompliance".

5.4.1 **Finding of No Noncompliance:** If the Executive Committee determines that noncompliance with the IRB-approved protocol, regulations, or Rutgers policies did not occur for any incident that was investigated. The IRB Administrator will prepare a letter to be sent in the eIRB+ system to the PI/study team.

5.4.1.1 If the allegation of noncompliance was reported by an individual(s), a separate communication will be made to inform them of the outcome. The communication will be made separately in order to protect their confidentiality.

5.4.1.2 When appropriate the IRB Chair or designee will determine whether the finding of no noncompliance should be communicated to the individual reported the allegation.

5.4.2. **Finding of Minor Noncompliance:** If the Executive Committee determines that minor noncompliance with the IRB-approved protocol, regulations, or Rutgers policies did occur

for any incident that was investigated, the Executive Committee will consider any appropriate corrective actions.

5.4.2.1 The IRB Administrator will prepare a letter to be sent in the eIRB system to the PI/study team.

5.4.2.2 When appropriate the IRB Chair or designee will determine whether the finding of minor noncompliance should be communicated to the individual reported the allegation.

5.4.3. **Finding of Serious or Continuing Noncompliance:** If the Executive Committee reviews the audit report in accordance with 12.007 (HRP-025e) – Role of the Executive Committee to the Audit Report and determines that allegation is potentially serious or continuing noncompliance with the IRB-approved protocol, regulations, or Rutgers policies, the Executive Committee will determine appropriate corrective actions. The IRB Administrator or designee will prepare a letter to be sent in the eIRB+ system to the PI/study team documenting the finding of serious or continuing noncompliance and the appropriate corrective actions. The audit report is attached with the letter.

5.4.3.1 The PI and any research staff who were determined to be in noncompliance will be given a deadline to review the report and its findings and given an opportunity to respond with any additional information or comments that may improve the accuracy of the report.

5.4.3.2 The IRB Executive Committee will then review the PI/research staff's response(s) and determine the final outcomes/actions.

6 REVIEW OF SUBJECT COMPLAINTS:

6.1 When contacted by an individual with a concern or complaint, the staff member will gather information from the complainant:

6.1.1 Individual's name, address, and phone number if they choose to provide it. Individuals may submit concerns or complaints anonymously.

6.1.2 Study protocol name (or acronym), if known, and the name of the Principal Investigator.

6.1.3 Date(s) when the concern or complaint arose.

6.1.4 Details about the concern or complaint.

6.1.5 How the individual would like to see the concern or complaint resolved.

6.1.6 Assure the individual that their confidentiality will be protected.

6.1.7 Inquire to determine whether the individual wishes a follow-up communication with resolution of the concern or complaint.

6.1.8 When possible, the staff member will document the concern or complaint using 10.301 (HRP-024b) - Complaint or Allegation Intake Form.

6.1.9 Once intake is completed, the staff member will notify the QA&E Director and/or HRPP Director of the concern or complaint and ask for direction on how to proceed, such as collecting additional information about the research protocol.

6.2 Upon receipt of a written concern or complaint, the staff member will notify the QA&E Director and/or designee and ask for direction on how to proceed—whether to contact the complaint to collect the information outlined at 5.1, above, or something else, such as collecting additional information about the research protocol.

6.3 The QA&E Director and/or HRPP Director or designee handles the concern or complaint in a confidential manner to the extent allowed by law and determines whether (a) the information does not require management; (b) the information can be managed administratively; or (3)

that an investigation is necessary and, if so, to whom the investigation will be delegated. All activities related to investigating and resolving concerns and complaints will be conducted confidentially limiting contact to individuals with responsibilities that require knowledge of the concern or complaint. When the QA&E Director and/or HRPP Director or designee determines that the concern or complaint does not require management, no further action is taken.

6.4 When the QA&E Director and/or HRPP Director or designee determines that the concern or complaint is non-serious and may be managed administratively, s/he will delegate to QA&E or IRB staff a task to resolve the concern or complaint.

6.5 When a concern or complaint involves potential harm to subjects or others, or the death of a subject, the QA&E Director and/or HRPP Director or designee notifies the IRB Chair for immediate action pending formal inquiry. The HRPP Director and/or QA&E Director or designee reports concerns or complaints involving a serious issue immediately to the IRB Chair, the IO, and, if appropriate, Legal Counsel. The IRB Chair, IO or designee may institute a Suspension of IRB Approval when it is assessed that subjects may be at risk of adverse efforts or their rights and welfare before action may be considered by a convened IRB. [See 10.004 (HRP-026) – SOP – Suspension or Termination Issued Outside of Convened IRB.]

6.6 The HRPP Director and/or QA&E Director or designee promptly notifies the QA&E team to investigate the concern or complaint who then notifies the Principal Investigator in writing that the QA&E team will contact them as soon as possible to conduct their investigation. After the investigation is complete, the QA&E team member(s) prepare a written report for the Executive IRB. The Executive IRB makes a determination and prepares a debriefing memo to the Principal Investigator informing him/her of the findings and a corrective action plan, as appropriate. [See 12.002 (HRP-025) – SOP – Directed Review (For Cause) Audits].

6.7 If the HRPP Director and/or QA&E Director or designee, in the process of investigation, suspects research misconduct or noncompliance has occurred, she/he or his/her designee will promptly notify the Executive IRB Chair(s), the IO, the Assistant Vice President for Research Regulatory Affairs (AVP for RRA), and Director of Research Integrity as appropriate and required by policy and standard operating procedures. [See Rutgers Policy 90.2.2 Research Misconduct;10.001 (HRP-024) – SOP – Reportable New Information]

6.7.1 Actions taken by the Executive IRB are appropriate for the circumstances, and the final course of action is dependent on the nature, severity, and seriousness of the findings. [See 10.201 (HRP-321) – WORKSHEET – Review of Reportable New Information]. The decisions of the Executive IRB may be reported to the IO and Legal Counsel, as appropriate.

6.7.2 The HRPP Director and/or QA&E Director or designee will contact the individual with the resolution of the concern or complaint if the individual expressed a preference for follow-up communication.

6.7.3 Decisions will be promptly reported to Sponsors, oversight agencies, and according to requirements specified in a reliance agreement, the Clinical Trials Agreement in the case of industry-supported studies, as applicable. [See 10.001 (HRP-024) – SOP – Reportable New Information]

6.7.4 The QA&E team compiles a list of all concerns and complaints received, their investigation, and disposition. Statistical details regarding QA&E concerns, and complaints activities are reported quarterly to the AVP for RRA, and the HRPP Director.

7 MATERIALS

7.1 Rutgers Policy 90.2.2 Research Misconduct

7.2 10.001 (HRP-024) – SOP – Reportable New Information
7.3 10.301 (HRP-024b) – FORM – Complaint or Allegation Intake Form
7.4 10.004 (HRP-026) – SOP – Suspension or Termination Issued Outside of Convened IRB
7.5 10.201 (HRP-321) – WORKSHEET – Review of Reportable New Information
7.6 12.002 (HRP-025) – SOP – Directed Review (For Cause) Audits

8 REFERENCES

8.1 21 CFR 56.108(b)
8.2 45 CFR 46.108(a)(4)
8.3 DoD Instruction 3216.02, Section 6 Procedures, 4.b(4)