1. PURPOSE
   1. This policy describes the process for the role of the IRB Executive Committee in making a determination when minor, serious, or continuing non-compliance is described in an audit report.
2. REVISIONS FROM PREVIOUS VERSION
   1. None
3. POLICY
   1. The IRB has the responsibility for assessing findings of noncompliance and for determining when noncompliance is serious and/or continuing and appropriate corrective actions for the protection of human subjects and the ethical and compliant conduct of research.
4. RESPONSIBILITIES
   1. The IRB Executive Committee serves as the Rutgers IRB panel that reviews reports and findings of routine or for-cause audits and allegations of noncompliance for the purpose of determining whether findings meet the definition of Serious Non-Compliance or Continuing Non-Compliance and for appropriate corrective actions to eliminate or manage such noncompliance.
5. PROCEDURE
   1. Response to the audit report by the IRB Executive Committee
      1. If there were no significant findings, the routine review is presented and attached to the IRB Executive Committee agenda to be reviewed and accepted.
      2. The significant findings of the routine or for-cause audit report are placed on the agenda and the HSPP analysts will give an oral presentation of the findings and cite the areas of Non–Compliance to the IRB Executive Committee.
      3. No formal written response will be required if the audit findings are deemed “accepted with no further action” by the IRB Executive Committee.
      4. However, a formal written response from the Principal Investigator (PI) is required if the audited protocol requires a corrective action plan or clarification by the IRB Executive Committee.
      5. The IRB Executive Committee has the opportunity at this point to take immediate action. This includes, but is not limited to, suspension of the protocol and/or recommendation of closure to the IRB, among other actions.
      6. Immediate action by the Executive Director, HSPP and notification of the Institutional Official would take place in the event of suspected subject safety risks, possible research misconduct, or an extremely deficient audit.

5.2 The IRB will make one of the following determinations:

5.2.1 There is no noncompliance,

5.2.2 The noncompliance is minor, or

5.2.3 The noncompliance is serious and/or continuing.

5.3 Possible board actions for noncompliance includes, but limited to:

5.3.1 Place an administrative Hold on the research;

5.3.2 Initiate audits of all or some of the investigator's active protocols;

5.3.3 Suspend any or all components of the research (i.e., new enrollment, treatment, follow-up and data analysis) until a Corrective Action /Prevention Plan (CAPA) can be developed and implemented or until additional review can occur;

5.3.4 Require that the PI modify the protocol to minimize risk;

5.3.5 Require the interval at which continuing review is conducted to be modified to less than one year as appropriate to the degree of risk;

5.3.6 Require that the PI modify the informed consent;

5.3.7 Require observation of the research or the consent process and modify the information disclosed during the consent process;

5.3.8 Require notification of current and previously enrolled subjects of new information that may relate to a subject’s willingness to continue participation in the research;

5.3.9 Require submission of status reports on a defined set schedule to the IRB;

5.3.10 Require additional education and training for the investigators and support staff;

5.3.11 Accept and approve the PI’s proposed Corrective Action/Prevention Plan (CAPA) or changes;

5.3.12 Require a directed for-cause investigation by an outside consultant;

5.3.13 Terminate the research.

5.4 IRB discussion, action(s), the final determination, and vote will be documented in the meeting minutes.

5.5 If the PI and/or Designee does not develop a suitable corrective action plan for the Non-Compliance, the IRB Executive Committee and/or the IRB of record will require an appropriate corrective action plan.

1. MATERIALS
   1. HRP-024- SOP - Reportable New Information
   2. HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
   3. HRP-101 - SOP - Human Research Protection Program Plan
   4. HRP-430a - CHECKLIST - Investigator Quality Improvement Assessment - Drug, Devices, Clinical Trial
   5. HRP-430b - CHECKLIST - Investigator Quality Improvement Assessment - Participant File
   6. HRP-430c - CHECKLIST - Investigator Quality Improvement Assessment - Biomedical Research
   7. HRP-430d - CHECKLIST - Investigator Quality Improvement Assessment - Social Behavioral Research
   8. HRP-430e - CHECKLIST - Investigator Quality Improvement Assessment - Humanitarian Use Device
2. REFERENCES
   1. None