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1 PURPOSE

- 1.1 This procedure establishes the process to manage information reported to the IRB to ensure that information that represents Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others, Suspensions of IRB Approval, and Terminations of IRB Approval are managed to protect the rights and welfare of subjects.
- 1.2 The process begins when the IRB receives a reportable event informational item.
- 1.3 The process ends when the information item 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 Allegations of Serious or Continuing Non-Compliance on the part of IRB staff or IRB members will be referred to the Institutional Official or designee for further action.
- 3.2 When any for-cause investigation is undertaken by a federal department or agency or national organization, the organization will promptly notify the federal department or agency funding the research.
- 3.3 For Department of Defense (DOD) research the report is sent to the DOD human research protection officer.
- 3.4 The organization will promptly notify the DOD if the IRB of record changes.

4 RESPONSIBILITIES

- 4.1 The IRB staff or Designated Reviewer will carry out the procedures unless otherwise indicated.

5 PROCEDURE

- 5.1 Review the information reported, request more information as needed and answer the following questions needed to complete the Reportable New Information/Event Pre-review Activity.-(See attached flowchart for a diagram of the flow of this procedure.)
 - 5.1.1 Is this an Allegation of Non-Compliance?
 - 5.1.2 Is this a Finding of Non-Compliance?
 - 5.1.3 Is this an Unanticipated Problem Involving Risks to Subjects or Others?
 - 5.1.4 Is this a Suspension of IRB Approval or Termination of IRB Approval?
- 5.2 Review responses with the Human Research Protection Program (HRPP) Director, Quality Assurance & Evaluation (QA&E) Director or designee.
- 5.3 If the answer is no to all questions, no additional review is required, skip ahead to Section 5.6.
- 5.4 If the answer is yes to one or more questions, the HRPP Director in collaboration with the QA&E Director and/or the IRB Chair will place the Reportable New Information/New Event on the agenda for the next available convened IRB meeting in an IRB with appropriate scope as the item of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others.



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If, in the opinion of the IO or designee, or IRB Chair, the rights and welfare of subjects might be adversely affected before the convened IRB can review the information, they may request a Directed (For Cause) Audit 12.002 (HRP-025) - SOP Directed Review (For Cause Audit) or consider a Suspension of IRB Approval following the 10.004 (HRP-026) - SOP - Suspension or Termination Issued Outside of Convened IRB.

- 5.5 For Reportable New Information that create an **Unanticipated Problem Involving Risks to Subjects and Others**, the IRB staff and IRB Chair should follow 10.003 (HRP-024c) - Review of Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events.

- 5.6 For Reportable New Information that create an **Allegation of Non-Compliance, Subject Complaint, or Concern**, the QA&E Director, HRPP Director or designee should follow 10.002 (HRP-024a) - Concerns and Complaints about Human Subjects Research

- 5.7 The IRB will determine the following:

5.7.1 Allegations of Non-Compliance: The HRPP Director and/or the QA&E Director will determine whether each Allegation of Non-Compliance is reasonably supported. If yes, follow the procedures under Findings of Non-Compliance.

5.7.1.1 If no, follow any other corresponding sections.

5.7.2 Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.

5.7.2.1 If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.

5.7.2.2 If yes, follow the procedures under Serious or Continuing Non-Compliance.

5.7.3 Non-Serious/Non-Continuing Non-Compliance

5.7.3.1 Assist the study team with the Non-Compliance to develop and implement a suitable corrective action plan.

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

5.7.4 Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others


5.7.4.1 Follow the procedures of 10.002 (HRP-024a) and consider actions to be taken to mitigate harms to the rights and welfare of subjects 10.201 (HRP-321) - WORKSHEET - Review of Reportable New Information.

- 5.7.5 If the notification involves a subject becoming a Prisoner in a study not approved by the IRB to involve Prisoners:

5.7.5.1 Confirm that the subject currently qualifies as a Prisoner.

5.7.5.2 If the subject does not currently qualify as a Prisoner, no other action is required.

- 5.7.6 Consider whether stopping all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject until the regulatory requirements for research involving Prisoners are

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met or until the subject is no longer a Prisoner would present risks to the subject.

5.7.6.1 If the subject's involvement in the research cannot be stopped for health or safety reasons, the IRB Chair or convened IRB as appropriate do one of the following:

5.7.6.1.1 Keep the subject enrolled in the study and review the research for involvement of Prisoners. If the research is subject to DHHS oversight, notify OHRP.

5.7.6.1.2 Remove the subject from the study and provide the study intervention as clinical care or compassionate use.

5.7.6.2 If the subject's involvement in the research can be stopped, inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject must be stopped immediately until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner.

5.7.7 **FOR DOD Supported Research (entire Section of 5.7.7):** The following must be promptly (no longer than within 30 days) reported to the DoD Human Research Protection Officer (HRPO):

5.7.7.1 When significant changes to the research protocol are approved by the IRB. [Significant changes, in this context, include changes to investigators or institutions, decreased benefit or increased risk to participants in greater than minimal risk research, addition of vulnerable populations as participants, or addition of DoD-affiliated personnel as participants.]


5.7.7.2 When Rutgers is notified by any federal body, state agency, official governing body of a Native American or Alaskan native tribe, other entity, or foreign government that any part of the HRPP is under investigation for cause involving a DoD-supported research protocol.

5.7.7.3 Any problems involving risks to participants or others, suspension or termination of IRB approval, or any serious or continuing noncompliance pertaining to DoD supported human participant research.

5.7.7.4 Change in status when a previously enrolled participant becomes pregnant, or when the researcher learns that a previously enrolled participant is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with 45 CFR 46, Subpart B.

5.7.7.5 Whenever the IRB is notified that a currently enrolled subject becomes a prisoner, or the investigator submits an amendment to revise the recruitment plan to include prisoners, the convened IRB will promptly (within 30 days) re-review the research protocol to ensure that the rights and well-being of any human subject, who has become, or will include a prisoner, are not in jeopardy.

5.7.7.5.1 The IO or designee will promptly report all decisions to the Department of Defense (DOD).

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5.7.7.5.2 The Department of Defense (DOD) must concur with the IRB before the subject can continue to participate while a Prisoner.

5.7.7.5 The results of the IRB's continuing review, if required.

5.7.7.6 Closure of a DoD-supported study.

5.7.8 **AAHRPP Notification:** If the Reportable information involves any of the following, the IO or designee completes and sends 10.303 (HRP-529) - LETTER - AAHRPP Notice of Information Item to AAHRPP as soon as possible but generally within two days of the receipt of the information, in addition to other applicable procedures listed in this SOP:

5.7.8.1 Negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.

5.7.8.1 Litigation, arbitration, or settlements initiated related to human research protections.

5.7.8.2 Press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

5.8 Take any additional actions required to resolve any concerns or complaints associated with the information.

5.9 Whether or not the information involves a Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others and a response is expected, Executive Committee, or IRB Chair, or HRPP Director, or QA&E Director will complete review following the 3.012 (HRP-052) - SOP - Post-Review and the IRB staff will send a 10.304 (HRP-519) - LETTER - Information Item to the person submitting the information based on the determination entered in the eIRB+ system.

5.10 **For Cooperative Research/sIRB/Reliance Agreements**, check –the Relying Site Local Considerations form – Communication Plan (pages 5 – 9) in addition to the process in 5.9 above.

5.11 **Reporting of Incidents to federal agencies and/or sponsors** in accordance with federal regulations and/or contract requirements:

5.11.1 The HRPP, on behalf of the IO, will report any Incident(s) (i.e., Serious or Continuing Noncompliance, Suspension of IRB Approval, Termination of IRB approval, Unanticipated Problem Involving Risks to Subjects or Others) per the below situations:

5.11.1.1 If the research is federally supported or conducted, the Incident(s) will be reported to the Office for Human Research Protections (OHRP), copied to the Department supporting the research (i.e., to the Program Official).

5.11.1.2 If the study involves an investigational drug, the incident will be reported to the FDA Center for Drug Evaluation (CDER).

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- 5.11.1.3 If the study involves an investigational device, the Incident(s) will be reported to the FDA Center for Devices and Radiological Health (CDRH).
- 5.11.1.4 If the study involves an investigational biologic, the Incident(s) will be reported to the FDA Center for Biologics (CBER).
- 5.11.1.5 If the study is supported by the Department of Defense (DoD), the Incident(s) will be reported to the DoD Human Research Protection Officer.
- 5.11.1.6 If the study is supported by another federal department, the Incident(s) will be reported to the appropriate designee for that department, copied to the Department (i.e., Program Official).

6 MATERIALS

- 6.1 3.012 (HRP-052) - SOP - Post-Review
- 6.2 10.002 (HRP-024a) – SOP – Allegations of Non-Compliance Protocol Deviations- Violations and Subject Complaints
- 6.3 10.003 (HRP-024c) – SOP – Review of Unanticipated Problems to Subjects or Others or Adverse Events
- 6.4 10.004 (HRP-026) - SOP - Suspension or Termination Issued Outside of Convened IRB
- 6.5 10.202 (HRP-214) – WORKSHEET – eIRB+ - Requirements Document – Reportable Events
- 6.6 10.303 (HRP-529) - LETTER - AAHRPP Notice of Information Item
- 6.7 10.304 (HRP-519) - LETTER - Information Item
- 6.8 12.002 (HRP-025) - SOP - Directed Review (For Cause) Audits
- 6.9 13.304 - Relying Site Local Considerations

7 REFERENCES

- 7.1 21 CFR §56.108(b)
- 7.2 45 CFR 46.108
- 7.3 4.203 (HRP-318) - WORKSHEET - Additional Federal Agency Criteria
- 7.4 DOD i331602

7.5 Flowchart

