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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 an information 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 Item 5.1 revised to reflect electronic forms and internal review checklist.
- 2.2 Item 5.5.2 revised to reflect review by the Serious and Continuing Non-compliance Committee (SNCC) and to allow for pre-review of potential unanticipated problems by IRB Chair or designee.
- 2.3 Revisions made to clarify the review process.
- 2.4 Revisions to add requirement for submission for committee review agenda within 10 working days of receipt when the informational item involves new risk or a possible unanticipated problem involving risks to subjects or others.
- 2.5 Added information about Central IRB Review of non-compliance at external sites.

3 GUIDING PRINCIPLES

- 3.1 The institution will determine whether actions need to be taken to mitigate risks when unanticipated problems involving risks to subjects or others are reported
- 3.2 The Institution will promptly notify the federal department or agency funding the research of any for cause investigation of that research by another federal department or agency or national organization.
 - 3.2.1 For Department of Defense (DOD) research the report is sent to the DOD human research protection officer.
- 3.3 The Institution will promptly notify the Department of Defense (DOD) if the IRB of record changes.
- 3.4 Reports that include information about a newly identified risk or an unanticipated problem involving risks to subjects or others must be placed on an IRB meeting agenda within ten working days of submission, regardless of whether requests for clarifications are outstanding.

4 RESPONSIBILITIES

- 4.1 The HSRO staff members and IRB members carry out this procedure.

5 PROCEDURE

- 5.1 Review each item of information in the Reportable New Information electronic form, consider the following questions and complete “WORKSHEET: Review of New Information Items (HRP-321).”
 - 5.1.1 Is this an Allegation of Non-Compliance or a Finding of Non-Compliance?
 - 5.1.2 Is this an Unanticipated Problem Involving Risks to Subjects or Others?
- 5.2 If you are unable to answer a question, consult the IRB chair or HSRO Director.
- 5.3 If the answer is “no” to all questions, skip section 5.5 and continue with section 5.7.
- 5.4 If the answer is “yes” to one or more questions, then follow the corresponding sections below.
 - 5.4.1 Allegations or Findings of Serious Non-Compliance: For research conducted by University of Miami investigators, the review of and determinations regarding serious or continuing non-compliance shall be the charge of the Compliance Review Committee, as detailed in “SOP: Compliance Review Committee (HRP-027)”.
 - 5.4.1.1 For research conducted by individuals external to the University of Miami,



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the Central IRB will review Allegations or Findings of Non-Compliance

5.4.2 If the rights and welfare of subjects might be adversely affected before the convened IRB can review the information, contact the IRB Chair or HSRO Director to consider a Suspension of IRB approval, following “SOP: Suspension or Termination (HRP-026)” and place the report on the agenda for the next available convened IRB meeting in an IRB with appropriate scope for confirmation of any required follow-up actions.

5.4.2.1 Recommend follow-up actions using “WORKSHEET: Review of New Information Items (HRP-321)”.

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

5.5.1 Confirm that the subject is currently a Prisoner.

5.5.1.1 If the subject is currently not a Prisoner no other action is required.

5.5.2 Use CHECKLIST – Prisoners (HRP-415) to determine next actions.

5.5.2.1 If the CHECKLIST indicates subject’s involvement in the research must stop, but the prisoner’s involvement in the research cannot be stopped for health or safety reasons, do one of the following:

5.5.2.1.1 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.

5.5.2.1.2 Remove the subject from the study and provide the study intervention as clinical care or through an expanded access mechanism.

5.5.2.2 If the CHECKLIST indicates the subject’s involvement in the research must stop and the prisoner’s involvement can be safely 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.

5.5.3 For Department of Defense (DOD) research promptly report all decisions to the Department of Defense (DOD).

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

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

5.7 If the information does not involve 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, complete and send an acknowledgement determination.

6 MATERIALS

6.1 Reportable New Information electronic SmartForm

6.2 SOP: Investigations (HRP-025)

6.3 SOP: Suspension or Termination (HRP-026)

6.4 SOP: Investigations (HRP-025)

6.5 WORKSHEET: Protection of Human Subjects During Review of Information (HRP-321)

6.6 CHECKLIST: Prisoners (HRP 415)

6.7 TEMPLATE LETTER: Information Item (HRP-519)

6.8 TEMPLATE LETTER: External Report (HRP-520)

7 REFERENCES

7.1 21 CFR §56.108(b)

7.2 45 CFR § 46.103(b)(5); § 46.108(a)



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- 7.3 OHRP guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events (January 15, 2007)
- 7.4 FDA Guidance: Adverse Event Reporting to IRB's – Improving Human Subject Protection (January 2009)