UNIVERSITY OF MIAMI

SOP: New Information				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
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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.

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 corresponding board 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.

2.6 Revised to remove the Serious or Continuing Non Compliance Committee (SNCC) and Compliance Review Committee review and remove 10day deadline for IRB review of new risk information.

2.7 Revisions for HRSO reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

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, when applicable, 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 The IRB reviews reports of newly identified foreseeable risks promptly.

3.5 The institution will promptly notify appropriate regulatory authorities, institutional officials, and the principal investigator when it determines a reportable event:

3.5.1 Is an unanticipated problem involving risks to subjects or others; or

3.5.2 Meets the institution's definitions of serious or continuing non-compliance.

3.6 Allegations of Serious or Continuing Non-Compliance on the part of IRB staff or IRB members will be referred to the Organizational Official for further action.

4 RESPONSIBILITIES

4.1 The HRSO staff members carry out this procedure.

5 PROCEDURE

5.1 Review each item of information and answer the following questions and complete the Submit RNI Pre-Review Activity: *(See attached flowchart for a diagram of the flow of this procedure.)*

5.1.1 Does this report include information about a newly identified foreseeable risk?

5.1.1.1 If yes, add the report to an agenda for an IRB committee that occurs within 21 days of receipt.

5.1.1.1.1 Consider follow-up actions using HRP-321 - WORKSHEET - Review of Information Items.

5.1.2 Is this an Allegation of Non-Compliance?

5.1.2.1 If yes, determine whether each Allegation of Non-Compliance has any basis in fact and follow any other corresponding sections below

5.1.3 Is this a Report or Finding of Non-Compliance?

5.1.3.1 If yes, follow 5.4.1 below.

5.1.4 Is this an Unanticipated Problem Involving Risks to Subjects or Others?

5.1.4.1 If yes, follow 5.4.3 below.

5.1.4.2 Consider follow-up actions using HRP-321 - WORKSHEET - Review of Information Items

5.1.5 Is this a Suspension of IRB Approval or Termination of IRB Approval?

5.1.5.1 If yes, follow 5.4.3 below

5.1.5.2 Consider follow-up actions using HRP-321 - WORKSHEET - Review of Information Items

5.2 If you are unable to answer a question, consult the IRB chair, IRB manager, or IRB Director.

5.3 If the IRB chair and IRB manager are unable to answer a question, follow HRP-025 - SOP - Investigations.

5.4 If the answer is “yes” to one or more questions, then follow the corresponding sections below.

5.4.1 Findings of Non-Compliance: Determine whether each Finding of Non-Compliance appears to meet the University’s definition of Serious Non-Compliance or Continuing Non-Compliance.

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

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

5.4.2 Non-Serious/Non-Continuing Non-Compliance

5.4.2.1 Work with the individual or group responsible for the Non-Compliance to develop and implement a suitable Corrective Action Preventive Action (CAPA) plan and determine whether the report is adequate.

5.4.2.2 If unable to work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan, consider the Non-Compliance to be Continuing Non-Compliance and follow the procedures for Serious or Continuing Non-Compliance.

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

5.4.3.1 If the notification involves enrollment of a Prisoner in a study not approved to enroll Prisoners, see 5.6 for additional considerations to aid in decision-making.

5.4.3.2 Place on the agenda for an IRB committee that occurs within 21 days of receipt with appropriate scope as an 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.

5.4.3.3 Consider whether any actions or determinations need to take place to protect the rights and welfare of subjects before the convened IRB reviews the information and discuss with IRB chair or manager.

5.5 If in your opinion the rights and welfare of subjects might be adversely affected before the convened IRB can review the information, contact the IRB chair or IRB Director for a determination following the HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB.

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

5.6.1 Confirm that the subject is currently a Prisoner.

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

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

5.6.2.1 If the subject's involvement in the research cannot be stopped for health or safety reasons, do one of the following:

5.6.2.1.1 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.

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

5.6.2.2 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,

5.6.3 For Department of Defense (DOD) research, have the convened IRB promptly (within 30 days) re-review the research protocol to ensure that the rights and well-being of the human subject, now a prisoner, are not in jeopardy.

5.6.3.1 Promptly report all decisions to the Department of Defense (DOD).

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

5.7 If the information involves any of the following, complete and send HRP-529 - LETTER - AAHRPP Notice of Information Item to AAHRPP as soon as possible but generally within five business days of the receipt of the information, in addition to other applicable procedures listed in this SOP:

5.7.1 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.

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

5.7.3 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 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 review and send an acknowledgement determination per HRP-052 - SOP - Post-Review.

6 MATERIALS

6.1 HRP-025 - SOP - Investigations
6.2 HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
6.3 HRP-052 - SOP - Post-Review
6.4 HRP-321 - WORKSHEET - Review of Information Items
6.5 HRP-415 - CHECKLIST - Prisoners
6.6 HRP-519 - LETTER - Information Item

6.7 HRP-520 - LETTER - External Report NOT Including OHRP
6.8 HRP-520a - LETTER - External Report OHRP and Other Agencies
6.9 HRP-529 - LETTER - AAHRPP Notice of Information Item

7 REFERENCES

7.1 21 CFR §56.108(b)
7.2 45 CFR §46.103(b)(5), 45 CFR §46.108(a)
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)
7.5 AAHRPP elements I.5.A, I.5.D, I-9, II.2.D, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.4.A, III.2.D

7.6 Flowchart