SOP: New Information

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 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 (IO)/Organizational Official (OO) for further action.

3.2 All incidents of serious and/or continuing noncompliance that occur either at a UCI site, or at a non-UCI site where the UCI IRB is the IRB of record, must be reported to the IRB in ZOT IRB within 5 business days of the occurrence or within 5 business days from the date in which the Principal Investigator (PI) learned of the occurrence.

3.3 Such reports may come from any source including, but not limited to, an IRB Committee Member, an Investigator, a participant or their family members, institutional personnel, other institutional Committees, UC Irvine Whistleblower Office, UCI Health Affairs Compliance Officer, the media, anonymous sources, or the public.

3.4 By investigating and managing issues of potential noncompliance, the IRB seeks to:

3.5 Assure the safety of human research participants;

3.6 Develop action plans to prevent reoccurrence, and promote future compliance;

3.7 Educate research staff to assure their understanding of Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP) guidelines and regulations, and UCI IRB Policy; and

3.7 Fulfill its obligation and responsibility to report Serious Non-Compliance and/or Continuing Non-Compliance to applicable government oversight agencies.

3.8 If the non-compliance appears to meet the definition of research misconduct, forward to the Vice Chancellor for Research.

3.9 The organization 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.

3.9.1 For Department of Defense (DOD) research the report is sent to the DOD human research protection officer.

3.10 The organization will promptly notify the Department of Defense (DOD) if the IRB of record changes.

3.11 Substantiated allegations related to classified Department of Defense (DOD) Human Subjects Research must be reported immediately.

3.12 For Veterans Administration (VA) research:

3.12.1 The following events involving exempt or nonexempt VA human subjects research must be reported to the local VA medical facility per the facility's required reporting timelines:

3.12.1.1 Deaths of a human subject participating in VA human subjects research that is believed to be both unexpected and related or possibly related to participation in a

VA human subjects research study (applies to the death of a human subject enrolled in the study under the auspices of the VA medical facility).

3.12.1.2 Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) in VA human subjects research.

3.12.1.3 Occurrence of serious or continuing noncompliance with applicable laws, regulations, policies, and agreements pertaining to VA human subjects research.

3.12.1.4 The suspension or early termination of a VA human research study by the IRB, R&DC, or IO due to the study not being conducted in accordance with applicable regulations, policies, agreements, or IRB requirements or due to concerns about the safety, rights, or welfare of human subjects or others.

3.12.1.5 A change in the status (e.g., expiration, restriction, suspension, or termination) of the VA medical facility's human subjects research FWA.

3.12.1.6 The termination or non-renewal of the HHS-OHRP registration of any IRB relied upon by the VA medical facility for review and oversight of VA research.

3.12.1.7 A failure of the VA medical facility to achieve or maintain full accreditation of its HRPP if such accreditation is sought by the VA medical facility.

3.12.1.8 The issuance of a research-related citation or determination of noncompliance by a state or Federal entity (including the VA Office of Inspector General) or an accrediting organization, pertaining to the VA medical facility's HRPP and human subjects research portfolio.

3.13 IRB members or staff who believe they are being or have been subject to undue influence must report this to the Associate Vice Chancellor for Research Administration, the Senior Director, Human Research Protections, or utilize the University of California Whistleblower Policy.

3.14 Attempts to unduly influence an IRB committee member or IRB staff will be investigated in accordance with Sec. 480-7, Resolving Regulatory Non-compliance.

3.15 If IRB staff become aware of an information item that has not been submitted in the IRB system, they will enter the new information using the "Report New Information" activity and associate the information item with the appropriate study as applicable.

3.16 A modification is required in order to lift a suspension of IRB approval and must be reviewed by the convened IRB to determine whether all corrective actions are met.

4 RESPONSIBILITIES

4.1 The IRB staff members carry out this procedure.

5 PROCEDURE

5.1 Review each item of information within 1 business day 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 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 If you are unable to answer a question, consult the IRB chair or IRB Compliance manager.

5.3 The IRB may request that additional information be obtained by the IRB Education and Quality Improvement (EQUIP) team.

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

5.5 If the answer is "yes" to one or more questions, then follow the corresponding sections below.

5.5.1 Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.

5.5.1.1 If yes, follow the procedures under Findings of Non-Compliance.

5.5.1.2 If no, follow any other corresponding sections.

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

5.5.2.1 If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.
5.5.2.2 If yes, follow the procedures under Serious or Continuing Non-Compliance.

5.5.3 Non-Serious/Non-Continuing Non-Compliance
5.5.3.1 Determine whether the individual or group responsible for the Non-Compliance has developed and implemented a suitable corrective action plan.
5.5.3.2 If the individual or group responsible for the Non-Compliance is unwilling or unable 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.

5.5.4 Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others
5.5.4.1 If the notification involves enrollment of a Prisoner in a study not approved to enroll Prisoners, please see below for additional considerations to aid in decision-making.
5.5.4.2 Confirm your decision with the IRB chair or IRB manager.
5.5.4.3 Place on the agenda for the next available convened IRB meeting in an IRB 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.

5.6 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 manager to consider a Suspension of IRB Approval following the HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB.

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

5.7.1 Confirm that the subject is currently a Prisoner.
5.7.1.1 If the subject is currently not a Prisoner no other action is required.

5.7.2 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.
5.7.2.1 If the subject's involvement in the research cannot be stopped for health or safety reasons, do one of the following:
5.7.2.1.1 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.
5.7.2.1.2 Remove the subject from the study and provide the study intervention as clinical care or compassionate use.
5.7.2.2 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.

5.7.3 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.
5.7.3.1 Promptly report all decisions to the Department of Defense (DOD).
5.7.3.2 The Department of Defense (DOD) must concur with the IRB before the subject can continue to participate while a Prisoner.

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 prepare and send letter 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

7 REFERENCES

7.1 21 CFR §56.108(b)
7.2 45 CFR §46.103(b)(5), 45 CFR §46.108(a)
7.3 VHA Directive 1200.05(3), Amended July 13, 2023
7.4 VHA Directive 1058, November 8, 2024
7.5 DoDI 3216.02
7.6 University of California Whistleblower Protection Policy
7.7 Sec. 480-7, Resolving Regulatory Non-compliance

7.8 Flowchart