	OIA-024 SOP: Reportable Events				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	OIA-024	09/06/2023	B. Mooso	G. Firestein	1 of 5

1 PURPOSE

- 1.1. This procedure establishes the process to manage reportable event information submitted to the Office of IRB Administration (OIA) to ensure that information associated with non-compliance, unanticipated problems involving risks to subjects or others/unanticipated problem report, suspensions of IRB approval, and terminations of IRB approval is managed to protect the rights and welfare of human subjects.
- 1.2. The process begins when the OIA receives a reportable event.
- 1.3. The process ends when the reportable event is determined not to represent a problem that requires management, is managed administratively, is reviewed by a designated reviewer or by the convened IRB, and the final determination is sent.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1. None

3 GUIDANCE


- 3.1. The IRB will require corrective and preventive action (CAPA) plans, the detail and scope of which will be determined by the nature, risk and gravity of the non-compliance, when IRB receives reportable events that are determined to be non-compliance.
- 3.2. The IRB will determine whether actions are required to mitigate risks when unanticipated problems involving risks to subjects or others/unanticipated problem report are reported.

4 RESPONSIBILITIES

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


5 PROCEDURE

- 5.1. Review each reportable event reported to OIA and answer the following questions:
 - 5.1.1. Is this a report of a minor deviation?
 - 5.1.2. Is this an unanticipated problem involving risks to subjects or others/unanticipated problem report?
 - 5.1.3. Is this an allegation of non-compliance?
 - 5.1.4. Is this a finding of non-compliance?
 - 5.1.5. Is this a suspension/termination of IRB approval?
- 5.2. If unable to answer a question, consult the IRB chair, OIA director, IRB medical director, OIA assistant director, or designee.
- 5.3. If the answer is “no” to all questions, go to section 5.6.
- 5.4. If the answer is “yes” to one or more questions, then follow the relevant corresponding sections below.
 - 5.4.1. Minor deviations: Determine whether the information reported meets the definition of a minor deviation as described in *OIA-001 SOP: Definitions*.
 - 5.4.1.1.If yes, complete steps at section 5.10.
 - 5.4.1.2.If no, follow any other corresponding sections.
 - 5.4.2. If the issue involves a potential unanticipated problem involving risks to subjects or others/unanticipated problem report, work with the investigator/research staff to develop a plan to mitigate the risk to subjects or others, if a suitable plan was not already submitted by the investigator/research staff.
 - 5.4.2.1.Place on the agenda for the next available convened IRB meeting in an IRB with appropriate scope as an item of unanticipated problem involving risks to subjects or others/unanticipated problem report.
 - 5.4.3. Allegations of non-compliance: Determine whether each allegation of non-compliance has any basis in fact.
 - 5.4.3.1.If yes, follow the procedures under findings of non-compliance.
 - 5.4.3.2.If no, follow other corresponding sections.
 - 5.4.4. Findings of non-compliance: Determine whether each finding of non-compliance appears to meet the definition of serious non-compliance or continuing non-compliance.
 - 5.4.4.1. If neither serious non-compliance nor continuing non-compliance applies, follow the procedures under non-serious/non-continuing non-compliance.
 - 5.4.4.2. If either serious non-compliance or continuing non-compliance appears to apply,


	OIA-024 SOP: Reportable Events				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	OIA-024	09/06/2023	B. Mooso	G. Firestein	2 of 5

follow the procedures under serious non-compliance or continuing non-compliance.

- 5.4.5. Non-serious/non-continuing non-compliance
 - 5.4.5.1. Work with the investigator/research staff responsible for the non-compliance to develop and implement a suitable CAPA plan, if no plan has been submitted by the investigator/research staff. If a suitable CAPA plan has been submitted by the investigator/research staff, complete the steps at Section 5.9.
 - 5.4.5.2. If unable to work with the individual or group responsible for the non-compliance to develop and implement a suitable CAPA plan, consider the non-compliance to be continuing non-compliance and follow the procedures for serious or continuing non-compliance.
- 5.4.6. Serious non-compliance, continuing non-compliance, suspension of IRB approval, termination of IRB approval, or unanticipated problem involving risks to subjects or others/unanticipated problem report.
 - 5.4.6.1. Confirm the decision with the IRB chair, OIA director, or designee.
 - 5.4.6.2. If the issue involves non-compliance, work with the investigator or research staff to develop an adequate CAPA plan, if no suitable plan has been submitted by the investigator/research staff.
 - 5.4.6.3. 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/unanticipated problem report.
- 5.5. If, in the OIA staff's opinion, the rights, safety, or welfare of human subjects might be adversely affected before the convened IRB can review the information, contact the IRB chair, OIA director, IRB medical director, or OIA assistant director to consider a suspension of IRB approval following the *OIA-026 SOP: Suspension or Termination of IRB Approval*.
- 5.6. If the event reported indicates potentially new or increased human subjects risk, which is not described in the consent document, for which the risk management practices in the protocol are no longer sufficient to protect human subjects, or the new or increased risk is described in the consent document with a different frequency or severity than in the report, follow the corresponding sections below.
 - 5.6.1. For minimal risk studies, determine if the new information increases the study risk level above minimal risk.
 - 5.6.1.1. If so, forward the report and any supporting information for placement on the next agenda for the appropriate IRB.
 - 5.6.1.1.1. If the IRB determines that the new or increased risk is adequately described in the consent document such that the study continues to meet criteria for approval, complete and send *OIA-524 TEMPLATE LETTER: Acknowledgment of Report*, or equivalent, to the investigator and the person submitting the reportable event.
 - 5.6.1.1.2. If the IRB determines that the new or increased risk is not adequately described in the consent document such that the study does not continue to meet criteria for approval, the IRB will generally hold enrollment in the study until the IRB approves a modified consent document containing the required elements of informed consent, unless the IRB determines that there is an acceptable or compelling reason for enrollment to continue. Complete and send *OIA-524: TEMPLATE LETTER: Acknowledgment of Report*, or equivalent, to the investigator and the person submitting the reportable event, notifying them of the required hold on enrollment and the need to submit a modification.
 - 5.6.1.2. If not, determine if the new or increased risk is adequately described in the consent document, as appropriate, and that the study continues to meet criteria for approval.

	OIA-024 SOP: Reportable Events				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	OIA-024	09/06/2023	B. Mooso	G. Firestein	3 of 5

- 5.6.1.2.3. If so, complete and send *OIA-524 TEMPLATE LETTER: Acknowledgment of Report*, or equivalent, to the investigator and the person submitting the information.
- 5.6.1.2.4. If not, place enrollment on hold by notifying the investigator of the required hold on enrollment and the need to submit a modification request with a modified consent document that incorporates the required elements of informed consent. Once the revised informed consent submission has been received, follow the procedures in *OIA-032 SOP: Non-Committee Review Conduct* for review and approval. Upon issuance of approval, the investigator will be notified that enrollment in the study may resume.
- 5.6.2. For greater than minimal risk studies, forward the report and any supporting information for placement on the next agenda for the appropriate IRB.
 - 5.6.2.1. If the IRB determines that the new or increased risk is adequately described in the consent document such that the study continues to meet criteria for approval, complete and send *OIA-524 TEMPLATE LETTER: Acknowledgment of Report*, or equivalent, to the investigator and the person submitting the reportable event.
 - 5.6.2.2. If the IRB determines that the new or increased risk is not adequately described in the consent document such that the study does not continue to meet criteria for approval, the IRB will generally hold enrollment in the study until the IRB approves a modified consent document containing the required elements of informed consent, unless the IRB determines that there is an acceptable or compelling reason for enrollment to continue. Complete and send *OIA-524: TEMPLATE LETTER: Acknowledgment of Report*, or equivalent, to the investigator and the person submitting the reportable event, notifying them of the required hold on enrollment and the need to submit a modification.
- 5.7. If the event reported does not indicate a potentially new or increased risk to subjects but does necessitate changes to the description of any other required elements of informed consent, then follow the corresponding sections below.
 - 5.7.1. Does the required change to the consent document represent more than a minor modification AND is the study greater than minimal risk?
 - 5.7.1.1. If no, determine if the change to the required elements of informed consent are adequately described in the consent document, as appropriate, and that the study continues to meet criteria for approval.
 - 5.7.1.1.1. If so, complete and send *OIA-524 TEMPLATE LETTER: Acknowledgment of Report*, or equivalent, to the investigator and the person submitting the information.
 - 5.7.1.1.2. If not, place enrollment on hold by notifying the investigator of the required hold on enrollment and the need to submit a modification request with a modified consent document that incorporates the required elements of informed consent. Once the revised informed consent submission has been received, follow the procedures in *OIA-032 SOP: Non-Committee Review Conduct* for review and approval. Upon issuance of approval, the investigator will be notified that enrollment in the study may resume.
 - 5.7.1.2. If yes, the required change to the elements of informed consent represent more than a minor modification AND the study is greater than minimal risk, forward the report and any supporting information for placement on the next agenda for the appropriate IRB.
 - 5.7.1.2.1. If the IRB determines that the required elements of informed consent are adequately described in the consent document such that the study continues to meet criteria for approval, complete and send *OIA-524 TEMPLATE LETTER: Acknowledgment of Report*, or equivalent, to the investigator and the person submitting the

	OIA-024 SOP: Reportable Events				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	OIA-024	09/06/2023	B. Mooso	G. Firestein	4 of 5

- reportable event.
- 5.7.1.2.2 If the IRB determines that the required elements of informed consent are not adequately described in the consent document such that the study does not continue to meet criteria for approval, the IRB will generally hold enrollment in the study until the IRB approves a modified consent document containing the required elements of informed consent, unless the IRB determines that there is an acceptable or compelling reason for enrollment to continue.
 Complete and send *OIA-524: TEMPLATE LETTER: Acknowledgment of Report*, or equivalent, to the investigator and the person submitting the reportable event, notifying them of the required hold on enrollment and the need to submit a modification.
- 5.8. If the notification involves a subject becoming a prisoner in a study not approved by the IRB to involve prisoners:
- 5.8.1. Confirm whether the subject is currently a prisoner.
- 5.8.2. If the subject is currently not a prisoner, no other action is required
- 5.8.3. If the subject is currently a prisoner, instruct the researchers to stop 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. Refer to *OIA-415 CHECKLIST: Prisoners*, or equivalent, to determine whether review by convened IRB is required.
- 5.8.3.1. If convened IRB review is required, place on appropriate agenda and follow *OIA-021 SOP: Pre-Review*.
- 5.8.3.2. If the expedited review procedure is permitted, follow *OIA-031 SOP: Non-Committee Review Preparation*.
- 5.8.4. For Department of Defense (DOD) research, promptly report all decisions to the DOD.
- 5.8.5. The DOD must concur with the IRB before the subject can continue to participate while a prisoner.
- 5.9. Take any additional actions required to resolve any concerns or complaints associated with the reportable event. For example, it may be necessary to refer the matter to appropriate institutional offices to conduct investigations or audits.
- 5.10. If the event does not involve serious non-compliance, continuing non-compliance, suspension of IRB approval, termination of IRB approval, or unanticipated problem involving risks to subjects or others/unanticipated problem report, or it is a minor deviation reported as a stand-alone report via the electronic submission system reporting pathway, and a response is expected from the IRB, complete and send *OIA-524 TEMPLATE LETTER: Acknowledgment of Report*, or equivalent, to the person submitting the reportable event.
- 5.11. If the event does involve serious non-compliance, continuing non-compliance, suspension of IRB approval, termination of IRB approval, or an unanticipated problem involving risks to subjects or others/unanticipated problem report, complete and send *OIA-524 TEMPLATE LETTER: Acknowledgment of Report*, or equivalent, to the person submitting the reportable event. In addition, take any or all of the below actions that apply:
- 5.11.1. If the IRB, IRB chair, or institutional official has determined that a suspension/termination of IRB approval is necessary to protect human subjects, refer to *OIA-026 SOP: Suspension or Termination of IRB Approval*.
- 5.11.2. If the IRB, IRB chair, institutional official, OIA director, IRB medical director, OIA assistant director or designee has determined that an enrollment hold is necessary to protect human subjects, send *OIA-524 TEMPLATE LETTER: Acknowledgment of Report*, or equivalent.
- 5.11.3. If the study is federally funded or FDA-regulated, send *OIA-520 TEMPLATE LETTER: External Report*, or equivalent.
- 5.11.4. If the study is not federally funded and is not FDA regulated, send the letter developed in 5.11 to the cc list on *OIA-520 TEMPLATE LETTER: External Report*, or equivalent.

UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-024 SOP: Reportable Events				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	OIA-024	09/06/2023	B. Mooso	G. Firestein	5 of 5

6 MATERIALS

- 6.1 *OIA-001 SOP: Definitions*
- 6.2 *OIA-021 SOP: Pre-Review*
- 6.3 *OIA-026 SOP: Suspension or Termination of IRB Approval*
- 6.4 *OIA-031 SOP: Non-Committee Review Preparation*
- 6.5 *OIA-032 SOP: Non-Committee Review Conduct*
- 6.6 *OIA-052 SOP: Post-Review*
- 6.7 *OIA-415 CHECKLIST: Prisoners*
- 6.8 *OIA-520 TEMPLATE LETTER: External Report*
- 6.9 *OIA-524 TEMPLATE LETTER: Acknowledgment of Report*

7 REFERENCES

- 7.1 [21 CFR 50.25\(a\) and \(b\)](#)
- 7.2 [21 CFR 56.108\(b\)](#)
- 7.3 [21 CFR 56.111](#)
- 7.4 [21 CFR 56.113](#)
- 7.5 [45 CFR 46.103\(a\)](#)
- 7.6 [45 CFR 46.108\(a\)\(4\)](#)
- 7.7 [45 CFR 46.111](#)
- 7.8 [45 CFR 46.113](#)
- 7.9 [45 CFR 46.116\(a\) and \(b\) pre-2018 Rule](#)
- 7.10 [45 CFR 46.116\(b\) and \(c\) 2018 Rule](#)