

 INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-026 SOP: Suspension or Termination of IRB Approval				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	OIA-026	09/06/2023	B. Mooso	G. Firestein	1 of 2

1 PURPOSE

- 1.1 This procedure establishes the process for someone other than the convened IRB to institute a suspension of IRB approval or a termination of IRB approval.
- 1.2 The process begins when the institutional official or designee institutes a suspension of IRB approval or a termination of IRB approval.
- 1.3 The process ends when the suspension of IRB approval or termination of IRB approval has been placed on the agenda for review by the convened IRB.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 GUIDANCE

- 3.1 The IRB chair, IRB medical director, Office of IRB Administration (OIA) director, or OIA assistant director may refer a recommendation for suspension of IRB approval to the institutional official, except in case of emergent risk when the institutional official is not available, before the action has been reviewed by the convened IRB when, in the opinion of the IRB chair, IRB medical director, OIA director, or OIA assistant director, subjects' rights and welfare may be at risk. In the case of emergent risk when the institutional official is not available, the following people (listed in order of decisional authority),¹ may suspend the research: the vice chancellor for research, the OIA director, the IRB chair, and the OIA assistant director.
- 3.2 The convened IRB or institutional official may initiate a suspension of IRB approval or termination of IRB approval for any reason.
- 3.3 Whenever possible, the individual following these procedures communicates with investigators orally and in writing.

4 RESPONSIBILITIES

- 4.1 The individual initiating a suspension of IRB approval or termination of IRB approval follows these procedures.

5 PROCEDURE

- 5.1 Notify the investigator of the suspension of IRB approval or termination of IRB approval along with the reason for the decision.
- 5.2 Ask the investigator for a list of human subjects currently involved in the research.
- 5.3 Ask the investigator whether any actions are required to protect those or other subjects' rights and welfare or to eliminate an apparent immediate hazard.
- 5.4 Consider whether any of the following additional actions are required to protect those or other subjects' rights and welfare or to eliminate an apparent immediate hazard:
 - 5.4.1 Transfer subjects to another investigator.
 - 5.4.2 Make arrangements for clinical care outside the research.
 - 5.4.3 Allow continuation of some research activities under the supervision of an independent monitor.
 - 5.4.4 Require or permit follow-up of subjects for safety reasons.
 - 5.4.5 Require adverse events or outcomes to be reported to the IRB and the sponsor.
 - 5.4.6 Notify current human subjects.
 - 5.4.7 Notify former human subjects.
- 5.5 If any of the actions in 5.3 or 5.4 above would result in the withdrawal of one or more subjects from the study, consider whether the procedures for withdrawal of the subject(s) are acceptable in light of the subject's rights and welfare.
- 5.6 Refer to the OIA staff to place on the agenda for a convened IRB meeting with an IRB of appropriate scope as an item of suspension of IRB approval or termination of IRB approval.
- 5.7 Complete and send *OIA-520 TEMPLATE LETTER: External Report*, or equivalent.

¹ The individuals listed at the end of Section 3.1 are to be consulted in the order described based on availability. If an individual is not available to make a decision, the decision delegates to the next highest level of decisional authority. For example, if the institutional official and vice chancellor for research are not available, the OIA director would make the decision whether or not to suspend the research.

UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-026 SOP: Suspension or Termination of IRB Approval				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	OIA-026	09/06/2023	B. Mooso	G. Firestein	2 of 2

6 MATERIALS

- 6.1 *OIA-001 SOP: Definitions*
- 6.2 *OIA-520 TEMPLATE LETTER: External Report*

7 REFERENCES

- 7.1 [21 CFR 56.108\(b\)\(3\)](#)
- 7.2 [21 CFR 56.113](#)
- 7.3 [45 CFR 46.108\(a\)](#)
- 7.4 [45 CFR 46.113](#)