

Suspension or Termination	
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1. PURPOSE

- 1.1. Federal regulations require that the IRB have the authority to suspend or terminate approved human subjects research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected and serious harm to subjects.

2. DEFINITIONS

- 2.1. *Suspension*, means that all project activities must cease until any pending issues can be resolved satisfactorily. Suspended studies are still approved, but in a "hold" status until the pending issues can be resolved.

Termination, means that the study is no longer approved. All project activities must cease immediately, including data analysis and any resulting data or analysis is null and void. A study may be terminated by the IRB or by the sponsor for administratively, regulatory, or other reasons. Regardless of the reason, terminated studies are not considered completed.

Closure, means an administrative status whereby a previously approved protocol's expiration date has passed and an investigator has not submitted a renewal, or the investigator has submitted a request to close a study, The IRB assumes that no human subjects research activities are ongoing and, for administrative record keeping, the study record may be closed.

3. POLICY and PROCEDURE

- 3.1. The IRB has the authority to suspend or terminate research involving human subjects that has been determined to not be in accordance with the IRB's requirements, federal, state, local, or institutional policies, or research activities that were not reviewed and approved or determined to be exempt by the IRB prior to initiation of those studies.
- 3.2. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action. Suspensions or terminations shall be reported in writing promptly to all appropriate parties as listed under the Responsibilities section of this document.
- 3.3. The IO also has the authority to not approve research approved by the IRB and to suspend or terminate research protocols previously approved by the IRB for institutional reasons.
- 3.4. **Reasons for Suspension or Termination**
 - 3.4.1. The IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with federal and state regulations, University of California Office of the President or UCSB policies and procedures, or IRB requirements, or research that has been associated with unexpected serious harm to subjects. A research project may be suspended or terminated for a variety of reasons, including but not limited to:
 - a. Serious adverse event(s) and unanticipated problem(s)
 - b. Detrimental change in the risk-benefit ratio of the study
 - c. Conduct of research activities without prior IRB approval

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- d. Failure to obtain appropriate consent
- e. Failure of investigators to complete required training
- f. Other non-compliance issues

3.5. Authorities

- 3.5.1. The IRB is authorized to suspend or terminate research protocols.
- 3.5.2. The IRB Chair/Designee is authorized to suspend research protocols in emergency situations (i.e. when the rights, safety, or welfare of the subjects are in immediate jeopardy).
- 3.5.3. The IO has the authority to suspend or terminate research protocols for institutional reasons.

3.6. Suspension and Termination Process and Notification

- 3.6.1. When potential cause for further investigation is demonstrated, an inquiry into the specific circumstances giving rise to concern with a specific protocol will be conducted. If a protocol is determined to be in non-compliance or a detrimental change in the risk/benefit ratio occurs, further action will be taken by the IRB.
- 3.6.2. In most instances, the IRB will review the circumstances of the case and make a determination of suspension or need for termination. Other IRB members or the Research Integrity Director may be consulted as needed in the decision making process leading up to bringing the issue to the full board at a convened meeting.
- 3.6.3. In emergency situations, the IRB Chair in consultation with the Research Integrity Director, IO, (whenever appropriate), will make a determination of the need to suspend or terminate a study immediately.
- 3.6.4. The IRB Chair, or Designee, will write a report of the event and action that includes the following:
 - a. A description of the event
 - b. The determination of the IRB (i.e. suspension, termination)
 - c. Justification for the determination
 - d. Requirements for the investigator to follow (e.g. cease all data collection)

The report will be sent to the investigator or faculty advisor (if applicable), department head, IO, Research Integrity Director, Sponsored Projects and any sponsors (if applicable), and applicable federal agencies (e.g. OHRP). A copy of the form will be filed in the Human Subjects Office.
- 3.6.5. If the suspension or termination results in a reporting requirement to OHRP, the Research Integrity Director will utilize the guidelines defined by OHRP for types of information to include in an incident report.
- 3.6.6. The lead investigator or faculty advisor is responsible for notifying (in a timely manner) all co-investigators, key personnel, and other research staff associated with the project, as well as any subcontract grantees if the protocol has been suspended or terminated.

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3.7. Participant Involvement in Suspended or Terminated Protocols

- 3.7.1. When a protocol is suspended or terminated, the investigator must stop all activity on the protocol, including subject recruitment and enrollment, procedures, and analysis and/or publication of existing data.
- 3.7.2. When a suspension or termination of a research protocol involving the withdrawal of current participants from the research, the investigator will be required to:
 - a. Inform the enrolled participants that the study has been suspended or terminated; and,
 - b. Develop procedures for withdrawal that protect the rights, safety, and welfare of participants, and describe those procedures to participants.
- 3.7.3. In certain circumstances, project activities may continue if stopping study procedures/treatment will adversely affect the welfare of a subject. If the suspension or termination of a research protocol does not involve the withdrawal of current participants from the research, the investigator may be required to:
 - a. Notify the IRB immediately of the need to continue any procedures;
 - b. Inform the enrolled participants that the study has been suspended or terminated; and,
 - c. Report any serious adverse events or unanticipated problems involving risks to the participants to the IRB.

3.8. Reinstatement of Suspended or Terminated Protocols

- 3.8.1. To reinstate a project that has been suspended, the investigator must resolve satisfactorily any pending issues as required by the IRB. After one year of suspension or the expiration date of the study (whichever comes first), if adequate progress has not been made on the pending issues, then the IRB will administratively close the study protocol.
- 3.8.2. To reinstate a protocol that has been suspended, the investigator must contact the IRB in writing within 60 days of the suspension. The investigator must address the following requirements in a letter, to be reviewed by the IRB at a convened meeting:
 - a. Reason for requesting the study to be reinstated.
 - b. Short summary of the purpose of the study and intended objects/outcomes. This may be incorporated into the protocol, noting any changes, revisions, or clarifications to the protocol.
 - c. Description of how the study has changed, if applicable, since initial approval.
 - d. Summary of the status of the study, including:
 - 1) How many subjects were enrolled and anticipated enrollment;
 - 2) At what point in the procedures were the subjects at the time of the suspension;

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- 3) Any adverse events since the last continuing review and how these adverse events will be mitigated in the future;
 - 4) Any additional relevant information.
 - e. Documented plan to ensure that the reason for suspension will not occur again and that the study will be in compliance with all applicable laws and regulations.
 - f. In the case that IRB-approval of a protocol is reinstated, the IRB may require that subjects who were previously enrolled be re-consented.
- 3.8.3. Terminated studies may be reinstated or reactivated with appropriate modifications to address the reason(s) for why the study was terminated. Investigators must submit a completely new application if they wish to resume a terminated study. Previously terminated studies must be reviewed by the IRB at a convened meeting to ensure risks of harm to the subjects are minimized.

4. SCOPE

These policies and procedures apply to all human subject research conducted by investigators affiliated with UCSB, regardless of whether the protocol was ever submitted, reviewed, or approved by the IRB or determined to be exempt.

5. RESPONSIBILITY

The IRB Chair is responsible for bringing terminations to the IRB for review. The IRB Chair is also responsible for determining whether a protocol should be suspended or terminated in emergency situations.

The IRB staff, Research Integrity Director, IRB Chair, are responsible for receiving reports of non-compliance, unanticipated problems involving risks to subjects and/or serious adverse events and initially evaluating the report.

The IRB Chair, in consultation with the Research Integrity Director, and IRB staff, are responsible for ensuring that protocol suspensions and terminations are reported to the appropriate individuals (e.g. IO, Department Chair, etc.) and organizations (OHRP, sponsor) in a timely manner. Initial verbal reports may be made, followed by written notification. The Research Integrity Director will submit a written report to OHRP (as appropriate) when a protocol has been suspended or terminated.

The Principal Investigator, or Faculty Advisor, is responsible for ensuring prompt reporting of suspensions or terminations that are determined outside of UCSB's IRB (i.e. if the investigator used a commercial or external IRB for review). The investigator is also responsible for notifying enrolled participants of any suspensions, terminations, and describing any new procedures to protect the welfare of subjects upon reinstated of the protocol.

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The IRB staff are responsible for overseeing the process by which protocols that have not been updated, reviewed, and approved with proper continuing review paperwork are identified and administratively closed if appropriate.

6. PROCESS OVERVIEW

6.1. Suspensions or Terminations for Cause

- 6.1.1. When the IRB receives reports of circumstances which may affect the rights, safety, or welfare of the human research participants, or reports of research not being conducted in accordance with federal or state regulations, University policies or procedures, or IRB requirements the IRB will review the report and make a determination as to whether the protocol should be suspended or terminated. The IRB will follow the process of reviewing any reports as described in SOP 021 – *Protocol Deviations and Non-Compliance*. Under normal circumstances and when the severity of the event in terms of risk to the subjects is low (e.g. failure to compensate a participant in a timely fashion), the IRB Chair/Designee may require retraining of the research team in lieu of a suspension or termination of the project.
- 6.1.2. If the risk of harm to the subjects is deemed to be high, such that the non-compliance is serious and/or continuing and/or puts the rights, safety, or welfare of the subjects at an immediate and/or increased risk, then the IRB Chair/Designee will review the report and can make an interim initial determination of suspension to halt all activities until the full board has convened to review the reported information. In addition, the IRB Chair/Designee may appoint an ad hoc committee to meet prior to the next convened meeting to review the case to make a determination of suspension or termination, if deemed necessary. The IRB will review the reported case at the convened meeting to determine whether to continue the suspension, terminate the protocol, reinstate the protocol, or require additional sanctions.
- 6.1.3. The IRB Chair may consult with the IO as needed to make an initial determination as to whether to suspend or terminate a protocol prior to the full board meeting.
- 6.1.4. Protocols that have been terminated will be closed immediately after the full board has voted to terminate a study. Investigators who wish to reactivate a terminated protocol may do so, following the procedures described above in Section 3.8.

References:

45 CFR 46 Regulations

UC Berkeley Guidelines and Policies

OHRP – Guidance on Reporting Incidents to OHRP (May 2005)