

Standard Operating Procedures		
SOP #403.3 Revision 3	TITLE: Suspension or Termination of Approved Research	Effective Date: 5/30/2019
Approved By: OIRB Director	Signature 	Date 5/30/2019
Approved By: IRB Chair	Signature 	Date 5/30/2019

PURPOSE

To describe policies and procedures for suspending or terminating research approved by the Institutional Review Board (IRB).

REVISIONS FROM PREVIOUS VERSION

Clarification regarding exempt research

POLICY

The convened IRB (or the IRB Chair if there is immediate risk to participants) has the authority to suspend or terminate approval of human research, including exempt research, that is not being conducted in accordance with the IRB approval, that has been associated with serious or continuing noncompliance, or that has been associated with substantive harm to the rights and welfare of research participants. Any suspension or termination of approval shall include a statement of the reason for the IRB action.

The IRB Chair or designee has the authority to request that the IRB suspend approval when the continuation of the research may adversely affect the rights and welfare of research participants or when the IRB needs additional information to ensure that the rights and welfare of participants are protected and there is insufficient time to have the convened IRB review the situation.

The IRB reports the suspension or termination promptly to the researcher and appropriate institutional official(s). If the research is funded by an extramural agency, federal regulations dictate whether the funding agency must be informed that IRB approval has been suspended or terminated. Principal Investigators (PIs) are responsible for informing the funding agency of any suspension or termination of funded research and notifying the IRB of such communication.

Reporting to federal regulatory agencies is not required if the PI voluntarily closes down a project to new participant accrual or temporarily halts the research procedures. The IRB, IRB Chair, or administrative officials may recommend voluntary closure to the PI, but the PI makes the decision whether closure is appropriate. However, if the IRB or IRB Chair requires suspension or termination, then the incident is reportable under the Mandated Reporting to External Agencies SOP.

Definitions

A *suspension* of IRB approved research is a temporary interruption in the enrollment of new participants, activities involving previously enrolled participants, or other research activities.

A *termination* of IRB approval refers to a permanent halt in the enrollment of new participants, activities involving previously enrolled participants, or other research activities.

RESPONSIBILITIES

Execution of SOP: Researchers, IRB Chair, IRB, OIRB,.

PROCEDURE

Suspension of IRB Approval

1. The convened IRB determines and documents in the minutes the reasons for suspending the research and any information needed from the PI and/or corrective actions or events that need to take place for the IRB to consider a withdrawal of the suspension.
2. If the IRB Chair or designee suspends IRB approval, the IRB Chair documents the reason for suspension and notifies the PI in writing or requests that OIRB staff prepare the correspondence. OIRB staff inform the IRB, and the IRB discusses the suspension at a convened meeting.
3. When a suspension involves the withdrawal of current participants from a research protocol, the IRB considers alternatives that protect participants currently enrolled to ensure that harm is not incurred from such withdrawal. Such considerations may include possible transfer of participants to another researcher, continuation of some research activities under the supervision of an independent monitor, permitting follow-up of participants for safety reasons, or requiring reporting of adverse events or outcomes to the IRB and the sponsor, if applicable.
4. OIRB staff notify the PI in writing of the suspension. The correspondence may include, but is not limited to, the following:
 - An explanation of the extent of the suspension in terms of enrollment, recruitment, interventions, interactions, and data analysis;
 - The reasons for the suspension, an explanation of the reasons for the decision, and an offer to the researcher to respond to the convened IRB in writing;
 - A request for a description of any procedures needed to protect the rights and welfare of current participants if the suspension involves currently enrolled participants;
 - A description of whether follow-up of participants for safety reasons is permitted or required.
6. The PI notifies enrolled participants of any suspended research protocol, and the PI considers the appropriate procedures for withdrawal of enrolled participants, taking into account their rights and welfare.
7. The IRB determines which institutional officials to notify of the suspension and whether to report the suspension to an external agency (see Mandated Reporting to External Agencies SOP). Also, OIRB staff send copies of suspension correspondence to other UNM administrative units (e.g. Institutional Biosafety Committee, the Office of Sponsored Projects, Contract & Grant Accounting, etc.) as applicable.

Termination of IRB Approval

1. The convened IRB determines and documents in the minutes the reasons for terminating the research.
2. When a termination involves the withdrawal of current participants from a research protocol, the IRB considers alternatives that protect participants currently enrolled to ensure that harm is not incurred from such withdrawal. Such considerations may include possible transfer of participants to another researcher, continuation of some research activities under the supervision of an independent monitor, permitting follow-up of participants for safety reasons, or requiring reporting of adverse events or outcomes to the IRB and the sponsor, if applicable.

3. OIRB staff notify the PI of the termination. The notification may include, but is not limited to, the following:
 - An explanation of the extent of the termination in terms of enrollment, recruitment, interventions, interactions, and data analysis;
 - The reasons for the termination, an explanation of the reasons for the decision, and an offer to the researcher to respond to the convened IRB in writing;
 - A request for a description of any procedures that need to be followed to protect the rights and welfare of current participants if the termination involves currently enrolled participants;
 - A description of whether follow-up of participants for safety reasons is permitted or required;
 - An explanation that any request for the IRB to reconsider the termination must be made within 30 days from date of the notification.
4. The PI notifies enrolled participants of any termination of a research protocol, and the PI considers the appropriate procedures for withdrawal of enrolled participants, taking into account their rights and welfare.
5. The IRB determines which institutional official to notify of the termination and whether a report to an external agency is required (see Mandated Reporting to External Agencies SOP) Also, OIRB staff send copies of the termination notification to other administrative units (e.g. Institutional Biosafety Committee, Office of Sponsored Projects, Contract & Grant Accounting, etc.) as applicable.

Review Outcomes

If a project is suspended or terminated, the IRB may require the PI to take additional actions, including but not limited to:

- Transfer of participants to another project;
- Make arrangements for clinical care outside the research;
- Allow continued implementation of some research activities under the supervision of an independent monitor;
- Require or permit follow-up of participants for safety reasons;
- Notify current participants;
- Notify former participants.

Reporting of Suspension or Termination

See the Mandated Reporting to External Agencies SOP for a description of policies and procedures regarding reporting of projects under the oversight of the UNM IRB.

REFERENCES

45 CFR 46.113

21 CFR 56.113