UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-041
AAHRPP:	Element II.2.H.
Date Adopted:	8/24/2020
Last Updated:	11/25/2024
Prepared By:	Casey Webster
Updated By:	Casey Webster
Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Termination or Suspension of Research

1.0 Objective

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

2.0 Responsibility

2.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator or (RCA), IRB, and investigators to execute this Standard Operating Procedure (SOP).

3.0 General Description

3.1. The convened IRB has the authority to suspend or terminate approval of 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 human subjects.

3.1.1. Any suspension or termination of approval shall include a statement of the reason for the IRB action.

3.2. 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 subjects or when the IRB needs additional information to ensure that the rights and welfare of subjects are protected and there is insufficient time to have the convened IRB review the situation.

3.3. The IRB reports the suspension or termination promptly to the investigator and Institutional Official (IO).

3.3.1. If the research is funded by an extramural agency or private funding, federal regulations dictate whether the funding source must be informed that IRB approval has been suspended or terminated.

3.3.2. Principal Investigators (PIs) are responsible for informing the funding agency of any suspension or termination of funded research.

3.4. Reporting to federal regulatory agencies is not required if the PI voluntarily closes down a study to new subject accrual or temporarily halts the research procedures.

3.4.1. The IRB, IRB Chair, or ORIO staff may recommend voluntary closure to the PI, but the PI makes the decision whether the closure is appropriate.

3.4.2. However, if the IRB or IRB Chair requires suspension or termination, then the incident is reportable in accordance with HRPP-034 Mandated Reporting to External Agencies SOP.

3.4.3. When appropriate, the IRB may ask the PI to explain the reasons/circumstances around a suspension/termination of research to their supervisor.

3.5. Suspensions and terminations by someone other than the convened IRB must be reported to and reviewed by the convened IRB.

4.0 Definitions

4.1. Suspension of IRB approved research means a temporary interruption in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

4.2. Termination of IRB approval means a permanent halt in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

5.0 Procedure

5.1. Suspension of IRB Approval

5.1.1. 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.

5.1.2. 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 ORIO staff prepare the correspondence.

5.1.2.1. ORIO staff inform the IRB, and the IRB discusses the suspension at a convened meeting.

5.1.3. When a suspension involves the withdrawal of current subjects from a research protocol, the IRB considers alternatives that protect subjects currently enrolled to ensure that harm is not incurred from such withdrawal.

5.1.3.1. Such considerations may include:
5.1.3.1.1. Possible transfer of subjects to another investigator;
5.1.3.1.2. Arrangement of clinical care outside the research;
5.1.3.1.3 Continuation of some research activities under the supervision of an independent monitor;
5.1.3.1.4. Permitting follow-up of subjects for safety reasons; or
5.1.3.1.5. Requiring reporting of adverse events or outcomes to the IRB and the sponsor.

5.1.4. ORIO staff notify the PI in writing of the suspension. The correspondence may include, but is not limited to, the following:

5.1.4.1. An explanation of the extent of the suspension in terms of enrollment, recruitment, interventions, interactions, and data analysis;
5.1.4.2. The reasons for the suspension, an explanation of the reasons for the decision, and an offer to the investigator to respond to the convened IRB in writing;
5.1.4.3. A request for a description of any procedures needed to protect the rights and welfare of current subjects if the suspension involves currently enrolled subjects;
5.1.4.4. A description of whether the follow-up of subjects for safety reasons is permitted or required.

5.1.5. The PI notifies enrolled subjects of any suspended research protocol, and the PI considers the appropriate procedures for the withdrawal of enrolled subjects, taking into account their rights and welfare in accordance with HRPP-035 Roles and Responsibilities of Investigators SOP.

5.1.6. The IRB determines whether to notify the Institutional Official of the suspension and whether to report the suspension to an external agency in accordance with *HRPP-034 Mandated IRB Reporting to External Agencies SOP.*

5.2. Termination of IRB Approval

5.2.1. The convened IRB determines and documents in the minutes the reasons for terminating the research.

5.2.2. When a termination involves the withdrawal of current subjects from a research protocol, the IRB considers alternatives that protect subjects currently enrolled to ensure that harm is not incurred from such withdrawal.

5.2.2.1. Such considerations may include:
5.2.2.1.1. Possible transfer of subjects to another investigator;
5.2.2.1.2. Arrangement of clinical care outside the research;
5.2.2.1.3. Continuation of some research activities under the supervision of an independent monitor;
5.2.2.1.4. Permitting follow-up of subjects for safety reasons; or
5.2.2.1.5. Requiring reporting of adverse events or outcomes to the IRB and the sponsor.

5.2.3. ORIO staff notify the PI of the termination. The notification may include, but is not limited to, the following:

5.2.3.1. An explanation of the extent of the termination in terms of enrollment, recruitment, interventions, interactions, and data analysis;
5.2.3.2. The reasons for the termination, an explanation of the reasons for the decision, and an offer to the investigator to respond to the convened IRB in writing;
5.2.3.3. A request for a description of any procedures that need to be followed to protect the rights and welfare of current subjects if the termination involves currently enrolled subjects;
5.2.3.4. A description of whether follow-up of subjects for safety reasons is permitted or required; and
5.2.3.5. An explanation that any request for the IRB to reconsider the termination must be made within thirty (30) days from the date of the notification.

5.2.4. The PI notifies enrolled subjects of any termination of a research protocol, and the PI considers the appropriate procedures for withdrawal of enrolled subjects, taking into account their rights and welfare in accordance with HRPP-035 Roles and Responsibilities of Investigators.

5.2.5. The IRB determines whether to notify the Institutional Official of the suspension and whether to report the suspension to an external agency in accordance with HRPP-034 Mandated IRB Reporting to External Agencies SOP.

5.3. Reporting and Recordkeeping of Suspension or Termination

5.3.1. ORIO staff report and maintain records of suspension or termination in accordance with HRPP-034 Mandated IRB Reporting to External Agencies SOP.

6.0 References

6.1. 45 CFR 46.103;

6.2. 45 CFR 46.113;

6.3. 21 CFR 56.108;

6.4. 21 CFR 56.113;

6.5. OHRP Guidance on Reporting Incidents to OHRP; & FDA Information Sheets: Continuing Review After Study Approval