

Suspension or Termination of Research

SOP 109
Revised: January 5, 2017

Purpose and Scope

The SOP describes the procedure for suspending or terminating IRB approval of research, if warranted, and for reporting these actions, when appropriate.

SOP applies to all HSP staff, IRB members and Investigators (PI) at the University of Hawaii involved in the conduct or the review of human subjects research.

Definitions

- **Suspension of IRB Approval:** An action of the IRB, IRB designee, Institutional Official, or designee of the Institutional Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a "Termination of IRB Approval" due to concerns regarding the safety, rights, or welfare of human participants, research investigators, research staff, or others.
- **Termination of IRB Approval:** An action of the IRB to permanently withdraw IRB approval of all research procedures" due to concerns regarding the safety, rights, or welfare of human participants, research investigators, research staff, or others.

Procedures

Convened IRB

1. The IRB shall:
 - a. Notify the PI in writing of it the IRB decision to suspend or terminate its approval along with a statement of the reasons for the IRB action and any terms and conditions of any suspension.
 - b. Report the decision to suspend or terminate to the Vice President for Research and Innovation and others in accordance with the procedures set forth in SOP 108 and SOP 116, for non-compliance or serious adverse events, respectively.
2. The PI shall be provided with an opportunity to respond in person or in writing to the IRB on a suspension or termination.
 - a. ***If the IRB action in relation to the suspension or termination involves the withdrawal or modification of participation of current participants*** from the research, the IRB shall direct the PI to contact the participants to:
 - 1) Make such notification with an explanation, after its review and approval by the IRB
 - 2) Describe any monitoring and follow-up for safety reasons that will be conducted
 - 3) Provide contact information for the PI and the IRB where the participant may report any adverse events or unanticipated problems.

Authorized Individual

The following individuals or parties are authorized to *suspend* IRB approval pending review by the IRB responsible for continuing review of the protocol:

- The Human Studies Program Director;
- The IRB Chair;
- The IRB; or
- The Institutional Official is authorized to suspend, provided with justification.

Only a convened IRB may *terminate* a protocol or proposal.

The authorized individual or party who makes a suspension of a protocol shall immediately:

1. Notify the PI:
 - a. to halt the portion of the IRB approved protocol that poses immediate, material risk to participant health and welfare,
 - b. of the reasons for the suspension or termination, and
 - c. of the opportunity to respond in person or in writing to the official and IRB on the suspension or termination
 - d. Report the suspension or termination and its basis to the IRB.
2. The HSP staff shall:
 - a. Report the suspension or termination as a “suspension or termination of IRB approval” to the Institutional Official and others as appropriate within twenty (20) business days from the date of suspension or termination of the research.
 - b. Immediately initiate the appropriate procedure for review of the basis for the suspension or termination (e.g., the procedure for reviewing possible non-compliance or a possible unanticipated problem).
3. ***If the halt in some or all of the protocol involves the withdrawal from the research or modification of participation of current participants***, the IRB shall direct the PI to contact the participants to:
 - a. Make such notification with an explanation, after its review and approval by the IRB
 - b. Describe any monitoring and follow-up for safety reasons that will be conducted
 - c. Provide contact information for the PI and the IRB where the participant may report any adverse events or unanticipated problems.

Protection of Participants Who May Be Affected by the IRB Action

If the suspension or termination will affect participants in the protocol (e.g., requires withdrawal of participants), the IRB shall utilize a process that takes into account the impact on their health and safety. This should occur before the suspension or termination, when it is feasible and delay will not jeopardize their health and safety. Examples include:

1. Requiring the PI to submit proposed procedures for any withdrawal of participants
2. Allowing participants to continue (e.g., treatment with an investigational drug) if the IRB determines that it is in their best interests
3. Requiring submittal for review and approval of the IRB or its designee of all communications by the PI to participants about the IRB action
4. Designating an investigator other than the PI to be responsible for carrying out the IRB decision
5. Requiring the appointment of a new PI or transferring responsibility for participants to another investigator
6. Requiring the PI to carry out follow-up or monitoring of participants appropriate to the circumstances (e.g., for any adverse impact on participants after suspension or termination)
7. Requiring special reporting (e.g., adverse events or outcomes) concerning participants by the PI.

Reporting Suspension and Terminations to Federal Agencies (i.e., OHRP, FDA)

1. The HSP files an incident report to the OHRP and other HHS-supporting federal agencies. The report includes the following information¹:
 - (a) the name of the institution conducting the study,
 - (b) The title of the research and grant proposal that was suspended or terminated,
 - (c) the name of the Investigator,
 - (d) the number of the research assigned by the IRB that was suspended or terminated and the number of any applicable federal awards such as grants, contracts, or cooperative agreements,
 - (e) a detailed description of the reason for the suspension or termination, and
 - (f) the actions taken or planned to take to address the suspension or termination.
2. The HSP files an incident report to the FDA, when applicable. The report includes the following information²:
 - (a) IND or IDE number
 - (b) Full name of the research protocol
 - (c) Name(s) of the clinical investigators
 - (d) Reason(s) for the suspension or termination.
3. Location/ contacts for submitting the Report:

Office for Human Research Protections
U.S. Department of Health and Human Services
200 Independence Avenue S. W.
Washington, D. C. 20201

¹ OHRP Guidance on Reporting Incidents, supra note **Error! Bookmark not defined.** at II.C; see [FDA Section](#) for the content requirements by the FDA.

² FDA: Suspension or Termination of IRB Approval.

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ReportProblemstoFDA/ucm136102.htm>

irpt.os@hhs.gov

For Drug Products (FDA):

Ms. Dana Walters
Dana.Walters@fda.hhs.gov
Division of Scientific Investigations (HFD-45)
Office of Compliance
Center for Drug Evaluation and Research
White Oak Campus
10903 New Hampshire Ave.
BLDG 51, Rm. 5341
Silver Spring, MD 20993
Phone: (301) 796-3150
Fax: (301) 847-8748

For Biologic Products (FDA):

Ms. Patricia Holobaugh
Patricia.Holobaugh@fda.hhs.gov
Bioresearch Monitoring Branch (HFM-664)
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research/FDA
10903 New Hampshire Ave.
Building 71, Room 5133
Silver Spring, MD 20993
Phone: (240) 402-8955
Fax: (301) 595-1304

For Medical Devices (FDA):

Phone (301) 796-5490
Fax: (301) 847-8136
Email: bimo@cdrh.fda.gov

4. The Report is filed no later than twenty (20) business days after the suspension or termination.

Materials

- **TMP 470:** Reporting Letter – FDA Notification of Suspension or Termination of Research Involving a Biologic
- **TMP 471:** Reporting Letter – FDA Notification of Suspension or Termination of Research Involving a Drug
- **TMP 472:** Reporting Letter – OHRP Notification of Non-compliance