

SOP: 410 Effective Date: 07/01/2019	SUSPENSION OR TERMINATION OF RESEARCH	Supersedes Document Dated: 07/19/2018
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## 1. POLICY:

The Institutional Review Board (IRB) may to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, the Institutional Official (IO), the HRPP Director, and if the research is externally funded, to the sponsor. The IRB has authority to suspend or terminate human subject research activities that have never been reviewed by the IRB upon learning of such activities.

These policies and procedures apply to all Human Subjects Research conducted by Investigators affiliated with Purdue University, regardless of whether the protocol was ever submitted, reviewed, or approved by the IRB.

## 2. DEFINITIONS

- 2.1 *Department or Agency Head.* The head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.
- 2.2 *Suspension.* Temporary cessation of some or all activities in a currently approved research study.
- 2.3 *Termination.* Determination made by the IRB to permanently withdraw approval for some or all activities of a currently approved research study.

## 3. PROCEDURES

- 3.1 Federal regulations give an IRB the authority to terminate or suspend approval of research under its jurisdiction.
  - 3.1.1 An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.
  - 3.1.2 A research study may be suspended or terminated for a variety of reasons, including but not limited to:
    - (a) Failure to obtain appropriate consent or keep appropriate study-related paperwork;
    - (b) Conduct of research activities without prior IRB approval;
    - (c) Serious adverse event(s);
    - (d) Detrimental change in the risk-benefit ratio of the study;

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- (e) Failure of investigators to complete required training; or
- (f) Other noncompliance issues.

### **3.2 Authority**

- 3.2.1 The convened IRB is authorized to suspend or terminate research protocols.
- 3.2.2 The IRB Chair (or his/her designee) is authorized to suspend research protocols in emergency situations (i.e., when the rights, safety, or welfare are in immediate jeopardy).
- 3.2.3 The HRPP Director, IO, and the IRB Chair are authorized to suspend or terminate human subject research activities that were not properly reviewed and approved (or determined to be exempt) by the IRB.

### **3.3 Process and Notification for Suspension or Termination**

- 3.3.1 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. The initial inquiry and investigation procedures are described in SOP 408: Noncompliance and SOP 409: Unanticipated Problems and Adverse Event Reporting. If a protocol is determined to be in noncompliance or if an adverse unanticipated problem has occurred, further action will be taken by the IRB.
- 3.3.2 In most cases, the IRB will review the circumstances of the case and make a determination of suspension or need for termination. The IRB Administrator and/or consultants will be consulted as needed in the decision-making process. Under normal circumstances and when the severity of the event is low, the determination will be made at the next regularly-scheduled IRB meeting.
- 3.3.3 In emergency situations (that is, severe noncompliance that puts the rights, safety, or welfare of human subjects at immediate risk), the IRB Chair (or designee) may make the determination to suspend a study after consulting with at least one of the following: an IRB Associate Chair, IRB Administrator, an IRB Investigative Subcommittee, or the HRPP Director. If an IRB Chair (or designee) suspends research, the matter will be reported and reviewed by the convened IRB at the next regularly scheduled meeting. The convened IRB will review the circumstances of the case and make a determination to continue the suspension, to lift the suspension and reinstate active approval, or to terminate the protocol.

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3.3.4 Once action has been taken by the IRB Chair or the convened IRB, the IRB Chair (or his or her designee) will send a letter 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 of the investigator (e.g., cease all data collection)

3.3.5 The letter will be forwarded to the Investigator, IO, any Sponsor(s), and applicable federal agencies (e.g., FDA, OHRP), and any other individuals or entities deemed appropriate by the IRB Chair. A copy of the form is filed with the protocol's IRB file.

3.3.6 The Investigator is responsible for notifying (in a timely manner) all co-PIs, key personnel, and other research staff associated with the protocol as well as any subcontract grantees if the protocol has been suspended or terminated.

**3.4** Points to Consider When Suspending or Terminating Research Activities. When suspending or terminating a research activity, the following should be considered:

- 3.4.1 Whether the suspension or termination protects the rights and welfare of participants;
- 3.4.2 Whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., continuation of medical care after cessation of the research study, continuation in the research under independent monitoring);
- 3.4.3 Whether to inform current participants of the suspension or termination;
- 3.4.4 Whether to require participant follow-up for safety concerns; and
- 3.4.5 Whether to inform current participants of reported matters (unanticipated problem, adverse events, noncompliance, etc.).

**3.5** Consequences of Suspension or Termination

3.5.1 When a protocol is suspended or terminated, the Investigator must stop all activity on the protocol, including subject recruitment and enrollment, treatment, and analysis and/or publication of existing data. If any data was collected between the date of the termination notice and receipt of the termination notice, the Investigator must discard that data. Additionally,

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data that were collected during the study approval period may no longer be used since approval for the study has been terminated.

3.5.2 When the suspension or termination of a research protocol involves the withdrawal of current participants from the research, the Investigator will be required to:

- (a) inform 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.

3.5.3 In certain circumstances, project activities may continue if stopping study procedures/treatment would adversely affect the welfare of a subject. When the suspension or termination of a research protocol does not involve the withdrawal of current participants from the research, the Investigator will be required to:

- (a) notify the IRB office immediately of the need to continue any procedures/treatment;
- (b) inform enrolled participants that the study has been suspended or terminated; and
- (c) report any adverse events or unanticipated problems involving risks to participants.

3.5.4 When the IRB suspends or terminates any research activities, the Institutional Official shall report the event to the Office for Human Research Protections and/or to the Food and Drug Administration, promptly. Though prompt reporting is dependent on factual details and the severity of the event, a preliminary report should be made to OHRP within 30 calendar days of the IRB's notification.

### 3.6 Reinstatement of Protocols

3.6.1 *Suspended Studies.* To reinstate a project that has been suspended, the Investigator must satisfactorily resolve any pending issues as required by the IRB. After six months, if adequate progress has not been made on the pending issues then the IRB will close the study. The Investigator must contact the HRPP in writing within thirty (30) days of the suspension, and must address the following issues:

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- (a) Reason for requesting the study be reinstated;
- (b) Short summary of the purpose of the study and intended objectives/outcomes;
- (c) Description of how the study has changed, if any, since initial approval;
- (d) Summary of status of the study, including:
  - (i) how many subjects were enrolled
  - (ii) at what point in the treatment/procedures were the subjects
  - (iii) any adverse events or amendments since last continuing review, including a description of each
  - (iv) any additional relevant information;
- (e) Documented plan to ensure that reason for suspension will not happen again and that the study will be in compliance with all applicable laws and regulations; and
- (f) Anticipated enrollment, if the study is reactivated.

In the case that IRB-approval of a protocol is reinstated, the IRB may require that subjects who were previously enrolled be re-consented.

3.6.2 *Terminated Studies.* Terminated studies cannot be reinstated. Instead, Investigators must submit a new research study application.

## **4. RESPONSIBILITY**

### **4.1 Investigator Responsibilities**

- 4.1.1 Submit all research proposals to the IRB for approval or exemption determination prior to the commencement of any research.
- 4.1.2 Conduct research according to the approved IRB protocol.
- 4.1.3 Report any unanticipated problems or adverse events according to SOP 409: Unanticipated Problems and Adverse Event Reporting.
- 4.1.4 Report any deviations or noncompliance according to SOP 408: Noncompliance.

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4.1.5 Notify (in a timely manner) all co-researchers, key personnel, and other research staff associated with the protocol as well as any subcontract grantees if the protocol has been suspended or terminated.

#### **4.2 IRB Responsibilities**

4.2.1 HRPP Support Staff and Protocol Analysts should report matters to the IRB Chair or designee according the reporting procedures for noncompliance, unanticipated problems and adverse events.

4.2.2 IRB Chair (or designee) or IRB considers reported events and, if necessary, suspends research activities and reports those suspensions to the Investigator, IO, and convened IRB.

4.2.3 Convened IRB considers event reports, lifts suspensions, and if necessary, terminates research activities and reports those terminations to the Investigator and IO.

4.2.4 Institutional Official reports any suspensions or terminations of research activities to the Office for Human Research Protections and/or to the Food and Drug Administration in accordance with their requirements.

#### **5. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.113

21 CFR 56.113

#### **6. REFERENCES TO OTHER APPLICABLE SOPs**

408 Noncompliance

409 Unanticipated Problems and Adverse Reporting