

<b>Oklahoma State University Institutional Review Board Standard Operating Procedures</b>		
<b>Suspension and Termination of IRB Approval</b>	SOP #	RR 410
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	Revision #	1
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## **1. POLICY**

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB, federal, state or university requirements, or has been associated with unexpected serious harm to subjects or others.

Research will be suspended or terminated for the following reasons, including but not limited to:

- Unexpected serious harm to research participants (i.e. human subjects);
- Serious and continuing non-compliance with federal regulations, IRB policy or the approved IRB protocol;
- Failure to submit a complete Continuation/Renewal Request form in sufficient time to allow an appropriate review to be conducted;
- Inappropriate involvement of human subjects in research;
- Failure to obtain appropriate informed consent;
- Change in risk : benefit ratio of the research and /or an increase in risk due to changes in oversight of the research or changes in research procedures that have not been approved by the IRB.

### **Specific Procedures**

#### **1.1 Definitions**

1.1.1 Suspension: An action taken by the IRB that halts all or some of the research activities associated with an active, approved protocol until issues of concern have been satisfactorily resolved. Suspended projects retain IRB approval and require continuing review at appropriate intervals.

1.1.2 Termination: An action taken by the IRB that halts all or some of the research activities permanently except for the continuation of follow-up activities necessary to protect the participants' safety. In certain situations, the IRB may find it appropriate to allow enrolled participants to continue their participation in the research intervention(s) or interaction(s), if it is in the best interest of the individuals.

#### **1.2 Suspension of IRB Approval**

1.2.1 At a convened meeting of the IRB, the IRB Chair will present the facts for IRB consideration of suspension of the research. This will include the determination of the category(s) of suspension, which include(s):

- Suspension of recruitment;
- Suspension of screening and enrollment;
- Suspension of interaction and intervention; and/or
- Suspension of follow-up.

The IRB will consider the following during its deliberations:

- Actions to protect the rights and welfare of currently enrolled participants;
- How current participants will be informed of the suspension;
- Reporting of unanticipated problems or adverse events.

The IRB will detail any information, corrective actions or events that are needed for the IRB to consider withdrawal of any suspension and establish a time line for their completion. The discussion, action, and vote will be recorded in the meeting minutes.

1.2.2 The principal investigator and any other investigator(s) for the research, the associated research staff, appropriate department heads, college research deans, and the institutional official will be notified by letter of the suspension and any required response. The letter will include:

- An explanation of the extent of the suspension in terms of enrollment, recruitment, interventions, interactions and data analysis;
- The reasons for the suspension, the rationale for the decision and an offer to the investigator to respond to the IRB in writing; and
- A request for a description of any procedures needed to protect the rights and welfare of currently enrolled subjects (if any) including procedures for notifying participants of suspension and procedures for safe withdrawal from the study.

1.2.3 In instances when serious or continuing non-compliance or incidents of unexpected serious harm pose imminent threat to participants' rights and welfare (e.g. safety), the IRB Chair, in consultation with the IRB Manager and Assistant Vice President for Research Compliance, may act immediately to temporarily suspend previously approved research. The investigators, research staff, appropriate university department heads, college research deans, the institutional official, and appropriate federal department and regulatory agency personnel will be notified of the suspension. Further review by the convened IRB will determine the length and terms of any suspension.

### **1.3 Termination of IRB Approval**

1.3.1 At a convened meeting of the IRB, the IRB Chair will present the facts for IRB consideration of termination of the research. The IRB will decide on a course of action and establish a time line for the completion of that action. The discussion, action and vote will be recorded in the meeting minutes.

1.3.2 The principal investigator and any other investigator(s) for the research, the associated research staff, appropriate department heads, college research deans and the institutional official will be notified by letter of the termination and any required response. The letter will include:

- An explanation of the extent of the termination in terms of enrollment, recruitment, interventions, interactions and data analysis;
- The reason(s) for the termination, the rationale for the decision and an offer to the investigator to respond to the IRB in writing;
- A request for a description of any procedures needed to protect the rights and welfare of currently enrolled subjects (if any) including procedures for notifying participants of suspension and procedures for safe withdrawal; and
- A description of whether follow-up of subjects for safety reasons is permitted or required.

During its deliberations, the IRB will consider, but is not limited to the following:

- Actions to protect the rights and welfare of currently enrolled participants;
- Procedures for safe withdrawal of enrolled participants;
- How current participants will be informed of the termination; and
- Reporting of unanticipated problems or adverse events.

1.3.3 In instances when serious or continuing non-compliance or incidents of unexpected serious harm pose imminent threat to participants' safety, the IRB Chair, in consultation with the IRB Manager and Assistant Vice President for Research Compliance, may act immediately to temporarily terminate previously approved research. The investigators, research staff, appropriate university department heads, college research deans, the institutional official, and appropriate federal department and regulatory agency personnel will be notified of the termination. The termination action will be further reviewed by the convened IRB as detailed in 1.3.1 and 1.3.2.

## **1.4 Reporting**

1.4.1 If the research is supported by an external sponsor, the sponsor will be notified of the suspension/termination of the research.

For all non-exempt research, if the IRB suspends or terminates the protocol, a report must be submitted to the Office for Human Research Protections (OHRP). The report should be prepared according to the OHRP Guidance on Reporting Incidents to OHRP and must include the following;

- Name of the institution;
- Title of the research project/grant in which the problem occurred;
- Name of the principal investigator;
- IRB number and (if appropriate) the number of any applicable federal award;
- A detailed description of the reason for the suspension or termination; and
- Actions the institution is taking or plans to take to address the suspension or termination.

All suspensions and terminations will be reported to the appropriate individuals and agencies in accordance with federal regulations and university policy within one month of the IRB's actions.

## **2. SCOPE**

This procedure applies to all research approved by the IRB.

## **3. RESPONSIBILITY**

The IRB Chair is responsible for presenting the facts to the IRB at a convened meeting.

IRB members are responsible for determining if the facts are sufficient to require suspension or termination of the research.

IRB members are responsible for determining a course of action and a timeline for the completion of that action.

IRB Manager is responsible for notifying the appropriate individuals, departments and agencies of the suspension or termination.

#### 4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.113

#### 5. REFERENCES TO OTHER APPLICABLE SOPS

RR406, RR408 RR409

#### 6. IMPLEMENTATION OF PROCEDURES

Who	Task
<i>IRB Chair</i>	Present the facts to the IRB at a convened meeting In the event of imminent threat to participants' safety, act to immediately suspend or terminate research
<i>IRB Members</i>	Review the facts and make determination, establish an action plan and timeline for investigator(s)
<i>IRB Manager</i>	Notify all appropriate parties and agencies of the action