1. PURPOSE

The purpose of this procedure is to establish the documenting requirements for suspension or termination of IRB-approved research projects.

2. PROCEDURE

The IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements, federal, state or local requirements, or has been associated with unexpected serious harm to human subjects. A project may be suspended or terminated for the following reasons, including, but not limited to:

- Serious and continuing non-compliance with federal regulations and IRB policy.
- Repeated failure to submit a Continuation submission in sufficient time to allow for an appropriate review to be conducted.
- Repeated failure to obtain appropriate informed consent.
- Change in the risk benefit ratio of the research.
- New information regarding the increased risk to the participant.

2.1 Definitions:

***Suspension*:** An action issued by the IRB that all or some of the research activities must temporarily stop enrollment of new human subjects or other ongoing research activities until issues have been satisfactorily resolved. Suspended projects still have IRB approval.

Termination: An action issued by the IRB that requires a permanent halt in the enrollment of new human subjects or other research activities except for the continuation of follow-up activities necessary to protect the participants' safety.

The terms "suspension" and "termination" apply to interruptions related to concerns regarding the safety, rights, or welfare of human research subjects, research PI, research staff, or others. Suspension and termination usually do not include:

- Interruptions in research resulting solely from the expiration of the IRB approval period.
- "Administrative holds" or other actions initiated voluntarily by an appropriate facility official, research PI, or sponsor for reasons other than those described above.

3. SPECIFIC PROCEDURES

3.1 Procedures for Suspension and Termination

1. IRB Staff or designee may suspend a study *prior* to a fully convened IRB meeting based on any of these conditions including but not limited to:
    a. If there are continuing alleged serious non-compliance with the regulations or determinations of the IRB.
    b. Any incidence that has been associated with the unexpected serious harm to participants.
    c. There appears to pose an imminent threat to subject safety.
    d. IRB staff or designee are authorized to suspend IRB approval prior to the review by the full board of the IRB, with Chair approval. The above action must be reported and reviewed by the convened IRB in a timely manner.

2. At a convened meeting of the IRB, the Chair or designee will present the facts for consideration. The IRB will:
    a. Consider the actions to protect the rights and welfare of currently enrolled participants.
    b. Consider whether procedures for withdrawal of enrolled human subjects take into account their rights and welfare (e.g. making arrangements for medical care of a research study participant, transfer to another PI, and continuation under independent monitoring).
    c. Consider informing current human subjects of the termination or suspension.

    Note: The IRB may request a review from an independent source with expertise in the type of research being conducted or expertise in the specific area of concern.
3. The IRB will decide on a course of action and establish a time line for the completion of that action. The IRB may act at any time during the investigation to modify the terms of the suspension or termination.
4. For suspensions, the IRB deliberates and determines the category(s) of suspension which are:
    a. Suspension to recruitment;
    b. Suspension to screening and enrollment;
    c. Suspension to interaction and intervention; and/or
    d. Suspension to follow-up.
5. The IRB will notify the PI in writing of its decision at its earliest opportunity. The notification should include:
    a. Reason and rationale for the suspension or termination.
    b. IRB action plan, including a timeline for response and reporting progress to the IRB.
    c. If appropriate, require the PI to submit:
        i. Procedure for the withdrawal of currently enrolled human subjects that considers the human subjects' rights and welfare;
        ii. Letter template, email template script, or script notifying all currently enrolled human subjects who are affected by the suspension or termination; and/or
        iii. A reminder that all study activities such as reporting unanticipated problems, revisions to ICFs or IBs/IFU, and updated package inserts must still be reported to the IRB.
    d. If appropriate, require the PI to:
        i. Attend PI training.
        ii. Provide a plan for oversight for current and future research.
    e. If applicable, notification that an internal audit of the study will be conducted.
6. To reinstate a project that has been suspended, the PI must satisfactorily resolve any pending issues required by the IRB. If the issues have not been resolved after one year, the study will be terminated.
7. To reinstate a project that has been terminated, the PI must submit the project to the IRB as new and past issues must be resolved to the satisfaction of the IRB.

3.2 Reporting Suspensions and Terminations

Suspensions or Terminations will be reported promptly to the appropriate agencies. The notification will outline the following:

- Nature of the event.

- Name of institution conducting the research.
- Title of the research project and/or grant proposal in which the problem occurred.
- Name of PI.
- Detailed findings and/or actions taken by the IRB.
- Reasons for the IRB's action.
- Plans for continued investigation or action, if appropriate.

The notification is sent to the Institutional Official for review, approval and signature.

The Suspension or Termination notification is then sent to one or more of the following agencies:

- FDA, when the research is FDA-regulated;
- OHRP; and/or
- Other federal agencies when the research is overseen by those agencies, and they require reporting separate from that to OHRP.

4. RESPONSIBILITY

IRB chair, staff, or a convened IRB has the authority to suspend or terminate research.

The Chair or the IRB Staff are responsible for presenting the facts to the IRB at a convened IRB meeting.

IRB members are responsible for determining if the facts are sufficient to require suspension or termination of the research and for determining course of action and establishing a timeline for completion of that action.

IRB staff are responsible for notifying the appropriate individuals and agencies of the suspension or termination.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.113 and 21 CFR 56.113

6. REFERENCED DOCUMENTS

None

REVISION HISTORY

Revision Number	Version Date	Approved By Date Approved
02	7/03/2019	Avera Institutional Official 7/23/19
• Added in the steps to follow if a suspension or termination occurs, and who to contact, since SOP-408 is being retired. Including those steps in this specific SOP instead. • Other administrative edits.		
01	August 2016	Director HSRP August 2016