OBJECTIVE

To describe the policies and procedures for suspending or terminating an IRB approved research.

POLICIES

1. The IRB shall have the 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 participants.

2. IRB shall justify the reason for its action in their correspondence to the investigators and the reportable entities.

3. Suspension or termination of approved research shall be reported but not limited to the investigator, appropriate institutional officials, and the department or agency head.

DEFINITIONS

Suspension of previously approved research: Temporary stop of some or all research activities. This includes suspension of (1) some or all research activities from a single study and may also affect (2) other active studies involving human participants.

Termination of previously approved research: Permanent stop of all research activities. This includes termination of (1) all research activities from a single study and may also affect (2) other active studies involving human participants.
Suspension of Previously Approved Research

1. The IRB Chair (or designee), IRB Director (or designee) or IRB committee can suspend previously approved human participant research or an investigator or key personnel’s privilege to conduct human participant research. There must be sufficient justification to determine that the research is not being conducted in accordance with the applicable regulations and IRB requirements, has been associated with unexpected serious harm to the participants, or the conduct of the research is such that the participants are placed at unnecessary risk with potential cause for harm. If the IRB Chair designee or Director (or designee) initiated the suspension, he/she will confirm the decision with the IRB Chair as soon as possible.

2. The IRB Chair (or designee), IRB Director (or designee) or IRB committee should consider the effect of the suspension on the rights and welfare of the current participants, including:
   a. Consequences of withdrawal for participants currently enrolled if intervention or interaction was temporarily stopped.
   b. Transition of participants from research to standard clinical care during the suspension.
   c. Requirement of follow-up on the participants after the intervention has temporarily stopped.
   d. Continued study treatment/intervention by the same or different investigator.
   e. Continued reporting of unanticipated problems, adverse events or outcomes to IRB and study sponsor.
   f. Notification of all current and/or past participants of the suspension.
   g. Requirement for existing participants to be re-consented after reinstatement.

3. In addition, the IRB Chair (or designee), IRB Director (or designee) or IRB committee should consider the following:
   a. Whether there is serious and/or continuing non-compliance.
   b. Whether the investigator can use the data from currently enrolled participants, if re-instated.
   c. Whether the investigator can use the data from participants who have completed the study.
   d. General and topic-specific education for the investigators and research staff.

4. Office for the Protection of Human Subjects (OPHS) staff will generate a letter of suspension and require that the research be immediately stopped. The letter will be
signed by the Chair and sent to the principal investigator (PI). The correspondence will include, but not limited to the following items.

a. The reason for the suspension.

b. Explanation of the extent of the suspension in terms of recruitment, screening/enrollment, interventions/interactions, follow-up activities, and data analysis. It may also include suspension of the investigator’s research privileges with regards to human participant research for a specified time period.

c. A request for a description of any procedures needed to protect the rights and welfare of the current participants enrolled in the study during the suspension period. This would entail a plan for orderly withdrawal of treatment or transition to clinical care outside of research setting. If the safety of the participants is at risk during the suspension period, the investigator should immediately consult with the IRB Chair (or designee).

d. Any additional information or supplemental documentation for clarification.

e. Any appropriate corrective action plans.

f. Submission of research data, in addition to signed informed consent documents, as necessary.

g. May request that the investigator attends the fully convened IRB meeting within 30 days.

h. Identification of entities for reporting requirements.

i. Request acknowledgement and response from the PI within 72 hours of receipt of the letter.

5. OPHS staff will generate a letter to report the investigator’s suspension, but not limited to, Office for Human Research Protections (OHRP), FDA, funding agencies, university officials and compliance offices, collaborating institutions, and other appropriate agencies. The letter will be signed by the IRB Director (or designee).

6. The IRB Chair, IRB Director or designees will report the suspension at the next convened IRB meeting.

7. IRB committee members’ review materials may include but not limited to (1) suspension letter, (2) PI’s response letter, (2) research protocol, (3) IRB application, (4) most recently approved informed consent document, (5) study related correspondences, (6) audit reports, (7) other relevant documents. The committee members can request any other information upon request.

8. The IRB should discuss the following:

   a. Whether it is a serious and/or continuing non-compliance.
   
   b. Concerns described in #2 and #3 above.
   
   c. Does the research activity need to be terminated?
9. The IRB will confirm or reverse the decision of the Chair or the Director to suspend previously approved research, in addition to adding any further actions. The IRB will also determine whether the corrective action plan is adequate and make appropriate changes, if necessary.

10. OPHS staff will generate a letter to the investigator with the determinations, justifications, and corrective action plans. The letter will also include that the appeal must be made to the IRB in writing within 30 days from the date of notification. The letter is copied to all reportable entities.

11. OPHS staff will track investigators with suspension by putting a flag next to the PI’s name. The IRB database will indicate the date in which the suspension was originally issued, the date in which the convened IRB committee confirmed or approved the suspension and the reason for suspension.

12. OPHS staff will generate a letter to report the investigator’s suspension, but not limited to the university officials, OHRP, FDA, funding agencies, collaborating institutions, and other appropriate agencies. The letter will be signed by the IRB Director (or designee).

13. Studies that are suspended by the IRB still have IRB approval. Investigators are still required to submit continuing review, unanticipated problems, adverse events, safety reports, etc.

**Termination of Previously Approved Research**

1. The Chair (designee), OPHS staff (designee), and IRB can terminate an approved research.

2. The IRB Chair may request that the PI attend the meeting.

3. IRB committee members’ review materials may include but not limited to (1) termination letter, (2) PI’s response letter, (2) research protocol, (3) IRB application, (4) most recently approved informed consent document, (5) study related correspondences, (6) audit reports, (7) other relevant documents. The committee members can request any other information upon request.

4. IRB must consider alternatives for those participants who are currently enrolled in a study to ensure that no harm occurs as a consequence of research termination. These alternatives include, but are not limited to
a. Consequences of withdrawal for participants currently enrolled if the research study was terminated.
b. Require follow-up on the participants
c. Transition participants from research to standard clinical care
d. Transfer of research study to another investigator
e. Arrangement to provide customary clinical standard of care
f. Continued reporting of unanticipated problems, adverse events or outcomes to IRB and study sponsor
g. Notification of current and/or past participants of the termination

5. In addition, IRB should consider the following:

a. Whether there was serious and/or continuing non-compliance.
b. Whether the investigator can use the data from currently enrolled participants.
a. Whether the investigator can use the data from participants who have completed the study.
c. General and topic-specific education for the investigators and research staff
d. Restriction of investigator’s research privileges with regards to human subject research
e. Recommend that an institutional official review and evaluate the research privileges of the investigator.

6. OPHS staff will generate a termination letter to the PI, which is signed by the IRB Chair (or Vice Chair in his/her absence). The letter includes, but not limited to the following:

a. The reason for the termination.
b. Explanation of the reasons for the decision.
c. A request for a description of any procedures needed to protect the rights and welfare of the current participants enrolled in the study due to termination. PI considers the appropriate procedures for withdrawal of enrolled participants. If the safety of the participants is at risk due to withdrawal from the study, the PI should immediately consult with the IRB Chair or Vice Chair.
d. Any appropriate corrective action plan to reinstate the PI to conduct research in the future.
e. Identification of entities for reporting requirements.
f. A requirement or permission for follow-up of participants for safety reasons.
g. An explanation that any appeal must be made to the IRB in writing within 30 days from the date of notification.

7. OPHS staff will track investigators with termination by putting a flag next to the PI’s name. The IRB database will indicate the date in which the termination was originally issued, the date in which the convened IRB committee confirmed or approved the termination and the reason for the termination.
8. OPHS staff will generate a letter to report the investigator’s termination, but not limited to the university officials, OHRP, FDA, funding agencies, collaborating institutions, and other appropriate agencies. The letter will be signed by the IRB Director (or designee).

**Suspension or Termination of Studies by the Investigator or Sponsor**

1. The PI must notify the IRB as soon as possible if the PI or a sponsor decides to suspend or terminate a protocol.

2. The PI must make adequate arrangements for caring of participants currently enrolled in the study, but may not recruit or enroll additional participants.

3. The IRB will review the PI’s request to suspend or terminate approval at a convened meeting.

**Suspension of Studies on an Urgent Basis**

1. The IRB Chair (or designee) or IRB Director (or designee) has authority to suspend or terminate any research on an urgent basis, when there has been an unexpected serious harm to the participants or there is an immediate potential risk to the participants for harm.

2. The individual should notify the IRB Chair of the circumstances that lead to the determination and the justification as soon as possible.

3. All correspondences, reports, and supplemental material will be reviewed at the next convened IRB meeting. At the discretion of the IRB Chair, the PI may be requested to attend the meeting.

4. A letter will be generated by OPHS and signed by the IRB Chair, with the determination, and copied to all reportable entities.

### REGULATIONS

21 CFR 56.113  
45 CFR 46.113  
45 CFR 46.103(b)  
21 CFR 56.108(b)