KENNESAW STATE UNIVERSITY
OFFICE OF RESEARCH
Research Compliance

Policy Title	Suspension and Termination of IRB Approval
Last Updated	12/21/2021
Responsible Office	IRB Office
Contact Information	IRB Office/ Email: irb@kennesaw.edu Phone: 470-578-4941

1. Policy Purpose Statement

   The Kennesaw State University Institutional Review Board (KSU IRB) has the authority to suspend or terminate approval of human subjects research that is not being conducted in accordance with IRB requirements, or that has been associated with unexpected serious harm to participants. This document establishes the policy and procedures for instituting a suspension of IRB approval or a termination of IRB approval of human subjects research at KSU.

2. Definitions

   2.1. Suspension: A determination made by the IRB to temporarily withdraw IRB approval for some or all activities of a currently approved research study.

   2.2. Termination: A determination made by the IRB to permanently withdraw IRB approval for some or all activities of a currently approved research study.

3. Policy

   3.1. The IRB has the authority to suspend or terminate the approval of research when it is suspected or determined that any of the following has occurred:

      3.1.1. an unanticipated problem involving risks to subjects or others,

      3.1.2. the research is not being conducted in accordance with the IRB requirements with possible risk of harm to research participants, and/or

      3.1.3. serious or continuing non-compliance (IRB Policy: Non-Compliance).

   3.2. Determination to suspend the approval of research is made by:

      3.2.1. the IRB at a convened meeting, or

      3.2.2. the IRB Chair, in an emergent situation when review by a convened IRB is not possible

         3.2.2.1. When this authority is exercised, it will be reported at the next convened IRB meeting.

   3.3. Determination to terminate the approval of research will be made only at a convened IRB meeting.

   3.4. Suspended studies remain open and are subject to continuing review. Terminated studies are permanently closed and no longer require continuing review

3.5. The termination of IRB approval applies to all research activities, i.e., recruitment, data collection, treatment and/or intervention, follow-up activities, and data analysis.
3.6. After a suspension of an IRB approval, the convened IRB has the authority to terminate the research if the event(s) prompting the suspension of research approval cannot be corrected in a way that protects the rights and welfare of the research participants.
  3.6.1. The IRB may terminate a research study if the non-compliance with the IRB requirements is serious and/or continuing and the proposed corrective action plan is not sufficient to alleviate or rectify the non-compliance.
3.7. Eventually, a notice of suspension is either withdrawn by the IRB or the suspended study becomes subject to termination procedures by the IRB according to this policy. The research may resume upon withdrawal of a suspension.
3.8.. If the Principal Investigator (PI) wishes to resume research that was terminated by the IRB, he/she must submit a new human research application for IRB review and approval via Cayuse.
3.9. The PI has the right to request for a reconsideration of the IRB's determination regarding the suspension or termination of research under any of the circumstances below. This request is reviewed by the convened IRB. Justifications for requesting reconsideration:
  3.9.1. There is new information not reasonably available at the time of the IRB review/investigation.
  3.9.2. The IRB did not follow the procedures outlined in this policy.
  3.9.3. The sanctions are considered by the PI to be excessive.
3.10. The study sponsor or the PI of the study may voluntarily decide to suspend or terminate some or all research activities of a study. If this occurs, the PI must notify the IRB in writing within three (3) business days of this suspension or termination.
3.11. The outcome and determinations related to suspensions or terminations must be documented in the IRB record housed in Cayuse, in an IRB correspondence to the PI, reported to the appropriate organizational officials, the appropriate federal departments or agencies, and any sponsor, and in the relevant IRB meeting minutes.

4. Procedures: Researchers

4.1. The PI is responsible for reporting any unanticipated problems and/or study violations or incidents that may require a simultaneous IRB action such as Suspension of IRB Approval or Termination of IRB Approval.
4.2. If the study sponsor or the study PI voluntarily decides to suspend or terminate some or all research activities of a study (e.g., due to occurrence of an unanticipated problem, evidence of non-compliance, or serious and/or continuing non-compliance), the PI must notify the IRB within three (3) business days of the suspension or termination by using the Cayuse Incident Report form, describe the actions that have been taken or will be taken to protect the rights and welfare of currently enrolled participants, and include any corrective actions to address the cause for the research suspension or termination.

4.3. The PI must promptly respond to any IRB terms and conditions as outlined in the IRB correspondence related to any of the above occurrences.
4.4. The PI must be provided an opportunity to respond in writing or in person to the IRB about the suspension or termination. If the PI disagrees with the IRB's determination regarding the suspension or termination of research, he/she may submit a written request for reconsideration of the decision to the IRB Chair.

5. PROCEDURES: IRB

5.1. For review by a convened IRB meeting, the IRB/ Staff must make available all relevant material to the IRB members approximately five (5) business days prior to a meeting, if possible.
5.2. The IRB must obtain information from the investigator whether any actions are required to protect the subjects' rights and welfare or to eliminate an apparent immediate hazard.
5.3. The IRB must consider whether any additional actions and procedures are required to protect the rights and welfare of currently enrolled participants and during withdrawal of enrolled participants, or to eliminate an apparent immediate hazard. These actions and procedures may include, but are not limited to
    5.3.1. transferring subjects to another investigator
    5.3.2. making arrangements for clinical care outside the research
    5.3.3. allowing continuation of some research activities under the supervision of an independent monitor
    5.3.4. requiring or permitting follow-up of subjects for safety reasons
    5.3.5. requiring adverse events or outcomes to be reported to the IRB and the sponsor
    5.3.6. notification to current human subjects
    5.3.7. notification to previous human subjects
5.4. If the IRB Chair determines in an emergent situation that a suspension of research is warranted, the IRB members will be notified of and review the circumstances surrounding the suspension at a convened IRB meeting.
5.5. In a situation where the study sponsor or the study PI voluntarily decides to suspend or terminate some or all research activities, the report submitted by the PI must be reviewed at a convened IRB meeting.
    5.5.1. After reviewing the report for suspension or termination of some research activities, the IRB must determine whether it concurs with the PI's decision or if IRB approval for the entire study must be suspended or terminated.
    5.5.2. After reviewing the report for suspension or termination of all research activities, the IRB must determine whether it concurs with the PI's decision to suspend or terminate the IRB approval for the entire study.
5.6. The IRB Chair must send a written correspondence to the PI via Cayuse of the suspension or termination of IRB Approval within five (5) business days of the decision. The correspondence must include the reasons for the decision, the corrective action(s),

and stipulations necessary for the convened IRB to consider reinstatement of the research approval.

5.7. The IRB will monitor the PI's implementation of the corrective plan. If the PI is successfully implementing the plan according to the requisite timeframe, the convened IRB or the IRB Chair may withdraw the suspension and research may resume. If, however, the suspension has not been resolved according to the requisite timeframe, the item will be placed in the agenda of the next available meeting of the convened IRB in order to proceed with the termination of IRB approval.

5.8. The IRB Chair must report the outcome and determinations related to suspensions or terminations to the appropriate organizational officials, the appropriate federal departments or agencies, and any sponsor.

5.9. The IRB Staff must document the outcome and determinations related to suspensions or terminations in the relevant IRB meeting minutes.