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### 1. PURPOSE

- 1.1. The University of Georgia Institutional Review Board (UGA 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 UGA.

### 2. DEFINITIONS

- 2.1. **Suspension of IRB Approval:** an action to temporarily withdraw IRB approval of some or all research activities.
- 2.2. **Termination of IRB Approval:** an action to permanently withdraw IRB approval of some or all research activities.
- 2.3. **Non-compliance:** failure (intentional or unintentional) of the **Principal Investigator** or member(s) of the research team to adhere to the terms of IRB approval or other requirements or determinations by the IRB; or failure to abide by applicable laws or regulations or UGA policies, including failure to submit research for IRB review and approval before initiating research.
- 2.4. **Serious non-compliance:** non-compliance that may reasonably be regarded as: involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others, or substantively compromising the integrity of a facility's human research protection program.
- 2.5. **Non-serious or minor non-compliance:** non-compliance that does not place, or have the potential to place, participants and others at greater risk than previously anticipated, compromise participants' rights or welfare, or affect, or affect the integrity of a facility's human research protection program; and result from willful or knowing misconduct on the part of the investigator(s) or study team members.
- 2.6. **Continuing non-compliance:** a pattern of repeated non-compliance actions or omissions that, if unaddressed, may compromise the integrity of the UGA human research protection program. The pattern may reflect a lack of knowledge on the part of the investigator or a lack of commitment by the investigator and/or research team to human subjects protection.

### 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**,



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- 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.
  - 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.
  - 3.3. Suspended studies remain open and are subject to **continuing review**. Terminated studies are permanently closed and no longer require continuing review.
  - 3.4. Determination to terminate the approval of research will be made only at a convened IRB meeting.
  - 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 the electronic protocol submission portal.
  - 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.
    - 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.
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3.11. The outcome and determinations related to suspensions or terminations must be documented in the IRB electronic portal, 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. See *Investigator Manual, Appendix A: Reporting Events and Information to the IRB*.
- 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 IRB electronic portal’s Reportable New Information 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. See *Investigator Manual, Appendix A: Reporting Events and Information to the IRB*.
- 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



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- 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 the IRB electronic portal 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.
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**6. MATERIALS**

6.1. None

**7. REFERENCES**

7.1. 45 CFR §46.103(b)(5)(ii), 45 CFR §46.108(a), 45 CFR §46.113

7.2. 21 CFR §56.108(b)(3), 21 CFR §56.113

7.3. Investigator Manual, Appendix A: Reporting Events and Information to the IRB

7.4. ORC Policy and Procedures: Responding to Allegations of Research Non-Compliance