

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

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- 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

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.