

**Western Carolina University
Office of Research Administration
Institutional Review Board Standard Operating Procedures**

SOP# 303.1	TITLE: Suspension or Termination of a Project by the IRB	Date Effective: 01/01/2022 Last Revision Date: 06/30/2021
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I. Purpose

This sets for the process by which the IRB may suspend or terminate an approved project.

II. Scope

The IRB has the authority to suspend or terminate any approved research protocol that is not conducted in accordance with IRB requirements or has involved serious or unexpected harm to participants.

III. Definitions

Suspension is a temporary halt in any ongoing research activities including enrollment of new participants or activities involving previously enrolled participants.

Termination is a permanent halt in all ongoing research activities and closure of the project.

IV. Procedure

1. The convened IRB may vote to suspend or terminate a previously approved project if they become aware (via either internal or external report) that a project is not conducted in accordance with IRB requirements. The decision and rationale is documented in the meeting minutes.
2. If the IRB Chair becomes aware (via either internal or external report) that a project has involved serious or unexpected harm to a participant, they may immediately suspend the project until the convened IRB is able to meet.
3. If the IRB Chair or the convened IRB suspend or terminate a project, the PI must be promptly informed in writing with a statement of the reasons for the suspension or termination.
4. The PI must notify enrolled participants of the suspension or termination of the study and create an appropriate procedure for withdrawal of subjects.
5. The RCO and Director of ORA assists the IRB in reporting any suspension or termination decisions to external sponsors and/or regulatory agencies, if applicable to the study.
6. The IRB Chair is responsible for informing the investigator's department head, dean, and the institutional official of action and the reasons for suspension or termination.
7. If the study is suspended or terminated, the IRB may require the PI take additional actions, including but not limited to:
 - Transferring of participants to another study.
 - Notifying current or former participants.
 - Arranging for care of participants.
 - Requiring follow-up with participants for safety reasons.
8. A suspended study may be re-instated by a vote of the convened board after the PI has provided in writing evidence of the steps taken to rectify the issues that led to suspension.

V. Responsibilities

IRB administrators, IRB members, Investigators

VI. References

45 CFR 46.113