

**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.

IV. Procedure

1. The convened IRB may vote to suspend or terminate a project if it becomes aware (via either internal or external reporting) of non-compliance with IRB requirements. The decision must be made in accordance with IRB requirements. The decision must be made by a majority of the convened IRB.
2. If the IRB Chair becomes aware (via either internal or external reporting) of serious or unexpected harm to a participant, the IRB Chair must call a convened IRB meeting. The convened IRB is able to meet.
3. The IRB Chair must develop an appropriate procedure for withdrawing a project from the IRB.
5. The RCO and Director of ORA assists the IRB Chair in making decisions to external sponsors and/or research sites.
6. The IRB Chair is responsible for informing the appropriate institutional official of action and the research site of the decision.
7. If the study is suspended or terminated, the IRB Chair must develop a plan including but not limited to:
 - Transferring of participants to another study
 - Notifying current or former participants of the decision
 - Arranging for care of participants
 - Requiring follow-up with participants
8. A suspended study may be re-instated if the IRB Chair provides in writing evidence of the steps taken to ensure compliance with IRB requirements.

V. Responsibilities

IRB administrators, IRB members, Investigators

VI. References

45 CFR 46.113