

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

SOP# 207.2	TITLE: Modifications to Approved Projects	Date Effective: 01/01/2022 Last Revision Date: 10/3/2023
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I. Purpose

This sets forth the process for conducting review of modifications to previously approved or determined exempt projects.

II. Scope

Modifications to any previously approved or determined exempt projects must be submitted to the IRB prior to implementation, unless there is an immediate hazard to participants. Modifications include any change to the project, including administrative changes such as research personnel changes.

Failure to submit a modification request prior to implementing a change to an approved or a determined exempt project will constitute non-compliance and will be handled in accordance with SOP #302.

III. Procedure

Submission and Screening

1. Investigators must complete the *Request for Modification* application in InfoEd and include any new or updated documents referenced in the application.
2. The research compliance office receives the package in InfoEd and conducts an initial review for completeness as described in SOP 202.
3. The research compliance office and the IRB have the authority to determine when a modification request constitutes a change in scope or the addition of major new activities such that a new

6. For projects that were originally approved by the full IRB, the following applies:

- a) Minor modifications and those involving no more than minimal risk will be routed by the research compliance office to an IRB member for expedited review in accordance with SOP 204.
- b) Significant modifications and those involving more than minimal risk will be reviewed by the convened board in accordance with SOP 205.

IV. Responsibilities

Research compliance office, IRB members, Investigators

V. References

45 CFR § 46.109