

**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: 12/06/2022
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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.

Minor modifications to projects reviewed by the full-board or modifications that involve no more than minimal risk may be reviewed utilizing expedited review procedures. All other modifications must be reviewed by the convened board.

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 application is required rather than a modification to an existing application.
4. If the modification is to a previously determined exempt project, the research compliance office determines whether the modification alters the exempt determination. If it does not, then the research compliance office issues an exempt determination letter. If the modification causes the project to no longer qualify for exemption, the research compliance office notifies the investigators and continues processing the project as a non-exempt review. The entire project must undergo either expedited or full-board review.
5. Depending on content of the modification request, the project is assigned for review in accordance with either SOP 204 or SOP 205.

IV. Responsibilities

Research compliance office, IRB members, Investigators

V. References

45 CFR § 46.109