

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

<b>SOP# 207.2</b>	<b>TITLE: Modifications to Approved Projects</b>	<b>Date Effective: 01/01/2022 Last Revision Date: 10/3/2023</b>
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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 application is required rather than a modification to an existing application.
4. For projects previously determined to be exempt, 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 results in the project no longer qualifying 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. For projects that originally received expedited review, the following applies:
  - a) For modifications only involving extending the project end date and/or changes to research personnel, the research compliance office may review the modification and issue a determination letter.
  - b) For modifications beyond extending the end date and/or changing research personnel, the research compliance office will route the protocol to an IRB member for expedited review in accordance with SOP 204.

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