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

SOP# 205.2	TITLE: Full-Board Review	Date Effective: 01/01/2022 Last Revision Date: 12/06/2022

I. Purpose

This sets forth the full-board review process and criteria for approval.

II. Scope

The IRB has the authority to approve, require modifications, or disapprove all human subjects research. The IRB reviews all research projects at a convened meeting, except where the project qualifies for expedited or exempt review.

Full board review may only be conducted when a quorum of IRB members is present. A quorum consists of a majority of the members of the IRB, and must include at least one non-scientific member. Quorum must be met prior to initiating any discussion of a research proposal and must be maintained through the entire discussion and voting. Maintenance of quorum must be documented in meeting minutes. All members present at a meeting have full voting rights, unless they have recused themselves due to a conflict of interest. Meetings will be held in person or remotely.

The IRB meets once a month throughout the academic year. The IRB does not perform full-board reviews during the summer months (May – July). Investigators must submit proposals two weeks prior to a scheduled meeting. Meeting dates are published at the beginning of the semester on the WCU IRB website.

III. Procedure

Submission and Screening

1. Investigators must submit a Request for Initial Review of Research through InfoEd and include all applicable supplemental documents.

2. The research compliance office receives the package in InfoEd and conducts an initial review for completeness as described in SOP 201. If the project does not meet the criteria for expedited or exempt review, the project is assigned to the next convened meeting with available capacity to review the application.

3. After all documents have been received and the project is ready for full-board review, the research compliance office will notify investigators that their project has been assigned for full board review and the planned review date.

4. If the project meets the criteria for one of the expedited review categories, but the IRB determines the project requires full-board review, the rationale describing why the project involves more than minimal risk must be documented.

5. The research compliance office screens the project to determine whether additional expertise may be required to adequately evaluate the project. If additional expertise is needed, the research compliance office coordinates with the chair in identifying an appropriate consultant. The consultant is granted access to the project materials and asked to evaluate the study. Consultants do not need to attend the meeting, but their comments must be shared with all IRB members. Consultants that attend the meeting have no voting rights.

Assigning Reviewers

1. The IRB Chair, or other qualified reviewer, serves as the primary reviewer for the project. They are granted access to the project at least two weeks before the scheduled meeting. The primary reviewer is responsible for conducting an in-depth review and presenting an overview of the project to the other members at the convened meeting.

2. Each IRB member is granted reviewer access to the project at least one week before the scheduled review and has access to all submitted documents. All members should review the package in enough depth to be able to discuss the project at the meeting.

3. The IRB Chair is responsible for communicating project questions and modifications to the investigators, through InfoEd.

IRB Full-board Review

1. The primary reviewer briefly summarizes the project and identifies any initial items for discussion.

2. All IRB members have the opportunity to discuss each project on the agenda. The board discusses issues related to the approval criteria (45 CFR § 46.111) and determines the risk level. The board also evaluates any additional protocol-specific criteria to determine whether the project meets the federal requirements (e.g. waiver of informed consent).

3. The IRB determines the approval period. Projects must undergo continuing review at least annually, unless the project has progressed to a point that it involves only data analysis (may include identifiable data) or accessing clinical data that a subject undergoes as part of normal clinical care. The board must provide justification if the approval period will be shorter than a year.

4. After all issues are discussed, an IRB member motions to vote on one of the three review outcomes listed below. Each IRB member casts one of the following votes – yes, no, abstention. The outcome must receive a "yes" vote from the majority of the members present to pass. All votes (including abstentions and recusals) are recorded in the meeting minutes.

Review Outcomes

1. The IRB makes one of the following four determinations:

    a) Approved: The study is approved as submitted. The research compliance office issues an *Approval Letter* in InfoEd. The start of the approval period is the date of the convened IRB meeting.
    b) Modifications Required: The study requires minor changes or clarification as detailed in the minutes. These items are communicated to the investigators in writing through InfoEd within 10

days of the meeting. A designated reviewer grants final approval once verifying the investigator has satisfactorily addressed the comments. Once the designated reviewer grants approval, the research compliance office issues an *Approval Letter* through InfoEd. The start of the approval period will be the date of the final approval.

c) Disapproved: The committee disapproves the project for reasons outlined in the minutes. This decision and the justification is communicated to the investigators in writing through InfoEd. The investigator has the option to appeal the decision with the IRB. Appeals and re-submissions are evaluated by the convened committee at a subsequent meeting.

2. The investigator is notified of the outcome of the review in writing via InfoEd letter. The letter will specify the approval period for the project. The Office of Research Administration retains all records and correspondence related to the project.

3. Modifications to projects must be submitted to the IRB, prior to implementation. Modifications may be reviewed using the expedited review process (minor changes) or full-board review.

IV. Responsibilities

Research compliance office, IRB members, IRB Chair, Investigators

V. References

45 CFR § 46
21 CFR § 56
21 CFR § 50