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

SOP# 206.2	TITLE: Continuing Review of Projects	Date Effective: 01/01/2022 Last Revision Date: 12/06/2022

I. Purpose

This sets forth the continuing review process and the calculation of project expiration dates.

II. Scope

Research approved under full-board review is subject to continuing IRB review at least annually (or more frequently if specified by the IRB based on the degree of risk) until the research involves only data analysis of information (including identifiable information) or accessing clinical data from procedures that the subjects would undergo as part of clinical care. The IRB may require continuing review for projects subject to expedited review but must provide a rationale for this requirement at time of approval.

Prior to the expiration date, investigators must submit a continuing request for review. Once the project has expired, all activity must cease. If there is a lapse in approval while the continuing review is conducted, the investigator must cease activity, unless the IRB has determined that it is in the best interest of the participants for research activities to continue due to an overriding safety or ethical concern. Research activity conducted on an expired protocol constitutes serious non-compliance and is handled in compliance with SOP #302.

Continuing review may be conducted using expedited or full-board review procedures. The IRB may conduct continuing review using expedited procedures, for projects initially reviewed by the full-board under the following circumstances:

1. The project is closed to enrollment of new participants, all participants have completed research related interventions, and continuing interaction with participants is limited to long term follow-up; OR
2. The project is still active, but no additional risks have been identified

Continuing review must be conducted at least annually. At the discretion of the IRB, projects may require review at more frequent intervals. Reasons for more frequent review may include, but are not limited to:

1. The project presents a significant risk to participants without the possibility of a direct benefit to the participant.
2. The project involves a vulnerable population likely to be at risk of coercion.
3. A history of serious, continuing non-compliance by the principal investigator.

III. Procedure

Submission and Screening

1. At time of initial submission approval, the investigator receives a letter documenting the approval and expiration dates. InfoEd issues project expiration reminder alerts to the investigator 60, 30, and 1 days prior to the project expiration date. It is the investigator's responsibility to submit a *Request for Continuing Review* in InfoEd prior to the project expiration date.

2. If the *Request for Continuing Review* is received more than 30 days after the project expiration date, the investigator will be required to re-submit their project as a new project. Once the project expires, all activity on the project must cease immediately.

3. Investigators must submit the *Request for Continuing Review* as a subsequent package within their initial project submission in InfoEd.

4. The research compliance office receives the package in InfoEd and conducts an initial review for completeness as described in SOP #202. The research compliance office determines whether the continuing review request meets the criteria for expedited or full-board review.

5. Depending on the review type, Continuing Review will be conducted in accordance with either SOP #204 or SOP #205.

IV. Responsibilities

Research compliance office, IRB members, Investigators

V. References

45 CFR §§ 46.109(e), 46.109(f)