Continuing Review

Table of Contents: Continuing Review

Policy Statement

UIW policy requires all non-exempt human subjects research protocols to be reviewed on at least an annual basis throughout the life of the study. The IRB may require more frequent review, depending on the risks and nature of the study.

Description and Procedures

A. Continuing Review of Expedited and Full Board Studies

Continuing Review requests must be submitted online via the Ethical Review Manager system to the IRB as long as any of the research activities described in the protocol are being conducted. For example, if all subjects have completed a study and identifiable data are being analyzed, the study is considered "active" because research activities that create risk for the subjects are being carried out. Any one member of the IRB can call a meeting to review a progress report.

The IRB sends courtesy reminders to investigators with active protocols at 60, 30, and 14 days before expiry of approval (IRB protocols are approved for a one year period).

B. Administrative Closure

Failure to submit the request for Continuing Review and obtain continuous IRB approval or report the closure of a non-exempt study will result in action to inactivate the study protocol and the administrative closure process will begin. Subsequent reactivation of the study will require complete resubmission of the protocol as a new study.

Upon administrative closure, all research activities must stop, except as necessary to ensure

1. the rights and welfare of participants are protected,
2. participants are not put at risk, and
3. participants receive appropriate care.

Subjects currently participating in an administratively closed study should be notified immediately that the study has been terminated. Any adverse events or outcomes should be reported to the IRB and the sponsor.

According to the above regulations, the IRB must report the closure action promptly to the investigator, appropriate institutional officials [academic dean or provost and dissertation/thesis advisor(s)], and any funding agencies supporting the research.

C. Continuing Review of Exempt Studies

Exempt studies do not require Continuing Review. In lieu of Continuing Review, an annual notification is sent 60, 30, and 14 days before expiry of approval to the Principal Investigator requesting either closure of the study or confirmation that the study is ongoing. The annual notification includes a reminder of the Principal Investigator's responsibilities, including the responsibility to report changes to the protocol, adverse events, serious problems, and/or significant findings that might increase the risks to subjects. Failure to respond to the annual notification with a Study Status Update within the 60 days will result in administrative closure of the protocol. Subsequent reactivation of the study will require complete resubmission of the protocol as a new study.

Effective Date

August 24, 2020

Revision History