

IRB Policy #:	290
Policy Title:	<i>Continuing Review and Protocol Closure</i>
Date Approved:	
Date Reviewed:	

Purpose: To describe the requirements for continuing review, and for protocol closure.

Policy:

As required by 45 CFR 46.103(b)(4), the IRB is required to re-evaluate research projects at intervals appropriate to the degree of risk but not less than once a year. For research involving no more than minimal risk, the approval period is generally one year from the date of the convened meeting at which the protocol was reviewed and approved. For research involving greater than minimal risk, the IRB will determine the appropriate approval period. Exempt research is subject to continuing review every three years.

At the time of continuing review, the IRB must make the same determinations about risks, potential benefits, informed consent, and safeguards for human subjects, among other things, that were made at the time of initial review. The IRB must also determine whether any new information has emerged – either from the research itself or from other sources – that could alter the IRB’s previous determinations, particularly with respect to risk to subjects. Information regarding any unanticipated problems that have occurred since the previous IRB review in most cases will be pertinent to the IRB’s determination at the time of continuing review.

A request for renewal is required for new or continuing analysis of identifiable information, new subject enrollment or follow-up meetings even after data collection is closed or continued data collection. Request for continuation is not required if enrollment and data collection are complete or was never begun or for continued analysis of a dataset that has been de-identified.

Continuing reviews may be either expedited or reviewed by the full board.

Expedited review may occur where:

- a. the research is permanently closed to the enrollment of new participants, all participants have completed all research-related interventions, and the research remains active only for long- term follow-up of participants.
- b. no participants have been enrolled and no additional tasks have been identified.
- c. the remaining research activities are limited to data analysis. *See also* Expedited Review for more information.

When the full Board reviews a request for continuing review, the approval date must occur within 1 year of the convened meeting at which: a) the protocol was approved without any conditions, b) the protocol was approved contingent on specific minor conditions that the IRB chair or his/her designee could verify; or c) the protocol with serious concerns or incomplete significant information that the IRB chair or his/her designee could verify is subsequently reviewed and approved at another convened meeting.

The minutes of the IRB meetings shall document deliberations, actions and votes for each protocol undergoing continuing review by the convened IRB.

Review of currently approved or newly proposed consent/assent documents must occur during the scheduled continuing review of research by the IRB, but informed consent/assent documents should be reviewed whenever new information becomes available that would require modification of information in the informed consent/assent document.

There is no grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, the IRB and investigators must plan ahead to meet required continuing review dates. If the PI has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved the protocol by the deadline, the research must stop, unless the IRB finds that it is in the best interests of individual participants to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval.

If, after courtesy reminders sent 60 and 30 days prior to the expiration of an approval, no application for continuing review is received, the study will be administratively closed and the investigator, study team and IRB notified.

If an investigator terminates the study, the investigator shall notify the IRB and shall:

1. Indicate the reason for closure (current activity status of the study)
2. Supply information on the subject numbers, complaints received, protocol deviations, variances or adverse events reported to the IRB
3. Supply any additional information the PI deems necessary to inform the IRB about the reasons for closure.

Investigators submit a completed closure form. These forms are emailed to the investigator approximately 60 days prior to expiration of the approval and can be found on the IRB

website. The PI can request closure of the study at any time by completing a brief final report form.

Once the PI has completed the research and so notified the IRB, he or she may not recruit or enroll human research subjects. There can be no intervention, interaction or follow-up with enrolled human subjects, nor any continued collection of data or analysis of individually identifiable data previously collected as part of the research protocol.