

Section 21: Continuing Review

In addition to reviewing all new protocols, the IRB also reviews the goals, accrual, and status of each active protocol at least once a year. The IRB also reviews the consent forms for each active protocol.

The PI or designee must complete the “Continuing Review” form and submit it to the OHRS. This form includes such information as current accrual data, reasons for participant withdrawals, trial status and objectives, treatment description, summaries of toxicities and adverse reactions, any results obtained thus far, and any new information since the last IRB review including premature completion of a study. Depending on the type and status of the trial, the continuing review may qualify for an expedited review.

If no further research continues and data are no longer being collected or analyzed on a trial, the PI must notify the OHRS that the trial is complete and must fill out and submit a final “Continuing Review” form covering the period between the previous review and the date the trial was completed. Once a trial is complete, no further research can take place.

As a courtesy to investigators, the OHRS sends a reminder memo to the PI and designated trial staff 90 and 60 days prior to IRB approval expiration. The OHRS strongly suggests submitting the continuing review form *at least 45 days prior to the expiration date*.

If a continuing review form is not received and IRB approval expires, the protocol will be placed on hold and a memo will be sent to the PI. The consent form is removed from OncPro. Participant enrollment, treatment of participants considered on trial, and data collection/analysis must immediately cease. The PI must submit a “Request to Continue Research Interventions” form to the IRB to request continued treatment of participants currently enrolled. These requests are considered on a case-by-case basis. OHRS may submit to the trial sponsors, the FDA and OHRP reports of expired studies if they meet the definition of serious or continuing non-compliance.