



QuickGuide: Continuing Review: Reminders & Process

When a study's expiry date is approaching, the Lead Applicant study team is responsible for submitting a **Study-Wide Continuing Review (SWCR)** application. In addition, each participating site is responsible for submitting submit a **Participating Site Continuing Review (PSCR)** application – which can be submitted even if the SWCR has not been submitted yet.

The SWCR and the PSCRs must be submitted by the submission deadline of the applicable full board meeting date that occurs **prior to the study expiry date**. This helps ensure the REB of Record has access to all necessary site information when reviewing the information for the study overall. Applicants should submit by the full board submission deadline even if they believe their application(s) will undergo delegated review.

Reminders:

The Lead Applicant (LA) and anyone with a study-wide role¹ on the Clinical Trial Initial Application (CTIA) or Observational Study Initial Application (OSIA) for the study are sent reminders **45, 30 and 15** days prior to the **study expiry date**. Similarly, the Principal Investigator (PI) and anyone with a role on the Participating Site Initial Application (PSIA), are sent reminders **45, 30 and 15** days prior to the **site expiry date**. These are courtesy reminders only, and the LA/PI are expected to submit their renewal applications on time regardless of whether or not they receive the reminders.

Lapse/Expiration:

A lapse in ethics approval (either study-wide or site-specific, as applicable) occurs if the continuing ethics approval letter has not been received prior to the ethics approval expiry date.

Note: If ethics approval expires for the study overall, ethics approval for all research sites is automatically considered to have expired as well.

Users with a role on the CTIA/OSIA¹ or PSIA² for their site are automatically notified of a lapse in ethics approval. The Department Head and Institutional Representative will also be notified (among other recipients) when there is a lapse in ethics approval at a research site. If ethics approval lapses, the LA/PI is instructed to cease all research-related activities, including the enrollment of new participants. If there is a need to continue the research intervention to ensure the rights, safety, or well-being of participants enrolled prior to the lapse in approval, they are instructed to notify the REB of Record via the correspondence feature in CTO Stream. If a lapse occurs, the study and/or site's status will automatically update from "Active" to "Expired".

Reinstating Ethics Approval:

To resolve a lapse in ethics approval, the LA/PI must submit a SWCR/PSCR application, and the form must receive approval from the REB of Record.

¹Does not include the Lead Site Study Staff or Sponsor/CRO (read-only) role.

²Does not include the Site Study Staff (Read-only) role.

Creating a Continuing Review application (SWCR or PSCR):

The SWCR and PSCR are sub-forms of the CTIA/OSIA and PSIA, respectively. For instructions on how to create sub-forms, please view the "Creating a Sub-form" QuickGuide on the CTO website [here](#).

Questions? Submit a support ticket at support.ctontario.ca