

Title	Guidance for Renewing a Study
Related SOP	405 – Continuing Review
Effective Date	31 October 2017

Renewing a Study

All approved research must be reviewed by the HREBA-Cancer Committee (CC) on an annual basis, at a minimum, in order to determine whether ethics approval of the research will be continued or withdrawn. Continuing review (i.e. renewal) of the research must occur until a closure has been acknowledged by the CC (see the Guidance for Closing a Study).

Submission methods differ depending on whether the research is in paper format (ethics ID: xxxxx) or on the IRISS system (ethics ID: HREBA.CC-xx-xxxx).

Renewal Submission Deadline

A study's renewal, regardless of the type of review process it may undergo, must be received in time to be reviewed at the HREBA-CC meeting prior to the study's expiry date.

In order to be reviewed at the meeting, the renewal must be received no later than one week before the meeting date. This is the renewal deadline. ([2017 meeting dates and deadlines](#); [2018 meeting dates and deadlines](#))

A renewal not received by the renewal deadline may not be reviewed before the expiry date, resulting in a lapse of ethics approval.

The study team will be notified of the lapse, during which:

1. All research activities must be suspended until ethics approval for the renewal is issued. If there is a need to continue research-related medical treatment of current participants for their safety and well-being, the Principal Investigator (PI) is responsible for notifying the CC.
2. The PI must document the reasons for the lapse and identify steps taken to prevent future lapses.

Renewal Notifications

It is the PI's responsibility to submit the renewal prior to the renewal deadline. Renewal notifications are sent as a courtesy. Notifications sent by IRISS are system generated and do **NOT** correspond with HREBA renewal deadline as indicated in this guidance.

This guidance takes precedence over any notifications issued.

Submitting a Renewal

For research currently in paper format: e-mail a completed [Renewal for Approved Studies Form](#) to cancer@hreba.ca or mail to the HREBA Ethics Office. Note that this form is to be used for all studies in paper format (single and multi-site). A formal response from the CC will be provided, either approving the renewal or requesting additional information.

For research on IRISS:

Where the file is only associated with one site:

1. Submit a renewal by clicking the “Create a Renewal” button within IRISS. Note that this button is:
 - only available starting 30 days before the ethics expiry date (renewal window), and
 - not available if a modification is open. Ensure all modifications are submitted and approved prior to the opening of the 30 day renewal window.
2. If no further information is needed, a certificate approving the renewal will be posted in IRISS.

Where the file is associated with multiple sites in Alberta:

1. The participating site should complete the paper document [Renewal for Participating Sites \(IRISS Multisite Studies\)](#) and upload to the renewal file in IRISS by clicking “Log Comment to REB Admin”.
2. The lead site then initiates the renewal by clicking the “Create a Renewal” button within IRISS.
3. The lead site is to complete the renewal form within IRISS, and submit the renewal.
4. If no further information is needed, a certificate approving the renewal, and letter indicating that it applies to multiple sites, will be posted in IRSS.

Renewal Dating

The effective and expiry dates of a renewal (**whether paper or electronic format**) are determined as follows:

Review Type	Effective Date	Expiry Date
Full Committee	Date of the meeting the Committee approved the renewal	A maximum of one year from the approval date (ex. 01 June 2016 to 31 May 2017)
Delegated	Date the Chair or Vice-Chair approved the renewal	A maximum of one year from the approval date (ex. 01 June 2016 to 31 May 2017)

SOP Code	Effective Date	Summary of Changes
SOP 405.001G	01-July-2016	Original version
SOP 405.002G	01-July-2016	Version 2 - updated hyperlinks
SOP 405.002G	30-Aug-2017	<ul style="list-style-type: none"> • Deadline for renewal submission changed to no later than one week before the meeting • Re-organized content • Added multisite process and lapse of ethics approval process • HREBA renewal deadlines take precedence over system notifications (2017 meeting dates and deadlines)
SOP 405.002G	31-Oct-2017	<ul style="list-style-type: none"> • Updated 2018 meeting dates and deadlines