Title	Guidance for Closing the Ethics Approval of a Study
Related SOP	406 – Research Completion
Effective Date	11 August 2017

Research Completion (Closures)

The submission of a closure indicates that all research activities have ceased, the research does not require continuing ethics approval, and the HREBA-Cancer Committee (CC) file can be closed.

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).

Determining When a Closure is to be Submitted

For research that involves:

Direct interaction with participants a closure may be submitted when:

- there is no further participant involvement/interaction,
- all data collection, clarification and transfer is complete (this includes access to participants' records that have personally identifying health information) and,
- (if applicable) the sponsor has conducted the appropriate closeout activities.

No direct interaction with participants (i.e., secondary use of data, biological samples) - a closure may be submitted once all data acquisition is complete, samples are no longer being withdrawn from a bank or acquired from another research team. There should be no further access to participants' records that have personally identifying health information.

Other considerations**:**

- In cases where the research is grant funded, there may be a requirement by the funder to keep the file open while the funds continue to be accessed.
- If the research is funded or supported by the US Federal Government (i.e., NIH) the file cannot be considered closed until follow-up of subjects is final and there is no further data analysis involving individually identifiable information.
- When the closure is submitted either the results should have been disseminated, or a plan is in place for their dissemination.

Submitting a Closure

If your research meets the above criteria, it can be closed.

- **For research currently in paper format:** e-mail a completed CC Site Closure/Study Completion Form along with any supporting documentation to cancer@hreba.ca or mail to the HREBA Ethics Office. A formal response from CC will be provided, either approving the study/site closure or requesting additional information.

- **For research on IRISS where the entire file can be closed (i.e., file associated with only one site, or file associated with multiple sites where all sites are closing):** submit a closure by clicking the "Request Closure" button within IRISS. The study team(s) will receive a notification indicating that a closure request has been submitted. The Principal Investigator(s) (PI) will be further contacted if additional information is required. Once the closure request has been processed (i.e., reviewed and approved) the study team(s) will receive a notification confirming that the file is closed.

- **For research on IRISS where the entire file CANNOT be closed (i.e., file is associated with multiple sites, but not all sites are closing):**

  If a **participating site is closing**, and the lead site is remaining open:
  1. Open a modification (i.e., an amendment)
  2. Keep one study coordinator from the participating site on file, who will continue to have access to the research after the site is closed; all other members from the study team of the participating site can be removed;
  3. Complete the paper CC Study Closure/Site Completion Form for the participating site and attach to the Documentation Page of the IRISS application (Section 11.0 – Other Documents);
  4. The remaining PI can then submit the modification;
  5. A letter confirming that the participating site has closed will be posted in IRISS.

  If the **lead site is closing**, and a participating site is remaining open:
  1. Open a modification (i.e., an amendment)
  2. Edit the PI of the study; the PI of the lead site can be removed, and the PI for a participating site can be moved from Co-Investigator to PI;
  3. Keep one study coordinator from the lead site on file, who will continue to have access to the research after the site is closed; all other members from the study team of the lead site can be removed;
  4. Complete the paper CC Study Closure/Site Completion Form for the lead site and attach it to the Documentation Page of the IRISS application (Section 11.0 – Other Documents);
  5. The remaining PI can then submit the modification;
  6. A letter confirming that the lead site has closed will be posted in IRISS.

Once a research study is "*Closed*" with the CC, no further submissions for that research will be permitted. However, if relevant information, such as that listed below, becomes available, it should be submitted following the method for submitting a reportable event. If applicable, further investigation and/or action may be undertaken by the Committee.

- Documentation that impacts the safety of participants previously involved with the research (e.g. dear investigator letter, change in Health Canada or FDA safety labeling, etc.)
- Privacy Breaches
- Participant Complaints

If a sponsor requests additional data following the closure of the research, a request for ethics approval must be submitted.

For more information refer to HREBA SOP 406.

SOP Code	Effective Date	Summary of Changes
SOP406.001	01-July-2016	Original version
SOP 406.002	01-July-2016	Version 2 - updated hyperlinks
SOP 406.002	28-Nov-2016	In IRISS a confirmation that a study closure request was received will be generated; not one that the closure itself was successful
SOP 406.002	11-Aug-2017	• Provides further guidance on determining when a closure is to be submitted • Updated processes for submitting a closure including the processes for dual site submissions • Included details on activities once a file is closed