





## 1. Purpose

The purpose of this operating procedure is to outline the process the methods centre should follow when a research study enters the closeout phase.

## 2. Responsibilities

**Methods Centre (MC):** The MC, under the direction of the Principal Investigator, is responsible for ensuring all closeout phase activities are compliant with regulations and appropriately completed.

## 3. Procedures

3.1 Study closeout can be defined as the process undertaken to fulfill administrative, regulatory and study participant requirements following the favourable or unfavourable termination of a research project.

3.2 Reasons for study closure vary. The most frequent and desired reason for study closeout is the project is completed as per the original project plan. Examples of other reasons for study closeout, whether favourable or unfavourable, include:

- 3.2.1 Overall study enrolment goals are achieved, though individual sites may not have met their recruitment goals.
- 3.2.2 The investigational product is so beneficial; it would be unethical to have a study where participants may not receive treatment.
- 3.2.3 The investigational product was found to be unsafe.
- 3.2.4 Interim analysis reveals lack of efficacy of the investigational product.
- 3.2.5 Unable to enroll sufficient study participants.
- 3.2.6 Lack of compliance and/or other issues at the research sites.

3.3 Closeout activities should begin following completion of participant recruitment, or the decision to prematurely terminate/suspend the study.

3.4 Study closeout involves the following activities:

- 3.4.1 Data query resolution
- 3.4.2 Final investigational product accountability and return/destruction
- 3.4.3 Storage or destruction of laboratory samples
- 3.4.4 Preparation of records for archiving
- 3.4.5 Research site closeout
- 3.4.6 Database lock
- 3.4.7 Data analysis
- 3.4.8 Preparation of final reports to granting agencies
- 3.4.9 Notification an/or report to governing regulators

3.5 If a project is closed out prematurely, refer to SOP 502: Premature Termination or Suspension of a Study.

3.6 Refer to SOP 503: Research Site Closeout, for procedures regarding the closure of individual research sites.



## Study Closeout 501-00

- 3.7 The MC should formulate a project specific plan including milestones for completion of all closeout phase activities. Refer to the Study Closeout Checklist (see Appendix 4.1).
- 3.8 For studies where Health Canada is the governing regulator, as per the following guidance statement provided by Health Canada, a notification of study completion is required: *“For a study that has completed, the sponsor is encouraged to submit a notification to Health Canada indicating that the trial is now completed; however, no supporting information is required with the notification (i.e. a final study report is not required).”*
- 3.9 The MC should investigate study closeout reporting requirements for other governing regulators (e.g. FDA), if applicable.

## **4. Appendix**

- 4.1 Study Closeout Checklist

## **5. References**

- 5.1 Health Canada Guidance for Clinical Trial Sponsors: Clinical Trial Applications.
- 5.2 SOP 502: Premature Termination or Suspension of a Study.
- 5.3 SOP 503: Research Site Closeout



# Study Closeout Checklist

<b>Study Title</b>	
<b>Principal Investigator</b>	
<b>Reason for Study Closeout</b>	<input type="checkbox"/> Recruitment Complete <input type="checkbox"/> Premature Termination, please specify:

Task/Item	Target Completion Date	Complete
Project Leader formulates project closeout plan, including milestones for closeout activities		<input type="checkbox"/>
Notify research sites the study is entering the closeout phase, including activities and timelines		<input type="checkbox"/>
Research site closeout		<input type="checkbox"/>
Final investigational product accountability and return/destruction		<input type="checkbox"/>
Storage or destruction of laboratory specimens		<input type="checkbox"/>
Data query resolution		<input type="checkbox"/>
Database lock		<input type="checkbox"/>
Data analysis		<input type="checkbox"/>
Final study report / manuscript preparation		<input type="checkbox"/>
Preparation of records for archiving		<input type="checkbox"/>
Notify Health Canada of study completion		<input type="checkbox"/>
Notify other governing regulators of study completion, if applicable		<input type="checkbox"/>
Other:		<input type="checkbox"/>
Other:		<input type="checkbox"/>
Other:		<input type="checkbox"/>
<b>If Study Terminated or Suspended Prematurely (in addition to the above):</b>		
Notify Health Canada within 15 days of official discontinuance of the study		<input type="checkbox"/>
Notify other governing regulators of official discontinuance of the study, if applicable		<input type="checkbox"/>
Notify research sites of official discontinuance of the study		<input type="checkbox"/>
Provide instruction for research sites regarding informing study participants of treatment and follow-up plan		<input type="checkbox"/>
Other:		<input type="checkbox"/>
Other:		<input type="checkbox"/>

All study closeout activities have been completed as indicated above.

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Project Leader

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Date