



1. Purpose

The purpose of this operating procedure is to outline the process to be followed in the event that there is an unforeseen termination or suspension of a study that is managed by CERU.

2. Responsibilities

CERU: CERU, under the guidance of the Principal Investigator, is responsible for notifying regulators, research sites, Research Ethics Boards (REB) and any other relevant individuals of a premature termination or suspension of a study.

3. Procedures

- 3.1 Possible reasons for premature termination or suspension of a study include, but are not limited to:
 - 3.1.1 Poor enrollment, as determined by the Principal Investigator
 - 3.1.2 Lack of efficacy, as determined by the Data Monitoring Committee
 - 3.1.3 Safety concerns, as determined by the Data Monitoring Committee
- 3.2 Regardless of the reason, if the decision is made to prematurely terminate or suspend a study, CERU under the guidance of the study PI should promptly inform:
 - 3.2.1 Health Canada no later than 15 days after the date of discontinuance, if applicable.
 - 3.2.2 Other governing regulatory bodies within the required time frames, if applicable.
 - 3.2.3 All participating research sites.
 - 3.2.4 Research participants, assuring him/her the appropriate treatment and follow-up.
- 3.3 Health Canada and other governing regulators should be informed of the reason for premature termination or discontinuation of the study as well as the impact on ongoing trials in respect of the investigational product.
- 3.4 Research sites, and when appropriate, research participants should be informed of the reason for the premature termination or discontinuation of the study.
- 3.5 CERU should provide research sites with written direction regarding the following:
 - 3.5.1 Study participants actively receiving treatment
 - 3.5.2 Follow-up of study participants
 - 3.5.3 Potential risks to the health of study participants
 - 3.5.4 Notification to the local REB
 - 3.5.5 Return or destruction of Investigational Product
 - 3.5.6 Return or destruction of laboratory samples
 - 3.5.7 Closeout of the study



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- 3.6 If the research site terminates or suspends a study without prior agreement of CERU, then the qualified investigator (QI) should promptly inform and provide CERU and the local REB with a detailed written explanation for the termination or suspension.
- 3.7 If a local REB terminates or suspends its approval of a study, then the REB and/or research site should promptly notify and provide CERU with a detailed written explanation for the termination or suspension.
- 3.8 Refer to SOP 501: Study Closeout, and SOP 503: Research Site Closeout.

4. References

- 4.1 Food and Drug Regulations, Division 5: Drugs for Clinical Trials Involving Human Subjects section C.05.015.
- 4.2 ICH GCP Section 4.12: Investigator – Premature Termination or Suspension of a Trial
- 4.3 ICH GCP Section 5.21: Sponsor - Premature Termination or Suspension of a Trial
- 4.4 SOP 501: Study Closure
- 4.5 SOP 503: Research Site Closeout
- 4.6 Network of Networks Standard Operating Procedures for Clinical Research ([N₂ organization](#)).