



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.

2. Responsibilities

Methods Centre (MC): The MC, 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 enrolment
- 3.1.2 Lack of efficacy
- 3.1.3 Safety concerns

3.2 Regardless of the reason, if the Principal Investigator (PI) prematurely terminates or suspends a study, the MC 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 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 The MC should provide research sites with written direction regarding the following, if applicable:

- 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

3.6 If the research site terminates or suspends a study without prior agreement of the MC, then the qualified investigator (QI) should promptly inform and provide the MC 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 the MC with a detailed written explanation for the termination or suspension.



Premature Termination or Suspension of a Study
502-01

3.8 Refer to SOP 501: Study Closeout, and SOP 503: Research Site Closeout.

4. 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