



1. Purpose

The objective of this operating procedure is to document the delegation of authority for a study. Delegation of authority should be documented at two levels: (1) from the Sponsor to members of the Methods Centre involved with management and operation of the study; (2) from the local Qualified Investigator at research site involved in the study.

2. Responsibilities

Sponsor: The Sponsor is ultimately responsible for the overall conduct of the study. The Sponsor has the authority to delegate responsibility to individual members of the research team.

Qualified Investigator: The Qualified Investigator is responsible for maintaining a list of individuals delegated significant study related duties at the research site.

3. Procedures

3.1 Delegation of authority documents the process of empowering members of the research team to assist with various elements of the research study.

3.2 Delegation of authority should be specific to each study.

3.3 Delegation of Sponsor Authority at the Methods Centre

3.3.1 Members of the research team should be performing functions under the guidance of the Sponsor of the study. Members of the research team should be informed about the protocol, the investigational agent(s) and their trial-related duties/functions.

3.3.2 The Sponsor should assess study procedures required for each protocol and assign responsibility to specific team members.

3.3.3 Examples of study related duties/functions which may be delegated by the Sponsor to another member of the research team, include but are not limited to:

3.3.3.1 Assessment of adverse events

3.3.3.2 Regulatory submissions

3.3.3.3 Ethics submissions

3.3.3.4 Development of site agreements

3.3.3.5 Financial tracking and management

3.3.3.6 Development of informed consent documents

3.3.3.7 Randomization system set-up and maintenance

3.3.3.8 Development of case report forms

3.3.3.9 Management of study product inventory

3.3.3.10 Compliance assessments

3.3.3.11 Site monitoring and source verification

3.3.3.12 Data management and query resolution

3.3.4 A Delegation of Authority and Responsibilities Form (see Appendix 4.1) should be used to document the tasks and functions delegated by the Sponsor. This document should be completed and updated over the course of the study.



3.4 Delegation of Authority by the Qualified Investigator at the Research Site

- 3.4.1 Members of the site research team should be performing duties under the guidance of the Qualified Investigator. Members of the site research team should be informed about the protocol, the investigational agent(s) and their trial-related duties/functions.
- 3.4.2 The Qualified Investigator should assess study requirements for each protocol and assign responsibility to specific team members.
- 3.4.3 Examples of study related duties/functions which may be delegated by the Qualified Investigator to the site research team, include but are not limited to:
 - 3.4.3.1 Screening study participants for study eligibility
 - 3.4.3.2 Obtaining informed consent
 - 3.4.3.3 Patient enrolment and randomization
 - 3.4.3.4 Daily monitoring of patient health, safety and study compliance
 - 3.4.3.5 Data collection
 - 3.4.3.6 Data entry and corrections
 - 3.4.3.7 Serious adverse event reporting
 - 3.4.3.8 Performing clinical assessments
 - 3.4.3.9 Product dispensing and accountability
- 3.4.4 A Delegation of Authority Log (see Appendix 4.2) should be used to document the tasks and functions delegated to the research team. This document should be updated by the Qualified Investigator over the course of the study.

3.5 The delegation logs should be maintained and filed with the study regulatory documents.

4. Appendices

- 4.1 Delegation of Authority Log (Sponsor)
- 4.2 Delegation of Authority Log (Qualified Investigator)

5. References

- 5.1 Health Canada Food and Drugs Regulations Section C.05.010(g): Good Clinical Practices
- 5.2 ICH GCP Section 4.1.5: Investigator Qualifications and Agreements



Delegation of Authority (Sponsor)

I <<Name>>, Principal Investigator for << Study Acronym>> entitled <<Study Title>> have ensured that the individuals listed below are properly qualified and have received appropriate training. I have delegated the following responsibilities to the individuals named below, and assert that these duties/functions will be performed under my supervision.

Principal Investigator

Date

Printed Name	Signature/Initials	Role within Study Team	Authorized Duties/Functions (list all that apply)	Start Date	End Date	PI Initials/Date
		Principal Investigator				

Key Delegated Tasks (Sponsor)

1	Regulatory submissions
2	Ethics submissions
3	Development of site agreements
4	Financial tracking and management
5	Development of informed consent documents
6	Randomization system set-up and maintenance
7	Development of case report form
8	Management of study product inventory
9	Compliance assessments
10	Site monitoring and source verification
11	Data management and query resolution
12	Assessment of adverse events
13	Other: please specify:
14	Other: please specify:
15	Other: please specify:
16	Other: please specify:
17	Other: please specify:
18	Other: please specify:
19	Other: please specify:
20	Other: please specify: