



1. Purpose

The purpose of this SOP is to outline the preparation, review and distribution of agreements between the methods centre (MC) and research sites.

NOTE: This SOP does not outline any legal requirements pertaining to agreements. The Office of Research Services at Queen's University will be consulted and is responsible for legal requirements and advice.

2. Responsibilities

Queen's University Office of Research Services (ORS): Responsible for legal review, legal approval and commentary concerning all MC agreements.

Methods Centre: Responsible for drafting site agreements and circulating to involved parties.

3. Procedures

3.1 During study start-up, the MC will draft a site agreement using the existing template. The template is provided by Queen's University Office of Research Services (ORS).

3.2 The agreement should include, at a minimum, the following:

- 3.2.1 Agreement to conduct the study in compliance with ICH GCP and any governing regulations.
- 3.2.2 Agreement to comply with procedures for data recording/reporting.
- 3.2.3 Agreement to permit monitoring, auditing and inspections.
- 3.2.4 Agreement to retain study related essential documents and records for the specified retention period.
- 3.2.5 Financial aspects of the study.

3.3 The study Sponsor will review the draft agreement prior to forwarding to Queen's University ORS.

3.4 When completed, the Sponsor approved draft agreement (together with all appendices and schedules) must be forwarded to the Queen's University ORS.

3.5 Queen's University ORS will review and approve the draft agreement.

3.6 Once the draft agreement has been approved by Queen's University ORS, the MC will forward the agreement to the research site.

3.7 Communication will continue between the MC, Queen's University ORS and the research site until all outstanding issues are resolved and both parties are prepared to finalize the agreement.

3.8 The finalized agreement will be forwarded to all parties for signatures.

3.9 The number of original copies circulated for signature will be determined by the ORS and the research site.

3.10 Once the agreement is fully executed (i.e. fully signed) both parties will file and maintain copies as per their institutional policies.



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3.11 All MC studies should have a fully executed site agreement in place prior to recruitment of study participants at a particular site.

4 **References**

4.1 ICH GCP Section 5.6.3: Investigator Selection

4.2 ICH GCP Section 5.9: Financing