



Work Instructions
002-01

1. Purpose

The objective of this standard operating procedure (SOP) is to identify how to develop work instructions (WI) which are specific to a particular project.

2. Responsibilities

Responsible Research Team Member: Identify when a WI is needed to supplement an established SOP. Develop a project or study specific WI when needed.

3. Procedures

3.1 A WI will be used by Methods Centre (MC) staff with responsibilities pertaining to a particular project or study. Study or project specific Implementation Manuals and other procedural documents may also serve to supplement MC standard operating procedures.

3.2 A WI is required when the SOP does not provide the necessary level of specificity to ensure a task is properly and completely performed.

3.3 All WIs will be written using the MC WI Template (see Appendix 1). The WIs will contain a minimum of:

- 3.3.1 Brief, informative title
- 3.3.2 WI Number
- 3.3.3 Referenced SOPs
- 3.3.4 Author
- 3.3.5 Procedures
- 3.3.6 Version Date

3.4 A WI will be prepared by the most responsible person, or delegate, for a particular task or function.

3.5 The most responsible person, or delegate, will include project or study specific details not provided in SOPs. Some examples include: contact names and details, referenced web sites).

3.6 It is the responsibility of the most responsible person, or delegate, to maintain up-to-date WIs.

4. Appendices

4.1 Work Instruction Template

5. References

5.1 ICH GCP section 5.1: Quality Assurance and Quality Control

5.2 Food and Drug Regulations, Division 5: Drugs for Clinical Trials Involving Human Subjects section C.05.010(c).



Work Instruction

WI No.:

Title:

Referenced SOP:

Author: Signature: _____ Date: _____

Intended Audience:

Procedures