





Work Instructions  
002-02

## 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 at CERU.

## 2. Responsibilities

**Project Leader, or delegate:** 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 CERU staff with responsibilities pertaining to a particular study. Study specific Implementation Manuals and other procedural documents may also serve to supplement CERU standard operating procedures.

3.2 A WI is required when the CERU 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 CERU WI Template (see Appendix 4.1). 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 Project Leader, or delegate, for a particular task or function.

3.5 The WI should include study specific details not provided in CERU SOPs. (Some examples include: contact names and details, referenced web sites).

3.6 It is the responsibility of the Project Leader, 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).

5.3 Network of Networks Standard Operating Procedures for Clinical Research (N<sub>2</sub> organization).



# Work Instruction

---

WI No.:

Title:

Referenced SOP:

Author:                      Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Intended Audience:

---

Procedures