





## 1. Purpose

The objective of this operating procedure is to ensure Research Site staff participating in CERU clinical trials are appropriately trained to perform their protocol related responsibilities.

## 2. Responsibilities

**Methods Centre:** The methods centre is responsible for providing participating research sites with adequate training to fulfill protocol related responsibilities.

**Research Site:** The research site is responsible for participating in protocol specific training.

## 3. Definitions

- 3.1 Research Site Staff: Refers to an individual or group of individuals involved with the initiation, management and conduct of protocol specific duties and functions. This includes, but is not limited to, the qualified investigator, research coordinators, pharmacy staff, laboratory staff.
- 3.2 Qualification: Professional experience and relevant education that an individual of the research team possesses which corresponds to the education and experience necessary for the individual to perform his/her protocol related duties and functions.
- 3.3 Training: Any formal or informal education designed to enhance knowledge and/or skill set of a research site staff member.

## 4. Procedures

- 4.1 In agreement with ICH Good Clinical Practices, the following is required:
  - 4.1.1 The qualified investigator is knowledgeable and complies with Good Clinical Practices and other governing regulations (GCP 4.1.3);
  - 4.1.2 The qualified investigator is able to rely on an adequate number of qualified employees and facilities to conduct protocol related procedures in a safe and appropriate manner for the duration of the clinical trial (4.2.3);
  - 4.1.3 The qualified investigator ensures that all individuals with trial related duties and responsibilities are informed about the study protocol, investigational products and study related procedures (4.2.4).
- 4.2 The training of all research site staff is the joint responsibility of both themselves and the Methods Centre (MC).
- 4.3 The MC will provide protocol specific training during study start-up and on an ongoing basis, as required.
- 4.4 The format and content of training will vary from one clinical trial to another, however some basic elements to incorporate into site specific training include:
  - 4.4.1 Protocol review
  - 4.4.2 Study Procedures
    - 4.4.2.1 Patient Screening, Recruitment & Enrolment (including informed consent)
    - 4.4.2.2 Data Collection
    - 4.4.2.3 Data Entry



Research Site Qualifications and Training  
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4.4.2.4 Documentation

4.4.3 Governing regulatory requirements

4.4.4 ICH GCP

**Documentation of Training and Qualifications**

- 4.5 A signed and dated curriculum vitae (CV) should be provided to the MC for each member of the site research team. The CV attests to an individual's qualifications by providing a record of employment, education and experience. It is suggested that the CV be updated every 2 years.
- 4.6 For physicians, documentation to confirm the right to practice medicine may be collected by the MC. This usually involves a copy of the physician medical license or registration number.
- 4.7 The qualified investigator is responsible for ensuring that all training conducted at the site is appropriately documented for all staff involved with MC clinical trials.
- 4.8 The MC is responsible for documenting all protocol specific training conducted with research site staff.
- 4.9 Training documentation should include the title of the training, duration, participant name and training date, the trainee and a summary of the training. Refer to Appendix 5.1.
- 4.10 All training documentation at the research site should be available for verification by MC personnel or inspection by external auditor, if applicable.

**5. Appendix**

5.1 Sample Site Training Record

**6. References**

5.1 ICH GCP Section 4.1: Investigator Qualifications and Agreements

5.2 ICH GCP Section 4.2: Adequate Resources



# Site Training Record

**Title of Training:**

**Date:**

**Time:**

**Research Site:**

**Training Topics:**

- Topic 1
- Topic 2
- Topic 3

**Participants:**

- Name, Role
- Name, Role
- Name, Role

**Training Confirmation:**

I confirm that the above mentioned training topics were presented to the participants as outlined above.

\_\_\_\_\_  
Trainer Name

\_\_\_\_\_  
Date