



1. Purpose

The objective of this operating procedure is to ensure the Methods Centre research team is appropriately trained to perform their responsibilities.

2. Responsibilities

Methods Centre Research Team Member: All research team members are responsible for participating in training opportunities and maintaining an up-to-date training record.

3. Definitions

- 3.1 Research Team Member: Refers to an individual or group of individuals involved with the initiation, management and conduct of study-related duties and functions.
- 3.2 Qualification: Professional experience and relevant education that an individual of the research team possesses which meets the minimal education and experience requirements as described in the Methods Centre (MC) job description.
- 3.3 Job Description: A written and approved document which details the duties and tasks for which an individual member of the research team is responsible.
- 3.4 Training: Any formal or informal education designed to enhance knowledge and/or skill set of a research team member.

4. Procedures

- 4.1 All Methods Centre (MC) research team members should have adequate knowledge of ethical principals, professional standards and governing regulations to perform their responsibilities.
- 4.2 Research team members should be qualified to conduct their responsibilities through education, training and experience.
- 4.3 The training of all research team members is the joint responsibility of both themselves and the Methods Centre (MC).
- 4.4 All training related to qualification of research team members should be documented in a Training Record.

Training Records

- 4.5 It is the responsibility of individual research team member to create and maintain their own training record.
- 4.6 The Training Record should contain the following:
 - 4.6.1 Current Job Description – outlining roles and responsibilities
 - 4.6.2 Current Curriculum Vitae (CV) – demonstrates education and experience, including the current position
 - 4.6.3 Licenses, Accreditations – demonstrates qualifications
 - 4.6.4 SOP Training Log – Lists all training the individual has participated in concerning MC SOPs



Methods Centre Staff Qualifications and Training

207-00

- 4.6.5 Training Logs – Lists all training the individual has participated in to ensure they are able to undertake the responsibilities delegated to them.
- 4.6.6 Continuing Education – Documentation of course/meeting attendance including topics covered.
- 4.7 Training records should be updated on an ongoing basis.
- 4.8 Training records should be reviewed annually during individual performance appraisals. Annual review will facilitate the identification of future training needs.
- 4.9 When an individual member of the research team leaves their position a complete copy of the training file should be archived at the MC in the event it is required for an audit or inspection.

Training Forms and Logs

- 4.10 A Training Log should be used to document all MC training (Appendix 5.1).
- 4.11 For individuals not participating in formal SOP training sessions, individual review of SOPs should be documented on the SOP Training Log (Appendix 5.2).

5. Appendix

5.1 Sample Training Log

5.2 Sample SOP Training Log

6. References

5.1 ICH GCP Section 4.1: Investigator Qualifications and Agreements

Training Log



Employee Name: _____

Date of Training	Type of Training	Description of Training
	<input type="checkbox"/> Formal Presentation <input type="checkbox"/> Conference, Seminar, Workshop <input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____	Title / Presenter / Location
	<input type="checkbox"/> Formal Presentation <input type="checkbox"/> Conference, Seminar, Workshop <input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____	Title / Presenter / Location
	<input type="checkbox"/> Formal Presentation <input type="checkbox"/> Conference, Seminar, Workshop <input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____	Title / Presenter / Location
	<input type="checkbox"/> Formal Presentation <input type="checkbox"/> Conference, Seminar, Workshop <input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____	Title / Presenter / Location
	<input type="checkbox"/> Formal Presentation <input type="checkbox"/> Conference, Seminar, Workshop <input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____	Title / Presenter / Location
	<input type="checkbox"/> Formal Presentation <input type="checkbox"/> Conference, Seminar, Workshop <input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____	Title / Presenter / Location
	<input type="checkbox"/> Formal Presentation <input type="checkbox"/> Conference, Seminar, Workshop <input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____	Title / Presenter / Location
	<input type="checkbox"/> Formal Presentation <input type="checkbox"/> Conference, Seminar, Workshop <input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____	Title / Presenter / Location

SOP Training Log



**Clinical Evaluation
Research Unit**

Employee Name: _____

SOP #	SOP Title	Date	Type of Training
			<input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____
			<input type="checkbox"/> Self-Review <input type="checkbox"/> Other: _____