The University of Manchester

Standard Operating Procedure

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1. Background

Schedule 1 Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004 states "Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his or her respective task(s)".

2. Purpose and Scope

This Standard Operating Procedure (SOP) describes the standard process for the University of Manchester (UoM) Research Governance, Ethics and Integrity Team (RGEIT) (Clinical Trials) to ensure that the RGEIT are demonstrably qualified by education, training and experience to perform their roles.

The UoM expects all staff involved in clinical research that it sponsors to be demonstrably qualified for their role, however members of staff outside the RGEIT team may follow their own training procedures. Where external vendors are used in UoM Sponsored trials, their training process is reviewed by the Sponsor at the point of vendor assessment for compliance with minimum requirements and UoM expectations, as outlined in the UoM Policy on CTIMPs and other Clinical Research.

3. Roles and Responsibilities

RGEIT	Each individual member of RGEIT must maintain a personal training record
CTMG	Determines training requirements following significant regulatory changes

4. Procedure

4.1 Training Record

At induction, each member of the RGEIT (Clinical Trials) must create and then maintain a personal training record, either paper or electronic. The training record must be securely held, but accessible for update when necessary and available for review on request by authorised parties. The training record should include the following, as a minimum:

- A CV, stating current role, signed and dated within the last 3 years
- GCP training certificate, updated every 3 years or following significant regulatory changes
- Current signed job description
- SOP training log (see appendix for required contents)
- Details of other relevant training (see appendix for required contents) to be recorded and updated throughout employment to record further training that is undertaken.

4.2 SOP Training

At induction, each member of the RGEIT (Clinical Trials) must read the current versions of the UoM RGEIT SOPs prior to performing any of the procedures, and document on a SOP training log that they have read and understood these. When new or updated SOPs are released, the individual should ensure the updated SOP is read before they carry out the relevant procedure, and document this by adding to their SOP training log.

4.3 Provision of Training

The RGEIT should maintain an up to date awareness of the relevant regulatory requirements and upcoming regulatory changes. Relevant regulatory changes will be raised by RGEIT at Clinical Trial Management Group (CTMG) meetings, where appropriate training and method of provision will be agreed.

5. References and Bibliography

UoM Policy on CTIMPs and other Clinical Research:
http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=29056

6. Appendices

Training Log

Employee Name:

Employment start date:

Date	Training title	Description	Summary of Content	Trainer Name & Organisation

SOP Training Log

Employee Name:

Employment start date:

SOP Title	Version	Date read