MANCHESTER 1824
The University of Manchester

Standard Operating Procedure

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Title:	Training		
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Version	Date	Reason for change
1.0	July 2020	N/A (First version)
2.0	May 2024	Procedure expanded to include training review, handovers, cover in periods of absence.

When using this document please ensure that the version you are using is the most up to date either by checking on the Research Governance, Ethics and Integrity Office website (https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/) for any new versions or contacting the author to confirm the current version.

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. Oversight of the training record should be maintained either by routine monitoring and audit, or review of training records by the line manager (for example, at Performance and Development Reviews)
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 (25/A)
- Log of other relevant training (25/B) 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.

4.4 Staff leaving RGEIT

Staff leaving the RGEIT must provide a handover prior to their departure, leaving sufficient time for queries to be resolved. The handover should include details of any ongoing work. Other items to consider may be the handover of relevant contact details, scheduled meetings, or deadlines. Responsibilities should be reassigned, and additional training given to remaining members of the RGEIT where necessary.

The staff member's access to any systems specific to RGEIT (e.g. clinicaltrials.gov, MHRA Submissions) should be removed and replacement users set up where necessary.
Prior to leaving, staff must ensure that an up-to-date copy of their training record has been provided for retention by the RGEIT.

4.5 Periods of extended absence

If possible, depending on the circumstance (e.g. planned secondment), the staff member should provide a handover as per 4.4. Responsibilities should be reassigned, and additional training given to remaining members of the RGEIT where necessary.
When a staff member returns to the RGEIT after a period of leave, consideration should be given to whether training needs have changed or require updating. If any SOPs have been updated during their absence, these should be provided to the staff member to read within 30 days of their return to the RGEIT.

5. References and Bibliography

UoM Policy on CTIMPs and other Clinical Research:
http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=29056
ICH GCP E6 (R2)
Medicines for Human Use (Clinical Trials) Regulations 2004 and amendments

6. Appendices

25/A Training Log

Employee Name:

Employment start date:

Date	Training title	Description	Summary of Content	Trainer Name & Organisation

25/B SOP Training Log

Employee Name:

Employment start date:

SOP Title	Version	Date read