MRC Clinical Trials Unit

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UCL

SITE TRAINING

VERSION 1.0

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All appropriate approvals must have been completed prior to uploading to SOPbox. The effective date of this SOP is the day on which it was signed by the SOPbox Administrator and is available to use.

For the Revision History please see the Version History Summary in SOPbox.

STANDARD OPERATING PROCEDURE TITLE

TABLE OF CONTENTS

The following symbols may be used in this SOP:

Indicates a link to a related document

Indicates instructions to document trial-specific processes elsewhere

Throughout this document the MRC Clinical Trials Unit at UCL, will either be referred to as 'MRC CTU at UCL' or 'the unit'. In instances where neither read well in the sentence, 'the CTU' may be used.

1 PURPOSE

The ICH GCP Guideline E6(R2) states that "each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)" and "each investigator should be qualified by training and experience and should have adequate resources to properly conduct the trial for which the investigator is selected."

The purpose of this SOP is:

- To define the roles and responsibilities involved in the site training process.
- To outline the procedures for study specific training of investigator(s)/site staff in order to ensure that:
  - Investigator(s) are qualified by training to conduct the study.
  - Investigator(s) have the required information to assume responsibility for the enrolment of eligible patients and for the conduct of the study in accordance with the protocol and applicable regulations. This includes training the site staff on their responsibilities and updating training requirements as deemed appropriate.
  - Adequate information/training is provided to the investigator(s) and site staff.
- To ensure training needs at sites are identified and fulfilled.
- To ensure training has been documented by both Sponsor and Site.

2 RESPONSIBILITY AND ROLES

The following table lists the roles relevant to this SOP and a brief description of their responsibilities.

This SOP will be circulated to be Read and Understood to all appropriate roles identified in the training matrix.

ROLE	RESPONSIBILITIES
Trial Management Team (TMT)	▪ Arrange and conduct site training including site initiation training when appropriate to do so. ▪ Identify additional training needs e.g. for new staff, ongoing training or following the release of an amendment or major adaptation to the study. ▪ Drafting and provision of training materials. ▪ To document training provided. ▪ Participation at investigators training meetings (if any). ▪ Participation in site training including site initiation visits (if any).
Trial Management Group (TMG)	▪ Participation at investigators training meetings (if any). ▪ Participation at site initiation visits (if any).
External Collaborators (e.g. international collaborators)	Where appropriate: ▪ Participate in investigators meetings (if any). ▪ Participate in appropriate training when required. ▪ Document training received.

3 PROCEDURES

3.1 SITE INITIATION TRAINING

Site training constitutes a fundamental part of the study initiation process and is essential for staff who will conduct the clinical trial or study. Training at the beginning of a study may take place during a site initiation visit (SIV). It is important to note that training of site staff should be ongoing throughout the duration of the trial, as described in section 3.3.

Options for site initiation training:

- Centralised training
  - Where all investigators are invited to a central training meeting, referred to as an investigator's meeting.
    This generally takes place before a study starts, but other centralised training can take place throughout the study. In certain circumstances this might take place remotely (e.g. in the case where travel is not permitted).

- Remote training
  - Site staff will be sent a meeting link and the training conducted via conference call, webinar or training slides, etc.
  - Often held where;
    i. Site staff have been unable to attend the investigators meeting.
    ii. The site has previous experience with clinical trials in the specific disease area and/or if the Principal Investigator (PI) is known to the MRC CTU staff.
    iii. The TMT deems that the content of the training is suitable to be delivered remotely.
    iv. Staff are working remotely e.g. during COVID-19 pandemic.

- On-site training
  - Attended by all relevant site staff (e.g. local PI, Trial Co-ordinator, Research Nurse, Data Manager, Pharmacists, other investigators and laboratory staff).
  - Often held where;
    v. The site has not participated in any previous studies in the specific disease area.
    vi. The site is not known to MRC CTU staff.
    vii. The PI is not experienced in clinical trials.
    viii. The site has participated in previous MRC CTU studies but some issues were identified, e.g. poor data return.
    ix. The study procedures are particularly complicated or high-risk.

The appropriate method of training should be decided upon by the TMT for each site and must be considered in the study Risk Assessment. The plan for training throughout the trial must be documented in the study Monitoring Plan.

Risk Assessment SOP (MRC_CTU_SOP_059)
Monitoring SOP (MRC_CTU_SOP_060)

3.2 SITE INITIATION VISIT

For some studies, a site initiation visit (SIV) may be appropriate and the following may be conducted prior to study start:

- Investigator Site File review
- Pharmacy Site File review
- Laboratory file review
- Review of site facilities

The TMT should determine whether a SIV is necessary for each study/site and this must be considered in the trial Risk Assessment.

Risk Assessment (MRC_CTU_SOP_059)

Where a SIV is conducted, this should be documented in a Site Initiation Visit Report, a template is available and can be adapted for specific studies as necessary. The completed Site Initiation Visit Report must be filed in the TMF and a copy sent to the site to file in the Investigator Site File (ISF). If applicable a Pharmacy Initiation Report should also be completed and filed in TMF; see Pharmacy Initiation, Training and Closure SOP.

Template Site Initiation Visit Report (MRC_CTU_TT_0111)

Pharmacy Initiation, Training and Closure (MRC_CTU_SOP_100)

3.3 ONGOING SITE TRAINING

Throughout the study, there will be instances when it is deemed appropriate by the TMT to hold refresher training sessions for site staff. Refresher training sessions may be held remotely as described above or it may necessitate an on-site visit. The following list gives examples of where ongoing training may be required, but is not exhaustive:

- New site staff have joined the study once it has already opened including new PIs.
- Following substantial amendments to the protocol and study procedures.
- Following critical findings at site.
- Following a serious breach/protocol deviation at site.
- Identification of errors occurring across multiple sites requiring clarification.
- Ad-hoc training if requested by a particular site.

Ongoing and refresher training taking place may not require all sites or all site staff to attend, depending on the reason for holding the training – it may be optional or mandatory, but this must be documented in the study Monitoring Plan.

Monitoring SOP (MRC_CTU_SOP_060)

3.4 TRAINING CONTENT

The following list details items that should be considered when preparing training materials. This list is not exhaustive and not all areas will be relevant for every study.

- The study protocol and other reference documents
  - Study background and rationale
  - Study procedures
  - Identifying and reporting protocol deviations
- Informed consent process
- Data management
  - Data collection (including details on electronic data capture)
  - Case report forms, procedures for completion and return to the MRC CTU Trial Team
  - Data sharing processes for sending patient identifiable data via secure email
  - Source documentation requirements
  - Query resolution processes
  - Database training (where required)
- Investigational Medicinal Product
  - Receipt and storage
  - Dispensing
  - Accountability
  - Drug allocation process
  - Blinding procedures (if applicable)
- Adverse event reporting procedures
  - Investigators' responsibilities for expedited reporting of SAEs and SUSARs
- Randomisation procedures including back-up (if applicable)
- Laboratory samples
  - Handling Procedures
  - Material re-supply procedures
- Storage, accessibility and archiving of CRFs and other study documents
- Administrative and budgetary details
- Frequency of and expectations for any monitoring visits
- Training on study equipment and certification if required
- GCP training (as required)
- Responsibilities with respect to indemnity/insurance if required
- The investigator's responsibility to report to the REC/regulatory authority (if applicable)
- Site Activation and Green Light process

All training presentations will be prepared by and/or in collaboration with the:

- Chief Investigator and/or Trial Physician on the medical and safety aspects of the trial
- TM on the protocol and study procedures
- TM/DM on the CRF completion
- Database Programmer and Data Scientist on electronic data capture/remote data entry aspects of the study or general database training (if applicable).

Where necessary, the pharmacy and IMP training process should be conducted in line with the Pharmacy Initiation, Training and Closure SOP, for both initiation and ongoing training.

Protocol Deviations and Violations (MRC_CTU_SOP_033)
Pharmacy Initiation, Training and Closure (MRC_CTU_SOP_100)

3.4.1 STUDY-SPECIFIC PROCEDURE TRAINING

In some studies, the protocol may require a specific procedure to be performed on participants, for example venesection, bronchodilator spirometry or ECG. The study protocol may require these procedures to be standardised across all sites or these may be procedures unfamiliar to site staff. The TMT should determine whether such procedures are required for the study and should put in place a process to provide training to individuals at sites. The types and level of training must be considered in the study Risk Assessment.

Risk Assessment (MRC_CTU_SOP_059)

The TMT should identify appropriately trained individuals to provide training to site staff (evidence of training of the trainer must be documented in the Trial Master File (TMF) as appropriate e.g. CV or training certificate). Training must be provided prior to performing procedures on study participants. Assessment of competency and completion of training must be documented in the ISF and TMF.

Template Procedure Competency Assessment Checklist (MRC_CTU_TT_0420)
Template Procedure Competency Certificate (MRC_CTU_TT_0419)

3.4.2 TRAINING OF PATIENT IDENTIFICATION CENTRES (PICS)

Patient Identification Centres (PICs), as described in the Site Evaluation and Activation SOP, are not considered research sites and therefore do not have the same requirements as study sites. Site training may not be necessary for PICs and should be tailored to the local research team's/ study's needs.

Site Evaluation and Activation (MRC_CTU_SOP_106)

3.5 DOCUMENTING TRAINING

Evidence that all required site staff have received mandated training must be obtained by the TMT before the site is opened to recruit participants to the study, by completion of a training log. The training log must have a list of attendees as a record of participants present at the training event. Evidence of site initiation training must be stored in both the TMF and ISF. For ongoing training, a training log must be kept in the ISF (at a minimum) but trial teams can decide whether they should be collected and stored in the TMF too. Training logs must be signed by the delegate. The method chosen for documenting site training must be detailed in the study Monitoring Plan.

Template Trial Training Log (MRC_CTU_TT_0112)

Monitoring SOP (MRC_CTU_SOP_060)

Training materials should be made available to site staff following training. Any updated training materials should continue to be provided to sites throughout the duration of the study. For new site staff who join whilst the study is ongoing, updated training/delegation logs must be sent to the study team.

4 RELATED DOCUMENTS

SOPs
Risk Assessment (MRC_CTU_SOP_059)
Monitoring (MRC_CTU_SOP_060)
Protocol Deviations and Violations (MRC_CTU_SOP_033)
Pharmacy Initiation, Training and Closure (MRC_CTU_SOP_100)
Site Evaluation and Activation (MRC_CTU_SOP_106)

Tools and Templates
Template Procedure Competency Assessment Checklist (MRC_CTU_TT_0420)
Template Procedure Competency Certificate (MRC_CTU_TT_0419)
Template Site Initiation Visit Report (MRC_CTU_TT_0111)
Template Trial Training Log (MRC_CTU_TT_0112)