Research Governance Office Sponsorship Standard Operating Procedures

Qualification and Training for Staff Engaged in Trials

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1.0 Introduction and Scope

This Standard Operating Procedure (SOP) describes the training requirements for all personnel who are involved in research sponsored by the University of Leicester (UoL; referred to as 'trials' hereafter). Personnel must be trained in the trial protocol and be appropriately qualified by training, experience and education to discharge their responsibilities competently. They must demonstrate an understanding of the trial and disease area in order to offer a full explanation of the trial to participants, and be deemed competent in the pharmacological aspects of the trial, where applicable.

2.0 Procedure

As part of the initial Sponsor review, evidence of relevant training, qualification and experience must be provided for the Chief Investigator (CI) and student researcher (where applicable) of a trial.

The CI retains overall responsibility for the management and conduct of the trial. In the case of multi-site trials, training must be provided in advance of the trial commencing at any given research location (e.g., as part of protocol training, or via a Site Initiation Visit (S-1011)). Furthermore, the Principal Investigator (PI) is responsible for ensuring that all trial personnel at their location are suitably qualified and experienced, and have received appropriate training prior to them undertaking these duties.

3.0 Training Requirements

Regardless of the type of trial or research activities being conducted, all trial personnel, including but not limited to pharmacy, laboratory and other support service staff, must demonstrate they have received **adequate** and **proportionate** training to undertake their role and delegated activities. SOP S-1010 should be followed when delegating activities and should cover the responsibilities of researchers set out in relevant legislation and standards. Where audit/monitoring findings indicate that training is required, training may be mandated as part of the Corrective And Preventative Action (CAPA) Plan.

The CI and PI are responsible for ensuring that personnel carry out only those tasks for which they have been delegated and appropriately trained.

4.0 Training Evidence

Where appropriate and applicable, evidence of training in the following areas should be provided;

- Good Clinical Practice (GCP)
- Human Tissue Act/Laboratory based activity
- Obtaining Informed Consent
- UoL Sponsor Standard Operating Procedures
- Protocol and Study Specific training
- Trial Master File/Site File Management training
- Chief Investigator training

Further guidance on the requirements for each is detailed in the sections below. The UoL recommends and accepts training obtained via NIHR Learn (account and log in

required). Training obtained by other providers may be accepted if the content of the course(s) can be verified as appropriate to the role and trial.

4.1 Investigator Site File (ISF) and Trial Master File (TMF) Requirements

The PI (or delegate) is responsible for ensuring that the ISF contains the relevant training documentation for all staff listed on the Delegation of Activity Log. The CI (or delegate) is responsible for ensuring that the TMF contains the relevant training documentation for the Chief Investigator (CI) and, where applicable, any Principal Investigators (PIs). Staff are responsible for ensuring that they have conducted all training applicable to their delegated duties and that training is refreshed/updated as necessary.

Where documents are maintained elsewhere (i.e., a central location within a department/organisation), the location needs to be clearly signposted (i.e., using a file note/ISF or TMF plan), and a contemporaneously maintained overview of training records must be present within the ISF.

In line with a pragmatic and proportionate approach, there is no requirement to duplicate all research-location staff training documents within the TMF. Instead, a contemporaneously maintained overview of training records for personnel at each research location should be held in the TMF to demonstrate effective oversight.

Copies of training documents for central staff must be retained in the TMF, as these individuals are not captured within the Investigator Site File (ISF)

Appendix 4 provides an Excel-based Investigator tracking tool that should be used, and may be adapted, to meet the needs of a specific trial. The tracker should list all the individuals who have been delegated activities on the Delegation of Activities Log and record the completion dates of all relevant training. Where training has been renewed, both the original and subsequent training dates should be documented. For SOPs and trial specific training, it may be easier to hold copies of SOP read logs/researcher training logs rather than transcribing the information onto the tracker. A copy of the tracker should be contemporaneously maintained and held in the relevant section of the TMF and ISF.

Training must be complete and current for the entire duration of an individual's involvement in the trial.

Any expired training documentation must be retained and marked as superseded to demonstrate that trial personnel were appropriately qualified and trained throughout the duration of the trial.

5.0 Curriculum Vitae (CV)

Evidence of qualification and experience, must be provided in the form of a current signed and dated curriculum vitae (CV).

- CVs should be reviewed every three (3) years (or more frequently if required as per local policy) and updated where appropriate

- CVs must be signed and dated to demonstrate the above. Signatures must be verifiable (ideally, 'wet ink' or using a verifiable e-signature platform (e.g., AdobeSign))
- The Health Research Authority's (HRA) Research CV template must be used
- CVs must not contain superfluous personal information (e.g., home address, date of birth, email and personal telephone number)

6.0 Good Clinical Practice (GCP)

For CTIMP and Medical Device Trials, GCP training is mandated A proportionate approach to GCP training will be considered on a case-by-case basis for trials authorised under the MHRA Notification Scheme.

All other types of trials should be conducted in a manner that provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data are reliable. As such, whilst not mandated, GCP training is recommended for everyone.

GCP training should be completed every three (3) years; the date of training and/or expiration must be on the certificate.

7.0 Human Tissue Act/Laboratory Based Training

Individuals employed by the UoL who are involved in the handling and management of human tissue must complete the HRA training on 'Research Involving Human Tissue'. In addition, UoL staff involved with a Research Tissue Bank (RTB) or Biobank must complete the Research Tissue Bank - An introduction. Both modules can be accessed via NIHR learn.

For research location personnel, in addition to any local Trust requirements regarding HTA training, trial-specific training on the handling and management of human tissue for the UoL sponsored trial should be provided and evidenced (i.e., this could be delivered during the SIV or a specific lab SIV).

The NIHR South Central Regional Research Delivery Network (RRDN) provides a Laboratory Based Skills for Research Delivery Staff course. While not mandated, researchers are strongly encouraged to undertake this training.

8.0 Consent Training

The approved trial documents must clearly explain the process for obtaining informed consent, including who is delegated the responsibility for the activity.

For CTIMP and Medical Device trials, written agreement from the Sponsor, CI, PI and Trust must be obtained for Nurse, Non-Medic or Allied Health Professionals to obtain informed consent.

For all trials, individuals that are not medically qualified (or undertaking medical training) must complete specific consent training. Whilst consent training is not mandated for medics it is recommended. In all cases, SOP S-1021 (Informed Consent for Research) should be followed.

Consent training should be completed every three (3) years; the date of training and/or expiration must be on the certificate.

9.0 UoL Sponsor Standard Operating Procedures (SOPs)

UoL Sponsor SOPs that are relevant to an individual's role should be read and detailed on the Sponsor SOP Read Log unless other arrangements have been made in advance and agreed with the Sponsor (e.g., Q-Pulse).

Staff must read relevant SOPs prior to undertaking tasks to which an SOP relates i.e SOPs around site initiation (S-1011), monitoring (S-1007), safety reporting (S-1009), training (S-1020), delegation of activities (S-1010) to name a few, should be undertaken at onset, but training around creating a statistical analysis plan (S-1030) and end of trial activities (S-1024) etc can be undertaken at a later date when the SOP becomes applicable to trial activities/status. Re-reading of SOPs should be undertaken as relevant e.g. when made aware by the Sponsor that a new version of an SOP(s) has been issued and significant/process changes have been made or at timely intervals as per the current status of a trial.

10.0 Protocol and Trial-Specific Training

Trial personnel must be trained appropriately to carry out all aspects of the protocol in advance of the trial commencing at their location, and/or undertaking their delegated duties.

The CI and PI must provide (or arrange the provision of) training on the approved protocol, trial documents and procedures required to successfully conduct the trial. This includes training in the use of trial equipment and devices (particularly if they are novel or being used unconventionally), safety reporting and the management of CTIMP supplies, and any additional training required following modifications.

Training must be documented as appropriate and may take the form of an Individual Researcher Training Log (Appendix 2) or a group level training log (e.g., SOP S-1011 Appendix 4 SIV attendance log). A risk based/proportionate decision should be made as to the most appropriate method of documenting an individual's training. It must be clear who has received what training and when for monitoring and auditing purposes.

Whenever a trial is modified, updated training must be undertaken as applicable to ensure that staff remain competent and appropriately trained for the tasks they perform.

11.0 Trial Master File/Site File Training

Personnel who are responsible for the creation and maintenance of the TMF/ISF etc may find it beneficial to complete the online Site File Management training provided via NIHR Learn. However, informal training in site file creation and maintenance is sufficient.

12.0 Chief and Principal Investigator Training

It is important that the CI understands the responsibilities and Sponsor expectations as laid out in the Delegation of Activities SOP (S-1010) and evidenced by the CI Roles

and Responsibilities document (Appendix 1 to SOP S-1010). During the Sponsor Review process the CI will have an opportunity to speak to the Sponsor to discuss any risks identified with the trial. Where gaps in knowledge or experience are highlighted, relevant support will be provided on an ad-hoc basis by the Sponsor. Formal training may be recommended or mandated in advance of the trial commencing.

The NIHR hosts a suite of training, including PI Essentials Training, which is freely available for individuals to access.

13.0 Non-Compliance

Where it has been identified that personnel have not been adequately trained, or the training certification has lapsed, the non-compliance SOP S-1016 UoL may be implemented at a minimum of 'other' finding.

14.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Issue Number	Description Of Changes (If Any)
April 2026	7.0	• Language updates in accordance with ICH GCP E6(R3) and UK Clinical Trials Regulations. • Minor wording updates. • Administrative changes • Clarification of the requirements for maintaining training evidence within the ISF and TMF. • Removal of responsibilities table as responsibilities are laid out within the body of the SOP. • Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive • New Appendix 4 – Investigator Training tracker. Previously an appendix within SOP 1015.