UNIVERSITY OF LEICESTER

University of Leicester Research Governance Office

Standard Operating Procedures

SOP S-1020 UoL

Qualification and Training for Staff Engaged in Research Sponsored by the University of Leicester

Version 6.0 May 2024

Effective Date: May 2024

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

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). Personnel must be trained in the study protocol and be appropriately qualified by training, experience and education to discharge their responsibilities competently. They must demonstrate an understanding of the study and disease area in order to offer a full explanation of the study to subjects, and be deemed competent in the pharmacological aspects of the study, 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 study.

The Chief Investigator (CI) retains overall responsibility for the management and conduct of the study. In the case of multi-site studies, training must be provided in advance of the study commencing at that site (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 study personnel at their site are suitably qualified and experienced, and have received appropriate training prior to them undertaking these duties.

3.0 Curriculum Vitae (CV)

Evidence of qualification and experience, in the form of a current signed and dated curriculum vitae (CV), must be retained in the Trial Master File and/or Investigator Site File (TMF/ISF) for all study personnel.

- CVs should be reviewed every three (3) years (or more frequently if required as per local trust 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 should be used
- CVs should not contain personal information (e.g., home address, date of birth, email and personal telephone number)
- Expired CVs must be retained and marked as superseded to demonstrate that study personnel were appropriately qualified and trained throughout the duration of the study.

4.0 Training Requirements

Regardless of the type of study or research activities being conducted, all study 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 duties (SOP S-1010 should be followed when delegating duties). Where audit/monitoring findings indicate that

training is required, training may be mandated as part of the Corrective Action and Preventative Action Plan.

Where appropriate and applicable, evidence of training in the following areas should be provided and retained in the TMF/ISF:

- 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 training
- Chief Investigator training

Further guidance on the requirements for each can be reviewed 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 research study.

5.0 Good Clinical Practice (GCP)

For CTIMP and Medical Device Trials, GCP training is required. 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 studies 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.

6.0 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.

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

The NIHR Thames Valley and South Midlands CRN provide a Laboratory Based Skills for Research Delivery Staff course. While not mandated, researchers are strongly encouraged to undertake this training.

7.0 Consent Training

The approved study 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 studies, individuals that are not medically qualified (or undertaking medical training) must complete 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.

8.0 UoL Sponsor Standard Operating Procedures (SOPs)

UoL Sponsor Standard Operating Procedures (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). Details of suggested SOP reading for study personnel are provided within Appendix 3 (SOP Read Log).

Staff must read the SOPs prior to or at Study Initiation, or within 1 month of joining the study (i.e., being on the Delegation of Authority and Signature Log). Re-reading of SOPs should be undertaken regularly (i.e., annually) and/or when made aware by the Sponsor that a new version of an SOP(s) has been issued and significant/process changes have been made.

9.0 Protocol and Study Specific Training

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

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

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,. Appendix 2 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.

10.0 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.

11.0 Chief and Principal Investigator Training

It is important that the CI understands the responsibilities and Sponsor expectations as laid out in the Delegation of Responsibilities 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 study. 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 study commencing.

NIHR host a suite of training, including PI Essentials Training, which is freely available for individual's to access.

12.0 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.

13.0 Responsibilities

Responsibility	Undertaken by	Activity
CI	CI/PI/delegate	Ensure all Investigators and staff working on the study are appropriate qualified and trained as appropriate and that this is reflected on the Delegation of Authority and Signature Log.
CI	CI/PI/delegate	To keep copies of all CV/training records and certificates in the Investigator Site File/Trial Master File covering the duration of involvement in the study/trial.
CI	CI/PI/delegate	To update themselves and all members of their research team in all aspects of the trial, including consent, GCP, standard operating procedures and pharmaceutical products (as appropriate) and any protocol amendments.
CI	CI/PI/Sponsor/delegate	To identify additional training needs of staff involved in research and seek relevant training.
CI	CI/PI/Sponsor/delegates	Ensure that personnel carry out only those tasks for which they have been delegated and appropriately trained.

Responsibility	Undertaken by	Activity
Sponsor	Sponsor/delegate	Ensure that the Chief Investigator is fully aware of their responsibilities to ensure appropriate training is provided and kept up to date for all study personnel.

14.0 Development and Approval Record for this Document

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Sponsorship Management and Operation Group (RSMOG)	Professor Nigel Brunskill 	16/05/2024

15.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
June 2015	1	Wendy Gamble	Updated to introduce a protocol training log and appropriate GCP certificates.
Oct 2016	2	Diane Delahooke	Updated logos, and amended to reflect UHL bite sized training and UoL GCP training.
Nov 2017	3.0	Michelle Muessel	Update of SOP to reflect changes to training provided, and frequency.
Sept 2021	4.0	Cat Taylor	Administrative changes and updates throughout to align with UHL SOP S-1008. Update training requirements and remove provision of training by UoL and UHL.
March 2023	5.0	Cat Taylor	Administrative changes Mandating that the HRA CV template must be used Reference to additional training available from the NIHR Mandating that any individual who is involved in a study using human samples of any kind should undertake the HRA HTA training even where they are not actively involved in the processing of samples. Clarification around training exemptions. Update to the responsibilities table.
September 2023	5.1	Cat Taylor	Minor updates to wording to reflect that the HRA CV template is recommended rather than mandated and that CVs should ideally be wet ink

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
			signed or signed via a verifiable e-platform however electronic signatures will be accepted. Clarification that CVs should be updated every 3 years or more regularly if required as per local trust policy. Addition of availability for Group training logs to be maintained in place of individual training logs where appropriate.
January 2024	5.2	Cat Taylor	Removal of Appendix 1 – Researcher Training Log Addition of new Appendix 2. This combines a revised researcher training log with a revised SOP Read Log. The SOP read log was previously an appendix to SOP S-1011. Update to SOP to reflect new Appendix 2
May 2024	6.0	Cat Taylor	Clarification of acceptable and proportionate training provision. Revisions throughout the document to improve accessibility and understanding. Updated to Appendix 2 following user feedback (reverting back to previous format of two separate documents – appendix 2 is the researcher training log and appendix 3 is the SOP read log). Length of the document has been reduced by combining sections and using overarching statements in the introductory section (which removes duplication of the same statement throughout the document). Removal of Office Address