



**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 5.2 January 2024

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Effective Date:

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. It is the responsibility of the Chief/Principal Investigator (PI) to ensure that **all** study personnel are suitably qualified and experienced, and have received training that is appropriate to their role and delegated duties, prior to personnel undertaking these duties. In the case of multi-site studies, training must be made available to all sites in advance of the study commencing at that site. Evidence of qualification and experience, in the form of a current signed and dated curriculum vitae (CV) and the relevant training records, must be retained in the Trial Master File and/or Investigator Site File (TMF/ISF) for all study personnel. The CV should be reviewed every three (3) years (or more frequently if required as per local trust policy) and updated where appropriate. It should be signed and dated to confirm the date and ownership by the named individual. Ideally signatures should be 'wet ink' or obtained using a verifiable e-signature platform e.g. Adobe Sign. Where this is not possible electronic/typed signatures will be accepted. We recommend that the Health Research Authority's [\(HRA\) Research CV template](#) is used and the CV should not contain personal information e.g. home address, date of birth, email and telephone number. Expired CVs and training records must be retained and marked as superseded to demonstrate that study personnel were appropriately qualified and trained throughout the duration of the study.

In addition to any training provided by the UoL, it is our policy to accept appropriate training evidence issued by the NIHR and companies registered as part of the Transcelerate Biopharma.Inc initiative. Training certificates from other external organisations will not be accepted. This is because it is not possible to review the content of external courses and there may be gaps in the training required by UoL.

3.0 Mandatory training requirements

Good Clinical Practice (GCP) training underpins the principles of Good Clinical Practice to be followed for all research studies to ensure:

- the rights and well-being of study participants
- that study results are valid and reproducible

To ensure implementation of the International Conference for Harmonisation in Good Clinical Practice (ICH GCP) Guidelines and the relevant legislation, UoL as Sponsor require study personnel to undertake ICH GCP training every three (3) years. Date of training and/or expiration must be on the certificate.

Proportionate GCP training will be considered on a case-by-case basis for Type A studies authorised under the MHRA Notification Scheme.

With effect from 1st October 2019 there is no longer a requirement for individuals that are new to research to attend a face-to-face training session. Either the NIHR online training course or the NIHR face to face sessions will be adequate. The only exception to this is if there have been findings at an audit or monitoring visit that indicate that the team would benefit from additional GCP training. In these cases, face to face training will be mandated.

Individuals must register with the NIHR in order to obtain access to the training. To create an account, follow the instructions on the [NIHR website](#). Once registered individuals will have access to GCP training and a range of other learning and development opportunities such as feasibility, site file management, Schedule of Events Cost Attribution Template (SoECAT) surgeries as well as local face to face workshops, training in various health research innovations and access to [DeLVE](#), the NIHR's new Dedicated Learning Virtual Environment.

Further information about all the learning and development opportunities provided by the NIHR can be found on their [Workforce Development site](#).

4.0 Human Tissue Act/Laboratory Based Training

It is now mandatory for personnel involved in a study using human samples of any kind to undertake the HRA's training on 'Research Involving Human Tissue', even where an individual is not actively involved in the processing of samples. Please note this also includes the CI/PI of a study. This e-learning module provides an overview of human tissue legislation in the UK, best practice and practical tips for compliance. Please note, in the case of UoL Sponsored multi-site studies, this is mandatory for all partaking research sites.

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. Where monitoring or audit findings indicate training gaps, the Sponsor reserves the right to mandate this training.

4.1 Process for Research Tissue Banks and Biobanks

A Research Tissue Bank (RTB) or Biobank is a collection of human tissue or other biological material, which is stored for potential research beyond the life of a specific project with ethical approval or for which ethical approval is pending.

It is a requirement that all staff involved with an RTB **must** undertake the Research Tissue Bank-an introduction eLearning Module found on the [HRA website](#).

The module has been designed to help research and development staff, tissue bank managers, designated individuals and other staff to be aware of the structure of RTBs and the regulations and ethics behind them. Copies of any training certificates should be made available in the individuals personalised training records and a copy given to the RTB manager.

5.0 Consent Training

ICH-GCP confirms that the CI has overall responsibility for the consent process. Other personnel may be delegated the task of obtaining informed consent, however they must be suitably qualified and trained and authorised to do so by the CI or PI. This must be reflected in the Sponsor and ethics application, and have received favourable opinion.

Personnel who are not medically qualified who wish to obtain consent from research subjects must complete consent training. Please see SOP S-1021 UoL Informed Consent for Research. Those wishing to obtain consent must be employed by the NHS Trust or hold an

appropriate permission (e.g., letter of access or an honorary contract) as detailed in the Research Passport Policy. The CI/PI is responsible for ensuring that all personnel working on the study have the necessary and appropriate permissions throughout the duration of the study

Consent training is valid for three (3) years and initial training must be undertaken prior to performing this duty. All training for consent can be accessed through the NIHR via the links below. Individuals must register with the NIHR prior to accessing training (details provided above).

NIHR learn CRN East Midlands; <https://learn.nihr.ac.uk/course/view.php?id=91>

NIHR learn; <https://learn.nihr.ac.uk/mod/page/view.php?id=9555>

5.1 Process to be followed to obtain permission for Nurses, Non-Medics, & Allied Health Professionals receiving informed consent from subjects

5.1.1 Process for Clinical Trials of Investigational Medicinal Products (CTIMPs)

Written agreement for non-medics to obtain informed consent for CTIMPs must be obtained from the Sponsor, CI and PI before commencing the process.

The person obtaining consent must be aware of all the aspects of the study protocol, and have adequate clinical experience to enable them to answer questions from the subject.

Subjects in Phase 1 trials must not be consented by a Nurse, Non-Medic or Allied Health Professional.

5.1.2 Process for all studies

It is not necessary for individuals to be named at the application stage.

It is the CI's responsibility to ensure that personnel listed to obtain consent are adequately qualified and trained in the study protocol to enable a fully informed consent process to take place. Staff who join the study following approval must be added to the Delegation of Authority (DoA) and Signature Log and the relevant training certificates must be retained.

Where medics are listed as obtaining consent, it is expected that they are appropriately qualified by experience and training. It is not mandatory for medically qualified personnel to undertake additional consent training, but it is highly recommended. If examples are identified during the monitoring or audit process that the documentation of consent is not adequate, corrective action required will include **all** personnel attending a consent training session.

It is a mandatory requirement that any non-medic/allied health professional attends an appropriate Consent Training course. The UoL acknowledges the NIHR Consent Training course.

Evidence of appropriate consent training must be retained within the TMF/ISF.

6.0 Training in Standard Operating Procedures, Protocol and Study Specific Training

For research sponsored by UoL, personnel must demonstrate knowledge of UoL Standard Operating Procedures (SOPs) relevant to their role within the study team. Confirmation that individuals have read the relevant SOPs must be filed in the ISF/TMF. Personnel should use the Researcher Training and SOP Read Log to document SOP training unless specific research team reporting arrangements have been made in advance e.g. alternative electronic data capture (Q-Pulse). Details of required/suggested SOP reading lists for the CI/PI and personnel are listed within Appendix 2 (Researcher Training and SOP Read Log).

Research activities have the potential to generate unique training needs. Staff involved must be trained appropriately to carry out the requirements of the protocol in advance of the study commencing and/or undertaking their delegated duties.

The CI/PI should provide or arrange training in the following to enable study teams to follow the protocol and facilitate recruitment:

- Training in the most recent approved version of the protocol (including the re-training of personnel following amendments to the protocol, where necessary and appropriate)
- Training in the use of devices, particularly if they are novel or being used unconventionally
- Training in the pharmacological aspects of a study, with support from pharmacy especially where an Investigational Medicinal Product is being used

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

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. In relation to the later, 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.

7.0 Trial Master File/Site File Training

Personnel who have not undertaken research as a CI previously or who have not been responsible for the creation and maintenance of a TMF/ISF may benefit from a session focusing specifically on the management of the file. Training can be requested at any time during the study, but may be most beneficial if completed during the initial Sponsor review or early stages of the study. While this training is not mandatory, where TMF/ISF management is identified as a finding following an audit or monitoring visit, training will be mandated. Online 'Site File Management' training is also available from the NIHR CRN East Midlands training pages using the following link; <https://learn.nihr.ac.uk/course/index.php?categoryid=11>

8.0 Chief Investigator Training

It is important that the CI understands the responsibilities and Sponsor expectations. During the Sponsor application process the experience of the CI will be taken into consideration. The risk profile of the study will determine whether or not individual training will be required and an assessment will be made by the individual undertaking the Sponsor review.

Where a Risk Assessment has been indicated, there is a requirement that the Sponsor representative and the CI meet face-to-face. The risks and mitigations will be discussed as well as the specific role and responsibilities of the CI. This is often deemed adequate and it is where gaps in knowledge or experience are highlighted and relevant support offered.

CIs of studies where a Risk Assessment is not required may wish to meet with the Sponsor representative as part of the Sponsor review. Where this is requested or advisable, the Sponsor representative will talk through the specific roles and responsibilities and the expectations of the CI.

9.0 Exceptions to GCP and Consent Training Requirements

UoL as a Sponsor recommend that all personnel complete training that is proportionate and relevant to their roles regardless of the type of study or research activities being conducted. However, the following types of research activity may be exempt from GCP and/or Consent training - a discussion with the Sponsor will determine the requirements on a case-by-case basis.

- Personnel providing information for a study for a Participant Identification Centre (PIC)
- Studies involving the use of surveys only or the use of anonymous data

It is expected that protocol training and SOPs read logs are still completed in addition to all mandatory training as required by the UoL/participating organisation (i.e., Data Protection Training).

10.0 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.

11.0 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
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

12.0 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 	19/01/2024

13.0 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 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.

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
			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