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JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

University of Leicester (UoL) Research Governance Office
SOP S-1020 UoL

Version 4.0, September 2021

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

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Effective Date: October 2021

1 INTRODUCTION

This Standard Operating Procedure (SOP) describes the qualification and minimum training requirements for personnel involved in research sponsored by the University of Leicester (UoL) for single and multi-centre studies. Personnel must be appropriately qualified by training, experience and education, to discharge their responsibilities competently, and be trained in the study protocol. 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.

To ensure implementation of the International Conference for Harmonisation in Good Clinical Practice Guidelines (ICH GCP) and the relevant legislation, UoL as Sponsor require researchers to undertake ICH GCP training every three (3) years.

Good Clinical Practice 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 & reproducible

Proportionate GCP training will be considered on a case by case basis for Type A studies authorised under the MHRA Notification Scheme. Sponsor confirmation on which delegated tasks where proportionate training is accepted will be required.

A current signed and dated Curriculum Vitae (CV) must be provided for all members of the research team to provide evidence of appropriate experience and education. The CV should be reviewed every three years and updated where appropriate and resigned and dated to confirm the date and ownership by the named individual. It is recommended that the HRA CV template is utilised as recommended by NRES.

The template can be accessed via the HRA website link:

https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv

In addition, researchers who are not medically qualified, who intend to consent subjects for research are required to undertake consent training. Please refer to the SOP S -1021 UoL Informed Consent for Research.

2 SCOPE

This SOP applies to all researchers who are involved in research sponsored by UoL.

3 PROCEDURE

Evidence of relevant qualification, experience and research training must be provided for all applications submitted for Sponsor review. It is expected that at the initial Sponsor review stage, this evidence is provided for the Chief Investigator and where applicable, for students and all supervisors named on the application. It is the responsibility of the Chief Investigator to ensure that **ALL** study personnel are suitably qualified and experienced, and have received training that is appropriate to their role and study activities to be

undertaken prior to their performing any of these activities on the study. Evidence of qualification and experience in the format 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. Evidence of expired CV and training records must also be retained on file to demonstrate that members of the study team were appropriately qualified and trained throughout the whole period of the study. Originals should be retained by the individual.

In addition to any training provided by the UoL, it is our policy to accept appropriate training evidence issued by UHL, 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.

4 MANDATORY TRAINING REQUIREMENTS

GCP training is available as either a classroom session or on-line. 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.

All training for GCP can be accessed through the NIHR. Individuals must register with the NIHR prior to accessing training. To create an account follow the instructions on this site https://hub.crncc.nihr.ac.uk/register

Typically, training is valid for 3 years, date of training and/or expiration must be on the certificate.

5 HUMAN TISSUE ACT TRAINING

Researchers who are collecting tissue or samples for the purposes of research are strongly encouraged to undertake training provided by the MRC. This e-learning module provides an overview of human tissue legislation in the UK, best practice and practical tips for compliance. This module was developed by the MRC Regulatory Support Centre in consultation with the Human Tissue Authority, National Research Ethics Service, Scottish Government and others.

To access the training you should register and log in using the following hyperlink:

http://byglearning.co.uk/mrcrsc-lms/login/index.php

While this training is not mandated, where monitoring or audit findings indicate training gaps, the Sponsor reserves the right to mandate

The NIHR East Midlands CRN also provide a Laboratory Based research training course. Researchers are strongly encouraged to undertake this training. While this training is not mandated, where monitoring or audit findings indicate training gaps, the Sponsor reserves the right to mandate.

6 CONSENT TRAINING

ICH-GCP confirms that the Chief Investigator (CI) has overall responsibility for the consent process. However other suitably qualified and trained professionals can receive informed

consent for the research study, provided that the Sponsor and CI / PI agree and that this is reflected in an ethics application and has received a favourable opinion.

All personnel who are not medically qualified who wish to receive consent from subjects for research must complete consent training, please see SOP S-1021 UoL Informed Consent for Research. Exceptions to this include researchers undertaking focus groups, self-completion questionnaires where written consent is not required, surveys or use of anonymous data / tissue studies.

Those wishing to receive consent must be employed by the NHS Trust or hold an appropriate permission as detailed in the Research Passport Policy. It will be important to confirm that appropriate permissions are in place when confirming appropriateness of staff receiving consent in multi-centre studies.

7 TRAINING IN STANDARD OPERATING PROCEDURES, PROTOCOL AND STUDY SPECIFIC TRAINING

For research sponsored by UoL, research staff must demonstrate knowledge of UoL Standard Operating Procedures relevant to their role within the study team. Confirmation that the relevant SOPs have been read by individual study team members must be filed in the Investigator Site File / Trial Master File using the SOP Read Log (See Appendix 3 to SOP S-1011).

Research activities have the potential to generate unique training needs. Staff involved must be trained appropriately to carry out the requirements of the protocol.

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 version of the protocol
- 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

Training must be documented as appropriate on the protocol training log (Appendix 1).

8 TRIAL MASTER FILE TRAINING

Individuals who have not undertaken research as a Chief Investigator previously or who have not been responsible for a Trial Master File may benefit from a session focusing specifically on the management of the file. Training can be requested during initial Sponsor review. While this training is not mandatory, where TMF management is identified as a finding following Monitoring or Audit the corrective action may mandate attendance.

9 CHIEF INVESTIGATOR TRAINING

It is important that the Chief Investigator understands the responsibilities and Sponsor expectations. During the Sponsor application process the experience of the Chief Investigator 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 Chief Investigator meet face-to-face. The risks and mitigations will be discussed as well as the specific role and responsibilities of the Chief Investigator. This is often deemed adequate and it is where gaps in knowledge or experience are highlighted and relevant support offered.

Chief Investigators 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 Chief Investigator.

10 EXCEPTIONS TO TRAINING REQUIREMENTS

Researcher Training (CTIMP or non-CTIMP) is recommended for all researchers however, the following types of research activity may be exempt - 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 focus groups, the use of surveys only or the use of anonymous data

11 NON-COMPLIANCE

Where it has been identified that study 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.

12 RESPONSIBILITIES

	Responsibility	Undertaken by	Activity
1.	CI/PI	CI/PI	Ensure all Investigators and staff working on the study are appropriate qualified and trained, and consent trained as appropriate and that this is reflected on the Delegation of Authority and Signature Log
2.	CI/PI	CI/PI	To keep copies of all CV/training records and certificates in the Investigator Site File/Trial Master File
3.	CI/PI	CI/PI	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
4.	CI/PI	CI/PI / Sponsor	To identify additional training needs of staff involved in research and seek relevant training
5.	Research Team Members	Research Team Members	Ensure that they carry out only those tasks for which they have been delegated and appropriately trained
6.	Sponsor	Research Governance Office	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

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

13 DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT

Author / Lead Officer:	Cat Taylor
Job Title:	Head of Research Assurance
Reviewed by:	UoL Research Management and Operations Group (RSMOG)
Approved by:	Professor Nigel Brunskill 
Date Approved	13/10/2021

REVIEW RECORD

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>.

DISTRIBUTION RECORD

Date	Name	Department	Received