1. Introduction

This Standard Operating Procedure (SOP) describes the qualification and minimum training requirements for personnel involved in research sponsored by the University Hospitals of Leicester NHS Trust (UHL). 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 compliance with relevant legislation, UHL as Sponsor require researchers to undertake relevant training proportionate to their individual role.

> 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 and who intend to consent subjects for research are required to undertake consent training. Please refer to the SOP S -1006 UHL Informed Consent for Research.

2. Scope

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

3. CV

The initial Sponsor review requires evidence of relevant qualification, experience and research training for the Chief Investigator. It is the responsibility of the Chief Investigator to ensure that **ALL** study personnel are suitable qualified and experienced and have received appropriate training and have provided evidence of that training before any study related activity is undertaken. Evidence of qualification and experience in the format of a current signed and dated curriculum vitae (CV) and the relevant training must be filed as appropriate in the Trial Master File (TMF). Evidence of expired CV and training records must also be retained to demonstrate that members of the study team were appropriately qualified and trained throughout the whole period of the study. Copies of original evidence is acceptable. Originals should be retained by the individual.

All CV's and relevant research training evidence must be uploaded to the EDGE database. Where the study team do not have the appropriate access, this task must be undertaken by the relevant administrator for the Speciality at UHL

In addition to training provided by the NIHR it is our policy to accept appropriate training evidence issued by the University of Leicester, 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 UHL.

4. Mandatory GCP / Refresher Training Requirements

GCP training is available as either a classroom/ virtual session or on-line. With effect from 1st October 2019 there is no longer a UHL 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/virtual 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.

UHL Training no longer provides GCP training. All training for GCP can be accessed through the NIHR. Individuals must register with the NIHR prior to accessing training.

In order to access the online or face to face training provided by the NIHR CRN you will need to create an NIHR Learn account. If you have an NHS, Trust, University or NIHR email address you will automatically be eligible to access NIHR Learn. To create an account follow the instructions on this site https://hub.crncc.nihr.ac.uk/register

Once you have an account you will have access to a whole range of other learning and development opportunities such as feasibility and site file management eLearning, local face to face workshops, training in various health research innovations and access to DeLVE, the NIHRs new Dedicated Learning Virtual Environment.

Further information about all the learning and development opportunities provided by the NIHR CRN East Midlands can be found on their Workforce Development site https://crnemwfd.nihr.ac.uk/

The training is valid for THREE (3) years.

4.1 On a case by case basis a proportionate GCP or study specific training may be accepted.

5. 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 in accordance with guidelines detailed in SOP S-1006 UHL.

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.

5.1) Initial Consent Training

A classroom/ virtual session must be undertaken by researchers who have not previously undertaken consent training for research studies at UHL. The training is valid for 3 (three) years - details of refresher training is provided in 5.2

5.2) Refresher Training for Consent Training

The online course is only intended as a refresher for those who have previously attended a classroom/ virtual session. This training is valid for 3 (three) years

The requirement for consent training is that alternate face to face and refresher courses will be undertaken every 3 (three) years.

UHL Training no longer provides consent training. All training for consent can be accessed through the NIHR. Individuals must register with the NIHR prior to accessing training.

In order to access the online or face to face/ virtual training provided by the NIHR CRN you will need to create an NIHR Learn account. If you have an NHS, Trust, University or NIHR email address you will automatically be eligible to access NIHR Learn. To create an account follow the instructions on this site https://hub.crncc.nihr.ac.uk/register

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Further information about all the learning and development opportunities provided by the NIHR CRN East Midlands can be found on their Workforce Development site https://crnemwfd.nihr.ac.uk/

6. Human Tissue / Laboratory Based 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:

https://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 provides 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.

7. Training in Standard Operating Procedures / Protocol and Study Specific Training

For research sponsored by UHL, research staff must demonstrate knowledge of UHL 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 (Appendix 1) Details of the relevant SOPs to be read by the CI/PI and research team are listed on Appendix 3 (CTIMP generic SOP list) and Appendix 4 (Non-CTIMP generic SOP list)

It is expected that the Sponsor 'Read Log' will be used unless specific research team reporting arrangements have been made in advance e.g. alternative electronic data capture (QPulse).

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

The training must be documented as appropriate in the Protocol Training Log (Appendix 2 SOP S-1021).

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. The training will be offered during initial Sponsor review and is provided on a quarterly basis by the UHL Monitor. 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 & mitigation are 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 Sponsor. An infographic / slide show is being designed to assist with this process.

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 Head of Research Operations 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

11. Multi-Centre Studies

For GCP and consent training, training provided by the NIHR, and companies registered as part of the Transcelerate Biopharma.Inc initiative certificate will be accepted.

It is the responsibility of the Chief Investigator to ensure that all relevant training has been made available to all sites in advance of the study commencing and that evidence of training is filed in the Site File appropriately.

12. 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 UHL may be implemented at a minimum of 'other' finding.

13. Responsibilities

	Responsibility	Undertaken by	Activity
1.	Chief Investigator	Chief Investigator	Ensure all Investigators and staff working on the study are appropriately qualified and trained and consent assessed as appropriate & that this is reflected on the Delegation of Authority and Signature Log
2.	Chief Investigator	Chief Investigator	To keep copies of all CV/training records and certificates in the relevant Investigator Site File / Trial Master File
3.	Chief Investigator	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.	Chief Investigator	Chief Investigator / Sponsor	To identify additional training needs of staff involved in research and seek relevant training
5.	Chief Investigator	Chief Investigator	Ensure that the research team are asked to carry out only those tasks for which they have been delegated and appropriately trained
6.	Sponsor	Sponsor	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. Legal Liability Statement

Guidelines or Procedures issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines or Procedures and always only providing that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional it is fully appropriate and justifiable – such a decision to be fully recorded in the patient's notes and in the research site file.

15. Supporting Documents and Key References

SOP S-1008 Appendix 1, 2, 3 & 4

SOP S-1006

SOP S-1016

SOP S-1021

16. Key Words

Research, Innovation, Volunteers, Participants, CTIMPS, Trials, Qualification, Training, ICH GCP, TMF, QPulse,

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

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Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	R&I Governance Meeting	
Approved by:	Professor Nigel Brunskill DocuSigned by: Nigel Brunskill EB83FF9A871E447...	**Date Approved:** 07-10-2021

REVIEW RECORD

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
April 2015	2	Carolyn Maloney	Changes to Logo & corporate identify. Removal of requirement for individuals to be approved by UHL R&I Office prior to commencing on the study.
June 2015	3	Carolyn Maloney	Changes to section 3 – acceptance of other certificates.
October 15	4	Carolyn Maloney	Version of SOP to correlate with Appendices
August 16	5	CM, LW, JJ	Consistency check. Changes from 2 years to 3 years for GCP certificates & bite sized training.
February 2017	6	Carolyn Maloney	Changes to Logo
March 2017	7	Carolyn Maloney	Clarification about access and frequency of consent training.
February 2019	8	Carolyn Maloney	Revision of SOP line listing appendix 3 and addition of generic SOP list for CTIMP and Non-CTIMP studies. Update of SOP to reflect changes to training provided, and frequency. Updated logo.
Mar 2021	11	CW/LW/JJ	Addition of qualification and experience requirements in the format of a signed and dated CV. Update to reflect proportionate GCP for Type A studies under the MHRA notification Scheme, Reformatting to new template
Sept 2021	12	LW/JJ	Update of CV renewal date from 2 years to 3 years in line with Training requirements. Revision to inform with regards to training providers.

DISTRIBUTION RECORD:

Date	Name	Dept.	Received