1. Introduction

This Standard Operating Procedure (SOP) describes the minimum qualification and training requirements for personnel involved in research HOSTED by the University Hospitals of Leicester NHS Trust (UHL) or where the UHL is a SITE.

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 the Medicines for Human Use (Clinical Trials) Regulations 2004 and Policy Framework for Health & Social Care, UHL as a HOST Organisation / SITE require researchers who are involved in Clinical Trials of Medicinal Products to undertake ICH GCP training every three (3) years. Previous SOPs, prior to April 2016 the requirement was every two (2) 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 demonstrate evidence of appropriate, qualification, experience and education. The CV should be reviewed every two years and updated where appropriate and re-signed 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 HOSTED by UHL or where the UHL is a SITE.

3. Procedure

Evidence of relevant qualification, experience and training must be provided for all personnel listed on the Delegation of Authority log held within the Investigator Site File. It is the Principal Investigator responsibility to ensure that all staff provide a current signed and dated CV and receive relevant training before commencing work on a study. Copies of superseded / expired qualification/training evidence 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.

The CV should be reviewed every two 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/

It is UHL policy to accept training evidence that have been accepted by the Study Sponsor.

All qualification (CV) and 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.

4. Mandatory GCP / Researcher Training Requirements

4.1 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.

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.

5. Consent Training

ICH-GCP confirms that the PI 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 A classroom 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

This training can be accessed as either the UHL HELM online course or via the face to face training provided by UHL. The training is valid for 3 (three) years. The online course is only intended as a refresher for those who have previously attended a classroom session.

Both the face to face training and online course provided by the UHL Team can be booked through the UHL HELM system.

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

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 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.

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

For research hosted 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 ISF using the SOP Read Log (Appendix 1) unless a suitable document is provided by the

Sponsor. UHL Hosted SOPs should be added to the Sponsor Log. It is expected that a '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 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. If a Sponsor Training Log is not available, Appendix 3 may be utilised.

8. Investigator Site File Training

Individuals who have not undertaken research as a PI previously or who have not been responsible for an Investigator Site File may benefit from a session focusing specifically on the management of the file. The training is run on a quarterly basis through the UHL Training Team. While this training is not mandatory, where ISF management is identified as a finding following Monitoring or Audit the corrective action may mandate attendance.

9. Principle Investigator Training

It is important that the Principal Investigator understands the role and individual responsibilities. PI Training is available through the CRN East Midlands While it is not mandatory, it is recommended that PIs with no previous experience attend. Where monitoring or audit findings indicate lack of PI oversight it is likely that corrective action will include a mandate to attend.

10. Exceptions to Training Requirements

Training in the principles of GCP 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. 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 C-2013 UHL may be implemented at a minimum of 'other' finding.

12. Responsibilities

	Responsibility	Undertaken by	Activity
1.	PI	PI/Study Team	Ensure all Investigators and staff working on the study are GCP trained and consent assessed as appropriate & that all relevant training records are kept on file & uploaded to EDGE
2.	PI	PI/Study Team/R&I	To identify additional training needs of staff involved in research and seek relevant training
3.	Research Team Members	Research Team Members	Ensure that they carry out only those tasks for which they have been delegated and appropriately trained
4.	Research Team Members	Research Team Members / R&I	Ensure that all training records are uploaded to EDGE

13. 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.

14. Supporting Documents and Key References

SOP S-1006

SOP C-2013

15. Key Words

Research, Innovation, SUSAR, SAE, Studies, Trials, EDGE, MHRA, Qualifications, Training, ICH GCP, CV, HELM, 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

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	R&I Governance Meeting	
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REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
June 2016	2	CM, LW, AG, SA	Changes to GCP requirements.
February 2017	3	CM	Update to logo
March 2017	4	CM	Clarification about Consent training renewal
Sept 2019	5	CM	Removal of mandated requirement for face-to-face GCP. Removal of information about UHL Training team offering GCP. Removal of information about UoL Training offering GCP.
February 2021	7	CM,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

DISTRIBUTION RECORD:			
Date	**Name**	**Dept.**	**Received**