1. Introduction

The purpose of this standard operating procedure (SOP) is to define the level of competence required by members of the multidisciplinary team that are developing, delivering and supporting research across University Hospitals of Leicester NHS Trust (UHL). All research staff must be appropriately qualified through a combination of education, training, and experience to carry out their duties competently. This SOP describes how records of competence should be documented and stored, and these should be easily accessible and available on request. Any training should be appropriate and proportionate to the research role undertaken.

2. Scope

This SOP applies to all staff conducting research at UHL.

3. Procedure

3.1 CVs and general training requirements

All staff involved in research should be trained appropriately for their role and this should be documented in a way that demonstrates to external reviewers that training and experience is adequate.

For UHL sponsored trials, the initial sponsor review requires evidence of relevant qualification, experience and research training for the Chief Investigator (CI). It is the responsibility of the CI to ensure that all relevant study personnel are suitable qualified and experienced, providing evidence of this before any research activity is undertaken. Evidence of qualification and experience in the format of a current signed and dated CV along with any relevant training must be filed as appropriate in the Trial Master File (TMF) for key sponsor personnel and Principal Investigators (PIs) at each research site.

For all trials, evidence of relevant qualification, experience and training must be provided for all personnel listed on the Delegation Log held within the Investigator Site File (ISF). It is the Principal Investigator's (PI) responsibility to ensure that all local research staff provide a current signed and dated CV and receive appropriate training before commencing any research activity. Copies of superseded/expired qualification/training evidence must also be retained on file (ISF and/or TMF) to demonstrate that members of the study team were appropriately qualified and trained throughout the whole period of the study.

CVs should be reviewed every 3 years and updated where appropriate (re-signed and dated to confirm the date and ownership by the named individual). It is recommended that the Health Research Authority (HRA) CV template is utilised.

3.2 Good Clinical Practice training (GCP)

The requirement for GCP training is proportionate and pragmatic at UHL.

GCP training is valid for 3 years. It is mandatory for all Clinical Trials of Investigational Medicinal Products (CTIMPs), Clinical Investigations of Medical Devices and interventional trials. However for CTIMPs that are not to be included as part of a marketing authorisation application and some interventional trials, an exemption for GCP training can be agreed and documented from the sponsor where it is practical to do so. Researchers where their involvement in the trial is minimal and entirely within their professional expertise are not expected to completed GCP training.

3.3 Consent training

For members of the research team who have not undertaken any form of clinical consent training and are consenting for an interventional trial, it is mandatory that the NIHR consent training is undertaken.

3.4 SOPs, Protocol and Study Specific training

Every research project is different with a range of individuals involved. Training and levels of skills can therefore also vary and can be generic or study specific. Staff involved must be trained appropriately to carry out the requirements of their role in accordance with the protocol.

Trial specific training should be provided by the CI/PI or delegated personnel. This training should be documented, available on inspection by the sponsor or regulatory authorities.

Research staff must also evidence knowledge of all SOPs relevant to their role. This training should be documented, available on inspection by the sponsor or regulatory authorities.

The training log template (T-1036) can be utilised for documenting training.

3.5 Human Tissue Training

This is not mandatory but NIHR provides training for researchers that are conducting a study that involves human tissue.

4. Supporting Documents and Key References

T-1036 - Training log template

5. Key Words

Research, Innovation, Training, Consent, GCP, CI, PI, FLORENCE

6. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Training requirements and staff folders	Random selection for audit	Carolyn Maloney	As and when	A report will be produced

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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:	Joana Louro/Jen Boston	**Job Title:** R&I Quality Assurance Manager/R&I Deputy Director of Operations
Reviewed by:	R&I Governance Meeting	
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REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
May 2025	1	JB/JL	Replaces S-1018 and C-2011
March 2026	1.1	JB/JL	Section 3.3 – replacement of 'recommended' with 'mandatory'

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