Technology, Infrastructure and Environment Directorate Clinical Research Governance Team

Standard Operating Procedure

Requirements for Training for University Sponsored Research

SOP012

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1. Introduction

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 state that all staff involved in the setup, management and conduct of Clinical Trials of Investigational Medicinal Products (CTIMPs) must be qualified by education, training, and experience to perform their respective tasks.

The UK Policy Framework for Health and Social Care Research also states that the Chief Investigator (CI) is responsible for ensuring each member of the research team, including those at recruiting sites is qualified by education, training and experience to discharge their role in the study and their qualifications are documented. CI's are also responsible for ensuring all new members of staff and students have adequate supervision, support and training.

The University of Liverpool (University), in collaboration with the Liverpool Health Partners (LHP) member NHS Trusts, have utilised the NIHR Delegation and Training Decision Aid[1] and the Joint Statement on the Application of Good Clinical Practice to Training for Researchers[2] in assessing the requirements for GCP and other research related training. Together these 2 documents encourage proportionate risk-based training for researchers whatever the type of research study.

2. Scope of Procedure

This SOP outlines the requirements for training for members of staff involved in the set-up, conduct and management of clinical research.

3. Who

This SOP applies to all members of staff involved in the set-up, conduct and management of clinical research. This includes, but is not limited to, the CI, Co-Investigators, the trial coordinator, research assistants, data managers and members of Professional Services staff.

4. When

This SOP should be referred to at the initial set up stages of any clinical research, and throughout the research life cycle to ensure training is undertaken and updated appropriately.

5. GCP Training

All staff members involved in CTIMPs and interventional trials not classed as CTIMPs (such as clinical investigations of medical devices and surgical trials) must ensure that they have undergone Good Clinical Practice (GCP) training before the trial opens to recruitment. The University, as Sponsor, recommends that this is undertaken as soon as possible to ensure the setup of the CTIMP is undertaken appropriately. Evidence of GCP training for the CI will be requested as part of the Sponsor

[1] https://drive.google.com/file/d/1n1stjqIfqK1OcD063enBMp3omjaO-tHI/view
[2] https://www.hra.nhs.uk/about-us/news-updates/updated-guidance-good-clinical-practice-gcp-training/

Permission to Proceed Process and recruitment cannot begin until this is provided. Please see SOP004[3] for further details of this process.

We recommend that the NIHR GCP training course is undertaken; however, we may accept other training courses following review of the content. GCP training can be tailored to meet the specific roles and responsibilities a person may be undertaking in a trial and for some members of research teams an awareness and understanding of GCP would suffice. This may be in cases where the trial related activity does not deviate from the person's daily work tasks. We request that any deviations from the requirement to undergo full GCP training are submitted to the Sponsor.

For new researchers and anyone who has not undertaken any form of GCP training, and for who, GCP training is required, the Introduction to Good Clinical Practice (GCP) eLearning course must be undertaken. This is also the case for those who have not undergone any GCP training in the past 3 years.

GCP training must be updated on a three-yearly basis throughout the life of the trial, or more regularly if there has been a change to regulations, or if it is requested by the Sponsor. Updates can be undertaken via the E-Learning package provided by the NIHR.

GCP training is not a standard requirement for other study types, however the Sponsor may request that research teams undertake GCP training if deemed appropriate.

The NIHR offer the below courses and information related to GCP[4];

- Introduction To Good Clinical Practice (GCP) eLearning
- Good Clinical Practice Refresher (GCP) eLearning
- Investigational Medicinal Product (IMP) Management: GCP E6(R3)
- GCP Glossary
- GCP Supporting Templates

6. Other Training

All staff working on Clinical research should ensure they are adequately trained and experienced to undertake their role.

University members of staff are advised to access the courses provided by Epigeum before undertaking their research. It is noted here that training for a research related role does not have to be undertaken as a formal training course or specific research training but may be from non-research specific training courses, professional development courses, qualifications, competencies and experience, undertaking shadowing or mentorship, attending conferences, reading SOPs and participating in workshops. It is a condition of applying to the University of Liverpool Ethics Committee that the Epigeum training is completed.

[3] **SOP004** Sponsorship Application and Approval Processes
[4] https://www.nihr.ac.uk/health-and-care-professionals/training/courses-and-support.htm

The NIHR also provide courses in the below areas;

- Delegation Of Duties In Research
- Research Practice for Laboratory Professionals
- Fundamentals of Clinical Research For IMP Management
- Research Practice In Clinical Settings
- Research Practice in Health, Care and Community Settings
- An Introduction to Decentralised Trials

Researchers should ensure they have training in the following areas;

6.1 Informed consent

All research staff who will be involved in approaching participants and gaining informed consent from participants must ensure they are aware of the process of obtaining consent. The below courses can be taken via the NIHR[5];

- Informed Consent With Different Communities
- Informed Consent course (locally delivered)
- Informed Consent With Children
- Informed Consent: Including Adults Lacking Capacity
- Informed Consent with Remote Considerations
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6.2 Data protection and confidentiality

Researchers must ensure they conduct their research in accordance with the Data Protection Act 2018 and UK General Data Protection Regulation (UK GDPR) and ensure their participant's confidentiality is protected. MRC offer an E-Learning Package titled "Research, GDPR and confidentiality – what you really need to know".

Employees of the University must also complete the mandatory GDPR & Information Security Essentials course. This should be refreshed every 3 years in line with University requirements.

6.3 Human Material

If research will involve collection or use of Human Material, it must be conducted in line with the Human Tissue Act 2004 and research ethics requirements. The University requires all members of staff and postgraduate students who intend to collect, store, use and/or dispose of human material on University of Liverpool premises to complete the online human material training as soon as reasonably possible before beginning activities involving human material. More information can be found on the Human Material Governance intranet page.

In line with GCP retraining requirements, human material training shall be repeated every 3 years.

[5] https://www.nihr.ac.uk/health-and-care-professionals/training/

6.4 Further Research Training

The HRA[6] and NIHR[7] also provide extensive courses for Researchers and their teams. Researchers are encouraged to explore the courses on offer and undertake training as it applies to their research.

6.5 University Training

The University does not currently operate a formal annual research training programme however courses relating to University Sponsorship, the Human Tissue Act or University Ethics are run on an ad hoc basis and training sessions can be requested by members of staff, departments and research teams. University Mandatory training must be maintained as per University requirements.

7. Training files and recording of training

Researchers and their teams are encouraged to maintain a training log (TEM019) and folder of training certificates to produce at the time of audit or inspection.

The training file should contain a CV that includes details of the level of training and experience held which enables them to carry out their role. Upon review the Sponsor may request that extra training is undertaken. The HRA provide a template CV which is recommended for use.

It is expected that training files will contain an accurate job description for the role they are undertaking for clinical research. It is acknowledged that study related roles can are often classed as temporary roles in line with the funding provision and contracts are extended, but the job description is not. Providing the job description matches the role, it is acceptable for the job description to be out of date with regards to the tenure period.

8. Roles and Responsibilities

All members of staff are responsible for ensuring their training is up to date and appropriate for their role. They are also responsible for keeping their CV and training log updated ready for provision at audit or inspection.

CI

The CI is responsible for ensuring that ensuring each member of the research team is qualified by education, training and experience to discharge his/her role in the study and their qualifications are documented.

The CI is responsible for ensuring that all members of their study team have read relevant Sponsor SOPs before undertaking their role on the study.

Sponsor

The Sponsor will review the CI's CV and training evidence and assess if further training is needed.

[6] https://www.hra.nhs.uk/planning-and-improving-research/learning/
[7] https://learn.nihr.ac.uk/local/swordfish_pages/index.php?id=3

The Sponsor will be responsible for providing specific training sessions upon request.

9. Abbreviations

CTIMP	Clinical Trials of Investigational Medicinal Product
CI	Chief Investigator
GCP	Good Clinical Practice
University	University of Liverpool

10. Associated Documents and References

SOP004 - Sponsorship Application and Approval Processes

TEM019 – Template training log

UK Policy Framework for Health and Social Care Research

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

Data Protection Act 2018

UK General Data Protection Regulation (UK GDPR)

HRA / MHRA Joint Statement on the Application of Good Clinical Practice to Training for Researchers

NIHR Delegation and Training Decision Aid

NIHR Learn

11. Training and Resources

Specific training is not required for this SOP.

12. Monitoring and Audit

An internal audit of Clinical Directorate SOPs will be conducted at a minimum of every two years.