SOP 002 Good Clinical Practice (GCP) Training

For Use in:	Research & Development
By:	All staff
For:	All staff involved in the conduct of research
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SOP 002 Good Clinical Practice (GCP) Training.

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website.

Copies printed from the website are only valid on the day of printing.

1. Contents

2. Definitions of Terms Used / Glossary

CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HRA	Health Research Authority
MHRA	Medicines and Healthcare Products Regulatory Agency
NIHR	National Institute of Health Research
R&D	Research and Development
SOP	Standard Operating Procedure
SOV	Sponsor Oversight Visit

3. Introduction

GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.

The Joint Statement from the MHRA/HRA on the Application of GCP to Training for Researchers advocates a proportionate approach to the application of GCP training.

Different types of research may require different training, and some researchers are already well trained and competent in their area of expertise.

Researchers can sometimes be required, inappropriately and often disproportionately, to undertake GCP training when they do not conduct research in the field of clinical trials of investigational medicinal products (CTIMPs)/Devices or where their involvement in the trial is minimal and entirely within their professional expertise.

4. Scope

This SOP describes the process, and expectations for researchers and staff involved in delivering different types of research. It is applicable to all research studies sponsored and hosted by NNUH and those studies sponsored by the UEA that are covered by the UK Policy Framework for Health and Social Care Research.

5. Rules

The frequency of GCP training is not defined in the regulations, however it is the responsibility of an organisation to demonstrate that staff are trained appropriately to ensure the general principles of GCP are adhered to

- At NNUH evidence of GCP training will be required at the initial stage of the project and prior to commencement (see Appendix 1 for quick reference guide)
- It must be demonstrated that GCP training is repeated to cover the duration of the research being undertaken.
- Following full, initial training a refresher training will be required:
  - every 3 years, or when:
  - there is a significant change to legislation
  - new policies or practice have been implemented
  - different research activities are to be undertaken

Staff involved in the conduct of a study need to be appropriately trained but the training does not need to follow a generic syllabus, or format. It should be appropriate and proportionate to the activities undertaken by staff involved in the study

- Two types of training will be accepted for NNUH sponsored and hosted studies:
  - GCP training (class room based or online) delivered by external provider
  - R&D Practical GCP training
- The required type of training will vary depending on the study type (please see section 5 for details).

It is important that research is always conducted in a manner that provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data is reliable. Members of the research team in such studies are expected to be qualified by education, training or experience and have an understanding in the principles of GCP.

- It is vital the staff members who are conducting research studies have a good knowledge of the protocol requirements for the specific work they are conducting. Any additional training relevant to the study may be required for this staff group, in particular when the research protocol requires further actions above standard practice (e.g. requirements to maintain samples which would normally be disposed of after analysis). It is the responsibility of the CI/PI to deliver protocol training.

Study specific training should be documented within the study site file to demonstrate that staff have a good understanding of the study requirements as well as GCP training.

- For GCP training delivered by an external provider a copy of the certificate must be filed in the study Trial Mater File / Investigator Site File
- For GCP training delivered by R&D a copy of the training slides and a training log must be filed in the study Trial Master File/Investigator Site File)
- Please refer to SOP 305 Creating and Maintaining the Trial Master File or Investigators Site File for information.
- A copy of a GCP certificate as well as evidence of other study specific training, SOP training matrix, CV, Job Description must be filed in Personal Training Files.
- It is the responsibility of the CI/PI to ensure that staff undertake relevant training, proprtionate to their role and have a proportionate experience and qualifications for the tasks they are performing.
- It is the responsibility of individual members of staff to ensure that relevant training as well as their personal training record is in date and complete.

6. GCP training requirements for different types of studies

a. **Clinical Trials of Investigational Medicinal Products (CTIMPs) and Medical Device Trials** (both sponsored and hosted by NNUH)

For CTIMPS and Medical Device Trials the following must have undertaken GCP training delivered by external provider

- CI/PI
- All members of staff who are named on the delegation log

This is not limited to NIHR GCP training, certificates from other external providers will be accepted.

Where a member of the research team is performing study tasks that they routinely and frequently undertake as part of standard clinical practice and they are not on the delegation log, they can opt to undertake the R&D GCP training but this is not mandatory.

If a study team member's tasks change an assessment will need to be made by the CI as to whether additional or full GCP training is required.

b. For other types of research:

i. Other studies sponsored by NNUH

For other studies sponsored by NNUH the following must have undertaken GCP training; this can be delivered by a member of the R&D team at the Sponsor Oversight Visit:

- CI/PI

CI/PI must ensure **all** study staff undertake relevant training and have appropriate experience and qualifications for the tasks they are performing. Ideally all members of staff should be present during the SOV, when GCP training is delivered.

Where a member of the research team is performing study tasks that they routinely and frequently undertake as part of standard clinical practice, they can opt to undertake the R&D GCP training.

If the study team member's tasks change an assessment will need to be made by the CI as to whether GCP training is required.

ii. Other studies hosted by NNUH

For externally sponsored non-regulated studies GCP training requirement will be a sponsor decision.

7. Studies Sponsored by UEA.

The study CI/PI must undertake GCP training relevant to the project which will be delivered. The CI/PI must ensure **all** study staff undertake relevant training and have appropriate experience and qualifications for the tasks they are performing.

8. Studies delegated to NCTU.

All NCTU staff working on clinical trials are required to undertake GCP training within three months of starting work at the NCTU. GCP training may be undertaken as a two-hour course provided by a local provider (e.g. Norfolk and Norwich University Hospital (NNUH)) or as an online course. New staff whose GCP training was provided by an NHS trust, HEI institution or accredited CTU, and is documented, will be exempt from the requirement to complete GCP training within three months, but should attend the next available NCTU course. The GCP certificate should be filed in an electronic format by the individual as directed by the NCTU.

9. How to book a course

NIHR GCP courses (online and face to face) can be booked via the NIHR learning platform https://learn.nihr.ac.uk/

For R&D GCP training liaise with the Research Study Officer responsible for the project. Alternatively email rdoffice@nnuh.nhs.uk

10. Appendix 1 – GCP training requirements for studies Sponsored and hosted by NNUH - Quick reference guide

Study Type		CTIMPS or Medical Device Trials	Other studies	
Sponsor		Sponsored or hosted by NNUH	Sponsored by NNUH	Hosted by NNUH
Staff group	**CI / PI**	GCP training delivered by external provider (online or class based)	R&D GCP training.	For externally sponsored non-regulated studies GCP training requirement will be a sponsor decision.
	Staff named on delegation log	GCP training delivered by external provider (online or class based)	It is recommended that this staff group is present during Sponsor Oversight Visit when R&D GCP training is being delivered.	
	Staff conducting study activities that are typically part of routine clinical practice	Staff members can complete R&D GCP training; however, this is not a requirement. Additional training relevant to the study may be required for this staff group, when the research protocol requires further actions above standard practice. It is the responsibility of the CI/PI to deliver protocol training.	Staff members can complete R&D GCP training; however, this is not a requirement. Additional training relevant to the study may be required for this staff group, when the research protocol requires further actions above standard practice It is the responsibility of the CI/PI to deliver protocol training.	

Study Type	**CTIMPS or Medical Device Trials**	**Other studies**	
Sponsor	Sponsored or hosted by NNUH	Sponsored by NNUH	Hosted by NNUH

Frequency	• every 3 years for the duration of the study, or when:
	  • there is a significant change to legislation
	  • new policies or practice have been implemented
	  • different research activities are to be undertaken
	  •		

Training record	• For GCP training delivered by external provider a copy of the certificate must be filed in the study Trial Mater File / Investigator Site File • For GCP training delivered by R&D a copy of the training slides and a training log must be filed in the study Trial Master File/Investigator Site File. • A copy of a GCP certificate as well as evidence of other study specific training, SOP training matrix, CV, Job Description must be filed in Personal Training Files.		If GCP training is required by the sponsor evidence of training needs to be filed in the Investigator Site File and a copy of a GCP certificate as well as evidence of other study specific training, SOP training matrix, CV, Job Description must be filed in Personal Training Files.

9. References and Related Documents

References
ICH GCP E6 / SI 2004/1041
HRA website **Health Research Authority (hra.nhs.uk)**

SOP No.	SOP Title
SOP 001	Production, Review, Approval and Control of SOPs Related to Research Activities
SOP 305	Creating and Maintaining the Trial Master File or Investigators Site File

10. Approval

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11. Reason for new version and Training Implication

This SOP replaces the previous version number v.1.0

Changes made	Significant re-write
Reason	Review of SOP due to change in NNUH requirements for GCP training.
Training Implication	**Yes**
Actions required	• Additional training may be required • Matrix to be updated