University of Hertfordshire

RESEARCH STAFF TRAINING

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for Clinical Research Staff Training at the University of Hertfordshire Including Good Clinical Practice, SOP, Staff Induction Training and Maintenance of the Training File

SOP Number: gSOP-07-02	**Effective Date: 10/08/22**
Version Number: 2.0	**Review Date:** 3 years (or as required)

1. BACKGROUND

It provides guidance on the steps involved in recording, maintenance and storage of the training records of research staff to ensure compliance with Good Clinical Practice. Where there are potential conflicts between different collaborating organisations' SOPs, project level working instructions should be developed, to determine precedence.

2. PURPOSE

- To ensure all UH staff participating in clinical research are appropriately qualified and trained to meet research governance, regulatory and UH requirements and are able to produce evidence of such training.
- To ensure new clinical research staff members are appropriately inducted and are able to produce evidence of such training.
- To outline the responsibilities of all research staff in the maintenance of their own individual training files
- To outline the requirements for all research staff to complete Good Clinical Practice training.

3. APPLICABLE TO

This applies to all UH staff involved in clinical research, including but not limited to: Chief Investigators, Principal Investigators, Research Fellows, Consultants, Statisticians, Clinical Trial Pharmacists, Research Managers, Research Nurses, Clinical Trial Practitioners, Allied Health Professionals, Trial Coordinators, Clinical Studies Officers, Data Managers, Research Assistants and Students.

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4. RESPONSIBILITIES

Responsibilities of UH

UH shall support and promote high quality research. UH are responsible for providing appropriate individual learning and competence for all clinical research staff. Staff must ensure they have completed all mandatory training required by the employer(s) in order to fulfil this responsibility and must adhere to relevant policies and procedures.

Responsibilities of the Sponsor

The Sponsor shall ensure appropriate management and documentation of research (clinical trials) to meet ethical and regulatory requirements. The Sponsor should ensure that:
Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s). ***ICH GCP.***

Employers of staff undertaking health and social care research have a responsibility for developing and promoting a quality research culture in their organisations and for ensuring that their staff are supported in, and held to account for, the professional conduct of research. ***This will involve careful attention to training, career planning and development, and the use of clear codes of practice and systems for monitoring compliance, dealing with non-compliance or misconduct, and learning from errors and complaints.***

Responsibilities of the Chief Investigator/ Principal Investigator

The Sponsor/Co-sponsor is responsible for ensuring all staff members participating in clinical research are appropriately qualified and trained.

If UH is the Sponsor/Co-Sponsor, this duty has been delegated to the CI/PI responsible for the trial. The CI/PI is responsible for ensuring all research staff working on their research study have received appropriate protocol specific training and are competent to perform the roles delegated to them.

In addition, CI/ PI's are responsible for ensuring all staff members participating in each clinical trial have attended GCP training within the last 2-3 years (as described in section 5.2). The CI/PI must ensure that research staff without relevant training are not involved in obtaining consent for research activities in compliance with UH gSOP-04.

Responsibilities of Research Staff

All research staff members that are working on research projects must ensure that they have demonstrated their competency in the areas that their role requires. All research staff members are responsible for maintaining their own training files and provide evidence of such training when requested by UH, the Sponsor or the regulatory authorities.

5. PROCEDURE

5.1 Induction Research Training

It is the responsibility of each individual's line manager to implement formal training plans that

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have been tailored to the individual needs of the clinical trial personnel and their role. It is recommended the formal training plan covers key training requirements that is not only reviewed regularly by the individual but also their line manager to ensure training needs are being met.

Education/ SOP Training Programme
It is recommended all new research staff attend the SOP training programme. Topics during this induction programme include mandatory SOP training sessions. Please contact the CTSN.

5.2 GCP Training

Mandatory for: All employees/ any other staff (or staff likely to provide cover) involved in performing trial-related procedures in clinical trials sponsored/co-sponsored by UH or adopted by the CTSN. This also includes all staff in support departments within UH who are performing research specific investigations (outside of their usual role) for clinical studies.

Procedure

- Staff who require GCP training are those staff who have any input into the running of a clinical trial particularly if the involvement is in an area that could impact on participant safety.

- These staff must be listed on the trial delegation log which must include their roles, start date on the trial and be signed off by the PI for that site.

- If a member of clinical staff can also be identified from the Trial Master File or investigator site file, for example through a signature on an Essential Document, then that member of staff should have attended a GCP course in the last 2-3 years and also be listed on the trial delegation log.

- Accredited GCP training courses are provided online by the Clinical Research Network and face to face by local NHS Trusts. Accredited training sessions may be accessed by staff at other sites.

- All research staff are required to update their GCP training every 2-3 years by attending the half-day update training courses or by completing the online GCP course.

For certain types of study GCP training may not be necessary for all research team members. Research team members who undertake limited duties working to well defined instructions and Standard Operating Procedures may find locally delivered short courses and training aids more appropriate. For clarification please contact the CTSN.

Evidence of such training should be kept in each individuals' training records.

Audit of GCP training

- Original copies of GCP certificates should be maintained securely in the individual's training file or centrally within units and a copy held in the TMF or ISF per trial. If this is not practical, a file note should be written documenting the central location where all certificates are held. This applies to all certificates as they are updated; Out of date certificates should be kept and not destroyed. Access to individual training files may be requested by the CTSN, UH, the Sponsor or the regulatory authorities as part of an audit or routine GCP inspection.

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SOP Training (Training in written procedures)

- Prior to roll out of new SOPs, the CTSN will organise targeted SOP training sessions for all relevant research staff. Targeted training sessions may form part of research team meetings or will be organised as separate sessions. An attendance log will also be produced by the CTSN after each delivered SOP training session.

- In addition to the SOP training sessions, all staff must read and complete the "agreement signature page" at the back of each SOP. This signature page will be used to confirm each staff member has read and understood the contents and requirements of the SOP. It will also confirm acceptance to follow the procedures outlined in the SOP once implemented.

- Dependent on the individual's role, SOPs defined as mandatory as per the matrix of roles and responsibilities must be read and acknowledged within 3 months of CTSN start date (new starters) or SOP roll out date (current staff).

6.0 RELATED DOCUMENTS

- UK Policy Framework for Health and Social Care Research
- gSOP-01: SOP on SOPs
- gSOP-02: Adverse Event Reporting (Sponsored/Co-sponsored)
- gSOP-04: Informed Consent
- gSOP-06: TMF/Site File

7.0 APPENDICES

- Appendix 1- Definitions

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8.0 VERSION HISTORY

Version Number	Effective Date	Reason for Change
2.0	10th Aug 2022	Review of content

9.0 AUTHORSHIP & APPROVAL

Author

Signature  **Date 25/07/2022**

Pro Vice-Chancellor (Research & Enterprise) Approval
Professor J M Senior

Signature  **Date 08/08/2022**

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10. AGREEMENT (MOVE ON TO A SEPARATE SHEET BEFORE PRINTING)

Please detach and retain within <u>your training files</u>

I have read and understood the contents and requirements of this SOP (ref gSOP-07-02) and accept to follow University policies implementing it.

Recipient Signature: ……Date: …….. Name & Position: ……

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Appendix 1: Definitions

Chief Investigator (CI) - A Registered Physician, Dentist, Pharmacist or Registered Nurse who has overall responsibility for the conduct of the trial.

Clinical Trial - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health outcomes.

Good Clinical Practice (GCP) - as defined in the Regulations.

International Conference on Harmonisation (ICH) – Produced a series of guidelines in 1996, E6 being the guideline on Good Clinical Practice, otherwise known as (ICH-GCP).

Investigational Medicinal Products (IMP) - means a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial. This includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial -

(a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation,

(b) used for an indication not included in the summary of product characteristics under the authorisation for that product, or

(c) used to gain further information about the form of that product as authorised under the authorisation

Mandatory – training which must be completed by all employees and any other staff involved in clinical trials and is therefore compulsory.

Principal Investigator (PI) - A Registered Physician, Dentist, Pharmacist or Registered Nurse who has responsibility for the conduct of the trial at a host site.

The Medicines & Healthcare products Regulatory Agency (MHRA) - UK Competent Authority responsible for regulation of clinical trials.

The Regulations - Medicines for Human Use (Clinical Trial) Regulations 2004 transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031. This became effective on the 1st May 2004. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928.

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