University of Hertfordshire

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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-07-01	**Effective Date:** 26th April 2018
Version Number: 1.0	**Review Date:** 3 years (or as required)

1. BACKGROUND

This is a University of Hertfordshire standard operating procedure. UH acknowledges WHHT R&D which has allowed UH to use the SOPs developed by WHHT where possible, modified for local implementation.

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.

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 as per the matrix of roles and responsibilities in Appendix 3. All research staff members are responsible for maintaining their own training files (Appendix 2) 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 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 (Appendix 3; Training needs analysis).

Education/ SOP Training Programme
It is recommended all new research staff attend the education/ 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 **CTIMP** clinical trials sponsored/co-sponsored or hosted by UH. This also includes all staff in support departments within UH who are performing research specific investigations (outside of their usual role) for CTIMP studies.

Recommended for: All employees/ any other staff involved in performing trial-related procedures in **non-CTIMP** research studies sponsored/co-sponsored or hosted by UH.

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 clarification please contact the CTSN.

Evidence of such training should be kept in each individuals' training records (see Appendix 2).

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.

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 (Appendix 3) 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
- Appendix 2- Staff training log
- Appendix 3- Analysis of training needs

8.0 VERSION HISTORY

Version Number	Effective Date	Reason for Change

9.0 AUTHORSHIP & APPROVAL

Author

Signature **Date**

Pro-Vice Chancellor (Research & Enterprise) Approval

Signature **Date**

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

Please detach and retain within your training files

I have read and understood the contents and requirements of this SOP (ref gSOP-07-01) and accept to follow University policies implementing it.

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

Please retain copy of the signed form for your reference in your training file

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.

Appendix 2: Staff Training Log

Name: **Training period:**

Job title:

Title of Course/ Study Day	Date(s) from/to	Organised by	Key objectives	Qualification/ certificate achieved

Appendix 3: Training Needs Analysis

Training Needs Analysis for UH research staff

This document has been designed to assess the training needs of UH research staff and has been developed to meet the local needs and requirements of UH.

This training needs analysis can be used prior to and discussed during your yearly appraisal

Name	
Role	
Grade	
Employer	
Line Manager	

Training Needs Analysis

This is a self-assessment tool. Please read the question and then answer 'Yes, 'No' or 'Not Applicable'. There is space for you to write comments against each question and also at the end of each section.

	Legislation governing Clinical Trials and Research Studies	Yes	No	Comments
A1	I am aware of and have a good understanding of the Medicines for human use UK Clinical Trials Regulations 2004 (as amended).			
A2	I am aware of and have a good understanding of the Human Tissue Act 2004			
A3	I am aware of and have a good understanding of the UK Policy for Health and Social Care Research			
A4	I have a good understanding of Good Clinical Practice (ICH GCP).			
A5	I am aware of the Health Research Authority (HRA) and Research Ethics Committee (REC) and what they do			
A6	I am aware of the Medicines and Healthcare products Regulatory Agency (MHRA) and what it does			
A7	I am aware of the Confidentiality Advisory Group (CAG) and what it does			
A8	I am aware of the implications in relation to the Data Protection Act, 1998			
A9	I am aware of the implications in relation to the Mental Capacity Act 2005			
A10	I am aware of the implications in relation to the Medical Devices Regulations 2002 (as amended)			
A11	I am aware of the implications in relation to the Ionising Radiation (Medical Exposure) Regulations 2000			
	Would you like to make any other comments in relation to this section?			
	Administrative Arrangements			
B1	I have read and understood all mandatory SOPs for my research position and accept to follow by UH policies in implementing them			
B2	I am aware of the location of all electronic SOPs			
B3	I am aware of the location of all electronic research protocols			
B4	I have been given a copy of my Employing Job Description and I am aware of the content. I have a good understand of my role and line management arrangements			
B5	I have had my local UH induction (i.e. Risk Management, Data Protection / Confidentiality, Serious Untoward Incidents, Health and Safety, Fraud and Misconduct, Intellectual Property, Personnel (HR) Policies)			
B6	I am aware of and able to follow general office procedures - attendance, annual leave, documents version control, telephone, e-mail, photocopying			
B7	I have attended a GCP training session in the last 2-3 years			Date of last GCP training session:
	Would you like to make any other comments in relation to this section?			

	Research Governance Processes	Yes	No	Free text for comments
C1	I have a good understanding of the effective and efficient use of research Management and governance systems (e.g. IRAS, NIHR Hub)			
C2	I am able to identify and seek appropriate guidance on potential research misconduct issues.			
C3	I have a good understanding of local research activity.			
C4	I have a good understanding of Research costs, NHS Support costs and Treatment costs.			
C5	I apply skills and knowledge to promote good research management and governance practice with Investigators and Researchers.			
C6	I am able to manage Study financials issues.			
C7	I have a good understanding of research methodology.			
C8	I have a good understanding of NHS Trust R&D functions, which impact R&D.			
C9	I am able to use the Integrated Research Application System (IRAS) competently to complete HRA and REC authorisation			
C10	I am aware of the UH sponsorship policy			
C11	I have a good understanding of the process for gaining R&D confirmation for hosted and sponsored studies.			
C12	I have a good understanding of the process for gaining R&D confirmation for sponsored studies.			
C13	I have a good understanding of the process for submission of amendments for hosted studies.			
C14	I have a good understanding of the process for submission of amendment to R&D for sponsored studies.			
C15	I am aware of the processes for notifying the R&D office of a change in status for sponsored and hosted trials			
C16	I am aware of the timeframes for declaring the end of study to the relevant regulatory bodies for sponsored studies			
C17	I am aware of the procedures for the archiving of essential clinical trial documentation as specified in the UK Clinical Trial Regulations and the UK Policy Framework for Health and Social Care research			
	Would you like to make any other comments in relation to this section?			
	Safety Reporting Processes	**Yes**	**No**	**Free text for comments**
D1	I have a good understanding of AE, SAE and SUSAR reporting arrangements for sponsored clinical trials			
D2	I am aware of the timeframes for reporting SUSARs to the Investigator, Sponsor, CTSN, R&D department and the regulatory bodies.			
D3	I am aware of the SAE/ SUSAR recording and reporting requirements for hosted CTIMPs			
D4	I am able to define AEs, SAEs and SUSARs confidently.			
D5	I am aware of my responsibilities for assessment of seriousness, causality, severity and expectedness of safety events by the sponsor and investigator.			
D6	I am aware of Development Safety Update Report (DSUR) submission for UH sponsored/co-sponsored-CTIMPs.			
	Would you like to make any other comments in relation to this section?			
	Trial Master File/ Investigator Site File Responsibilities	**Yes**	**No**	**Free text for comments**
E1	I have a good understanding of the content of a Trial Master File and its maintenance.			
E2	I am aware of where I can find TMF templates electronically to help with the creation and maintenance of the TMF for UH sponsored/co-sponsored studies			
	Would you like to make any other comments in relation to this section?			

	Serious Breach Processes	Yes	No	Free text for comments
F1	I am aware of the timeframes for reporting serious breaches to the Investigator, Sponsor, CTSN, R&D office and regulatory bodies.			
F2	I have a good understanding of the definition of a serious breach			
F3	I have a good understanding of the reporting processes for serious breaches that occur in hosted trials			
F4	I have a good understanding of the reporting processes for serious breaches that occur in sponsored trials			
	Would you like to make any other comments in relation to this section?			
	Monitoring/ Audit	**Yes**	**No**	**Free text for comments**
G1	I am aware that the CTSN/R&D office may conduct regular audits based on risk assessment data			
G2	I am aware that the CTSN/R&D office may conduct monitoring visits based on risk assessment data			
G3	I am aware of my responsibilities in the management of source data to ensure correct and consistent recording of all Clinical Trial data			
	Would you like to make any other comments in relation to this section?			
	Clinical Trials Room	**Yes**	**No**	**Free text for comments**
H1	I am aware of my responsibilities for tracking all samples			
H2	I am aware of the requirements to report all fridge/ freezer alarms to the relevant personnel within the specified timeframes			
H3	I am confident in the use of all equipment in the research departments			
	Would you like to make any other comments in relation to this section?			
	Personal Development	**Yes**	**No**	**Free text for comments**
I1	I have been employed for more than 12 months and have had a UH Appraisal			
I2	I have been employed for more than 12 months and have a Personal Development Plan			
	Would you like to make any other comments in relation to this section?			

Additional Training needs/ requirements

Completed by: **Appraisee's Signature:_____** **Date:_____**
Reviewed by: **Reviewer's Signature:_____** **Date:_____**