

University of Hertfordshire

SOP ON SOPS

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for the production, review, approval, distribution and revision of research SOPs

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

1.0 BACKGROUND

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

This document defines the procedures for preparing, managing and reviewing SOPs that describe the standard activities used in research at UH. This document clarifies the requirements for written SOPs to provide quality assurance in Good Clinical Practice (GCP) ‘a standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected.’

Where there are potential conflicts between different collaborating organisations’ SOPs, project level working instructions should be developed, to determine precedence.

All core clinical trial activities need to be supported by appropriate SOPs. This document provides guidance on the preparation and review of departmental SOPs to comply with policies on document preparation and control.

Two categories of SOPs will be produced:

- High level, generic, overarching SOPs (gSOPs) which apply to all staff conducting clinical trials.
- Unit SOPs and project level working instructions which apply to staff conducting research within a particular clinical unit or involved in a particular research project

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2.0 PURPOSE

- This procedure applies to SOPs written for clinical trials taking place at UH and its' partner organisations.
- The purpose of this procedure is to provide clear instruction on how SOPs for clinical trial research should be produced so that they are prepared in a consistent manner.
- To outline the procedures for preparing, managing and reviewing SOPs that describe the standard activities used in clinical trial research at UH.
- To ensure that the procedure for the management of SOPs is formalised, for example for the process of updating and version control.

3.0 APPLICABLE TO

This applies to all staff involved in clinical research sponsored/co-sponsored by UH, including: Chief Investigators, Principal Investigators, Research Fellows, Consultants, Statisticians, Clinical Trial Pharmacists, Research Managers, Research Nurses, Clinical Trial Practitioners, Allied Health Professionals, Trial Managers, Clinical Studies Officers, Data Managers and Research Assistants.

4.0 RESPONSIBILITIES

- The Pro-Vice Chancellor (Research & Enterprise) has overall responsibility for research.
- All staff are responsible for ensuring research is conducted in accordance with the clinical trial regulations that they are familiar with and adhere to all current SOPs and have signed to confirm that these documents have been viewed/understood.

5.0 PROCEDURE

5.1 Format

5.1.1 gSOPs shall follow a standard format containing as a minimum the following sections:

- Background
- Purpose
- Applicable to
- Responsibilities
- Procedure

5.1.2 The UH gSOP template shall be used for all gSOPs (Appendix 2).

5.1.3 SOPs should provide information in a clear and concise manner on the purpose of the SOP and the procedure itself. Responsibilities should also be defined.

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5.2 Authorship and Approval

- 5.2.1 gSOPs shall be drafted by a member of the Clinical Trials Support Network (CTSN) Standard Operating Procedures Working Group (SOPWG) or the SOPWG may delegate to any person considered appropriate by the group.
- 5.2.2 Draft gSOPs shall be presented to the SOPWG for amendment or rejection as considered necessary. Final drafts of gSOPs shall be presented to the SOPWG for approval.
- 5.2.3 Following approval by the SOPWG, gSOPs shall be presented to the UH Advisory Group on Research Governance for Clinical studies for comment, approval and recommendation for ratification. On completion SOPs are to be submitted to the Pro-Vice Chancellor (Research & Enterprise) for ratification.
- 5.2.4 All other written instructions should be written by a competent and experienced member of the Departments/Research Team assigned to the specified responsibility by the Head of the Unit or the Chief or Principal Investigator.
- 5.2.5 The author of an SOP shall be suitably knowledgeable, qualified, and experienced.

5.3 Version Control

- 5.3.1 A document control system shall be used for gSOPs. Superseded SOPs will be appropriately archived in the University Document Management System by the CTSN.
- 5.3.2 Departments/Research Teams producing other written instructions should use a document control system and should be appropriately archived.
- 5.3.3 All SOPs should be reviewed every 2-3 years or following the publication of new legislation/regulations and updated as appropriate. The SOPWG will review gSOPs.
- 5.3.4 Each SOP should indicate whether it replaces another version with a consecutive version number and date.

5.4 Distribution

- 5.4.1 SOPs will be distributed to research staff through all relevant channels. The CTSN manager (or delegated staff member) will submit the scanned version of the ratified signed SOP for inclusion on the document management system and UH Research webpage.
- 5.4.2 Shortly after the approval of a new SOP, SOP training will be provided as gSOP-07-01 – Research Training.

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5.4.3 SOPs will be signed as read and understood by individuals and the SOP signature sheet will then be retained in the training file.

5.5 SOP/Policy non-compliance

5.5.1 Where a significant and/or persistent deviation from research SOPs/Policy is identified the Escalation Plan and, as necessary, the University competency/disciplinary process will be followed.

6.0 RELATED DOCUMENTS

- Standard Operating Procedures Working Group Terms of Reference
- Membership of Standard Operating Procedures Working Group
- Template for gSOPs (Appendix 2)
- gSOP-19: QMS
- gSOP-07: Research Training
- UH Research Framework Policy- Escalation plan

7. APPENDICES

- Appendix 1 – Definitions
- Appendix 2 – gSOP template

8. VERSION HISTORY

Revision Chronology:		
Version Number	Effective Date	Reason for Change

9. AUTHORSHIP & APPROVAL

Author

Signature

Date

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Pro-Vice Chancellor (Research & Enterprise) Approval

Signature

Date

10. AGREEMENT

Please detach and retain within your training files

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

<p>Recipient</p> <p>Signature: Date:</p> <p>Name & Position:</p>

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.

Continuing Professional Development (CPD) – A process of setting goals and objectives for development and the charting of progress made against them. Development can be achieved by collection of CPD points allocated to approved training events.

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.

Case Record Form (CRF) - a printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject”.

Elective – training which is optional, that is available to any employees and any other staff involved in clinical trials, but is not compulsory.

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 – SOP TEMPLATE

University of Hertfordshire

**<STANDARD OPERATING PROCEDURE (SOP):
INSERT TITLE HERE>**

Clinical Trials Support Network (CTSN)

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University of Hertfordshire Template for SOP design

SOP Number :	Effective Date:
Version Number:	Review Date: 3 years (or as required)

1. BACKGROUND

2. PURPOSE

3. APPLICABLE TO

4. RESPONSIBILITIES

5. PROCEDURE

6. RELATED DOCUMENTS

7. APPENDICES

8. VERSION HISTORY/REVISIONS

Version Number	Effective Date	Reason for Change

9. AUTHORSHIP & APPROVAL

Author

Signature

Date

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Pro-Vice Chancellor (Research & Enterprise) Approval

Signature

Date

10. AGREEMENT

Please detach and retain within your training files

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

<p>Recipient</p> <p>Signature:Date:</p> <p>Name & Position:</p>
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Please retain copy of the signed form for your reference in your training file
