University of Hertfordshire

QUALITY MANAGEMENT SYSTEM

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for the Development and Management of the Quality Management System for Clinical Research Studies Conducted at the University of Hertfordshire

SOP Number: gSOP-19-01	**Effective Date:** 26th April 2018
Version Number: 1.1	**Review Date:** 3 years (or as required)

1. BACKGROUND

This is a University of Hertfordshire standard operating procedure. The 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. SOPs are required to assist Researchers in conducting research in accordance with the principles of ICH Good Clinical Practice (GCP) and relevant regulations and guidance.

2. PURPOSE

- To ensure all clinical research studies conducted meet sponsor, research governance, regulatory, University and Partner requirements as detailed in relevant UH SOPs and policies.
- To ensure that all key areas are identified and standardised in the form of an SOP or policy to minimise risks and to encourage good research practice.
- To outline the process for set up and management of the Quality Management System (QMS).
- To ensure new clinical research staff are appropriately trained and are able to produce evidence of such training in relation to QMS.

3. APPLICABLE TO

This applies to any UH employee involved with 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 Managers, Clinical Studies Officers, Data Managers and Research Assistants.

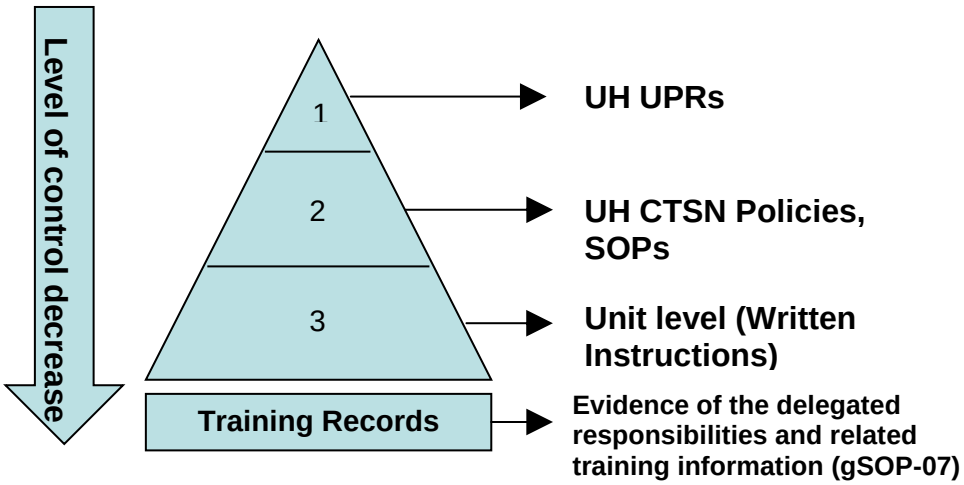
4. RESPONSIBILITIES

To ensure all clinical research staff are familiar with the QMS and can follow relevant policies and SOPs, training will be provided by the CTSN on a rolling basis (gSOP-07).

5. PROCEDURE

5.1 Key areas within the clinical research activities have been identified as summarised in Appendix 2. To ensure these areas are standardised to reduce risks, policies or SOPs have been developed to create a Quality Management System (QMS). The CTSN will maintain a Quality Assessment (QA) Folder containing hard-copies of all approved original SOPs, both current and obsolete versions. The electronic PDFs of the current SOPs will be stored electronically on the UH Document Management System and available on the UH CTSN webpage (access will be restricted to read only and no hard copies will be provided). Superseded SOPs will be appropriately archived in the University Document Management System by the CTSN.

5.2 The QMS is managed at three hierarchical levels within UH, as illustrated below:



5.3 At the top level, UH Policies and Regulations (UPRs) are high level documents describing institutional policies, procedures and regulations. This is developed and maintained by UH Governance Services. The line manager should highlight the key UH policies research staff are expected to follow and be familiar with.

5.4 At the second level, UH will develop CTSN SOPs with the SOP Working Group (SOPWG). The group has membership from key staff groups such as trial managers, clinicians, a statistician and research staff. Draft SOPs are reviewed and approved by the SOPWG and sent to the UH Advisory Group on Research Governance for Clinical Studies for comment. Once the final format is agreed, the SOP is then ratified by the Pro-Vice Chancellor (Research & Enterprise).

The third level are individual instructions written by the research team for study specific processes, such as screening or recruiting methods within a given setting.

5.5 The PDF version of the SOP is uploaded on to the UH Document Management System.

5.6 The SOPs are developed and version controlled in accordance with the SOPWG Terms of Reference (Appendix 3). The SOPs will be reviewed as indicated and if updated, the version number will be changed to one increment. If no changes are required, the effective date of the SOP will be extended and the SOP version number will remain the same. The format of the SOPs will follow the procedure described in gSOP-01 (Appendix 2.0).

5.7 The release of new SOPs and subsequent updates will be circulated by an e-mail from the CTSN to all UH staff ahead of the implementation date. **All staff involved in clinical trial activities should sign applicable SOPs and retain evidence within their training files.** Training for new SOPs will be provided to Research staff according to gSOP-07 (Research Training for Research staff).

5.8 Whilst the UH SOPs are expected to provide procedures for key areas within the clinical trial process, some units may have additional internal procedures to follow. In this case, department level SOPs will be created to support the QMS. The development, approval and management of these SOPs will be managed by the research teams.

5.9 The QMS will be reviewed regularly (every 2-3 years) to ensure it is kept up to date in compliance with current sponsor, UH and regulatory requirements and will be amended as necessary on a more frequent basis if required.

5.10 To ensure all staff are familiar with the QMS and can follow relevant policies and SOPs, training will be provided by the CTSN on a rolling basis (gSOP-07).

6. RELATED DOCUMENTS

- Standard Operating Procedures Working Group Terms of Reference
- Membership of Standard Operating Procedures Working Group
- gSOPs-01 SOP on SOPs
- gSOP-07 Research Training

7. APPENDICES

- Appendix 1 - Definitions
- Appendix 2 - SOP Document Map
- Appendix 3 - Standard Operating Procedures Working Group Terms of Reference
- Appendix 4 - List of UH University Policies and Regulations relevant to the CTSN

8. VERSION HISTORY

Revision Chronology:		
Version Number	**Effective Date**	**Reason for Change**

9. 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 <u>your training files</u>

I have read and understood the contents and requirements of this SOP (ref gSOP-19-01) 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 - Any investigation in human subjects, other than a non-interventional trial intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal product or to identify any adverse reactions to one or more such products and to study absorption, distribution metabolism and excretion in one of more such products with the object of ascertaining the safety or efficacy of those products.

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).

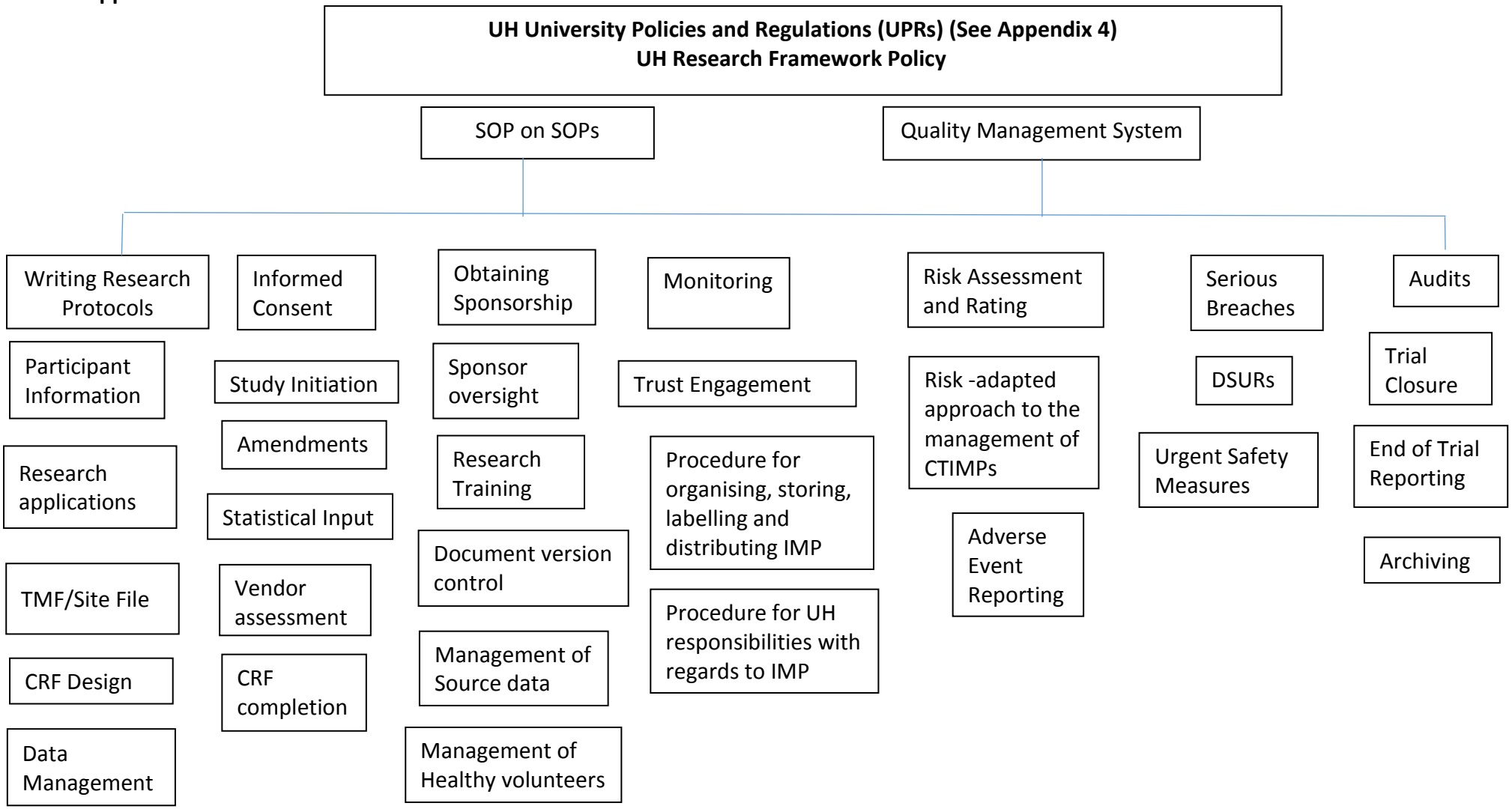
Principal Investigator (PI) - A Registered Physician, Dentist, Pharmacist or Registered Nurse who has responsibility for the conduct of the trial at a host site.

The 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.

QMS - A quality management system (QMS) can be defined as the organisational structure, responsibilities, procedures, processes and resources for implementing quality systems for conducting clinical trials.

SOP - A detailed, written instruction to achieve uniformity of the performance of a specific function. SOPs are used to disseminate best practice within the organisation and act as a good training tool for staff.

Appendix 2



Appendix 3 Clinical Trial Support Network Standard Operating Procedures Working Group Terms of Reference

TERMS OF REFERENCE

Purpose
The CTSN SOP working group will ensure that the necessary SOPs are in place to ensure good research governance and operations when conducting clinical studies.

Membership:

- Trial Managers – Solange Wyatt/Sarah Jane Besser
- Clinician – Ken Farrington
- Independent NHS Trust representative – Fiona Smith (WWHT)

Frequency of Meetings:
Meetings will be held on an "as required" basis. Documents for review will be circulated electronically inviting comment and feedback.

Duties/Remit.
The duties of the SOP working group are:

1. To identify requirements for standard operating procedures for the setup, conduct, monitoring and completion of clinical research relevant to the CTSN.

2. To identify priorities for SOP production and review.

3. To draft, input into and produce SOPs following the below procedure:

   - draft SOPs to be written by appropriately experienced individual(s) using an agreed SOP template. Draft to be circulated to SOP working group for review. Feedback will be sent electronically and collated by the SOP author.

   - SOP working group representative to send draft to Trust representative(s) (different from Trust representative on SOP working group) for independent review.

   - once comments addressed and incorporated SOPWG representative to send draft to UH Advisory Group on Research Governance for Clinical studies for comment, approval and recommendation for ratification.

   - final draft to be ratified by the Pro-Vice Chancellor (Research & Enterprise).

4. To advise and coordinate training in the use of SOPs in line with ICH GCP.

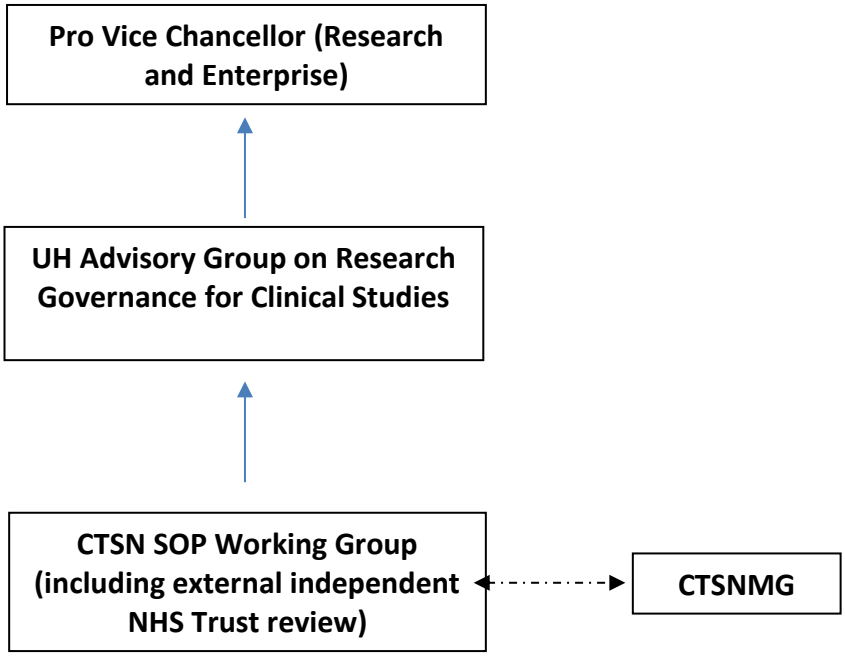
5. To advise on the use of a document control system for University SOPs.

6. To report regularly to the UH Advisory Group on Research Governance for Clinical Studies.

7. To provide advice to research staff producing team specific or study specific working instructions.

8. To keep written record of all SOPs developed and reviewed.

Approval process for SOPs:



Appendix 4 List of UH University Policies and Regulations relevant to the CTSN

- Studies Involving the use of Human Participants
- Research
- Research Misconduct
- Risk assessment and management
- Bribery and Corruption
- Data protection
- Data Management Policy
- Research data management
- Intellectual Property
- Information Management Policy
- Confidentiality Agreement
- Information security policy
- Freedom of information
- Open Access policy
- Records Management and Archiving and Retention of Prime Documents and Business Records