QMS

Research & Development

Standard Operating Procedure for the Development and Management of the Quality Management System for Research Studies Conducted at WHHT

SOP Number : SOP-19-06	**Effective Date:** October 2021
Version Number: v06	**Review Date:** 2-3 years

1.0 BACKGROUND

This document sets out the procedures to be followed by all West Hertfordshire Hospitals Trust (WHHT) staff who are involved in the development and management of the Quality Management System (QMS) for clinical trials conducted at WHHT.

2.0 PURPOSE

- To ensure all research conducted meet Sponsor, research governance, regulatory and Trust requirements as detailed in relevant Trust SOPs and policies
- To ensure that all key areas are identified and standardised in the form of a SOP or policy to minimise risks and to encourage good research practice
- To outline the process for setup and management of the QMS
- To ensure new research staff are appropriately trained and are able to produce evidence of such training in relation to QMS

3.0 APPLICABLE TO

Any Trust employee involved with clinical research including, but not limited to, Chief Investigators (CI), Principal Investigators (PI), Consultants, Co-Investigators, Clinical Trial Pharmacists, Research Managers, Research Nurses, Allied Health Professionals, Trial Coordinators & Data Managers.

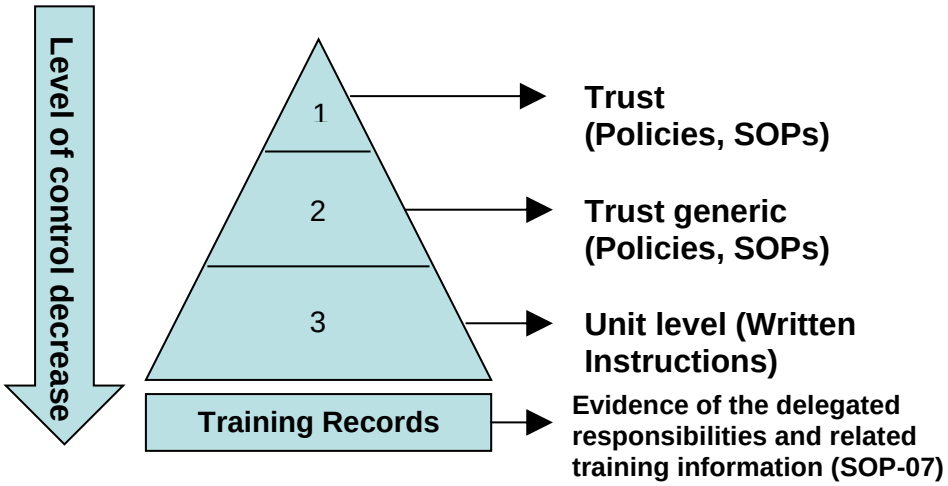
4.0 RESPONSIBILITIES

To ensure all staff are familiar with the QMS and can follow relevant policies and SOPs, training will be provided by the R&D Department on a rolling basis (see SOP-07).

5.0 PROCEDURE

5.1 Key areas within trial activities have been identified, along with an overview of all Trust policies and procedures, in Appendix 2. To ensure these areas are standardised to reduce risks, policies or SOPs have been developed to create a QMS. The R&D Department will maintain a Quality Assurance (QA) of all approved original SOPs, both current and obsolete versions. The electronic PDFs of the current SOPs will be stored electronically on the hospital intranet (access will be restricted to read only and no hard copies will be provided).

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



5.3 At the top level, Trust policies are high level documents describing approach, purpose and goal of a particular subject area. This is developed at Trust level and is maintained by the Trust Clinical Governance Department. The unit head or line manager should highlight the key Trust policies research staff are expected to follow and be familiar with.

5.4 Second level, the Trust will develop generic SOPs by the Standard Operating Procedures Working Group (SOPWG). The group has input from all key staff groups such as Trial Coordinators, Research Nurses, Pharmacy and Clinical R&D. Draft SOPs are reviewed by the group. The final draft version is sent to the R&D Steering Groups (RDSG) for comments. Once the final format is agreed, the SOP is signed off by the Director/Associate Director of R&D.

5.5 The PDF version of the SOP is uploaded onto the hospital intranet.

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 SOP-01.

5.7 The release of new SOPs and subsequent updates will be circulated by an e-mail from R&D ahead of the implementation date (effective date – when team has to follow the SOP). All staff involved in clinical trial activities should sign SOPs signature sheet and retain evidence within their training files. Training for new SOPs will be provided to research staff (see SOP-07).

5.8 Whilst the Trust generic 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, unit/department

level SOPs will be created to support the QMS. For example, Pharmacy and Radiology Department may have local SOPs. The development, approval and management of these SOPs will be managed by the departments themselves.

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, Trust and regulatory requirements and will be amended as necessary on a more frequent basis if required.

6.0 RELATED DOCUMENTS

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

7.0 APPENDIX

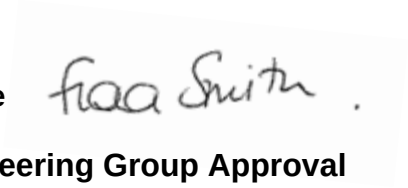
Appendix 1.0 - Definitions
Appendix 2.0 - SOP Document Map
Appendix 3.0 - Standard Operating Procedures Working Group Terms of Reference

8.0 VERSION HISTORY

Revision Chronology:		
Version Number	**Effective Date**	**Reason for Change**
SOP-19-06	**October 2021**	1. Change from general Standard Operating Procedures (gSOP) to SOP 2. Removal of the '10.0 Agreement' from the template - all agreement signatures will be collated on a new 'SOP Signature Sheet Document' 3. Amendments to Appendix 2 to reflect changes made to all SOPs 4. Other minor amendments and clarification of terms following review
gSOP-19-05	**October 2017**	Minor amendment following review
gSOP-19-04	**01/10/2015**	Minor amendment following dissolution of R&D consortium
gSOP-19-03	**22/05/2014**	Minor amendments following review
gSOP-19-02		SOP modified for implementation at ENHT /WHHT.
gSOP-19-01 (MVCC)		SOP modified for implementation at MVCC

9.0 AUTHORSHIP & APPROVAL

Author

Signature  **Date** 28/10/2021

R & D Steering Group Approval

Signature  **Date** 28/10/2021

Appendix 1: Definitions

Chief Investigator (CI)
The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites. All applications for ethical review should be submitted by the CI.

Clinical Trial
A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. A Study Type.

Good Clinical Practice (GCP)
Good Clinical Practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.

International Conference on Harmonisation (ICH)
International Conference for Harmonisation, a collaboration between regulators and the pharmaceutical industry in Europe, the United States and Japan to establish common standards for clinical trials. ICH GCP is a widely recognised standard for Good Clinical Practice in clinical trials.

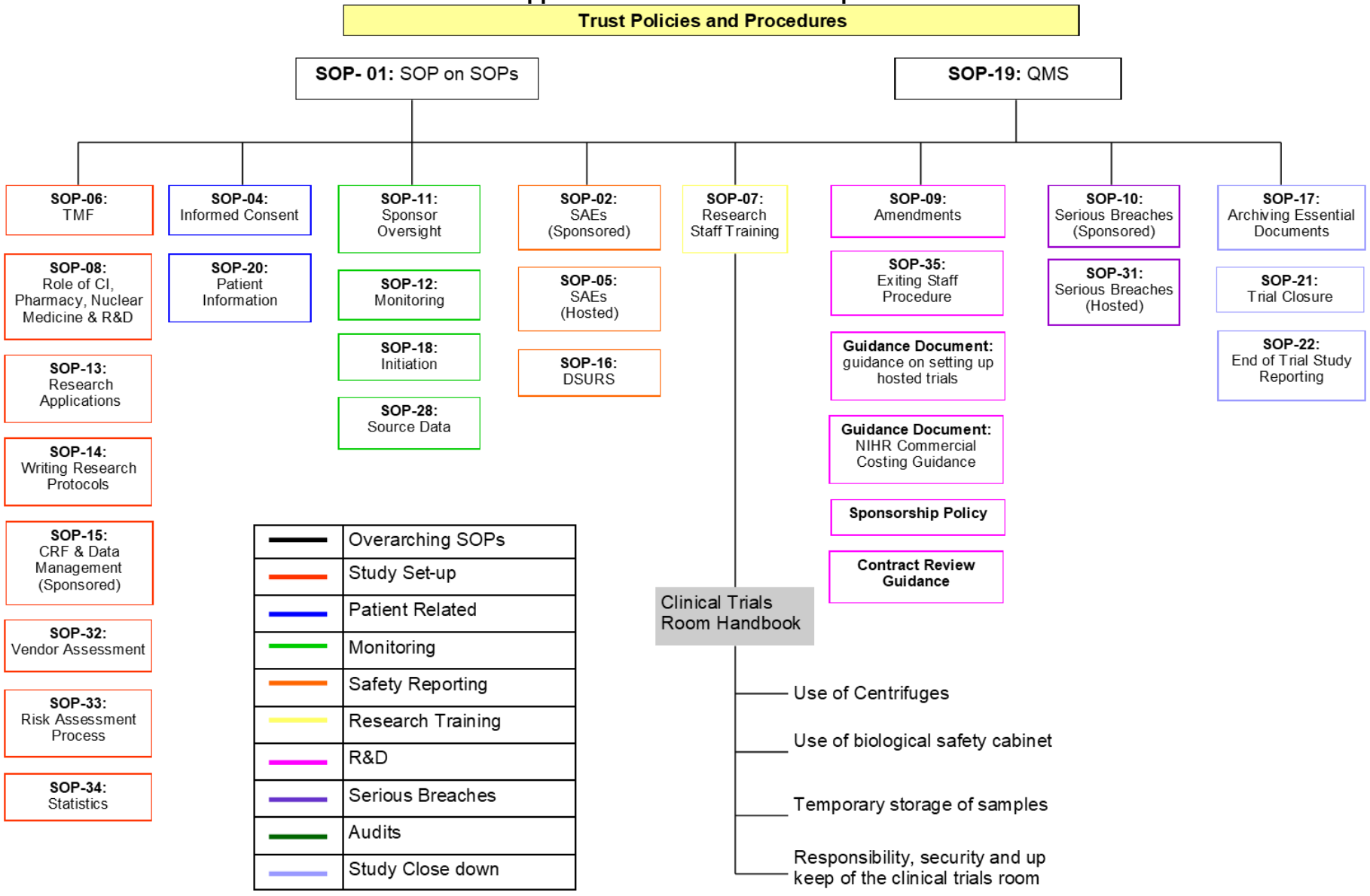
Monitoring
The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted and recorded in accordance with the protocol, Standard Operating Guidelines (SOP's), Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

Principal Investigator (PI)
The investigator responsible for the research site. There should be one PI for each research site. In the case of a single-site study, the chief investigator and the PI will normally be the same person.

Quality Management System (QMS)
A quality management system can be defined as the organisational structure, responsibilities, procedures, processes and resources for implementing quality systems for conducting 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 Document Map



Appendix 3: Standard Operating Procedures Working Group Terms of Reference

Standard Operating Procedures Working Group

TERMS OF REFERENCE

1. To identify requirements for standard operating procedures for the set up, conduct, monitoring and completion of research.
2. To identify priorities for SOP production and review.
3. To approve SOPs for ratification by the Director/Associate Director of R&D.
4. To advise and coordinate through the R&D Office training in the use of SOPs in line with ICH GCP.
5. To advise on the use of a document control system for Trust level SOPs.
6. Review of quality assurance reports to ensure SOPs are of a high standard.
7. To report regularly to the R&D Steering Group.
8. To provide advice to research staff producing team specific or study specific working instructions.
9. To keep written record of all SOPs developed and reviewed