SOP ON SOPs

Research & Development

Standard Operating Procedure for the Production, Review, Approval, Distribution and Revision of Research SOPs

SOP Number: SOP-01-08	**Effective Date:** October 2021
Version Number: v08	**Review Date:** 2-3 years

1.0 BACKGROUND

This document defines the procedures for all West Hertfordshire Hospitals Trust (WHHT) staff involved in preparing, managing and reviewing SOPs that describe the standard activities used in research at WHHT.

This document clarifies the requirements for written SOPs to provide quality assurance in Good Clinical Practice (GCP).

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.

2.0 PURPOSE

- This procedure applies to SOPs written for research taking place at WHHT
- The purpose of this procedure is to provide clear instruction on how SOPs for clinical research should be produced so that they are prepared in a consistent manner

3.0 APPLICABLE TO

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

& Data Managers.

4.0 RESPONSIBILITIES

- The Director(s) / Associate Director of R&D has overall responsibility for research
- All staff are responsible for ensuring research is conducted in accordance with the clinical trials regulations

5.0 PROCEDURE

5.1 Format

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

- Background
- Purpose
- Applicable to
- Responsibilities
- Procedure

5.1.2 The SOP template shall be used for all SOPs (Appendix 2).

5.1.3 All other SOPs should follow a similar format which is recognised as a standard for the Clinical Unit/Research Team to which they relate. Such 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.

5.2 Authorship and Approval

5.2.1 SOPs shall be drafted by a member of the R&D Standard Operating Procedures Working Group (SOPWG) or the SOPWG may delegate to an employee of the Trust considered appropriate by the group.

5.2.2 Draft SOPs shall be presented to the SOPWG for amendment or rejection as considered necessary. Final drafts of SOPs shall be presented to the SOPWG for approval.

5.2.3 Following approval by the SOPWG, SOPs shall be presented to the Research & Development Steering Group (RDSG) for comment and recommendation for approval. On completion SOPs are to be submitted to the Trust for ratification.

5.2.4 All other written instructions should be written by a competent and experienced member of the Clinical Unit/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 a SOP shall be suitably knowledgeable, qualified, and experienced.

5.3 Version Control

5.3.1 A document control system shall be used for SOPs. Superseded SOPs will be appropriately archived in the R&D Department.

5.3.2 Clinical Units/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 in accordance with SOP-19. The SOPWG will review SOPs.

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 and are available to all staff on the intranet/internet.

5.4.2 Shortly after the approval of a new SOP, SOP training will be provided to research staff as per SOP-07.

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 (Appendix 3) and, as necessary, the Trust 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
- SOP template (Appendix 2)
- SOP-19: QMS
- SOP-07: Research Staff Training

7.0 APPENDICES

Appendix 1 - Definitions
Appendix 2 - SOP template
Appendix 3 - Escalation Plan

8.0 VERSION HISTORY

Revision Chronology:

Version Number	Effective Date	Reason for Change
SOP-01-08	**Oct 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. Addition of appendix 3: Escalation plan 4. Other minor changes and clarifications of terms following review
gSOP-01-07	**Oct 2017**	Minor amendments following review
gSOP-01-06	**01/10/2015**	Minor amendments following review
gSOP-01-05	**07/05/2014**	Minor amendments following review
gSOP-01-04		SOP modified for implementation at ENHT/WHHT. gSOP-01-04 replaces 2011-149
gSOP-01-03 (MVCC)		SOP modified for implementation at MVCC
gSOP-01-02	**23/03/2010**	1. SOPs should be read and a copy of the signature page to be kept in the training file and not sent to the R&D office 2. SOP training will be provided as per gSOP-07 (GCP/ SOP Training for Research staff 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.

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.

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

{SOP short title}

Research & Development

Standard Operating Procedure for {full title}

SOP Number: SOP-XX-XX	**Effective Date:** TBC
Version Number: vXX	**Review Date:** 2-3 years

1.0 BACKGROUND

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2.0 PURPOSE

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3.0 APPLICABLE TO

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4.0 RESPONSIBILITIES

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5.0 PROCEDURE

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6.0 RELATED DOCUMENTS

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SOP-XX-XX	**TBC**	

9.0 AUTHORSHIP & APPROVAL

Author

Signature **Date**

R & D Steering Group Approval

Signature **Date**

Appendix 3: Escalation plan

Serious Breaches of GCP and Critical Audit Findings in Clinical Research

Summary
This paper summarises the process for escalating findings of non-compliance relating to the governance of clinical research activity.

CONTENTS

Section

1. Identification of non-compliance in clinical research

Non-compliance in clinical research may be identified through one of 3 routes:

1. By the clinical research study team conducting the trial
2. Through monitoring or auditing conducted by the R&D Department
3. Through monitoring or auditing conducted by partners

2. Categories of non-compliance in clinical research

Serious breach: A breach in compliance with clinical trial protocol or GCP regulations which is likely to affect to a significant degree the safety of the trial participant or the scientific validity of the trial.

Critical Finding: Where evidence exists through audit that significant and unjustified departure(s) from applicable legislative requirements has occurred with evidence that

- the safety or well-being of trial subjects either has been or has significant potential to be jeopardised, and/or,
- the clinical trial data is unreliable and/or,
- there are a number of Major non-compliances across areas of responsibility, indicating a systematic quality assurance failure, and/or,
- where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported Major non-compliances.

3 Reporting of non-compliance in clinical research

Reports of serious breaches and critical findings will be provided to:

- The R & D Steering Group
- The Risk and Quality Committee

All potential serious breaches of GCP in Trust sponsored studies are reported to the R&D Dept in accordance with the SOP on Notification of Serious Breaches of GCP

All confirmed serious breaches of GCP in hosted studies must be reported as required by the sponsor and in accordance with the SOP. It is the sponsor's responsibility to inform the PI.

In all cases, potentially serious breaches and critical audit findings are escalated to a governance review panel comprising of the following:

- Associate Medical Director [R & D]
- Director of R & D
- Senior Research Nurse

This panel may choose to consult further with the Medical Director

If any panel member is involved in the trial being reviewed, the next most senior clinician within the management structure will be called upon for their professional opinion.

The panel is responsible for reviewing non compliance reports, agreeing and taking the appropriate managerial action and if necessary notifying the relevant regulatory authority within the appropriate period. Where notification to a regulatory authority is required, a copy of this notification will also be sent to the Medical Director.

If a risk to organisational reputation is identified, the Medical Director is responsible for alerting the communications teams as appropriate.

Additionally the RDSG will review all clinical trial audit reports generated by the R&D Department.

Incidents relating to all clinical trials are also reported to the Trust via Datix and to the R&QC. Quarterly oversight of these incidents will be undertaken by the RDSG.