Preparation and Review of Standard Operating Procedures and Guidelines for Clinical Trials

The current version of all Hillingdon Hospital R&D Guidance Documents and Standard Operating Procedures are available from the R&D Intranet and Internet sites: www.thh.nhs.uk/Departments/Research/research_otherdocs#sops

Please ensure that you have the latest version

Version Number: 3.0
Effective Date: 01.08.13
Review Date: 31.07.15

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<th>Edited by</th>
<th>Effective Date</th>
<th>Details of Changes</th>
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</tbody>
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1. BACKGROUND

Standard Operating Procedures (SOP) are both a set of written instructions and a written record of procedure. SOPs aim to ensure that regularly performed tasks are completed consistently and uniformly across organisations, and can be effective measures to improve performance and results.

The Research and Development SOPs are generic documents applicable to research carried out within the Trust, and they should take precedence over trial-specific procedures of sponsoring organisations. If it is anticipated that trial-specific procedures will deviate from what is outlined in the Trust’s own SOPs, this must be discussed beforehand with the R&D Manager.

Compliance with SOPs and guidance documents will be assessed through annual auditing.

2. PURPOSE

This document describes the procedure for the preparation, approval, distribution and review of the R&D department SOPs and guidelines.
3. PROCEDURE

3.1 Who?

All individuals involved in clinical trials should review the SOPs which are applicable to their role within the research team. The R&D Manager will oversee the management of SOPs used in studies undertaken at the trust, having overall responsibility for the distribution and storage of current versions of the SOPs and the archiving of old versions.

3.2 When?

An SOP should be written as soon as the need for a standard written procedure is identified. SOPs should be formally reviewed every two years unless changes in legislation or procedures necessitate an earlier review.

3.3 How?

Preparation of a New SOP

1. All SOPs will be prepared in accordance with this SOP, and should follow the standard template for SOPs.

2. The SOP should be written by a person nominated by the R&D Manager. They should be appropriately qualified and experienced to carry out this task.

3. The R&D Manager will review the written draft and may suggest changes prior to the SOP being approved.

4. After approval the author of the SOP will insert the date from which the document is effective and provide a review date on the front of the SOP.

5. The R&D Manager should ensure that the new SOP is made available on the department’s intranet and internet sites, and that personnel are made aware of it, for example through the R&D Bulletin.

Review of an SOP

6. SOP’s should be reviewed every 2 years

7. An individual nominated by the R&D Manager will review the SOP together with the SOP author, where possible, or with another nominated individual.

8. Where changes are proposed, these should be reviewed by the R&D Manager, who may suggest changes prior to the revised SOP being approved.

9. Once approved, the version number, effective date and review date should be updated on the front of the SOP.
10. The details and reason for changes to the SOP should be identified in a ‘document history’ table at the front of the document.

11. The R&D Manager should ensure that the revised SOP is distributed as described above for new SOPs, and that copies of prior versions are archived.

**Managing SOPs**

12. Approved versions of SOPs should be given a version number. Major revisions should receive a new number (e.g. 1.0, 2.0). Minor changes will have a new increment (e.g. 1.1, 1.2). Draft SOPs are not approved for use and should carry a watermark.

13. Electronic copies of SOPs will be made available in read-only form via the R&D Department’s intranet and internet sites, and may be made available in paper form via the R&D office.

14. Information on where to obtain current SOPs, together with a reminder to ensure the version being read is up-to-date will be included at the front of each SOP.

15. Individuals using an SOP are reminded to ensure that they have the current version, and that these can be found via the intranet or internet. Printed SOPs are not version controlled documents.

**4. OTHER RELATED PROCEDURES**

None

**5. REFERENCES AND FURTHER READING**


This SOP was adapted from: University of Dundee, Standard Operating Procedure for the Preparation, Review and Approval of Standard Operating Procedures and Guidelines for Clinical Trials of Investigational Medicinal Products. Version 2.0, 1/1/2009.

**6. APPENDICES**

Appendix A: SOP Template
[Title of SOP]

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