

Joint Research Office

Research Standard Operating Procedures Policy

Effective: January 2011

Review: January 2013

1. Introduction.

The Newcastle Upon Tyne Hospitals NHS Foundation Trust and Newcastle University Standard Operating Procedures (SOPs) are designed to ensure that research, and its supporting activities, is carried out in accordance with the principles of Good Clinical Practice (GCP). GCP is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of trials that involve the participation of human subjects.

A SOP specifies in writing what should be done, by whom, where and when. The benefits of a system of well maintained SOPs include:

- Assuring the quality and consistency of service
- Ensuring the adherence to GCP at all times.
- Providing learning tools for new members of staff.
- Contributing to the audit process.
- Ensuring local research practices are in line with all current regulatory and legislative requirements for research in the UK.

2. Purpose

This policy has been drawn up by The Research SOP Group to assist staff in developing SOPs for research and describes the process of generation, approval, implementation and administration of SOPs within the Joint University/Trust system. Having a clearly defined SOP system ensures that all research SOPs are:

- In line with corporate governance requirements
- Clear and consistent in their format, compilation and dissemination
- Meet corporate and clinical standards
- Are approved, disseminated and implemented appropriately.
- Are monitored and reviewed in a regular, structured way.
- Promote equality and diversity

3. Scope

This SOP system applies to all personnel involved in the conduct of research within the University and Trust.

4. Responsibilities

4.1 Research SOP Group

The Research SOP Group is responsible for the development, maintenance and updating of the SOP system and associated documentation. The group shall also ratify newly approved SOPs. The Research SOP group membership shall consist of:

- Research Matron
- Representative from Clinical Research Platforms
- Research Governance Manager/representative from Joint Research Office
- Representatives from Newcastle Clinical Trials Unit

Additional members may be co-opted for their expertise if required.

The Group shall also be responsible for compiling a regular report on the status of research SOPs to the Joint Research Executive.

4.2 Research Groups/Departments/Platforms

All research groups within the University and Trust are responsible for identifying the SOPs they require, and assigning staff to write, review and approve the SOPs in accordance with the system described in this policy. The subject of SOPs should be included on the agenda of research departments on a regular basis so that any new issues can be discussed and required actions undertaken. For example, SOPs may need to be reviewed if there are changes to current practice, or in response to regulatory guidance updates, or for other reasons.

4.3 SOP Author

A SOP author needs to be someone who is appropriately qualified to write the SOP and has experience of performing, or currently performs the task. The SOP author shall:

- Be responsible for SOP ownership through development, approval and ratification processes.
- Ensure that review of the SOP is carried out by appropriately qualified staff (Reviewer checklist provided in Appendix 2).
- Ensure the SOP is written on the current version of the SOP Template (Appendix 1) and follows guidelines outlined in the Standard Operating Procedure SOP <http://www.ncl.ac.uk/crp/collaboration/standardop/library/>
- Ensure that compliance with the SOP is monitored through regular auditing and that any recommendations resulting from audits are implemented.
- Be responsible for instigating the review process when they are notified that the SOP is approaching or past its review deadline.
- Be responsible for updating the SOP to comply with any changes in legislation.

4.4 SOP Reviewer

The SOP reviewer is someone who currently performs, or is knowledgeable of a process.

4.5 SOP Approver

A SOP approver is a Head of Department or someone at the equivalent level, who has responsibility for overseeing that their Department/group has the appropriate SOPs in place for the research procedures being undertaken. In some cases it may be appropriate for more than one person to act as an approver.

5. Process for writing, reviewing and approving a research SOP

5.1 SOP Template Requirements

Each process/procedure shall use the current version of the SOP template, which includes:

- Background/Introduction
- Purpose
- Scope
- Procedure
- Review and Monitoring of SOP
- References
- Appendices
- Who prepared the SOP
- Who authorised the SOP
- Its date of production and date of review

The current version of the SOP template should be downloaded from the Trust R&D website:

http://www.newcastle-hospitals.org.uk/about-us/staff-information_research-development.aspx

5.2 Identifying the need for a SOP

The Research SOP group is responsible for maintaining a current list of SOPs and their status as regard to newly identified, submitted, undergoing revision, approved and archived. Each research group/department is responsible for identifying gaps in its listed procedures and ensuring that this is communicated to the Research SOP Group.

5.3 Generating an SOP

SOPs need to be generated to document defined process and procedures. The current version of the SOP template, available on the Trust R&D website, should be used. All sections of the template should be completed, apart from the SOP number. The approved SOP, with supporting documentation (Completed Lead Reviewer Checklist and Ratification Form) should then be sent to the SOP Administrator in the Joint Research Office. The SOP Administrator will assign the SOP a number and forward the SOP and supporting documentation to the Research SOP Group for ratification.

5.4 Research SOP Group review and ratification.

The Research SOP Group is responsible for ratifying all locally approved research SOPs. This will be undertaken as and when new SOPs are submitted to the SOP Administrator. The SOP Research Group will meet on a quarterly basis to review the status of all research SOPs. The group will confirm whether each SOP is current, requires updating or should be retired/archived.

There is a procedure in place to ratify urgent SOPs between the quarterly meetings of the Research SOP Group through the chair's action. These SOPs can then be reported to the next meeting of the Research SOP Group for information purposes.

A flow chart summarising the SOP generation, approval and ratification process is provided in Appendix 3.

6. SOP Dissemination Mechanisms

Current versions of approved SOPs will be available on the Trust R&D website - <http://www.ncl.ac.uk/crp/collaboration/standardop/library/>. Signed original hardcopies of the SOPs shall be filed by the SOP Administrator in the Joint Research Office.

Managers shall ensure that all staff expected to work under the relevant SOP have access to the up-to-date version of the SOP on the Trust R&D website. When SOPs are first approved or when new members of staff undergo induction or training, a record shall be kept to show that staff have read and understood the SOPs relevant to their role/job.

6.1 Document Control

In order to comply with the Trust's and University's internal governance processes, and external assessments, including regulatory inspections, review and electronic storage of all documents shall be controlled, by ensuring:

- SOPs are readily available for operational, legal, insurance and statutory obligations.
- SOPs are clearly identifiable as to their author, date of origin and date of review.
- Draft SOPs are controlled. Version control of SOPs will be via the Trust R&D website, which will be updated when changes have been made to a document. SOPs that have been superseded will be archived within the SOP database.

7. Review Criteria

SOPs should be reviewed on a regular basis to allow for any changes in procedures or circumstances e.g. regulatory legislation. If there is no need for changes reviews of the SOP should be undertaken at least once every two years. If there is a critical incident, the relevant SOPs should be reviewed.

8. Deviation

Circumstances may arise where it is necessary or appropriate to work outside the SOP. It is good practice to record instances of deviations. If it is possible to predict where changed circumstances will apply, this should be reflected in the SOP.

9. Audit trail

Where the SOP involves a requirement for an audit trail, these should be based on specific, accountable activities. Each group involved in research is responsible for ensuring that the appropriate quality control checks are undertaken on processes covered by SOPs.

10. Monitoring Policy Compliance

Compliance with this policy shall be monitored by the Research SOP Group. The Group will contact the approver of an SOP three months in advance of the SOP becoming out of date, and request them to have the SOP reviewed and updated where necessary.

Author: RM and G Manager

Standard Operating Procedure

SOP number:	(GET THIS FROM SOP LIBRARIAN)
SOP full title:	
SOP category:	
SOP effective:	Review date:
SOP author signature:	Date:
<name>, <title>	
SOP group authorisation:	Date:
<name>, <title>	

SOP HISTORY		
Version	Date	Reason for change

YOU SHOULD ALWAYS CHECK THE FOLLOWING WEBSITE AND FOLLOW ANY LINKS TO THE SOP LIBRARY TO ENSURE YOU ARE USING THE MOST CURRENT VERSION
http://www.newcastle-hospitals.org.uk/about-us/staff-information_research-development.aspx

SOP SHOULD INCLUDE THE FOLLOWING NUMBERED SECTIONS AND EACH SUB-SECTION NUMBERED – see the SOP ('Writing a Standard Operating Procedure or Work Instruction' for further details)

1. BACKGROUND/INTRODUCTION (any relevant background as to why the SOP is needed)
 - 1.1.
 - 1.2.

SOP XX-XXX-XX Date:

2. PURPOSE (purpose of SOP and what it covers/what the SOP is intended to achieve)
 - 2.1.
 - 2.2.
3. SCOPE (Describes who and what the SOP applied to – eg, a specific group of people, type of study etc)
 - 3.1.
 - 3.2.
4. PROCEDURE (details of what needs to be done)
 - 4.1.
 - 4.2.
 - 4.3.
5. REVIEW AND MONITORING OF THIS DOCUMENT
You have to describe here how compliance of this document will be monitored and reviewed
(eg – through training, audit etc)
6. REFERENCES (references of all documents used to write the SOP and links to relevant websites)
7. APPENDICES (if relevant)

Appendix 2 - SOP Review and Approval Checklist and Ratification Form

SOP title: _____

Author Name: _____ **Job Title:** _____

Signature: _____

Lead Reviewer:

Name: _____

Job Title: _____

Research Group/Department: _____

Lead Reviewer (Department head or equivalent) Signature: _____

Date: _____

Approved by (Department head or equivalent): _____

Date: _____

Approver Signature _____

SECTION 1 - REVIEWER				
	Question	Yes	No	Comments
1	Does the title reflect the purpose & scope?			
2	Is process clear & unambiguous (including language/terms)?			
3	Does the procedure reflect the purpose and scope?			
4	Does the procedure reflect current practice?			
5	Does the procedure reflect current guidance and regulations?			
6	Are references correct?			
7	Are references relevant?			
8	Are listed appendices present?			
9	Are attached appendices relevant?			
10	If not attached, would a flowchart be useful?			
11	If flowchart used, is it appropriate / useful?			
12	Other recommendations?			

SECTION 2 – SOP GROUP				
	Question			
1	Current SOP template used?			
2	All sections included?			
3	Header & footer on all pages?			
4	Are acronyms explained at first appearance?			
5	Is SOP categorised correctly?			
6	Are listed appendices present?			
7	Have all referenced hyperlinks been checked and found to be correct?			
8	Other recommendations?			

SOP Ratification Form.

This form must be used by the author of each new or updated SOP to detail the generation, review and approval process undertaken for the SOP. This form which includes the signed Reviewer and Approver Checklist and the final electronic and signed hardcopy of the SOP should be submitted to the SOP Administrator in the Joint Research Office who will forward it to the Research SOP group for final ratification.

SOP Title:

SOP Author:

Job Title:

Brief Synopsis of SOP

Is this a New or Updated SOP?

New?

Updated?

For Updated SOPs please quote the SOP title and number

For Updated SOPs please highlight the main changes in this version.

Has the SOP been compiled in accordance with the Research Standard Operating Procedures Policy?

Does the SOP contain a compliance monitoring process?

Who will be responsible for monitoring/auditing the SOP?

When will it be audited and frequency of auditing

Final SOP version (signed hardcopy and electronic version) should now be sent to the SOP Administrator, Joint Research Office, Level 6, Leazes Wing, RVI, telephone 0191 2825959.

SOP Administrator:

SOP Number Issued/Updated:

SOP Review Date:

Ratification process:

Group	Meeting Date/Chairperson's Action	Approved? Yes/No	Chairperson's Signature
Research SOP Group			

Appendix 3– Flow Chart of Approval Process for Research SOPs.

