

Joint Arrangements for Research

STANDARD OPERATING PROCEDURE

SOP 001

**Production, Review, Approval and Control of SOPs
Related to Research Activities**

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It is the responsibility of all users of this SOP to ensure that the correct version is being used.

All staff should regularly check the NNUH R&D website for information relating to the implementation of new or revised versions of SOPs. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use.

The definitive versions of all Joint NNUH/UEA health care research SOPs appear online. If you are reading this in printed form please check that the version number and effective date is the most recent one as shown on the NNUH R&D website.

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1 ABBREVIATIONS

CRF	Clinical Research Facility
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
ICH	International Conference for Harmonisation
NNUH	Norfolk and Norwich University Hospital
R&D	Research and Development
REN	Research and Enterprise Services UEA
SOP	Standard Operating Procedure
TMF	Trial Master File
UEA	University of East Anglia

2 INTRODUCTION

- 2.1 SOPs are detailed written instructions for a specific function which are required in order to ensure consistent and reproducible performance of the procedures within the SOP.
- 2.2 SOPs ensure that maximum safety and efficiency is achieved; provide quality assurance and allow appropriate training of staff across all clinical research activities within the sponsoring organizations.
- 2.3 For Clinical Trials of Investigative Medicinal Products: SOPs ensure compliance with ICH-GCP Principle 13 “Systems with procedures that assure the quality of every aspect of the clinical trial should be implemented” as stated in the Medicines for Human Use (Clinical Trial) Regulation 2004 and the Research Governance Framework April 2005.
- 2.4 SOPs define working methods however; written variations may be required for specific research studies. A written justification for any variations to SOPs must be approved by the SOP Approver and recorded in the appropriate study file.
- 2.5 The aim of this SOP is to describe the process for preparing, changing, updating, reviewing, approving, distributing and filing of Standard Operating Procedures (SOPs) for all health care research activities within the UEA and NNUH.

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3 SCOPE

This SOP applies to all healthcare research sponsored by NNUH or UEA which falls within the scope of the Research Governance Framework (2nd edition 2005). Where additional legislation applies for example the Medicines for Human Use (Clinical Trials) Regulations 2004 (and amendments) or the Medical Devices Regulations 2002, required procedures will be indicated. External sponsors may require use of their own SOPs and this will be specified in site agreements. It is the responsibility of the local PI to ensure that study specific SOPs can be operated without conflict to this SOP and in accordance with all organisational policies related to research.

4 DEFINITIONS

Department Head:	Head of Department for Sponsoring Organisation or the designee in their absence.
Designee:	Any NNUH or UEA personnel or external contractor who is appropriately qualified and competent to execute a defined task designated, assigned or contracted to them by a manager.
Policy:	Document describing specific action plans within an organisation in order to guide decisions and achieve rational desired outcomes. Policies which are set within the NHS are mandatory.
SOP Author:	Appropriately competent person designated to write SOPs for REN or NNUH R&D.
SOP Approver:	The Research Managers for the Sponsoring Organisation or in their absence an appropriately competent person assigned by the Department Head.
SOP Authoriser:	A person responsible for authorising, signing and releasing SOPs for both NNUH and UEA.
SOP Owner:	Owns the process of SOP preparation and the SOPs. Appoints designated person to implement process of preparing, revising and submitting SOPs.
SOP Reviewer:	Person designated by competency to review SOPs.
Baseline:	An approved revision of a document or source file from which subsequent changes can be made.

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5 RESPONSIBILITY

SOP Author:	Write new SOPs and revise existing SOPs as required according to the format and template in appendix 1.
SOP Approver:	Approve and sign all SOPs for use within the department.
SOP Authoriser:	Authorise, sign and release all SOPs for use at NNUH and UEA. This will usually be the Chief of Research and Innovation at NNUH.
SOP Owner:	This will usually be the Research Managers for the organization. Although it is the responsibility of the Research Managers to ensure that policies are in place a task of co-ordinating approval and review process as well as maintained of the documents can be delegated to the personnel within R&D office. This will be clearly identified in the SOP register.
SOP Reviewer:	Review and propose any further amendments to the SOP as required.
R&D Office:	Responsible for maintaining a register of all baseline copies of SOPs. This SOP register will contain all details of SOPs relating to their introduction, implementation, status and control. The office will also be responsible for maintaining the R&D website copies of the SOPs and notifying changes to SOPs.

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6 PROCEDURES

6.1 Preparation of SOPs and Associated Forms

6.1.1. Each SOP will be issued with a reference number. The reference number will identify the type of document and the organisations to which it applies

6.1.2. The Author of the SOP should contact the R&D office to obtain a reference number for the SOP.

6.1.3. The reference numbers will be in groups of hundreds e.g.

00	Document Management
200	Safety
300	Clinical Operations
400	Approvals/Initiations
500	Staff Training
600	Statistics
700	QA/QC
800	Data Management
900	Storage and Retention of Research

6.1.4. The format for each SOP will be identical:

- Each SOP will have a title page in the same format as Appendix 1 whenever possible
- All pages, including the title page will be numbered using the format 'page 1 of 3, page 2 of 3, and so on.
- Page numbering should commence from the first page (including the title page) and should appear in the footer section.
- The SOP reference number, version number, effective date and page number will appear in the footer section on each page.
- The names, of the Author, Approver and Authoriser will appear on the title page with signatures and dates they signed the SOP.
- A change control, revision and review sheet will be attached at the end of the SOP. The SOP Reviewer's name, signature, role will appear on this page with the date they reviewed the SOP.

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- The font for the title page; SOP title, reference number, will be Arial 12 and bold.
- The font for the footer will be Arial 9.
- The main text of the SOP should be Arial 11.
- The headers should be Arial 11 bold.
- The margins should be set as follows:
 - Mirrored
 - Top – 2.5cm
 - Bottom – 2.5 cm
 - Inside – 3.5cm
 - Outside – 3.5cm
- Line spacing should be single spaced. The main text should be justified.

6.1.5 Content of each SOP will be organised in numbered sections:

- Page 1 should contain a *Table of Contents*.
- Section 1 should define *Abbreviations* used in the SOP.
- Section 2 should form the *Introduction* and should include the aim of the SOP.
- Further sections should describe the Scope, Definitions and Procedures and define Responsibilities as appropriate to the purpose of the SOP. Although consistency in the use of section headers should be maintained, they may be varied where appropriate to meet the requirements of a particular SOP.

6.1.6 The SOP will have a 'Draft' watermark whilst in the preparation stage. This will be removed once any revisions have been made and agreed to become the Master Copy.

The Master Copy only will be signed as the 'Authorised' version.

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6.2 Final Approval and Authorisation

- 6.2.1 A draft of the SOP will be circulated to the relevant and appropriate personnel within the Joint Research Office for review and comment as required. Other personnel may be asked to comment on and review SOPs as appropriate to the nature of the SOP where specialist expertise is required. Where there is a difference of judgement on the content of SOPs, the advice of the Joint Research Governance Committee shall be sought as appropriate.
- 6.2.2 The Author will be the Joint Research Office from which a member of staff will be delegated responsibility for approving.
- 6.2.3 The SOP will be sent to the assigned SOP Approver. The Approver will print their name by '*Approver*' on the title page of the SOP. They will provide their *signature* and *Role* and the *date* on which they signed the SOP.
- 6.2.4 Following approval the SOP will be sent to the assigned SOP Authoriser by the Approver. The Authoriser will print their name by '*Authoriser*' on the title page of the SOP. They will provide their *signature* and *Role* and the *date* on which they signed the SOP.
- 6.2.5 Once the SOP has been authorized and returned to the R&D office it will be effective and implemented. The R&D office will be responsible for providing Trust Doc with the authorised SOPs so they can be uploaded to NNUH Trust Website. This will enable all relevant personnel within UEA and NNUH to access, read and receive appropriate training on the SOP.
- 6.2.6 Any forms/guidance documents associated with the authorised SOP will show an identical 'Effective Date' as the SOP.
- 6.2.7 Authorised SOPs will be available on line via the R&D office and REN Web Pages.
- 6.2.8 All SOPs released to any co-sponsors will be logged in and out and an updated *Index List* will be circulated to researchers and available following review and amendment of any SOP.
- 6.2.9 The SOP register is held in the R&D office which will include a configuration log of the status and issue of all SOPs. The log will include details of where the baseline copies of the SOPs are located and is maintained by the designated person. Names / roles of the designees will be listed in the SOP register

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6.3 Reviewing, Updating and Distributing SOPs

- 6.3.1 Once authorised the SOP must not be changed. Any amendments must be approved and authorised and a new version of the SOP issued via the R&D Office.
- 6.3.2 All SOPs will be reviewed on a maximum of biennial basis from the effective date or as changes to procedure are identified.
- 6.3.3 The R&D office will maintain the *SOP review schedule*; identify revision dates
- 6.3.4 A nominated person within RD office will be responsible for co-ordinating the review process including notifying assigned reviewers and sending necessary reminders.
- 6.3.5 The SOP review sheet will be signed and dated by the reviewer. If no changes are required the reviewer should state '*reviewed – not changed*'. Where essential further changes are required, the reviewer will record these on the review sheet.
- 6.3.6 The front page of the policy will be signed and dated by approver and authoriser.
- 6.3.7 Obsolete SOPs will be withdrawn by the R&D office, marked as superseded and filed in an electronic 'SOP Archive File'.
- 6.3.8 The correct logging, authorisation and distribution of SOPs will be within the operation of the R&D Office. It is the responsibility of Sponsoring organisation to monitor compliance with authorised SOPs. However it is the responsibility of the researcher to ensure that any they are familiar with the current version of the SOPs and ensure that their practice is compliant with the SOP.

6.4 Deviations from Authorised SOP

- 6.4.1. There should be no deviation from an authorised SOP except in exceptional circumstances for which the following procedures should be followed.
- 6.4.2 Any deviation must be documented and reported to the Sponsoring Organisation; and to the R&D Office if the research involves NNUH and to REN if the research involves the University.
- 6.4.3 Deviations to SOPs for study specific purposes should be submitted for approval and authorisation by the R&D Office before implementation.

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7 REFERENCES

Research Governance Framework (DH April 2005) or its successor.
Medicines for Human Use (Clinical Trial) Regulation 2004

8 LIST OF APPENDICES

- Appendix 1: SOP Template (Title Page)
- Appendix 2: SOP Template (Content)
- Appendix 3: Change Control, Revision and Review Sheet

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Appendix 1: SOP Template

TITLE PAGE

STANDARD OPERATING PROCEDURE

R&D SOP REFERENCE NUMBER

TITLE OF SOP

Version X	
Version date	
Effective date	
Number of pages	XX
Review date	
Author	
Approved by	
Role	
Signature	
Date	
Authorised by	
Role	
Signature	
Date	

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Appendix 2: SOP Template

CONTENT OF SOP (page numbers start after title page)

Page 1: Property Statement and Table of Contents

Section 1: Abbreviations

Section 2: Introduction

Section 3: Scope

Section 4: Definitions

Section 5: Responsibility

Section 6: Procedures

- Subsection as required e.g. 6.1, 6.1.1, 6.2, 6.2.2

References:

List of Appendices:

Change Control, Revision and Review Sheet:

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Revision Form: SOP XXX				
Version No	Change Date	Reason for Change	Reviewer	Signature and Date

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Appendix 3: Revision History

Revision Form: SOP 001				
Version No	Change Date	Reason for Change		
1.1	01/01/2012	Revision to incorporate changes to R&D and REN office processes.		
1.2	01/01/2014	Correction of version number and review dates. Addition of process if reviewer identifies further changes required. Minor corrections following reviewer comments. Changes to combined SOP control and revision sheets.	Reviewer: Lisa Chalkley Designation: Industry Manager, CLRN	Signature and Date: <i>Lisa Chalkley</i> 16th December 2013
1.3	25/11/2015	General formatting corrections. Changes to SOP title page layout and details. Inclusion of table to illustrate groups of SOP's. Minor spelling and grammar corrections. Updated and reformatted Appendix 3. Clarification on review process.	Reviewer: Thomas Clare & Basia Brown Designation: Research Governance Administrator & Research Governance Co-ordinator	Signature and Date: <i>Thomas Clare</i> <i>Basia Brown</i> 25.11.2016