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SOP 325 Study Start up Activities for Clinical Research Trials

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
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Name of document author:	Ania Spurdens / Victoria Hart
Job title of document author:	Commercial Coordinator / Research Study Officer
Name of document author's Line Manager:	Julie Dawson
Job title of author's Line Manager:	Research Services Manager
Supported by:	Julie Dawson NNUH Sarah Ruthven UEA
Assessed and approved by:	Julie Dawson: Research Services Manager NNUH Sarah Ruthven: Research Manager UEA
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies downloaded from the website are only valid on the day of downloading.

SOP 325 Study Start up Activities for Clinical Research Trials

1. Contents

2. Definitions of Terms Used / Glossary

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HRA	Health Research Authority
ICH	International Conference for Harmonisation
IMP	Investigational Medicinal Product
ISF	Investigator site file
MHRA	Medicines and Health Care Products Regulatory Agency
NNUH	Norfolk and Norwich University Hospital
NCTU	Norwich Clinical Trials Unit
PI	Principal Investigator
R&D	Research and Development
RIN	Research and Innovation Services
SOP	Standard Operating Procedure
TMF	Trial Master File
UEA	University of East Anglia

3. Objectives

The implementation and conduct of a study can be a complex process that involves a team from various disciplines and multiple steps that are dependent on one another. This document offers guidance for navigating the study start-up process.

4. Scope

This SOP gives an overview of the main activities involved in the start-up of studies sponsored by the NNUH or UEA. As not all research studies are the same, it is important that consideration is given to the nature and complexity of the study to ensure all appropriate set up activities are carried out.

5. Purpose

This SOP describes activities for the start-up for a clinical research trial.

6. Rules

Responsibility for Study Set-up

- Will be delegated by NNUH or UEA as the Sponsor to the CI.
- Will be recorded in the Sponsor's Delegation of Responsibility Log See **SOP 400: Arrangements for Authorisation of Research Sponsorship**.
- CI may delegate the responsibility for performing study site set-up activities to an appropriately trained and qualified member of the research team, this will be recorded in the Study Delegation Log.

Norwich Clinical Trials Unit (NCTU)

- Where the study is adopted by the NCTU, the Sponsor's Delegation of Responsibility agreed between NNUH, UEA and NCTU shall set out the responsibilities for performing study site set-up activities.
- NCTU may delegate responsibility for some activities to the CI, this will be recorded in the Study Delegation Log.
- This shall be guided by the **NCTU Working Practices document on trial management** (available from the NCTU).

7. Procedures

7.1 Initial enquiries into Research

Visit the NNUH website for useful information and links designed to support initial enquiries into research.

NNUH website – research and innovation – information for researchers.

Visit the UEA portal for useful information and links designed to support initial inquiries into research.

UEA portal – Research and Innovation Services – Research Support.
On this page you can select from the following headings for more information:

- Find Funding
- Bid Development
- Apply for Funding
- Manage your Project
- Research Integrity and Ethics

NCTU Supported Research

Trials with NCTU support should contact the unit directly for access to set-up documents, processes, and templates.

7.2 Sponsorship

- Most research studies conducted at NNUH are sponsored and led by other external organisations.
- Research that is initiated and led by NNUH researchers should be sponsored by NNUH if it can be demonstrated that the risks involved in that research are acceptable.

- Refer to **Research Sponsorship Policy** (Trust Docs ID 16161) available to download from the NNUH website - research and innovation – information for researchers – research management and **SOP 400 Arrangements for Authorisation of Research Sponsorship** for further information.

7.3 Approvals

- It is the CI's responsibility to ensure that the study has been submitted for review by an external REC, by the HRA, Trust R&D or RIN, where appropriate.
- For CTIMPs and Medical Device Trials, this also includes the MHRA see **SOP 405 Obtaining and Maintaining Medicines and Healthcare Products Regulatory Agency (MHRA) Approval for a Clinical Trial.**
- It is the responsibility of the Sponsor to ensure that all appropriate approvals have been given and that all agreements are in place before giving written Sponsor approval for the study to commence.
- It is the responsibility of the CI to ensure that **no** study-specific activities including advertising, screening, discussion with or recruitment of participants, commence before the Sponsor has given approval in writing confirming the approval to proceed with the study.

- It is the responsibility of the CI or PI to ensure that appropriate agreement(s) have been reached by the Sponsor.
- Any necessary site or other third-party agreements must be in place before commencement of the study.
- Where the study involves both NNUH and UEA, the R&D and RIN offices shall work together to ensure that all appropriate agreements, including those with external organisations, are in place prior to approval and the green light to proceed being given for the study.

- For multi-centre studies it is the responsibility of the CI to ensure that all relevant approvals are in place and that the PI at each site has the relevant Site-Specific paperwork before study activities commence.
- It is the responsibility of the PI to ensure that the Site Specific Agreement, local NHS R&D confirmation of capacity and capability and any approvals required by the host organisation, are in place before any study specific activities commence at that site.

7.4 Establishing a Trial Master File and Investigator Site File

- The CI or designee is responsible for establishing a Trial Master File (TMF) See **SOP 305 Creating and Maintaining the Trial Master File or Investigators Site File.**

- The PI or designee must establish an Investigator Site File (ISF) *See* **SOP 305.**

- It is the responsibility of the CI and PI(s) or designee to ensure that all essential documents are filed in the TMF and/or ISF respectively.

- All study related documents, including the TMF and ISF should be stored securely and in a manner that protects confidentiality according to ICH GCP.

- The TMF and ISF must be maintained in a ready state to allow for audit, inspection and/or monitoring on request, and that they are archived appropriately at the end of the trial see **SOP 900 Archiving, retrieval and destruction of Research Documents.**

7.5 Other start up activities

Risk Assessments

- The CI or PI should continue the risk assessment undertaken during the proposal/protocol development stage see **SOP 320 Developing a Research Protocol.**
- Risks may arise from the protocol and study procedures or from the risks associated with the training and experience of the trial team or host sites**.**
- For CTIMPs, the current regulatory framework allows for a range of risk adapted approaches according to how much is known about the medicine(s) being investigated.
- The appropriate mitigation, management and monitoring strategy for each risk identified should be discussed and documented see **SOPs 720 Risk Assessment of Trials Sponsored by the NNUH and UEA** or **725 Capacity Capability and Risk Assessment NNUH Hosted Studies** and if conducting a CTIMP or a Device Trial **SOP 330 Monitoring CTIMPs and Device Trials**.

Drug Accountability

- For CTIMPs, where NNUH is the Sponsor, the research support offices (R&D) will ensure that an IMP and Drug Accountability agreement has been reached with Pharmacy and that the study is registered with them as per their requirements, discussing specifics of the study with the CI and PI as necessary.

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NNUH Vendor Selection

- Not all research activities are conducted within the Norfolk and Norwich University Hospital (NNUH) therefore a variety of service models may be required to conduct research studies.
- A vendor is a person, organisation, facility, or agency external to NNUH that provides functions, services and products for studies sponsored by NNUH.
- The CI in consultation with R&D is responsible for ensuring that appropriate processes are adopted when selecting a potential vendor.
- See **SOP 700 NNUH Vendor Selection Approval and Oversight.**

Trial Supplies

- The CI or PI must ensure that all trial supplies are in place.

Training

- The CI or PI must ensure that all members of the study team are appropriately trained by qualification, previous experience and study specific training should be undertaken.
- Training must be documented in the training records of each individual.
- All staff working on the study and named on the Study Delegation Log must have undergone GCP training and hold a current certificate of this see **SOPs 505 Training Requirements, Creating and Maintaining Training Records** and **002 Good Clinical Practice (GCP) Training.**
- All members of the study team must be appropriately trained in pertinent SOPs and NNUH nursing, CRF, laboratory and radiological working practice documents, and/or external Sponsor SOPs as appropriate.

Delegation of Responsibility

- The CI or PI should ensure that the names of all members of the research study team, including the CI or PI, are listed in a Study Delegation Log with a definition of their individual study responsibilities see **SOP 305.**

Data Collection

- The CI in consultation with the Sponsor is responsible for ensuring appropriate collection of study data see **SOPs 350 Designing and Developing a Case Report Form**, **730 Computer System Validation** and **805 Clinical Data Management System – CDMS SET-UP.**

8. References and Related Documents

References
ICH GCP E6 / SI 2004/1041
EU Clinical Trials Directive 2001/20/EC
WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI Ethical principles for Medical Research Involving Human Subjects.
Description of the Medicines for Human Use (Clinical Trials) Regulations 2004
NCTU Working Practices document on trial management
Non-Clinical Policy for: NNUH sponsorship of research

SOP No.	SOP Title
SOP 002	Good Clinical Practice (GCP) Training
SOP 005	Grant Application
SOP 305	Creating and Maintaining a Trial Master File
SOP 320	Developing a Research Protocol
SOP 330	Monitoring Clinical Trials
SOP 350	Designing and Developing a Case Report Form
SOP 400	Authorisation of Sponsorship
SOP 405	Obtaining MHRA approval for a clinical trial
SOP 505	Creating and Maintaining Training Records
SOP 700	NNUH Vendor Selection Approval and Oversight
SOP 720	Risk Assessment of Trials Sponsored by the NNUH and UEA
SOP 725	Capacity Capability and Risk Assessment NNUH Hosted Studies
SOP 730	Computer System Validation
SOP 805	Clinical Data Management System – CDMS SET-UP
SOP 900	Storage and Retention of Research Documents

9. Approval

Author	Ania Spurdens / Victoria Hart
Role	Commercial Coordinator / Research Study Officer
Approved & Authorised NNUH	Julie Dawson
Role	Research Services Manager
Signature	DocuSigned by: Julie Dawson 4CBAB366CF354A2...
Date	28 December 2023 | 7:33 GMT
Approved & Authorised UEA	Sarah Ruthven
Role	Research Manager
Signature	DocuSigned by: Sarah Ruthven 50D5F3BEE2F04C1...
Date	18 January 2024 | 10:10 GMT

10. Training Implication

Training Implication	Yes
Actions required	• Additional training may be required