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SOP 410 Set up and Initiation of an Investigator Site for NNUH/UEA Sponsored Clinical Trials

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	Research, Investigator Site, set up
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Date of approval:	25/09/2024
To be reviewed before: This document remains current after this date but will be under review	25/09/2027 (3 years, unless legislation or process changes)
Reference and / or Trust Docs ID No:	14179
Version No:	3

Version and Document Control:

Version No:	Date of update	QPulse Change Request reference (CR no.)	Change Description	Author
3	25/09/2024		Scope clarified, PI/CI clarifications, SOP 002 GCP/study specific SOP /green light reference added	Ania Spurdens

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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SOP 410 Set up and Initiation of an Investigator Site

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2. Definitions of Terms Used / Glossary

CRFs	Case Report Forms (CRF)
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
HRA	Health Research Authority
ICH GCP	International Conference for Harmonisation of Good Clinical Practice
IMP	Investigational Medicinal Product
ISF	Investigator Site File
MHRA	Medicines and Healthcare Products Regulatory Agency
PI	Principal Investigator
R&D	Research and Development
RIN	Research & Innovation Services
RSO	Research Study Officer
SIV	Site initiation visit
SOP	Standard Operating Procedure
TMF	Trial Master File

3. Objectives

The aim of this SOP is to describe the process required for the set-up of an investigator site for a clinical trial, as either a single site or one of multiple sites in a trial sponsored by NNUH or UEA

4. Scope

This SOP applies to all trials where NNUH or UEA are sponsor. For the purpose of this SOP, the term ‘trial’ refers to the following types of studies:

- Clinical Trials of Investigational Medicinal Products (CTIMPs)
- Clinical Investigations of Medical Devices

- Combined trials of investigational medicinal products and investigational medical devices
- Other clinical trials to study a novel intervention or randomised clinical trials to compare interventions in clinical practice

Trials managed by Norwich Clinical Trials Unit (NCTU) follow NCTU working processes.

5. Purpose

This SOP provides information relating to planning for site initiation, the site initiation visit (SIV) and events following this.

6. Preparation

Before a trial can be initiated at a site, all necessary regulatory and local approvals need to be in place.

The SIV can take place by either a physical visit to the site, or remotely by teleconferencing. The site Principal Investigator (PI) **must** be present at the SIV. All staff who will be involved in the day-to-day operation of the trial will be invited to attend.

The site initiation process ensures that:

- All essential documentation is in place prior to the start of the trial
- Each site has the essential documents required to conduct the trial
- Each site is aware of its roles and responsibilities
- Each site is aware of the sponsor's requirements and the SOPs to be followed
- Site staff have evidence of current Good Clinical Practice (GCP) training (updated in line with the requirements in SOP 002 GCP training)
- A delegation log is completed prior to the start of trial activities
- The delegation log is authorised by the site PI
- Site pharmacy arrangements (if appropriate) are in place to allow Investigational Medicinal Product (IMP) ordering, receipt, dispensing and accountability
- Site arrangements are in place with the supplier of medical devices (if appropriate) to allow ordering, receipt, dispensing and accountability of the devices
- Site arrangements are in place with the laboratory (if appropriate) to allow for analysis, storage, shipment of samples.

- Contact details are up-to-date and clear lines of contact for enquiries are established between the Sponsor / CI, the research team, and pharmacy (if appropriate)

7. Responsibilities

The Trial Manager / Coordinator (or equivalent) will usually act as the main line of communication between the site investigator and the Sponsor Representative and, in consultation with the site CI / PI, will manage the process of site initiation.

Where there is no Trial Manager / Coordinator, for example where the trial is of short duration and of low risk, the Chief Investigator (CI) or delegate will manage the process of site initiation, leading the SIV, with support from the Research Study Officer (RSO) in the case of NNUH sponsored trials.

For all trials the Trial Manager / Coordinator, Trial Monitor, research study team and Sponsor representative or delegate will be involved in the process of site initiation (if in post for the trial), attending the SIV as required.

The Sponsor Representative will provide confirmation that the green light/site activation email can be sent to sites once the site initiation process is complete.

For non-CTIMPs sponsored by UEA, where NNUH is not a site, the CI / PI will be responsible for the process of site initiation and for keeping the records and reports from the site initiation in the Trial Master File (TMF).

All staff who will be involved in the day-to-day operation of the trial will be invited to attend.

8. Procedure

Prior to the site initiation visit, the Trial Manager / Coordinator / CI / PI:

- Must check that all essential documentation, approvals are in place, and contracts are agreed in principle
- Will ensure the NNUH / UEA sponsor file / Trial Master File (TMF) are held by the R&D / relevant UEA School or appropriate delegate.
- Will ensure that the site has the SIV checklist, see **Appendix 1** of this SOP, to identify requirements at site and to set up the investigator site file see **SOP 305 Creating and Maintaining the TMF or Investigators Site File**
- If study specific SOPs are to be developed (in addition to local Trust SOPs) these must be available to the Research Team and the Sponsor prior to the SIV
- For CTIMPs:
  - Will check with the sponsor that arrangements are in place for the sourcing and release of the IMP, in agreement with the Trial Pharmacist
  - Will ensure the Pharmacy site file is set up in agreement with the Pharmacist and following Pharmacy SOPs
- For trials involving medical devices:
  - Ensure arrangements for procurement of the device are in place at sites
- For trials involving a central laboratory or central storage of samples:

- Ensure arrangements are in place for shipment and/or storage of samples

Prior to Site Activation, the Trial Manager / Coordinator/ CI / PI will need to confirm that the site has:

- Confirmation of Capacity and Capability
- Completed Risk Assessment, a fully signed site agreement and agreements with third parties (if required)
- Site investigator CVs and GCP certificates
- Staff delegation log
- Clear arrangements for monitoring, with a completed monitoring plan in place
- Pharmacy and/or medical device supply agreements (if appropriate) in place (including formal confirmation from pharmacy)
- Arrangements in place with the laboratory (if appropriate)
- TMF and / or Investigator Site File

An initiation visit / meeting must be arranged and set up at site by the Trial Manager / Coordinator, in consultation with the CI / PI

- Staff involved in or responsible for the study must be invited to the meeting (CI / PI / Lead pharmacist) including the site Pharmacist, Laboratory Representative, Trial Monitor, Trial Nurses / Allied Health Professionals and Administrators who will be supporting the study at site
- An agenda, detailing the requirements to be covered for the meeting should be circulated with the invitation, see **Appendix 2** of this document
- Details of the meeting location or dial in details should be circulated in advance
- It may be helpful to develop and circulate a presentation or slide set based on the agenda items

8.1 Site Initiation Visit (SIV)

- The meeting must be held according to the agenda
- See **Appendix 4** for template slides which can be used to the form basis of the SIV
- A record of attendees at the meeting and notes from the meeting (see **Appendix 3** for a template SIV Report which can be used), shall be kept in the TMF and / or Investigator Site File (ISF)

- Time will be allowed for the research team to raise any queries. If these cannot be resolved by the Trial Manager / Coordinator / CI / PI at the meeting these shall be followed up after the visit and resolved prior to the start of participant recruitment

- For CTIMPs and studies involving the supply of drugs, the Pharmacy team must be familiar with the processes and documentation required
- Arrangements for storage / transport / supply of IMP shall be reviewed and approved by the Clinical Trial Pharmacist, the Trial Manager, Sponsor and the CI / PI

- Visits to local facilities such as laboratories and Pharmacy shall be arranged as necessary for the Trial Manager / Coordinator to discuss set-up arrangements either prior to or as part of the SIV

- For monitored studies the Trial Monitor must sign the Monitor's Log for the SIV. **See SOP 330 Monitoring Clinical Trials of an Investigational Medicinal Product and Device Trials**

8.2 After the Site Initiation Visit

- A report of the initiation meeting, along with any follow-up actions shall be prepared by the Trial Manager / Coordinator / Trial Monitor or Research Study Officer and sent to the site

- A copy of the report should be forwarded to the Sponsor, along with a copy of the signed delegation log

- For CTIMPs and device trials, the Sponsor will then issue a letter to the PI at site to allow release of IMP or medical devices at the site

- The Sponsor Representative will provide confirmation that the green light/site activation email can be sent to the site

- For NNUH sponsored or hosted studies, RIN / R&D will record details of the site initiation and delegation in the sponsor / R&D file

- For UEA sponsored studies not involving NNUH, the CI shall retain these records in the TMF

For CTIMPs and Device trials a Green Light confirmation letter will be produced by the Sponsor to confirm that the site is ready to recruit participants

- No study related activities can take place until Confirmation of Green Light/Site Activation from the Sponsor has been received by the CI / PI

Following the SIV, representatives from the site must be invited by the Trial Manager / Coordinator to attend any relevant Steering Group or Data Monitoring meetings.

9. References and Related Documents

References	
ICH GCP E6 / SI 2004/1031	
SOP No.	**SOP Title**
SOP 002	Good Clinical Practice Training
SOP 305	Creating and Maintaining the TMF or Investigators Site File
SOP 330	Monitoring Clinical Trials of an Investigational Medicinal Product and Device Trials
SOP 410 App 1	Sponsor Green Light Checklist
SOP 410 App 2	Agenda for Site Initiation Visit
SOP 410 App 3	Site Initiation Visit Report
SOP 410 App 4	Site Initiation Visit Template Slides

10. Approval

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Date	26 September 2024 | 8:27 BST

11. Training Implication

Training Implication	**Yes**
Actions required	• Additional training may be required