University of East Anglia

Our Vision
The best care for every patient

Norfolk and Norwich University Hospitals
NHS Foundation Trust

SOP 411 Sponsor Oversight and Site Initiation for Non-regulated Studies Sponsored by NNUH

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	Sponsor Oversight; Site Initiation
Name of document author:	Ania Spurdens
Job title of document author:	Research Governance Coordinator
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
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:	23568
Version No:	V1

Version and Document Control:

Version No:	Date of update	QPulse Change Request reference (CR no.)	Change Description	Author
1	25.9.24		New document	Ania Spurdens

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 411 Sponsor Oversight and site initiation for non-regulated studies

1. Contents

2. Definitions of Terms Used / Glossary

IRAS	Integrated Research Application System
NNUH	Norfolk and Norwich University Hospitals NHS Foundation Trust
R&D	Research and Development
RSM	Research Services Manager
RSO	Research Study Officer
SOP	Standard Operating Procedure
SOV	Sponsor Oversight Visit

3. Objectives

The aim of this SOP is to describe the process required for the set-up of an investigator site for studies that are not classed as clinical trials, sponsored by NNUH.

4. Scope

This SOP applies to all studies that are sponsored by NNUH that do not fall under the definition of a clinical trial or clinical investigation (as defined in **SOP 410**). For example:

- Basic science studies involving procedures with human participants
- Studies administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Studies involving qualitative methods only
- Studies limited to working with human tissue samples (or other human biological samples) and data
- Studies limited to working with data
- Research tissue banks
- Research databases

5. Purpose

This SOP provides information on the NNUH sponsor oversight process, planning for site initiation, the sponsor oversight visit (SOV), and Sponsor Oversight Review Visit.

For more information about NNUH sponsorship, see SOP 400 Arrangements for Authorisation of Research Sponsorship, SOP 401 Sponsorship Request and Approval for Research Studies and Clinical Trials, and POL1 Research Sponsorship Policy.

6. Rules

All research taking place in the NHS requires prior approval

- Health Research Authority (HRA) approval applies to all project-based research taking place in the NHS in England
- Most research will require favourable opinion from a Research Ethics Committee (REC)
- NHS organisations taking part in research will usually be required to provide confirmation of capacity and capability (C&C) to the Sponsor before opening the study
- Additional approvals may be required for certain studies

7. NNUH Procedure

- Researcher contacts NNUH R&D Office
- Researcher will be assigned a Research Study Officer (RSO) to support with Integrated Research Application System (IRAS) submission and next steps

↓

- RSO completes risk assessment to assess whether NNUH can act as sponsor for the study

↓

- Risk assessment signed off by Research Services Manager (RSM)
- RSO issues Confirmation of Sponsorship letter to Researcher

↓

- IRAS submitted for review

↓

- RSO sends out NNUH Sponsored Studies Training to Researcher/Research Team
- Researcher/Research Team works through training slides and confirms completion of this

↓

- R&D complete capacity and capability (C&C) assessment

- RSO conducts Sponsor Oversight Visit (SOV) with Researcher/Research Team

- R&D issue Sponsor green light for the study to begin

Following recruitment of the first participant into the study:

- The Researcher/Research Team will let R&D know when the first participant has been recruited to the study
- The RSO will arrange a Sponsor Oversight Review Visit with the Researcher/Research Team.

8. UEA Procedure

For UEA sponsored studies please refer to the RIN pages on the UEA portal pages which outline the process, or email researchsponsor@uea.ac.uk.

9. References and Related Documents

References	
ICH GCP E6 / SI 2004/1041	
SOP No.	**SOP Title**
SOP 400	Arrangements for Authorisation of Research Sponsorship
SOP 401	Sponsorship Request and Approval for Research Studies and Clinical Trials
POL1	Research Sponsorship Policy

10. Approval

Author	Ania Spurdens
Role	Research Governance Coordinator
Approved & Authorised NNUH	Julie Dawson
Role	Research Services Manager
Signature	DocuSigned by: Julie Dawson 4CBAB366CF354A2...
Date	25 September 2024 | 2:34 BST
Approved & Authorised UEA	Sarah Ruthven
Role	Research Manager
Signature	DocuSigned by: Sarah Ruthven 50D5F3BEE2F04C1...
Date	26 September 2024 | 8:24 BST

11. Training Implication

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