

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

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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

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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.

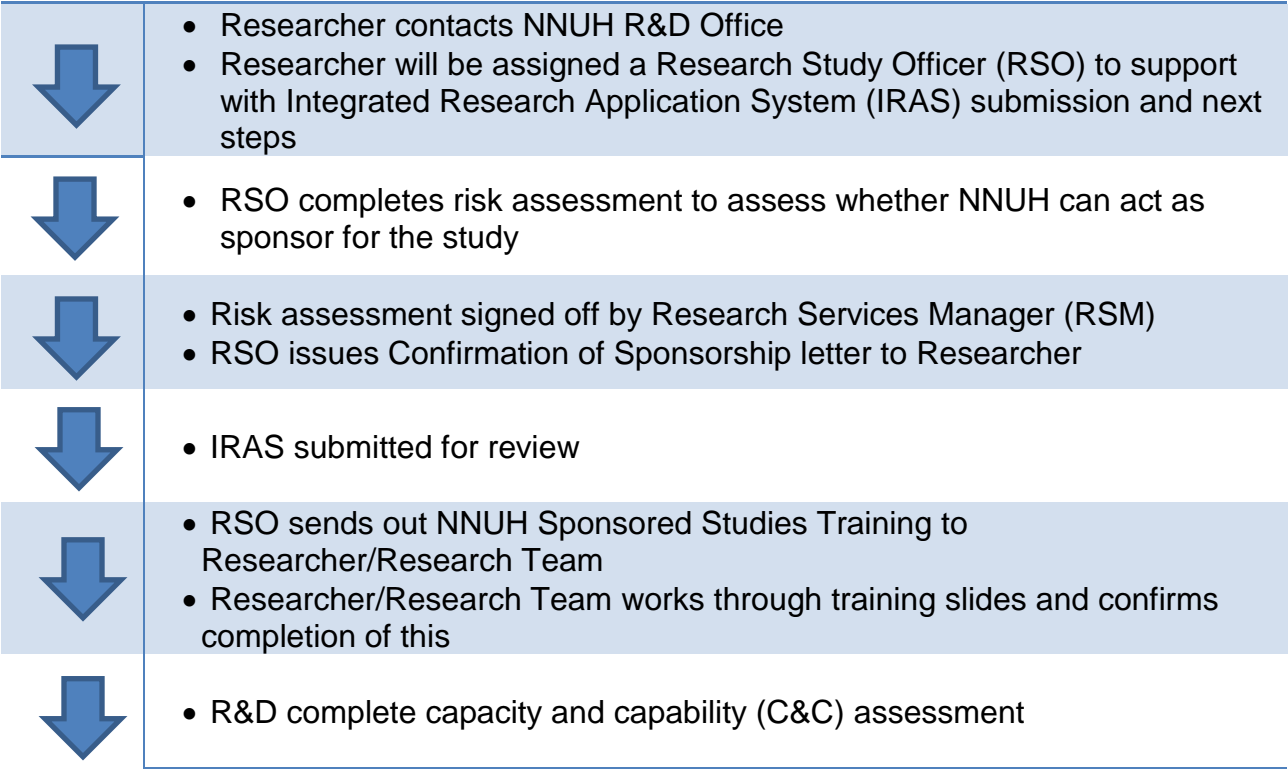
For more information about NNUH sponsorship, see SOP 400 Arrangements for Authorisation of Research Sponsorship, SOP 401 Sponsorship Request and Approval for Research Studies and Clinical Trials, and POL1 Research Sponsorship Policy.

6. Rules

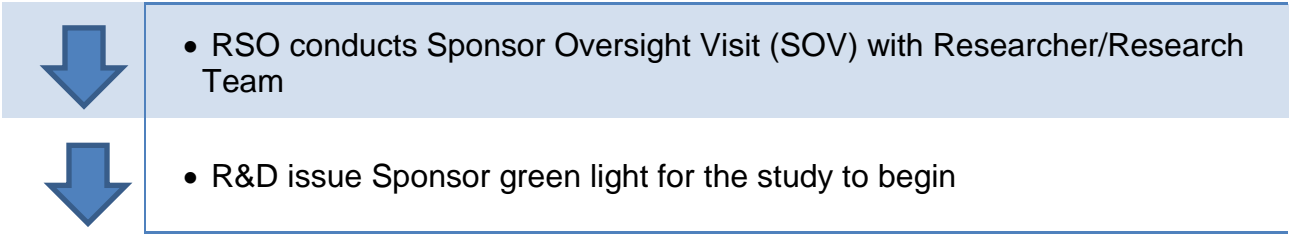
All research taking place in the NHS requires prior approval

- 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



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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

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10. Approval

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11. Training Implication

Training Implication	Yes
Actions required	<ul style="list-style-type: none">Additional training may be required