

## SOP 401 Sponsorship Request and Approval for Research Studies and Clinical Trials

<b>For Use in:</b>	Research
<b>By:</b>	All staff
<b>For:</b>	All staff involved in the conduct of research
<b>Division responsible for document:</b>	Research & Development
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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## SOP 401 Sponsorship Request and Approval for Research Studies and Clinical Trials

### 1. Contents

Section	Page
1. Contents	2
2. Definitions of Terms Used / Glossary	2
3. Objectives	2
4. Scope	2
5. Purpose	3
6. Rules	3
7. Procedure NNUH	4
8. References and Related SOP's	5
9. Approval	6
10. Reason for Update & Training Implication	6

### 2. Definitions of Terms Used / Glossary

CI	Chief Investigator
DRO	Director of Research Operations
NNUH	Norfolk and Norwich University Hospitals NHS Foundation Trust
R&D	Research and Development
RGC	Research Governance Coordinator
RGrantC	Research Grants Coordinator
RSM	Research Services Manager
RSO	Research Study Officer
SOP	Standard Operating Procedure
UEA	University of East Anglia

### 3. Objectives

The aim of this Standard Operating Procedure (SOP) is to outline the process for applying for research sponsorship from the Norfolk and Norwich University Hospital (NNUH).

### 4. Scope

Under the UK Policy Framework for Health and Social Care Research 2017, all health and social care research projects require a sponsor. The sponsor is the individual, organisation or partnership that takes overall legal responsibility for proportionate, effective arrangements being in place to fund, set up, run, and report a research project.

The sponsor has overall responsibility for the research project and will usually be the organisation employing the Chief Investigator (CI) in the case of non-commercial research. However, there are a few exceptions to this general rule, for example where research is being completed as part of an educational qualification, it would usually be expected that the educational institution would act as sponsor. Occasionally there are exceptional circumstances where the research cannot be sponsored by the substantive employer of the CI and in these situations the organisation may ask another organisation to sponsor the project (see POL 1 Sponsorship Policy for full details).

## SOP 401 Sponsorship Request and Approval for Research Studies and Clinical Trials

### 5. Purpose

The purpose of this SOP is to help CIs and research staff applying for sponsorship from NNUH.

### 6. Rules









It should be noted that:

- In principle, NNUH will accept sponsorship for research projects that meet the following conditions:
  - NNUH is the substantive employer of the CI (see Sponsorship Policy POL1 if the CI is not substantively employed by the NNUH)
  - The CI makes a formal request to the R&D department for NNUH to sponsor the study, in accordance with this SOP.
  - The CI and all research staff familiarise themselves with relevant NNUH research SOPs and Trust policies.
  - The CI and all research staff working on the study are suitably qualified by education and experience to carry out their delegated responsibilities. The CI is responsible for ensuring training is documented prior to the start of the study, and regularly monitoring compliance throughout.
  - That the study is adequately funded or the NNUH Division/Department has agreed to cover costs for the duration of the study.
- A sponsorship risk assessment will be carried out by the NNUH R&D department for any project applying for NNUH sponsorship. The risk assessment must demonstrate that the risk to NNUH of undertaking sponsorship is reasonable and significant risks are appropriately mitigated.
- For grant applications requiring sponsorship, if after assessment sponsorship is approved it will be a sponsorship in principle. If the study proceeds to set up, R&D will review sponsorship taking into account whether any conditions have been met and changes to the proposal.
- Sponsorship requests can be escalated to the Associate Medical Director for Research or Joint Research Governance Committee.
- Any appeals can be made to the Research Oversight Board, the decision of the Research Oversight Board is final.
- The CI is responsible for securing all relevant regulatory approvals and maintaining compliance with the UK Policy Framework for Health and Social Care Research and the principles of Good Clinical Practice.
- Sponsorship will be reviewed and the process undertaken again if circumstances or risk change significantly.







## SOP 401 Sponsorship Request and Approval for Research Studies and Clinical Trials

### 7. Procedure NNUH

#### a. Projects applying for sponsorship at the grant application stage

	<ul style="list-style-type: none"> <li>Request made by Chief Investigator to R&amp;D for sponsorship of their project</li> <li>Provided with relevant information e.g. proposal, etc</li> </ul>
	<ul style="list-style-type: none"> <li>Sponsorship risk assessment undertaken by RGrantC</li> </ul>
	<ul style="list-style-type: none"> <li>Any risks that are identified are appropriately mitigated if possible</li> </ul>
	<ul style="list-style-type: none"> <li>Risk assessment assessed by RSM and RGC</li> </ul>
	<ul style="list-style-type: none"> <li>Sponsorship decision confirmed by RSM or DRO</li> </ul>
	<ul style="list-style-type: none"> <li>Sponsorship in principle decision letter issued by RGrantC</li> </ul>
	<ul style="list-style-type: none"> <li>If the grant is awarded, the risk assessment will be re-reviewed by the RSO</li> </ul>
	<ul style="list-style-type: none"> <li>Confirmation of sponsorship decision letter issued by RSO</li> </ul>

#### b. Other projects

	<ul style="list-style-type: none"> <li>Request made by Chief Investigator to R&amp;D for sponsorship of their project</li> <li>Provided with relevant information e.g. protocol, proposal, etc</li> </ul>
	<ul style="list-style-type: none"> <li>Sponsorship risk assessment undertaken by RSO</li> </ul>
	<ul style="list-style-type: none"> <li>Any risks that are identified are appropriately mitigated if possible</li> </ul>
	<ul style="list-style-type: none"> <li>Risk assessment assessed by RSM and RGC</li> </ul>
	<ul style="list-style-type: none"> <li>Sponsorship decision confirmed by RSM or DRO</li> </ul>
	<ul style="list-style-type: none"> <li>Sponsorship decision letter issued by RSO</li> </ul>

## SOP 401 Sponsorship Request and Approval for Research Studies and Clinical Trials

### 8. References and Related Documents

#### References



ICH GCP E6 / SI 2004/1041

UK Policy Framework for Health and Social Care Research 2017

SOP No.	SOP Title
SOP 001	Production, Review, Approval and Control of SOPs Related to Research Activities
POL 1	Research Sponsorship Policy

## SOP 401 Sponsorship Request and Approval for Research Studies and Clinical Trials

### 9. Approval

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<b>Date</b>	28 November 2022   1:24 GMT

### 10. Reason for new version and Training Implication

This is a new SOP

Changes made	NA
Reason	<ul style="list-style-type: none"> <li>• New SOP</li> </ul>
Training Implication	<b>Yes</b>
Actions required	<ul style="list-style-type: none"> <li>• Additional training may be required</li> <li>• Matrix to be updated</li> </ul>