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Norfolk and Norwich University Hospitals
NHS Foundation Trust

SOP 400 Arrangements for Authorisation of Research Sponsorship

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
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Name of document author:	Michael Sheridan / Sarah Ruthven
Job title of document author:	Research Grants Coordinator / Research Manager
Name of document author's Line Manager:	Julie Dawson / Julia Sheldrake
Job title of author's Line Manager:	Research Services Manager / Head of Research Services
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 printed from the website are only valid on the day of printing.

1. Contents

2. Definitions of Terms Used / Glossary

ATIMPs	Trials of Advanced Therapies (medicinal products involving cell or gene therapy or tissue engineering)
CI	Chief Investigator
CTIMPs	Clinical Trials of Investigational Medicinal Products
IRAS	Integrated Research Application System
JRGC	Joint Research Governance Committee
MHRA	Medicines and Healthcare Products Regulatory Agency
NCTU	Norwich Clinical Trials Unit
NIW	Notification of Intention to Write a Grant Proposal
PO	Project Officer
R&D	Research and Development
RSM	Research Services Manager
RSO	Research Study Officer
RIN	Research & Innovation Services
SOP	Standard Operating Procedure

3. Objectives

To ensure that research is sponsored only if it can be demonstrated that the risks involved in that research are acceptable.

4. Scope

This SOP describes how arrangements for authorisation of Research Sponsorship are approved for all healthcare research activity within the UEA and NNUH

5. Introduction

Decisions about Research Sponsorship at NNUH are described in the Norfolk and Norwich University Hospitals NHS Foundation Trust Research Sponsorship Policy available at https://www.nnuh.nhs.uk/research-and-innovation/information-for-researchers/research-management-in-the-trust/ in association with this SOP

Under the UK Framework for Health and Social Care Research all health and social care research projects require a sponsor. The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to fund, set up, run and report on a research project. The sponsor has overall responsibility for the research and is normally expected to be the employer of the chief investigator in the case of non-commercial research.

Health and social care research covers a wide spectrum of research from non-interventional questionnaire studies to highly interventional trials. Some of the more interventional and high risk research falls under the jurisdiction of the Medicines and Healthcare Products Regulatory Agency (MHRA) and is required to comply with specific legal requirements for such trials (Regulated trials). These are Clinical Trials of Investigational Medicinal Products (CTIMPs); Device trials (Clinical Investigations), Trials of Advanced Therapies (medicinal products involving cell or gene therapy or tissue engineering) (ATIMPs) and combinations of these.

Making a decision to accept sponsorship of a study or trial is an important decision as the organisation accepts responsibility for the study and the risks associated with it.

The majority of 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.

The R&D Office at NNUH and the Research & Innovation Services (RIN) at UEA are responsible for all Sponsor related correspondence. When a study involves other units such as the Norwich Clinical Trials Unit (NCTU) or NNUH Pharmacy, those units should route any Sponsor related correspondence through the R&D Office or RIN. In turn, those units shall be copied into any formal correspondence concerning the study. Where appropriate to the study, e.g. when a study is formally adopted by the Norwich Clinical Trials Unit, some of the sponsor responsibilities may be formally delegated to the unit, as recorded in the Delegation of Responsibility form in the research project contract.

6. Procedure for UEA

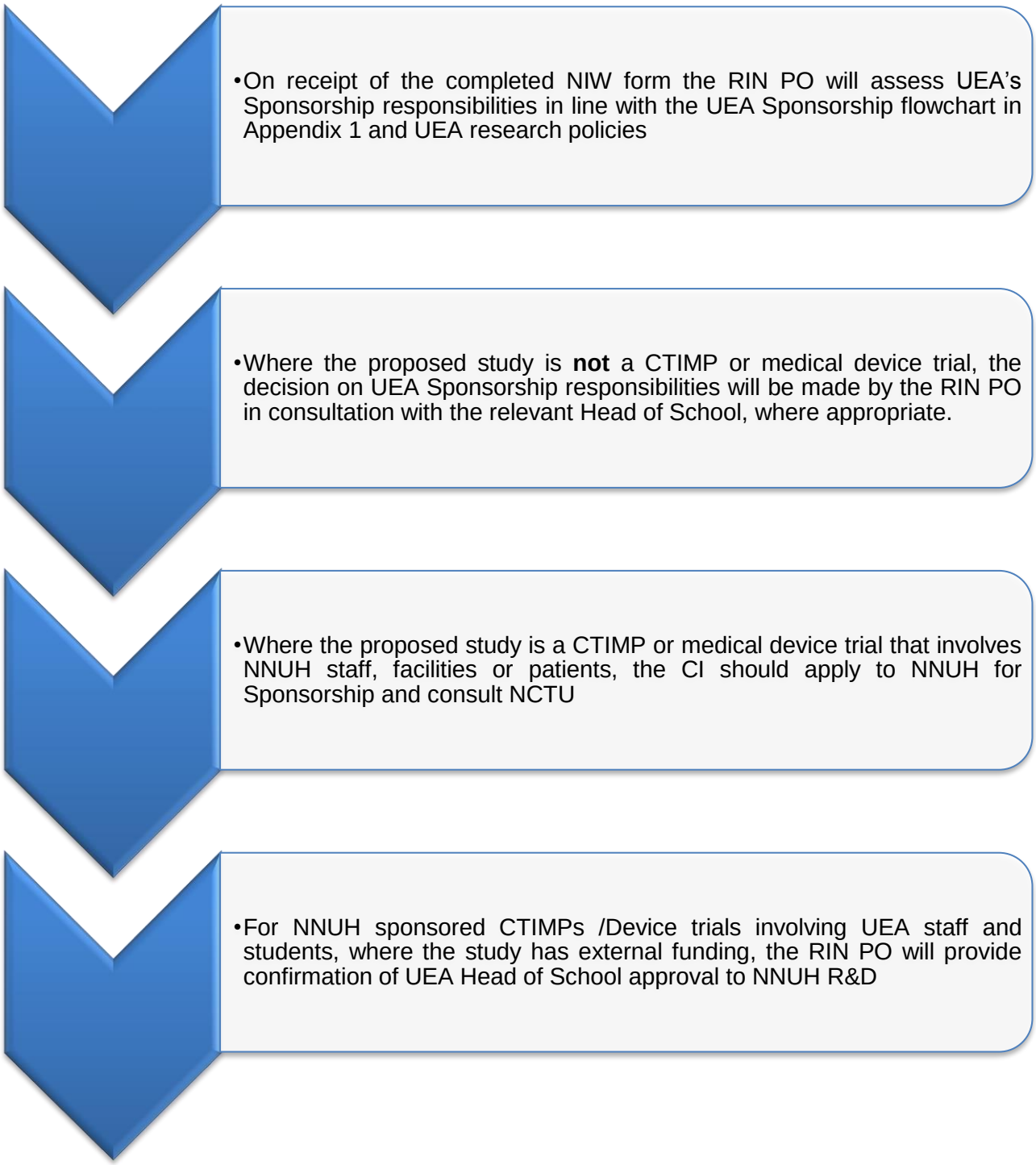
Rules:

- Apply for sponsorship as early as possible in the development of the project
- Early consultation with UEA Project Officer (PO) is advised
- The study sponsor needs to be decided before submitting the funding application
- The study CANNOT proceed without Sponsorship approval, as staff or students working on the project will not be insured through the University
- See SOP 325 Study Start up Activities for Clinical Research Trials

How to apply for sponsorship:

- The Chief Investigator (CI) should notify their Project Officer in RIN, sending the required forms. Guidance notes for researchers and supervisors are available from the RIN website https://portal.uea.ac.uk/rin - UEA login required

6.1 Sponsorship Responsibilities



6.2 Confirming Sponsorship

Where a provisional opinion about Sponsorship is formally required, e.g. on the application for funding, the UEA PO shall confirm provisional Sponsorship either by letter or by signing the funding application form.

For the study REC and HRA application, through the Integrated Research Application System (IRAS), the PO shall sign the Sponsor declaration.

7. Procedure for NNUH

Who should apply:

- All NNUH staff conducting research involving NHS staff, facilities and patients and all UEA staff and students undertaking a study where NNUH is the Sponsor (including CTIMP/Device trials)

When to apply:

- As early as possible in the development of the project
- In some cases a funder will require a named sponsor on submission of a funding application, so early consultation with the NNUH R&D is essential

How to apply:

- Contact the NNUH the R&D office mailbox Office.RD@nnuh.nhs.uk
- Sponsorship review will take place when near final copies of the study documents are received by a Research Study Officer (for Grant applications sponsorship in principle will be reviewed on a draft application)

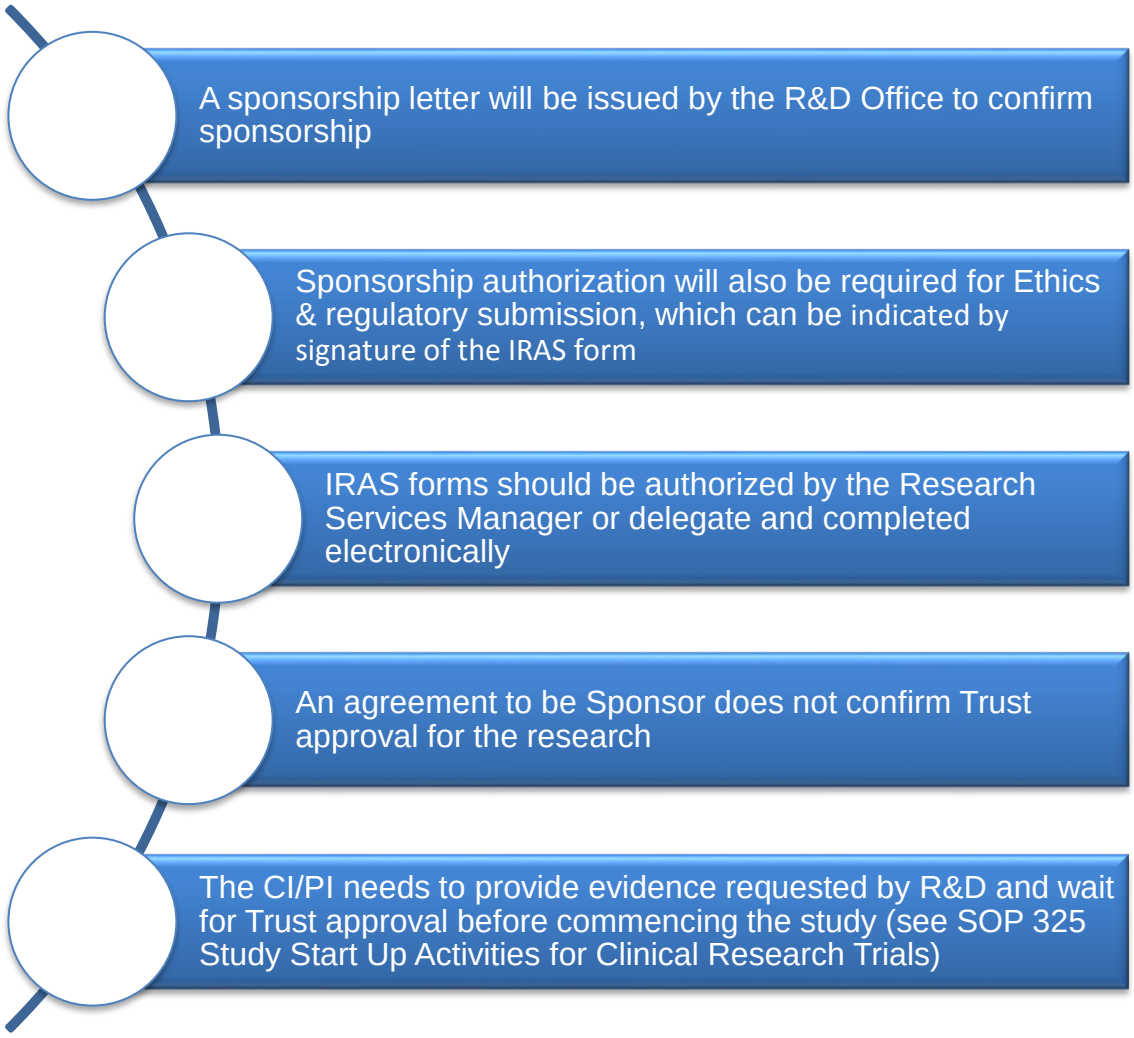
7.1 Sponsorship Responsibilities

The NNUH Research Study Officer (RSO) will assess your request (governance review including indemnity, funding, risk assessment, capacity and capability) and refer to the Research Services Manager (RSM) for further review as necessary.

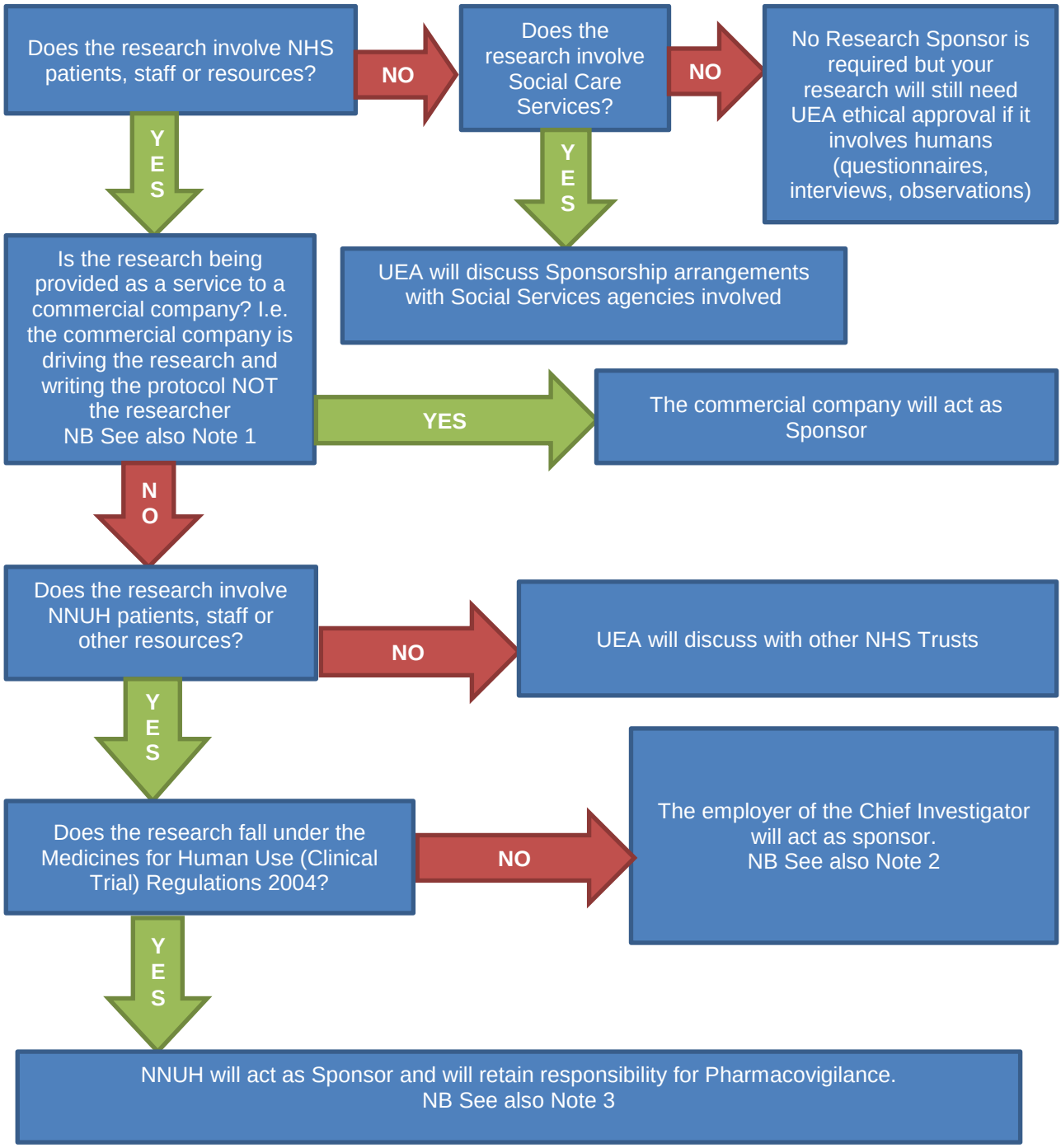
The RSM may refer your request to the Joint Research Governance Committee (JRGC).

Review will be undertaken to determine if the Trust is able to undertake sponsorship in accordance with the responsibilities of a research sponsor as defined in the UK Policy Framework for Health and Social Care Research and with the principles of the NNUH Research Sponsorship Policy (see link on page 3) and the UEA Sponsorship flowchart in Appendix 1.

7.2 Confirming Sponsorship and Issuing a Sponsor letter



8. Appendix 1 UEA Sponsorship Flow Chart



Note 1 Academic led research that is commercially funded WILL require UEA/NNUH sponsorship arrangements

Note 2 Where the Chief Investigator is employed by NNUH but is leading research under honorary contract at UEA, or where the Chief Investigator is employed by UEA but is leading research under honorary clinical contract with NNUH, then sponsorship arrangements will be agreed between UEA and NNUH. NB The lead contract organisation may not always employ the CI as is the case with bids to NIHR submitted by NNUH where CI is employed by UEA.

Note 3 Where the project team involves staff employed by UEA, NNUH may delegate specific responsibilities to UEA including the NCTU.

9. References and Related Documents

References
ICH GCP E6 / SI 2004/1041

SOP No.	SOP Title
SOP 325	Study Start-up Activities for Clinical Research Trials

10. Approval

Author	Michael Sheridan / Sarah Ruthven
Role	Research Grants Coordinator / Research Manager
Approved & Authorised NNUH	Julie Dawson
Role	Research Services Manager
Signature	DocuSigned by: Julie Dawson 4CBAB366CF354A2...
Date	21 March 2023 | 1:04 GMT
Approved & Authorised UEA	Sarah Ruthven
Role	Research Manager
Signature	DocuSigned by: Sarah Ruthven 6EB42B4E497249C...
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11. Reason for new version and Training Implication

This SOP replaces the previous version number 1.5

Changes made	What changes have been made to the contents of the document
Reason	• New layout • Revision in procedure
Training Implication	**No**
Actions required	• NA