Norfolk and Norwich University Hospitals NHS Foundation Trust Research Sponsorship Policy v5.0

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Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document: Bernard Brett, Medical Director. Various drafts were discussed with the University of East Anglia and the Joint Research Governance Committee.

The final version was approved by the Research Oversight Board. This version has been endorsed by the Hospital Management Board.

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g. changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a policy applicable to Norfolk and Norwich University Hospitals NHS Foundation Trust; please refer to local Trust's procedural documents for further guidance.

Norfolk and Norwich University Hospitals NHS Foundation Trust
Research Sponsorship Policy

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1. Introduction

This policy lays out the circumstances and conditions under which NNUH will sponsor regulated and non-regulated trials and research studies. The key considerations will be the level of risk associated with the research, benefits to NNUH and the contribution of the research to delivering NNUH Research Strategy 2020-2025.

1.1. Rationale

Under the UK Policy Framework for Health and Social Care Research 2023 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 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 (drugs) (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 can be sponsored by NNUH if it can be demonstrated that the benefits of the research outweigh the risks and risks can be adequately mitigated.

1.2. Objective

The objective of this policy is to clarify the principles and conditions under which NNUH will accept sponsorship of a study, the risks that need to be considered as part of the decision-making process, and the decision making and appeal processes.

1.3. Scope

This policy applies to all research studies that Chief and Principal Investigators would like to be sponsored by NNUH and lays out the circumstances and conditions under which NNUH will sponsor regulated and non-regulated trials and research studies.

1.4. Glossary

The following terms and abbreviations have been used within this document:

Term	Definition
ATIMPs	Advanced Therapy Medicinal Product (medicinal products involving cell or gene therapy or tissue engineering)
CIs	Chief Investigators
CTIMPs	Clinical Trials of Investigational Medicinal Products
CTU	Clinical Trials Unit
Device Trials	A clinical investigation designed to collect definitive evidence of the safety and effectiveness of a device for a specified intended use
GCP	Good Clinical Practice
HEI	Higher Education Institution
MHRA	Medicines and Healthcare Products Regulatory Agency
NNUH	Norfolk and Norwich University Hospitals NHS Foundation Trust
PIs	Principal Investigators
QIB	Quadram Institute Bioscience
SOP	Standard Operating Procedure
R&D	Research and Development
UEA	University of East Anglia

2. Responsibilities

Chief Investigator – the individual appointed to lead the research study, who is managed by their substantive employer. Overall accountability for the delivery of the trial. Responsible for following the requirements in this policy where NNUH is the substantive employer.
Principal Investigator – the individual responsible for the conduct of the research at the site. Responsible for following the requirements in this policy where NNUH is the substantive employer.
NNUH as Research Sponsor – will follow the requirements of the policy in deciding whether to sponsor regulated and non-regulated trials and research studies.

Director of Research Operations and Research Services Manager– responsible for taking the decision whether or not to accept sponsorship. Director of Research Operations is responsible for taking the decision to withdraw sponsorship
Joint Research Governance Committee – to provide advice as required
NNUH Associate Medical Director for Research – to provide advice as required

Research Oversight – responsible for considering appeals regarding sponsorship decisions. The Research Oversight Board's decision is final.

3. Principles

3.1. Principles of the UK Policy Framework for Health and Social Care Research 2023

The default principle is that the substantive employer of the lead Investigator (Chief Investigator) of a research study will be the sponsor of that study.

In general, educational research projects should be sponsored by the relevant Higher Education Institution (HEI).

It is recognised that occasionally there are exceptional circumstances when a particular trial or study cannot be sponsored by the substantive employer of the lead researcher. On these occasions the organisation may request another organisation take on sponsorship responsibilities which, depending on risk, funding and other circumstances, they may or may not agree to do.

NNUH reserves the right to refuse to review and approve requests for sponsorship (and associated grant costs) when the Chief Investigator has given insufficient notice of their intention to submit a proposal to a funding body or not followed the SOP.

3.2. Principles of NNUH Sponsorship

The NNUH SOP for Sponsorship Request and Approval for Research Studies and Clinical Trials must be adhered to. NNUH reserves the right to decline to sponsor any study if the Trust believes the risks are too high and are not able to be mitigated and/or the benefits to NNUH for acting as sponsor are too low or not well justified (see below).

Should NNUH agree to sponsor a study, then if circumstances or the risks change significantly and those risks cannot be mitigated, or there is persistent non-compliance with all applicable regulations, NNUH may, as a last resort, withdraw sponsorship.

For a study which NNUH has agreed to sponsor, should replacement of the Chief Investigator be necessary (for whatever reason), then NNUH will review and approve all reasonable requests, however, NNUH retains the right to decline replacement of the Chief Investigator and may withdraw sponsorship.

In instances when it is necessary for NNUH to withdraw sponsorship (see below for further explanation of the circumstances for sponsorship withdrawal), and no alternative sponsor is found, then for NNUH patients enrolled in the study, NNUH will seek to maintain on-going routine care of the research participants outside of the clinical trial. For research participants enrolled and participating in the study at non-NNUH sites then if sponsorship is withdrawn, the Chief Investigator must work with the site(s) Principal Investigator(s) to maintain on-going routine care of the research participants at the study site. NNUH will not be liable for any losses if sponsorship is withdrawn.

Where NNUH agree to sponsor a non NNUH trial, a sponsorship agreement with the substantive employer of the Chief Investigator will be put in place which will govern the ongoing sponsorship of the trial.

NNUH will follow all national guidance provided to sponsors by the Health Research Authority and National Institute of Health Research including in states of emergency such as the Covid-19 pandemic.

3.3. Non-regulated trials and research studies

In principle NNUH will accept sponsorship for a research project that meets the following conditions:

- NNUH is the substantive employer of the Chief Investigator.
- The Chief Investigator makes a formal request to R&D for NNUH to sponsor the study in accordance with the SOP. The sponsorship approval process must be followed which includes a risk assessment conducted by NNUH R&D. This must demonstrate that the risks to NNUH of undertaking sponsorship of the study are reasonable and any significant risks are appropriately mitigated (this may include involving a Clinical Trials Unit). The Chief Investigator must secure all relevant regulatory approvals (such as Health Research Authority and ethical approval), NNUH R&D confirmation of capacity and capability and understands and maintain compliance with the responsibilities expected of a Chief Investigator as set out in the UK Policy Framework for Health and Social Care Research 2023 and Good Clinical Practice.
- Chief Investigator and all staff working on the study make themselves familiar with and adhere to all relevant NNUH research SOPs and Trust policies.
- Chief Investigator and other colleagues involved in the research must have suitable and documented research training before starting the study and that the Chief Investigator regularly monitors compliance.
- As appropriate, R&D retains the right to arrange independent peer review of the protocol by individuals with relevant research and clinical expertise to confirm scientific merit, clinical relevance, participant safety and viability. This may include reviewers external to NNUH for example clinical researchers at the University of East Anglia, Quadram Institute Biosciences, other NHS trusts or academic institutions.

- The study is adequately funded or the NNUH Division / Department has agreed to cover costs for the duration of the study, and this is documented.

3.4. Regulated trials (CTIMP, ATIMP, device trials etc)

In principle NNUH will accept sponsorship for a regulated research trial if the following conditions are met:

- The Chief Investigator's substantive employer is NNUH (see below for Chief Investigators whose substantive employer is a Quadram Institute/ UEA partner).
- Everything described above for non-regulated trials is complied with, plus the following:
  - It is expected for a Clinical Trials Unit (CTU) to manage all regulated trials that NNUH are asked to sponsor, with the CTU being delegated by NNUH to undertake many of the sponsor responsibilities and tasks. In exceptional circumstances, on a case-by-case basis and subject to R&D having the required resources to provide the appropriate level of oversight, a CTU may not be required if the Chief Investigator can demonstrate that they have secured appropriate experienced support (for statistics and data management) and appropriate systems (validated clinical trials data base) to give NNUH confidence the study will be run in a compliant manner. The Chief Investigator must also demonstrate that they fully appreciate the additional responsibilities and workload they are accepting by not using a CTU.
- The Chief Investigator and all Principal Investigators (PIs) involved in the trial must be appropriately qualified clinicians and must be suitably experienced in conducting interventional (and ideally regulated) research studies. In general students are not allowed to be PIs for regulated studies sponsored by NNUH as they are unlikely to have sufficient or suitable experience. In exceptional circumstances, proposals for a suitably qualified and experienced student to be PI for a regulated trial will be considered if plans for very close day to day, appropriate training, local supervision and oversight by the Chief Investigator can be demonstrated on an ongoing basis.
- The trial must be able to demonstrate direct benefit for NNUH, for example provide opportunities for patients under NNUH care or NNUH staff to participate in the research which on balance outweighs the 'costs' associated with providing sponsorship and/or setting up and carrying out the trial. In this context NNUH 'costs' includes the level of risk in terms of participant safety, liability, prospect of the study delivering robust outcomes and external factors.
- Studies involving healthy adult volunteers must be conducted in the Quadram Institute Clinical Research Facility.
- The training requirement (as above) must include GCP training.
- Since sponsorship takes into consideration whether a trial is financially viable, Chief Investigators should engage with R&D in the early stages of development of the trial and before any grant applications to fund the trial are submitted. R&D must be engaged in providing costings for the grant application and given appropriate advance notice prior to the submission date (minimum of 4 weeks) to allow adequate time for review. Failure to engage with the R&D team in the early stages of development may lead to sponsorship being declined. Any funded time in the grant for Chief Investigators must be undertaken as part of their NNUH employment e.g.

Research PA time, additional hours, funding into department clinical trial account, etc.

3.5. Other circumstances

NNUH may also consider sponsoring other research (including regulated trials) on a case-by-case basis as it is recognised that partner research organisations (i.e. the University of East Anglia and Quadram Institute Bioscience) may not be able to sponsor regulated trials. While normally NNUH would only sponsor research led by its own employees, as part of the partnership and in support of research in the local area, NNUH is willing to consider sponsoring regulated trials from Chief Investigators for whom the University of East Anglia or Quadram Institute Biosciences is the substantive employer.

This will be reviewed and decided on a case-by-case basis and with the key consideration being the level of risk associated with the proposal, the direct benefits to NNUH as described above and the contribution to delivering NNUH Research Strategy 2020-2025.

In addition to meeting all the conditions above, if the Chief Investigator's substantive employer is not NNUH then a NNUH honorary contract must be secured before the final decision of accepting sponsorship can be made.

3.6. NNUH declines to sponsor

In general, NNUH declines to sponsor the following (although there may be exceptions, reviewed on a case-by-case basis for example research that is aligned with NNUH's strategic intent for developing research capability and will be supported by the Board's Risk Appetite relating to innovation & research):

- Phase I trials
- Trials conducted outside the UK
- Studies where identified risks, under the reasonable opinion of NNUH, cannot be adequately mitigated
- Research undertaken as part of a qualification for which a university or academic institution at which the student is registered should act as Sponsor
- Research where the documentation provided by the Chief Investigator is not sufficient to allow adequate review of risk assessment (at minimum draft protocol, draft participant information sheet, draft consent form are required).
- Research where the Chief Investigator has previously been found to be in breach of compliance with the R&D approval process or Trust policies and SOPs.
- Research that does not involve either researchers or research participants directly connected with NNUH, UEA or QIB.

4. Ongoing sponsorship

NNUH will periodically review studies and trials it has previously agreed to sponsor, particularly if circumstances change during the course of the research and where in the reasonable opinion of NNUH, risks have been identified that cannot be adequately mitigated and in a timely manner.

Any changes during the duration of the study that impact on these stated conditions (for example but not limited to, changes in the employment status of the Chief Investigator or funding arrangements) must be reported to the Sponsor by the Chief Investigator, and the sponsorship decision will be reassessed.

Under exceptional circumstances it may be necessary to withdraw NNUH sponsorship. NNUH would not consider withdrawal of sponsorship lightly and would first look to working with the Chief Investigator and the Clinical Trials Unit to put remedial actions in place.

5. Decision Making Process

- The decision of whether or not to accept sponsorship rests with the Director of Research Operations and the Research Services Manager.
- When relevant, advice will be sought from NNUH's Associate Medical Director for Research and/or the Joint Research Governance Committee.
- NNUH has limited capacity to review proposals to act as Research Sponsor. This means that requests will be prioritised taking into account the number of applications and the contribution the proposed project will make to the delivery of NNUH's Research Strategy 2020-2025.
- For proposals intended to be submitted to a funding body, then a decision in principle will be made. In the event a grant is awarded, then R&D will review the decision to act as sponsor taking into account any previous considerations or changes to the proposal that may result from peer review of the grant application.
- The decision to withdraw sponsorship rests with the Director of Research Operations.
- Appeals to reconsider must be made to the Research Oversight Board.
- The Research Oversight Board's decision is final.

6. Monitoring Compliance

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee / dept	Frequency of monitoring
Research Sponsorship	Quarterly review of trials	Joint Research Governance	Joint Research Governance Committee	Quarterly

		Committee		

The audit results are to be discussed at Joint Research Governance Committee meetings to review the results and take recommendations for further action. Concerns will be escalated to the Research Oversight Board who will ensure that the actions and recommendations are suitable and sufficient.

7. Appendices

There are no appendices for this document.

8. Equality Impact Assessment (EIA)

Type of function or policy	Existing

Division	Corporate	**Department**	Research and Development
Name of person completing form	Research Oversight Board	**Date**	07.05.2024

Equality Area	Potential Negative Impact	Impact Positive Impact	Which groups are affected	Full Impact Assessment Required YES/NO
Race	None	None	NA	No
Pregnancy & Maternity	None	None	NA	No
Disability	None	None	NA	No
Religion and beliefs	None	None	NA	No
Sex	None	None	NA	No
Gender reassignment	None	None	NA	No
Sexual Orientation	None	None	NA	No
Age	None	None	NA	No
Marriage & Civil Partnership	None	None	NA	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?	NA			

- **A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty**
- **Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service**
- **The policy or function/service is assessed to be of high significance**

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED

The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.