APPENDIX 2

Sponsorship of Clinical Research Studies

Category:	Policy
Summary:	The UK Policy Framework for Health and Social Care 2017 (UKPF) and The Medicines for Human Use (Clinical Trials) Regulations 2004 require that an organisation taking on the role of 'Sponsor' must ensure that there are proper arrangements in place to initiate, manage, monitor and finance a study. Prior to accepting this role, the Trust must undertake some form of risk assessment to ensure that the acceptance of sponsorship is desirable and appropriate. Accountability for certain functions may be formally delegated to the Chief Investigator (CI), where skills and facilities are in place to support this.
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Date of Next Review:	July 2027
Approval Date/ Via:	Trust Management Executive 01 August 2024
Distribution:	Via Research and Development to: • Researchers within OUH Foundation Trust • Trust website
Related Documents:	Capacity and Capability Approval of Clinical Research Policy Monitoring and Audit of Research Studies Safety Reporting in Clinical Research Policy Integrity in Research Policy Incident Reporting, Investigation and Learning Procedure
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This Document replaces:	Sponsorship of Clinical Research Version 4.0 February 2018

Lead Director: Chief Medical Officer

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It is the responsibility of all users to this document to ensure that the correct and most current version is being used.
This document contains many hyperlinks to other related documents.
All users must check these documents are in date and have been ratified appropriately prior to use.

Document History

Date of revision	Version number	Author	Reason for review or update
May 2007	2.1	Katerina Samouri-Christodoulos	Updated to incorporate change in policy
June 2010	3.0	Heather House, Research & Development Lead	Updated to incorporate change in policy
June 2014	3.3	Heather House, Research & Development Lead	General update
Jan 2018	4.0	Heather House, Head of Research Governance	Updated to incorporate change in policy and HRA. Incorporate detail from the Protocol Amendments policy
July 2024	5.0	Katie Flight, Deputy Head of R&D Governance	General update. Incorporate change in device marking following departure from EU.

Consultation Schedule

Use this table to evidence your involvement of staff and key stakeholders, where appropriate, in the development and review of documents.

Who? Individuals or Committees	Rationale and/or Method of Involvement
Shahista Hussain, Head of R&D Governance	Review of the document and changes
Jo Franklin, Senior Research Support Manager	Review of the document and changes
Lousie Willis, Research Support Manager	Review of the document and changes

Endorsement

Use this table to list relevant Divisional and/Directorate leads who have endorsed the policy/procedural document.

Endorsee Job Title
Head Of R&D Operations
Director of R&D

Contents

Who should read this document?

1. This policy should be read by anyone planning submission of applications to the Health Research Authority (HRA) and the appropriate Research Ethics Committee (REC) and Medicines and Healthcare products Regulatory Agency (MHRA) (where applicable) where it is requested that the Trust take on the role of Sponsor.

Key Standards/Messages

2. The UK Policy Framework for Health and Social Care 2017 (UKPF) requires that an organisation taking on the role of 'Sponsor' must confirm that there are proper arrangements in place to initiate, manage, monitor and finance a study.

3. The Medicines for Human Use (Clinical Trials) Regulations 2004 require that organisations which take on the role of Sponsor of clinical trials must have systems in place for the management of that trial.

4. Prior to accepting this role, the Oxford University Hospitals NHS Foundation Trust ('the Trust') must undertake some form of risk assessment to ensure that the acceptance of sponsorship is desirable and appropriate. Accountability for certain functions may be formally delegated to the Chief Investigator (CI), where skills and facilities are in place to support this

5. Responsibility for Sponsorship is ongoing for the duration of any research study, including where the research protocol is amended, until final reporting and publication.

Background/Scope

6. It is the policy of the Trust to:

    6.1. Protect the safety, dignity, rights and well-being of all patients involved in clinical research.
    6.2. Ensure that arrangements are in place for the management and monitoring of research studies, where the Trust has taken on the role of Sponsor, including compliance with the relevant regulations

7. This Policy applies to anyone planning submission of applications to the Health Research Authority (HRA) and the appropriate Research Ethics Committee (REC) and Medicines and Healthcare products Regulatory Agency (MHRA) (where applicable) where it is requested that the Trust take on the role of Sponsor

Key Updates

8. Incorporate change in device marking following departure from EU.

9. References to national guidelines have been updated.

10. The Equality Impact Assessment has been updated to the new template version.

Aim

11. This policy sets out a consistent procedure for the review and authorising of sponsorship for all research using human subjects for which the Trust has been asked to take on the role of 'Sponsor'.

12. This procedure aims to ensure that the Trust takes responsibility for quality research applications and ongoing compliance with the relevant legislation, throughout the conduct and reporting of the research study.

Content of the Policy

Identification of Sponsor

13. Sponsorship of a research study is largely determined by the employment status of the proposed Chief Investigator (CI). Usually sponsorship will be agreed for CIs whose primary contract is with the Trust and who are permanent members of staff, e.g. medical consultants. If the CI is employed by the University of Oxford they should usually approach the University Research Governance, Ethics & Assurance Team (RGEA)). However, there are, occasionally, exceptions to these guidelines. These can be discussed with the Head of R&D Governance on a case by case basis.
14. Researchers will be required on initial contact with R&D to complete a Sponsorship Request Form to assess suitability for the Trust to sponsor.

Submission timelines

15. For Clinical Trials of Investigational Medicinal Products (CTIMP), non-UKCA/CE UKNI/CE marked device trials and large scale randomised interventional trials, investigators requesting sponsorship should approach R&D at the protocol development stage.

16. For other research studies, R&D should be contacted prior to ethics submission. Prior to review, timelines for both parties will be agreed, to ensure prompt turnaround and seamless review.

Documents required

17. Any documents to be included in the submission to the HRA/REC/MHRA should be sent for review by the R&D governance team.

Review Process

18. On receipt of the required documents, relevant details contained therein will be reviewed to undertake a risk assessment; ensure compliance with relevant legislation; and provide advice to the applicant in order to enable the ethics review to run as smoothly as possible.

19. The CI or delegate will be advised of any required changes to documents with specified timelines and, once the final documents are received, a sponsor letter will be provided and the relevant page on the IRAS form will be signed to authorise sponsorship.

20. Where an investigator is new to the process of ethics applications and unsure of the content of the essential documents, the R&D team will provide additional support and guidance if required.

Delegation of Sponsor Responsibilities

21. For CTIMPs, accountability for certain functions will be formally delegated to the Chief Investigator (CI). However, as Sponsor, the Trust will continue to have overall responsibility.

Monitoring the Progress of Research Study applications

22. Once the research study has been granted all the relevant approvals, the Chief Investigator is responsible for ensuring that the study is conducted in accordance with the details outlined in the protocol and the HRA/REC/MHRA applications.

23. Prior to the local Trust Management Approval Letter being issued, all studies will have an initiation visit proportionate to the study type to confirm all the required documentation is present. Any queries and actions will be requested and will need to be confirmed as complete.

24. In the event that the PI/CI plans to leave the employment of the Trust, or take a period of prolonged absence, s/he should inform R&D as soon as possible. In such an event, the following options may be possible: transfer sponsorship of the trial to the future employer, with their consent; retain sponsorship and put an agreement in place to cover the CI's role; retain sponsorship in Oxford and appoint an alternative Chief Investigator; withdraw Oxford sponsorship and close the trial.

25. The progress of the study through the approvals process is monitored through on-going contact with the investigator. Copies of correspondence between the ethics committee and the investigator, HRA and the investigator and between the Medicines and Healthcare products Regulatory Agency (MHRA) (for CTIMPs) and the investigator, should be forwarded to R&D. The R&D project management system, Studyline, will be promptly updated on receipt of any information.

26. For sponsored CTIMPs and non-UKCA/CE UKNI/CE marked device trials additional monitoring of compliance will be undertaken according to the policy for Monitoring and Audit of Research Studies

27. If applicable, copies of Annual Progress reports and Development Safety Update Reports should be forwarded to R&D throughout the lifetime of the study.

28. End of study notifications should be submitted to R&D once the study has closed.

Protocol Amendments

29. Where a substantial amendment is requested to a study sponsored by the Trust, these must be reviewed by R&D and approved before submission to external bodies e.g. HRA, REC and/or MHRA (if applicable).

30. All documents that are to be changed should be submitted as tracked changed versions to R&D for review, discussion and approval before submission to any external organisation for their approval.

31. On receipt of the required documents, a member of the R&D Team will collate all relevant documents and assess whether there is any impact on the Trust and whether the amendment is compliant with the relevant legislation. Further information may be requested, where anything is unclear.

32. Once the details of the changes have been agreed with the study team, the Head of R&D Governance or delegated individual can approve the amendment. The amendment can then be submitted to appropriate external bodies, but cannot be implemented until appropriate external approvals have been received. Approval letters should be sent to R&D.

Review

33. This policy will be reviewed every 3 years, as set out in the the Developing and Managing Policies and Procedural Documents Policy.The policy may need to be revised before this date, particularly if national guidance or local arrangements change, where implementation is unsuccessful or where audits necessitate a policy review.

References

34. The Medicines for Human Use (Clinical Trials) Regulations 2004 and amendments.

35. The UK Policy Framework for Health and Social Care Research 2017

Appendix 1: Responsibilities

Head of R&D Governance/Deputy Head of R&D Governance/Senior Research Support Manager

1. Authorise 'in principle' initial acceptance of sponsorship on behalf of the Trust prior to sponsorship review.
2. Formal confirmation of sponsorship prior to HRA/ethics/regulatory submission

R&D Governance Team

3. Provide advice and information to investigators requesting that the Trust take on the role of sponsor to a clinical research study or CTIMP. Assessment of eligibility for sponsorship and review of associated documents.

Chief Investigator

4. Ensure that adequate funding is in place to cover the compliant conduct of the study.
5. Protocol development, generation of associated documents and relevant application forms.
6. Ensure appropriate conduct of the study throughout.
7. Maintain oversight and promote compliance with Regulatory requirements for safety reporting, on behalf of the Trust.
8. Ensure that R&D is informed of any change in the status of the Principal Investigator (e.g. leaving the Trust; maternity leave), prior to that change taking place.

Appendix 2: Definitions

1. **Sponsor**

   The organisation taking responsibility for initiation, management and financing (or arranging the financing) of a clinical trial or research study.

   Clinical Trial of Investigational Medicinal Product (CTIMP)

2. Any investigation in human subjects, other than a non-interventional trial*, intended: to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; to identify any adverse reactions to one or more medicinal products or; to study the absorption, distribution, metabolism and excretion of one or more such products with the object of ascertaining the safety or efficacy of those products. Such trials will be governed by the Medicines for Human Use (Clinical Trials) Regulations 2004 and updates.

   * The Medicines and Healthcare products Regulatory Agency (MHRA) view a trial as interventional where a drug is being given as an intervention and assessments are being undertaken to assess the effects. This is not dependent on the prescription of that drug being undertaken as part of the protocol.

   Device Trial

3. A clinical investigation designed to establish the performance of a medical device which is intended to reveal adverse events under normal conditions of use, and permit assessment of the acceptable risks having regard to the intended performance of the medical device. Such trials are regulated by the UKPF and would require the approval of an ethics committee. Trials using non-UKCA/CE UKNI/CE marked devices or using UKCA/CE UKNI/CE marked devices outside their current intended purposes or in modified forms are also regulated by the Medical Devices Regulations (2017).

   Interventional Trial / Study

4. Any investigation in human subjects which involves some form of clinical intervention: surgical, medical, or psychological, but which is not classified as a CTIMP as defined in 9. Such studies are regulated by the UKPF and would require the approval of an ethics committee.

5. N.B For purposes of classification, the term “interventional” should not be confused with “invasive”. Interventional studies involve changing the course of clinical care. Invasive studies would involve invasion of the body, for example venepuncture.

   Non-interventional Study

6. Any investigation in human subjects, which is observational and does not involve any intervention in addition to their normal clinical care. Such studies are regulated by the UKPF and would require the approval of a Research Ethics Committee (REC).

   Substantial Protocol Amendment

7. A substantial amendment is defined as an amendment to the terms of the protocol or any other supporting documentation that is likely to affect to a significant degree: the safety or physical or mental integrity of the subjects of the study; the scientific value of the study; the conduct or management of the study; the quality or safety of any investigational medicinal product used in the study**.**

   Non-substantial Protocol Amendment

8. These can be defined as changes to the details of the study which have no significant implications for the subjects, conduct, management, or the scientific value of the study.

Urgent Safety Measure

9. An amendment which needs to be implemented as a matter of urgency, in order to protect research participants against any immediate hazard to their health or safety.

Chief Investigator

10. The individual, as identified in the ethics application, who takes overall responsibility for the conduct of a clinical study

Principal Investigator

11. The individual who takes on responsibility for conduct of the study at a particular site.

Appendix 3: Education and Training

1. All staff involved in the conduct of clinical trials will undertake the relevant training in good research practice prior to beginning their involvement in the trial.

2. Training required to fulfil this policy will be provided in accordance with the Trust's Training Needs Analysis. Management and monitoring of training will be in accordance with the Trust's Core Skills Policy. This information can be accessed via the Practice Development and Education pages on the Trust intranet..

Appendix 4: Monitoring Compliance

What is being monitored:	How is it monitored:	By who, and when:	Minimum standard	Reporting to:
Approval of Sponsorship	Review of approved studies	Head of R&D Governance	Annual	Joint R&D Committee
Compliance with terms of Research Ethics approval	Monitoring, audit and compliance checks	Head of R&D Governance	Ongoing	Joint R&D Committee

Appendix 5: Equality Impact Assessment

Equality Impact Assessment Template

1. In accordance with Equality & Diversity legislation, this Policy has had an Equality Impact Assessment undertaken. It has been determined that this Policy does not discriminate against any individual or group and a full copy of the assessment can be viewed on the Research and Development intranet page.

What is being assessed	Existing Policy / Procedure
Job title of staff member completing assessment	Head of R&D Governance
Name of policy / service / function:	Sponsorship of Clinical Research Studies
Details about the policy / service / function	The policy details the roles, responsibilities and processes that occur for the OUH Trust to act as Sponsor of clinical research studies.
Is this document compliant with the Web Content Accessibility Guidelines?	Yes
Review Date	July 2024
Date assessment completed	09/07/2024
Signature of staff member completing assessment	Katie Flight
Signature of staff member approving assessment	Shahista Hussain

2. Screening Stage

Who benefits from this policy, service or function? Who is the target audience?

- Staff

Does the policy, service or function involve direct engagement with the target audience?

Yes - *continue with full equality impact assessment*

3. Research Stage

Notes:

- If there is a neutral impact for a particular group or characteristic, mention this in the 'Reasoning' column and refer to evidence where applicable.
- Where there may be more than one impact for a characteristic (e.g. both positive and negative impact), identify this in the relevant columns and explain why in the 'Reasoning' column.
- The Characteristics include a wide range of groupings and the breakdown within characteristics is not exhaustive, but is used to give an indication of groups that should be considered. Where applicable please detail in the 'Reasoning' column where specific groups within categories are affected, for example, under Race the impact may only be upon certain ethnic groups.

Impact Assessment

Characteristic	Positive Impact	Negative Impact	Neutral Impact	Not enough information	Reasoning
Sex and Gender Re-assignment – men (including trans men), women (including trans women) and non-binary people.			X		This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Race - Asian or Asian British; Black or Black British; Mixed Race; White British; White Other; and Other			X		This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Disability - disabled people and carers			X		This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Age			X		This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Sexual Orientation			X		This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Religion or Belief			X		This policy applies to clinical researchers conducting research studies within the Trust,

Characteristic	Positive Impact	Negative Impact	Neutral Impact	Not enough information	Reasoning
					regardless of race, religion, disability, age, gender or sexuality
Pregnancy and Maternity			X		This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Marriage or Civil Partnership			X		This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Other Groups / Characteristics - for example, homeless people, sex workers, rural isolation.			X		This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality

Sources of information
No protected groups were targeted during the consultation process.

Consultation with protected groups
List any protected groups you will target during the consultation process, and give a summary of those consultations

Group	Summary of consultation
N/A	

Consultation with others
Based on the previous version, the update has drawn on feedback from researchers, regulators and Joint R&D Committee.

4. Summary stage

Outcome Measures
List the key benefits that are intended to be achieved through implementation of this policy, service or function and state whether or not you are assured that these will be equitably and fairly achieved for all protected groups. If not, state actions that will be taken to ensure this.
The process of agreeing to sponsor a research proposal occurs in line with the UK Policy Framework for Health and Social Care Research 2017. Reviewing a proposal for research as a sponsor ensures that compliance. Agreement to sponsor is dependent on the science of the proposal, employment status of the investigators and the funding. Different research projects will be aimed at different patient and or staff groups with different age, sex, religious, sexual orientation, marital status, physical and mental status. Some or none of these may be important or unimportant in the research proposed.

In accordance with Equality & Diversity legislation, this Policy has had an Equality Impact Assessment undertaken. It has been determined that this Policy does not discriminate against any individual or group and a full copy of the assessment can be viewed on the Research and Development intranet page.

Positive Impact
List any positive impacts that this policy, service or function may have on protected groups as well as any actions to be taken that would increase positive impact.

No specific positive impacts on protected groups have been identified.

Unjustifiable Adverse Effects
List any identified unjustifiable adverse effects on protected groups along with actions that will be taken to rectify or mitigate them.

No specific adverse effects on protected groups have been identified.

Justifiable Adverse Effects
List any identified unjustifiable adverse effects on protected groups along with justifications and any actions that will be taken to mitigate them.

No specific adverse effects on protected groups have been identified.

Equality Impact Assessment Action Plan

Complete this action plan template with actions identified during the Research and Summary Stages

Identified risk	Recommended actions	Lead	Resource implications	Review date	Completion date
None identified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable