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.
Equality Impact Assessment undertaken:	27 December 2017
Valid From:	January 2018
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Distribution:	Via Research and Development to: • Researchers within OUH Foundation Trust • Trust website
Related Documents:	Trust Management Approval Policy Monitoring and Audit of Research Studies Safety Reporting in Clinical Research Policy Integrity in Research Policy Incident Reporting and Investigation Policy
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Contents

Introduction

1. 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.
2. 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.
3. 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.
4. Responsibility for Sponsorship is ongoing for the duration of any research study, including where the research protocol is amended, until final reporting and publication.

Policy Statement

5. It is the policy of the Trust to:

   5.1 Protect the safety, dignity, rights and well-being of all patients involved in clinical research.

   5.2 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.

Scope

6. 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

Aim

7. 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'.
8. 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.

Definitions

The terms used in this document are defined as follows:

Sponsor

9. 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)

10. 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

11. 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-CE marked devices are also regulated by the Medical Devices Regulations (2017)

Interventional Trial / Study

12. 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.
13. 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**

14. 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

15. 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

16. 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

17. 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

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

Principal Investigator

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

Responsibilities

Head of Research Governance/Research and Development Manager

20. Authorise 'in principal' initial acceptance of sponsorship on behalf of the Trust prior to sponsorship review.
21. Formal confirmation of sponsorship prior to HRA/ethics/regulatory submission

Research Governance Team

22. 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

23. Ensure that adequate funding is in place to cover the compliant conduct of the study
24. Protocol development, generation of associated documents and relevant application forms.
25. Ensure appropriate conduct of the study throughout
26. Maintain oversight and promote compliance with Regulatory requirements for safety reporting, on behalf of the Trust.
27. 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.

Content of the Policy

Identification of Sponsor

28. 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 Clinical Trials and Research Governance Team (CTRG). However, there are, occasionally, exceptions to these guidelines. These can be discussed with the Head of Research Governance on a case by case basis.

Submission Timelines

29. For Clinical Trials of Investigational Medicinal Products (CTIMP), Device Trials and large scale randomised interventional trials, investigators requesting sponsorship should approach R&D at the protocol development stage.
30. 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

31. Any documents to be included in the submission to the HRA/REC/MHRA should be sent for review by the research governance team.

Review Process

32. 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.
33. 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
34. 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

35. 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

36. 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 REC/MHRA applications.
37. 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.
38. 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.
39. 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 database will be promptly updated on receipt of any information.

40. For sponsored CTIMPs additional monitoring of compliance will be undertaken according to the policy for Monitoring and Audit of Research Studies
41. The copies of Annual Progress reports and Development Safety Update Reports should be forwarded to R&D throughout the lifetime of the study.

Protocol Amendments

42. Where a substantial amendment is requested to a study sponsored by the OUH Trust, these must be reviewed by R&D and approved before submission to external bodies e.g. HRA, REC and/or MHRA (if applicable
43. 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
44. 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.
45. Once the details of the changes have been agreed with the study team, the Head of Research Governance or delegated individual can approval the amendment. The amendment can therefore 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.

Training

46. 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.

47. 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 *Learning and Development Policy*. This information can be accessed via the Learning and Development pages on the Trust intranet.

Monitoring Compliance

Aspect of compliance or effectiveness being monitored	Monitoring method	Responsibility for monitoring (job title)	Frequency of monitoring	Group or Committee that will review the findings and monitor completion of any resulting action plan
Approval of Sponsorship	Review of approved studies	Head of Research Governance	Annual	Joint R&D Committee
Compliance with	Monitoring, audit	Head of	Ongoing	Joint R&D

Aspect of compliance or effectiveness being monitored	Monitoring method	Responsibility for monitoring (job title)	Frequency of monitoring	Group or Committee that will review the findings and monitor completion of any resulting action plan
terms of Research Ethics approval	and compliance checks	Research Governance		Committee

Review

48. This policy will be reviewed every 3 years, as set out in the Policy for the Development and Implementation of Procedural Documents.

49. 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

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

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

Equality Impact Assessment

52. 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.

List of Appendices

53. The following appendices are attached to support this document:

Appendix 1: Equality Impact Assessment: Full Analysis

Document History

of revision	Version number	Reason for review or update
May 2007	2.1	Updated to incorporate change in policy
June 2010	3.0	Updated to incorporate change in policy
June 2014	3.3	General update
Jan 2018	4.0	Updated to incorporate change in policy and HRA. Incorporate detail from the Protocol Amendments policy

Appendix 1: Equality Impact Assessment: Full Analysis

Equality Analysis
Policy / Plan / Proposal name: Sponsorship of Clinical Research Studies
Date of Policy: January 2018
Date due for review: July 2021
Lead person for policy and equality analysis: Head of Research Governance
The only policies and proposals not relevant to equality considerations are those not involving people at all (for example equipment such as fridge temperature)
Identify the main aim and objectives and intended outcomes of the policy The policy details the roles, responsibilities and processes that occur for the OUH Trust to act as Sponsor of clinical research studies.
Involvement of stakeholders Based on the previous version, update has drawn on feedback from researchers, regulators and Joint R&D Committee.
Evidence 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.
Disability This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Learning Disability This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Sex This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Age This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Race This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Sexual orientation This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Pregnancy and maternity This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Religion or belief. This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Gender re-assignment This policy applies to clinical researchers conducting research studies within the Trust,

Equality Analysis
regardless of race, religion, disability, age, gender or sexuality
Marriage or civil partnerships This policy applies to clinical researchers conducting research studies within the Trust, regardless of race, religion, disability, age, gender or sexuality
Carers NA
Safeguarding people who are vulnerable Where relevant to the research proposal, this issue is reviewed by the relevant sponsorship reviewer on behalf of the Trust and by the Research Ethics Committee
Other potential impacts, for example culture, human rights, socio economic, for example homeless people Where relevant to the research proposal, this issue is reviewed by the relevant sponsorship reviewer on behalf of the Trust and by the Research Ethics Committee
Summary of Analysis
Does the evidence show any potential to discriminate? No - The process of agreeing to sponsor a research proposal occurs in line with the UK Policy for Health and Social Care research governance framework published by the department of health. This references many acts of parliament with which the research must comply. 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
How does the policy **advance equality of opportunity?** Anyone may approach the OUH Trust if they are an employee of the trust for the trust to apply to act as sponsor of their research proposal. Authorisation of Sponsorship will be based on the quality of the application and the qualifications of the staff member wishing to take on the role of Chief Investigator
How does the policy **promote good relations between groups** (promoting understanding)? Any member of staff may come forward with a research proposal