APPENDIX 3

Policy for Capacity and Capability Approval of Clinical Research

Final Version 7.0

Category:	Policy
Summary:	Implementation of this policy will ensure that the Trust fulfils its statutory obligations which in turn will maintain public confidence in the safety, rights, and well-being of participants of research studies undertaken at the OUH Foundation Trust are protected.
Equality Impact Assessed:	July 2024
Valid From:	July 2024
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:	Sponsorship of Clinical Research Studies Policy Monitoring, Audit and Compliance Checks of Research Studies Policy Integrity in Research Policy Safety Reporting in Clinical Research Policy Incident Reporting, Investigation and Learning Procedure
Author(s):	Head of R&D Governance
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This Document replaces:	Trust Management Approval of Clinical Research Policy FINAL Version 6.0

Lead Director: Chief Medical Officer

Issue Date: 01 August 2024

This document is uncontrolled once printed.

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	1.5	Research Development Lead	Updated to cover developments in research.
May 2009	2.0	Research Development Lead	Updated to cover Quality Accounts Regulations; requirements for research databanks and tissue banks; and changes made in response to MHRA Inspection findings.
June 2011	3.0	Research Development Lead	Updated to cover new R&D process.
Dec 2013	4.0	Research Development Lead	Updated to cover new R&D process, NIHR reporting requirements and change in trust name
Sept 2015	5.0	Research Development Lead	Updated to include the HRA approval process move to new policy template.
August 2017	6.0	Head of R&D Governance	Updated to clarify requirement of Clinical Engineering and Psychological Medicine; and to incorporate protocol amendment policy
July 2024	7.0	Head of R&D Governance	Update to remove the NIHR reporting requirements and ongoing review on delivery by Trust Policy title updated Addition of LROG process

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
Katie Flight, Deputy Head of R&D Governance	Review of the document and changes

Louise 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 section should state who the policy or procedural document should be read by, i.e. who it applies to, and could specify particular teams, for example:

    - This policy should be read by all research staff across the Trust undertaking hosted research.

Key Standards/Messages

2. The Health Research Authority and the Medicines for Human Use (Clinical Trials) Regulations 2004 and amendments require that an organisation taking on the role of 'Sponsor' must have proper arrangements in place to initiate, manage, monitor, and finance a study.
3. Where the organisation is providing care to research participants within studies with other Sponsors, the organisation must ensure that legislation related to research is followed.
4. These requirements not only apply to the initial approval of a research protocol, but throughout the conduct of the research, including where the protocol is amended.
5. This policy covers the process of both capacity and capability approval (C&C) and agreement with the Sponsor that the Trust has the necessary capability and capacity to undertake the research.
6. Research activity will be reported regularly to the Trust Management Executive board.
7. The National Health Service (Quality Accounts) Regulations 2010 require that NHS trusts provide information on the clinical research undertaken, where a Research Ethics Committee has given a favourable opinion on an annual basis.

Background/Scope

8. This section should succinctly provide context to the policy or procedural document, explaining its purpose. It is the policy of the Trust to:

    8.1. Protect the safety, dignity, rights, and well-being of all patients involved in clinical research.
    8.2. Ensure that arrangements are in place for the management and monitoring of clinical trials/research studies, where the Oxford University Hospitals NHS Foundation Trust ('the Trust') has taken on the role of Sponsor or host institution, including compliance with the relevant regulations.
    8.3. Conduct research management and governance procedures using a consistent risk-proportionate approach to ensure timely approval and appropriate oversight of sponsored and hosted clinical research.
    8.4. To meet the required NIHR benchmarks for the trust approval of valid research applications and recruitment of the first patient to such studies, and then to recruit to time and target as contracted so to do.

9. This Policy applies to anyone conducting clinical research within the Trust, whether such research is sponsored or hosted by the Trust.
10. This document applies to all areas of the Trust, and all employees of the Trust, including individuals employed by a third party, by external contractors, as voluntary workers, as students, as locums or as agency staff.

Key Updates

11. The policy title has changed to Capacity and Capability Approval from Trust Management approval.

12. Update to remove the NIHR reporting requirements and ongoing review on delivery by Trust.

13. Equality impact assessment has been updated to the current version

Aim

14. This section should succinctly list the key aims of the policy, for example: This policy sets out a consistent procedure for the review and authorising of C&C for studies and subsequent amendments for which the Trust has been asked to take on the role of 'Sponsor' or host institution.

    Under the) UK Policy Framework for Health and Social Care Research 2017, REC approval for tissue banks is voluntary and neither sponsorship nor C&C is required. However, it is a requirement under the Human Tissue Act (HTA) 2004 that NHS organisations have procedures in place to ensure appropriate governance of research tissue banks, The Trust therefore requires that R&D are notified of all research tissue banks being set up to meet the requirement.

15. It is a requirement that NHS organisations have procedures in place to ensure appropriate governance of research databanks, The Trust therefore requires that R&D are notified of all research databanks being set up to meet the requirement.

16. This policy aims to ensure that the Trust takes responsibility for the ongoing quality of research studies.

17. This policy aims to ensure that the Trust achieves national benchmarks related to initiation of research and recruitment to time and target.

Content of the Policy

Capacity and Capability Approval Process

18. Prior to submission of any study for C&C approval, the Principal Investigator must ensure that all of the relevant Service Support Departments have been approached and have undertaken to accommodate the study; that the relevant directorate manager is aware of the study; and that the study team are, themselves ready to recruit, once permission has been granted.

19. The C&C process can begin once a study has been prioritised by the Local research Oversight group (LROG). This requires the local documents pack and relevant regulatory submission (Research Ethics Committee (REC), HRA, and MHRA, where applicable) to have been made. The C&C process can continue in parallel to these applications and evidence of those approvals can be provided when available. However, permission will not be granted until such approvals are in place.

20. When a valid application is received, along with all other required localised documents, the study will be validated, and a project identification (PID) number allocated.

21. Where a contract is required for any study, it is recommended that a standard agreement is used.

22. A member of the R&D Team will collate all relevant documents; assess feasibility with the PI; ascertain capacity and capability; and conduct the required level of governance review to assess the level of risk and impact on the Trust. Further information may be requested, where anything is unclear.

23. Once the final approval letters relating to the study have been provided, a letter to the PI, confirming C&C will be prepared and signed by the authorised signatory.

24. At this stage the fully executed contract (signed by all parties), or signed Organisation information document (OID) would be released to the sponsor as formal Confirmation of Capacity and Capability to conduct the project at the Trust.

25. A study may not begin until all the relevant approvals are in place and, if applicable, a contract, signed by all the relevant parties, has been received by the Trust R&D team.

Ongoing Approval

26. Once granted, C&C is conditional on regular updates being provided by the investigator team.

27. The investigator is required to inform R&D of the date of the first patient recruited to the study as soon as that occurs. Studies failing to recruit within the specified timeframe, without a valid reason for this failure, may have C&C withdrawn.

28. The investigator is also required to provide recruitment data to the trust on a quarterly basis to inform of progress of study recruitment to time and target, and to provide reasons where recruitment is not achieving agreed targets.

29. In addition, the investigator team will also be required to provide further information on an annual basis for the Trust Quality Accounts.

30. Other updates can generally be derived from progress reports, during monitoring visits (where relevant) and from end of study reports.

31. Any proposed change in the status of the PI (e.g. departure from the Trust, maternity leave) must be communicated to the R&D team, prior to that change taking place.

Protocol Amendments

Submission Process for Amendments of OUH Sponsored Studies

32. All protocol amendments should be submitted for review by the R&D Department. If a study is sponsored by the Trust, then the R&D department needs to approve the amendment before it is submitted to regulatory bodies.

33. Following an updated HRA Approval, arrangements can be made to implement amendments or very occasionally, and in discussion with the sponsor, withdraw from participation in the study if the amendment adversely affects the capacity and capability of the organisation to deliver the research to the new information.

Submission Process for Amendments to Hosted Studies

34. Submission of a Substantial Amendment to the HRA, REC, MHRA (where applicable) and R&D can be undertaken in parallel. R&D staff can process the amendment in anticipation of the relevant approvals being granted, providing that the approval letters are, ultimately provided.

35. All documents submitted to the Research Ethics Committee, should also be provided to R&D. Other than the approval letters, an amendment cannot be processed by R&D until all documentation has been provided.

36. 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.

37. Once the final approval letters relating to the amendment have been provided, ongoing capacity and capability approval will be authorised by email.

38. Non-substantial Amendments - Non-substantial amendments to research projects hosted at the OUH Trust should be copied to R&D for information for filing, updating the R&D database record and acknowledgement to the study team.

Review

39. This policy will be reviewed every 3 years, as set out in the *Developing and Managing Policies and Procedural Documents Policy.*

40. The Trust Management Executive has delegated authority to the Head of R&D Governance for the approval of any further supporting or associated documents.

References

41. The Medicines for Human Use (Clinical Trials) Regulations 2004 and Amendments

42. The UK Policy Framework for Health and Social Care 2017

43. ICH Harmonised Tripartite Guideline for Good Clinical Practice

44. The National Health Service (Quality Accounts) Regulations 2010

Appendix 1: Responsibilities

1. Insert the responsibilities here. It is good practice to start at the top of the organisation and work down to all staff then list relevant committees (see suggestion here). Adapt this section to fit the responsibilities required to carry out the policy or process described in the Content of the Policy section.

2. The **Chief Medical Officer** has overall responsibility for this policy.

3. The **Chief Medical Officer / Director of R&D / Head of R&D Operations/ Head of R&D Governance / Deputy Head of R&D Governance / Senior Research Support Manager** have delegated authority on behalf of the Trust to:

   3.1. Authorise the C&C approval letters to the PI as required.
   3.2. Authorise research contracts relating to research projects or amendments to research projects.
   3.3. Authorise acceptance of ongoing C&C approval with regard to the amendment of hosted research projects and clinical trials provide a mechanism for escalation for R&D and/or investigators when required, to ensure NIHR timelines are met.
   3.4. Give leadership, support and advice to the Research Governance Team relating to research governance and oversight.

4. **Research and Development Staff** have responsibility to:

   4.1. Provide advice and information to investigators on the process of attaining C&C and authorisation of amendments covered by this policy.
   4.2. Conduct proportionate reviews of the study including assessments of capability and feasibility assessments according to the type of study, size of study and level of risk, liaising with investigators and sponsors as required, to ensure NIHR timelines are met.
   4.3. Conduct Safety Reporting Risk Assessments for all hosted CTIMPs – commercial and non-commercial.
   4.4. Advise on training requirements for research teams involved in clinical research.

5. **Chief Investigator (CI) / Principal Investigator (PI)** (or delegate) has the responsibility to:

   5.1. Ensure that confirmation of support has been obtained from the relevant service support departments, prior to approaching R&D (e.g. pharmacy, radiology, labs, pathology) and that the relevant directorate manager is aware of the study.
   5.2. Ensure that Clinical Engineering is happy for the use of any devices or equipment that has not been obtained through the usual Trust procurement processes.
   5.3. Ensure that the Trust Lead for Psychological Medicine has been contacted, where the study includes patients with mental illness; uses psychological methods or interventions; involves psychology of psychiatric services; or includes patients who may have a risk of harming themselves or others.
   5.4. Ensure that recruitment targets are realistic, feasible and achieved wherever possible.

5.5. Ensure that the study team is in full readiness to begin study recruitment promptly, following agreement with the Sponsor and C&C being granted.
5.6. Provide all necessary information and documentation in a timely manner.
5.7. Provide information on research activity, as required for the quarterly reports to the NIHR and annually for the Quality Accounts Regulations in a timely manner.
5.8. Ensure that the local study team are appropriately qualified by experience and training to undertake the study including information governance training and appropriate training for conducting clinical trials and research.
5.9. Ensure that the conduct of the study is in compliance with the protocol, the terms of the Research Ethics approval, all relevant legislation, and any relevant contracts.
5.10. 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.
5.11. Comply with conditions of approval for the research as described in the C&C Approval Letter.
5.12. Have responsibility to communicate with R&D, following study approval, to provide all relevant documentation for any amendment, whether OUH sponsored or hosted.

Appendix 2: Definitions

The terms in use in this document are defined as follows:

Health Research Authority Approval

1. National permission for the conduct of a research study within all NHS Trusts.

Confirmation of Capacity and Capability

2. An NHS Trust's formal written confirmation that assessment has been undertaken that it has the capability and capacity to undertake the research. This will take the form of either a formal contract or Organisation Information Document.

Capacity and Capability Approval

3. Agreement on behalf of the Trust with the Principal Investigator that they may conduct the research.

Sponsor

4. The organisation taking responsibility for initiation, management, and financing (or arranging the financing) of a clinical trial of an investigational medicinal product (CTIMP) or research study.

Host Organisation

5. The organisation where the research is going to take place and will take local responsibility for the running of each research protocol.

Chief Investigator

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

Principal Investigator

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

Substantial Amendment

8. 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 trial; the scientific value of the trial; the conduct or management of the trial; and/or the quality or safety of any investigational medicinal product used in the trial.

Non-substantial Amendment

9. 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

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

11. Clinical Trial of an Investigational Medicinal Product (CTIMP)

12. Any investigation in human subjects, other than a non-interventional trial*, intended: a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; b) to identify any adverse reactions to one or more medicinal products; or c) 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 Trials

13. A clinical investigation designed to establish the performance of a medical device 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 UK Policy Framework (UKPF) and would require the approval of an ethics committee.

14. Trials using non-CE Marked devices are also regulated by the Medical Devices Regulations (2017). Where a trial involves a non-CE/UKCA Marked device, and the Sponsor is not intending to use the data for CE/UKCA marking, the contract must be clear that this is so and evidence of communication with the MHRA must be provided.

15. Confirmation of the approval of Clinical Engineering for use of the device within the Trust is also required.

Interventional Trial / Study

16. 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 Paragraph 16. Such studies are regulated by the UKPF and would require the approval of an ethics committee.

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

17. Any investigation in human subjects, who are patients, 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 an ethics committee.

Research Tissue Bank (Biobank)

18. A collection of human tissue or other biological material, as defined by the Human Tissue Act 2004, which is stored for research use beyond the life of a specific project with ethical approval or for which ethical approval is pending.

Research Databank (termed ‘Research Database’ on the Integrated Research Application System (IRAS)

19. A collection of data, which is stored for potential research, beyond the life of a specific project, with ethical approval, or for which ethical approval is pending. All studies using data supplied by a databank need C&C Approval, whether or not the Databank has ethics approval.

Appendix 3: Education and Training

1. Training in Good Clinical Practice GCP, or Good Clinical Research Practice GCRP is available to all those involved in the conduct of clinical research within the Trust. The approval process is covered within this training.

2. All staff involved in the conduct of C&C approval, or amendment review receive training in the use of the trust R&D SOPs. Everyone's training needs will be identified through annual appraisal and supervision.

Appendix 4: Monitoring Compliance

3. Compliance with the document will be monitored in the following ways.

What is being monitored:	How is it monitored:	By who, and when:	Minimum standard	Reporting to:
Issue of Confirmation of capacity and Capability letters	Report numbers approved	Head of R&D Governance	Annual	Trust Management Executive
GCP Training	Report numbers trained	Head of R&D Governance	Annual	Trust Management Executive
Provision of information for Quality Accounts	Report volume of non-responders	Head of R&D Operations	Annual	Quality Committee

Appendix 5: Equality Impact Assessment

Equality Impact Assessment Template

1. As part of its development, this policy and its impact on equality, diversity and human rights has been reviewed, an equality analysis undertaken and to minimize the potential to discriminate, no adjustments have been identified.

What is being assessed	Existing Policy / Procedure
Job title of staff member completing assessment	Head of R&D Governance
Name of policy / service / function:	Policy for Capacity and Capability Approval of Clinical Research
Details about the policy / service / function	Set out consistent procedures: • For the review and authorising of C&C for studies and subsequent amendments for which the Trust has been asked to take on the role of 'Sponsor' or host institution. • To ensure appropriate governance of research tissue banks, in compliance with the Human Tissue Act (HTA) 2004. • To ensure appropriate governance of research databanks. • To ensure that the Trust takes responsibility for the ongoing quality of research studies. • To ensure that the Trust achieves national benchmarks related to initiation of research and recruitment to time and target.
Is this document compliant with the Web Content Accessibility Guidelines?	*Delete as appropriate* Yes
Review Date	July 2024
Date assessment completed	July 2024
Signature of staff member completing assessment	Jo Franklin
Signature of staff member approving assessment	Shahista Hussain

2. Screening Stage

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

- Patients
- Staff
- Other – commercial and non-commercial sponsors

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 safety reports of events occurring in all trials conducted 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 safety reports of events occurring in all trials conducted within the Trust, regardless of race, religion, disability, age, gender or sexuality
Disability - disabled people and carers			X		This policy applies to safety reports of events occurring in all trials conducted within the Trust, regardless of race, religion, disability, age, gender or sexuality
Age			X		This policy applies to safety reports of events occurring in all trials conducted within the Trust, regardless of race, religion, disability, age, gender or sexuality
Sexual Orientation			X		This policy applies to safety reports of events occurring in all trials conducted within the Trust, regardless of race, religion, disability, age, gender or sexuality
Religion or Belief			X		This policy applies to safety reports of events occurring in all trials conducted 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 safety reports of events occurring in all trials conducted within the Trust, regardless of race, religion, disability, age, gender or sexuality
Marriage or Civil Partnership			X		This policy applies to safety reports of events occurring in all trials conducted 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 safety reports of events occurring in all trials conducted 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

Group	Summary of consultation
N/A	

Consultation with others
Based on the previous version, this update has drawn on feedback from researchers and other staff including members of the R&D team.

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 host a research project occurs in line with the UK Policy Framework for Health and Social Care. This references many acts of parliament with which the research must comply. Reviewing a proposal for research as a host organisation assures that compliance. 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

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.

Not applicable

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

Not applicable

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.

Not applicable

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