Policy for Research Governance

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1 Policy Statement

1.1 The objective of this policy is to ensure that all research undertaken in the Trust complies with the Department of Health’s Research Governance Framework, relevant UK legislation and accepted standards of good research practice.

1.2 Research Governance is a quality assurance system for improving the standards of research practice across health and social care and reducing unacceptable variations. It follows a standard model for defining and communicating quality standards; introducing mechanisms to ensure those standards are met; and monitoring adherence to the standards.

2 Scope

2.1 This Policy applies to all research (as defined in Appendix 1) that involves:

2.1.1 patients of the Trust;

2.1.2 Patient data or tissue samples held by the Trust;

2.1.3 Staff, equipment or facilities of the Trust.

3 Definitions

3.1 Chief Investigator (CI): The Chief Investigator (CI) is an individual who is primarily responsible for designing the research study and writing the protocol or, for industry-sponsored studies, the person designated by the Sponsor to provide overall leadership for the conduct of a study.

3.2 Monitoring: Is a quality control (QC) activity carried out by the Sponsor or research team for overseeing the progress of a study and confirming that it is appropriately conducted, recorded and reported in accordance with the protocol and any written procedures, and is consistent with the Ethics Committee and regulatory authority approvals.

3.3 Principal Investigator (PI): The Principal Investigator (PI) is the person in the Trust who takes responsibility for implementing the clinical components of a study in the Trust and is accountable through usual clinical management structures for overseeing the conduct of the study in the Trust.

3.4 Research Study: A research study is a formal piece of work that uses research methods (see Appendix 1) to answer a limited set of precise questions. Each research study should be written down in a clear protocol that sets out the background to the study, the aims and objectives of the study, how it will be conducted, what data will be collected and how it will be analysed.

3.5 Sponsor: The Sponsor of a clinical research study is defined in the Research Governance Framework as the organisation who takes responsibility for securing arrangements to initiate, manage and finance the study.
3.6 **Study Audit**: A study audit is a quality assurance (QA) activity to provide an independent check that a study is being conducted in accordance with the protocol, the principles of Good Clinical Practice, and the terms of any Ethics Committee and regulatory authority approvals for the study. Audits are usually conducted by someone who is independent of the research team and the sponsor.

3.7 **Substantial Amendment**: An amendment to the protocol, associated documents, management or conduct of a study is classed as substantial if it is likely to have a significant impact on the safety or physical or mental integrity of the research subjects, or could affect the scientific value of the study.

4 **Framework**

4.1 This section describes the broad framework for the management and oversight of research throughout the Trust. Detailed instructions are provided in the associated procedural documents and SOPs (see section 8).

4.2 The Research and Development Committee (R&D Committee) shall approve the procedural documents associated with this policy, and any amendments to such documents, and is responsible for ensuring that such documents are compliant with this policy. SOPs may be approved by such body or individual as determined by the R&D Committee.

4.3 The Trust will ensure that all research complies with all relevant legislation and the quality standards set out in the Department of Health’s Research Governance Framework\(^1\). The Trust’s framework for ensuring this consists of the following stages:

4.3.1 **General requirements**

a) All research studies must be registered with the Trust’s Research and Development Office;

b) All those undertaking research must have sufficient training and experience appropriate to their role in the study;

c) Each research study must have an identified Sponsor. The Trust may agree to act either as sole sponsor or as co-sponsor with another organisation (usually the University of Birmingham). Generally the Trust will only act as sponsor if it is the employer of the Chief Investigator. The Chief Investigator must formally request the Trust to act as sponsor and must submit a protocol to the R&D Governance Office. The Chief Investigator will be asked to complete a Sponsorship Request Form and Chief Investigator Agreement before the Trust can confirm sponsorship.

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d) The study must have an identified Principal Investigator (PI) and Chief Investigator (CI) appointed in accordance with the Policy on Chief Investigators and Principal Investigators in Research.

4.3.2 R&D Trust Authorisation

Research cannot proceed until it has been authorised by the Trust's R&D Governance Office. R&D Trust authorisation for any research study will only be given if all requirements, as detailed in the R&D Approvals Process (RDS012), have been met.

4.3.3 Conduct of Studies

a) All studies must be conducted in accordance with the relevant legislation and protocol, this policy and all associated procedural documents.

b) All amendments to a study protocol must be registered with the R&D Governance Office and any Substantial Amendments must be approved by the R&D Governance Office before the Study can continue.

c) The PI must report all protocol breaches in accordance with the R&D Trust Approval given for the study.

d) The PI must create and maintain a study file which, as a minimum, should follow the guidance issued with the R&D Trust Approval letter.

e) Recruitment to studies should be undertaken as soon as is practicable and in order, where appropriate, to meet NIHR/DH recruitment timescales.

f) The PI must submit to the R&D Governance Office a progress report within 60 days of each anniversary of the date of R&D Trust authorisation of the study, in accordance with the R&D Reports procedure (RDS004). Templates for the annual reports are provided by the R&D Governance Office.

g) All serious adverse events must be reported in accordance with the Policy for Reporting Research Incidents and Breaches.

h) All recruitment into a study must be recorded by research staff in the master study file and, where possible, using the research tab on the Trust’s online patient information system (PICS).

4.3.4 Study Audits and Monitoring

a) The R&D Governance Office will have in place a programme of study audits, to cover all Studies, and monitoring for all Trust sponsored trials of medicines and devices.
b) Studies will be selected for audit in accordance with Clinical Study Audits and Inspections procedures (RDS005).

c) Progress and outcomes of audits shall be reported to the R&D Committee.

4.3.5 Study Closure

a) The PI must notify the R&D Governance Office when the study has finished within [30] days following the end of the study.

b) The PI must submit a Trust end of study report within [60] days following the end of the study in accordance with the R&D Reports procedure (RDS004)

c) The PI must ensure appropriate arrangements are made for all study documentation to be archived in accordance with the Document Archiving Procedure.

5 Duties

5.1 Executive Director of Delivery

The Executive Director of Delivery is responsible for the development of the research strategy for the Trust and overseeing its implementation and effective governance in accordance with this Policy.

5.2 Divisional Directors and Clinical Service Leads

Divisional Directors and Clinical Service Leads are required to ensure that they keep abreast of all research within their area of responsibility. They should satisfy themselves that the researchers are sufficiently qualified and trained to undertake the research proposed, that the individual research studies fit with any broadly defined research strategy for the clinical service or division, and that adequate resources are available to enable the research to take place.

5.3 R&D Committee

5.3.1 The R&D Committee maintains oversight of the operations and governance of research in the Trust.

5.3.2 It is responsible for promoting and supporting high quality clinical research.

5.3.3 It is also responsible for reviewing the arrangements for the governance of research.

5.3.4 The terms of reference of the R&D Committee are set out in Appendix 2. Amendments to these Terms of Reference may be approved by the Executive Director of Delivery.
5.4 **Head of Research & Development Governance**

The Head of R&D Governance will:

5.4.1 Ensure all research projects are assessed and, when appropriate conditions have been met, duly authorised in accordance with the principles of the NHS Research Governance Framework and all relevant UK legislation;

5.4.2 Ensure that all Trust guidance and procedural documents on research governance are updated and maintained in accordance with the principles;

5.4.3 Ensure that the R&D Governance Office maintains a forward schedule of audits and monitoring visits to check compliance with Trust policies, national guidance and relevant legislation.

5.4.4 Put in place procedures to maintain effective oversight of the progress of individual research projects;

5.4.5 Oversee appropriate monitoring and auditing of individual research studies against established principles of good research practice, and to check compliance with Trust policies.

5.4.6 Suspend, pending formal investigation, any study where there is a suspicion of non-compliance with Trust policies and procedures, the principles of Good Clinical Practice (GCP), or legislation relevant to the governance of research, and report such suspensions to the Executive Director of Delivery.

5.5 **Researchers**

Researchers are required to:

5.5.1 Ensure that all potential research studies are registered with the Research & Development Office (R&D) and that they do not proceed with the studies without authorisation from the R&D Governance Office.

5.5.2 Familiarise themselves, and comply, with the Trust's policies on research governance, the NHS Research Governance Framework and other national guidance and legislation relevant to research and ensure that all other members of the research team are familiar, and comply, with these documents.

5.5.3 Cooperate with the R&D Governance Office in monitoring and auditing research studies.

5.5.4 Provide annual progress reports to the Trust's R&D Governance Office in accordance with [ ]
5.5.5 Comply with the reporting requirements of the National Research Ethics Service and regulatory authorities.

5.5.6 Ensure that they, and other members of the research team, have appropriate expertise, training and experience to fulfil their roles in research studies.

5.5.7 Provide evidence of suitable GCP training. The PI is responsible for ensuring all research team members are suitably qualified and supervised, including appropriate UHB authorisation for those with clinical contact.

6 Implementation and Monitoring

6.1 The Trust's research governance policies are available on the Trust intranet and will be disseminated to all researchers via the R&D Governance Office.

6.2 Researchers are required to provide annual progress reports to the Trust’s R&D Governance Office.

6.3 The R&D Governance Office maintains a forward schedule of audits and monitoring visits to check compliance with Trust policies, national guidance and relevant legislation.

6.4 The R&D Governance Office shall submit an annual report to the Board of Directors, providing an account of:

6.4.1 all ongoing research activity (newly registered, authorised, published and completed studies)

6.4.2 the progress and outcome of audits,

6.4.3 all ongoing monitoring activity, and

6.4.4 where required, matters of compliance with this policy, the protocol and relevant legislation.

7 References


8 Associated Policy and Procedural Documentation

Policy on the Collection and Use of Human Tissue for Research

Policy on Chief and Principal Investigators

Research Passport System Policy
Policy on Scientific Misconduct

Policy on Reporting Research Incidents and Breaches

Document Archiving Procedure

R&D Governance Office Procedures

R&D Approvals Process (RDS012)

R&D Reports procedure (RDS004)

Clinical Study Audits and Inspections procedure (RDS005)
Appendix 1

**Definition of Research**

The Department of Health defines research as “the attempt to derive generalisable (i.e. of value to others in a similar situation) new knowledge by addressing clearly defined questions with systematic and rigorous methods”. It is a systematic activity that provides new knowledge aimed at understanding the basis and mechanisms of disease, improving the diagnosis and treatment of disease or designing better ways of delivering healthcare. It may involve any of the following:

- patients of the Trust
- relatives carers of patients
- recently deceased
- members of staff
- healthy volunteers
- Trust facilities or resources

requiring:

- a direct intervention (drugs, devices, surgical procedures, therapies ...)
- taking samples (tissues, fluids,...) - whether specifically for research purposes or using material that would normally be discarded, or material held in diagnostic laboratories
- additional diagnostic tests
- completion of questionnaires
- interviews of staff, patients or relatives
- physical or psychological tests
- access to patient records
- use of Trust resources

Research should be distinguished from:

1. **Innovation**
   
   i. Introducing to the Trust new techniques that have been developed elsewhere

   or

   ii. Development and initial piloting of new techniques prior to formal assessment as part of a research project

   **Note that details of activity that comes under the category of innovation must be submitted to the Trust’s Clinical Innovations Committee**

2. **Clinical Audit**
   
   i. Monitoring clinical activity against established good practice guidelines
or

ii. Developing guidelines from accepted research evidence.

Note that developing guidelines where there is little existing research evidence may be better considered as innovation or research

3. *Routine data collection for monitoring clinical performance* (many people regard this as part of clinical audit)

4. *Patient Satisfaction Surveys*
Appendix 2

University Hospitals Birmingham
NHS Foundation Trust

Research and Development Committee (R&D Committee)

Terms of Reference

Reference to “the Committee” shall mean the Research and Development Committee.
Reference to “the Trust” shall mean the University Hospital Birmingham Foundation NHS Trust.

1. Purpose

The purpose of this Committee is to drive the Trust’s research agenda forward and embed it into daily Trust working. The Committee will support bringing together “research champions” and research resources, and ensure that a robust communications strategy is in place to publicise Trust research activity.

2. Scope

The scope of the Committee is to:

- Review divisional research performance against agreed key performance indicators
- Ensure that a robust research governance framework is in place to support research undertaken by divisions
- Receive financial reports on divisional research finances
- Recommend approaches to use of research resources
- Oversee the communications strategy for research and development

3. Membership

The membership comprises the following:

Chair: Executive Director of Delivery

Members:
- Trust Research and Development Co-Director
Committee members are expected to identify a deputy of equivalent seniority to attend in their place should they themselves be unable to attend a meeting.

5. Quorum

The Committee will be deemed quorate with the attendance of the Chair (or nominated deputy), a Trust Research and Development Director, Trust Deputy Director of Finance, Head of Research and Development Operations and Head of Research and Development Governance.

6. Frequency of Meetings

Meetings shall be held not less than four times a year. The Executive Director of Delivery may call additional meetings where considered necessary.

7. Agenda and reporting

a. Agendas and briefing papers should be prepared and circulated in sufficient time for Committee Members to give them due consideration. All agenda items should be approved by the Chair prior to the meeting. Additional papers shall only be tabled at the meeting with authorisation by the Chair.

b. Action points agreed at meetings, together with the minutes, will be circulated by the individual nominated by the Chair within 7 working days of the meeting, to the Chair and all members of the Committee.

c. An annual report from the Committee to the Board of Directors should be produced to demonstrate the Committee’s effective discharge of its duties. The report should include comment on the Committee’s work in relation to study registrations and authorisation, progress and outcome of research audits and any monitoring activity, and shall provide a generic overview of the efficacy of the Research Governance Assurance Framework.
8. **Review**

The Terms of Reference and membership of this Committee shall be reviewed on a yearly basis.