

Policy for Research Governance

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<ul style="list-style-type: none"> • Essential Reading for: 	Clinical Researchers, Site Directors, Clinical Service Leads, Site Directors of Operations, Senior Trust Managers, Service Managers
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1 Policy Statement

- 1.1 The objective of this policy is to ensure that all research undertaken at University Hospitals Birmingham NHS Foundation Trust (the 'Trust') complies with the UK Policy Framework for Health and Social Care Research, 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 areas and activities of the Trust and to all individuals employed by the Trust including contractors, volunteers, students, locum, agency staff and staff employed on honorary contracts who carry out **all** research that (as defined in Appendix 1) that involves:
- 2.1.1 Patients of the Trust;
- 2.1.2 Patient data and/or tissue samples held by the Trust; and
- 2.1.3 Staff, equipment and/or facilities of the Trust.

3 Definitions

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.
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.
Non Substantial Amendment	A change to the design, conduct, documentation, or management of the Research Study that does not have a significant impact on the safety of the subjects or the scientific value of the study
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.
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.
Sponsor	The Sponsor of a clinical research study is defined in the UK Policy Framework for Health and Social Care Research as the organisation which takes responsibility for securing arrangements to initiate, manage and finance the study.
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.
Substantial Amendment	An amendment to the protocol, associated documents, management or conduct of a Research 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 Standard Operating Procedures (SOPs) (see section 8).
- 4.2 The Research & Innovation Management Group meeting 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 Research & Innovation Management Group meeting.
- 4.3 Research studies may be carried out at one or more of the constituent sites of the Trust. Since the resources, capacity and capability of conducting research studies vary between the different sites, the Trust's R&D Department will assess suitability at each site.
- 4.4 The Trust will ensure that all research complies with all relevant legislation and the quality standards set out in the UK Policy Framework for Health and Social

Care Research published by the Health Research Authority. The Trust's framework consists of the following stages:

4.4.1 General Requirements

- a) All research studies must be registered with the Trust's R&D Offices. The R&D offices are based at the Queen Elizabeth and Heartlands Hospitals. Heartlands Hospital R&D predominantly covers Good Hope, Heartlands and Solihull Hospitals, Birmingham Chest Clinic and Solihull Community. The Queen Elizabeth R&D office predominantly covers the Queen Elizabeth Hospital site. The two R&D offices will ensure the relevant R&D governance teams are aware of and previewing studies being submitted for UHB registration.
- 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.
- 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.

4.4.2 R&D Trust Authorisation

Research cannot proceed until it has been authorised by the Trust's R&D Department. 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.

4.4.3 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, substantial and non-substantial, to a study must be registered with the Trust's R&D Governance Office and approval issued by the R&D Governance office prior to them being implemented.
- c) 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.

- d) Recruitment to studies should be undertaken as soon as is practicable and in order, where appropriate, to meet timescales set by the National Institute of Healthcare Research (NIHR).
- e) The PI must report all protocol breaches in accordance with the R&D Trust Approval and/or SOPs relating to the study.
- f) All serious adverse events must be reported in accordance with the Procedure for Reporting Research Incidents and Breaches. Serious protocol breaches and serious adverse events must be reported on the incident reporting system. For studies conducted at the Queen Elizabeth Hospital site this process is in place. At the sites covered by the Heartlands Hospital R&D Office, as the incident reporting system is rolled out.
- g) All recruitment into a study must be recorded by research staff in the Trial Master File and/or site file and, where possible, using the research tab on the Trust's online patient information system (PICS and EDGE). Recruitment that cannot be recorded on PICS and EDGE should be reported to the R&D Governance Office according to instructions from the office.
- h) 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.

4.4.4 Study Audits and Monitoring

- a) The R&D Governance Offices at the Queen Elizabeth Hospital and Heartlands Hospital 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 Research & Innovation Management Group meeting
- d) An account of all Study audits and monitoring will be presented annually to the Trust's Audit Committee, and included as a component of the Research Development & Innovation Department's annual report to Board of Directors.

4.4.5 Study Closure

- a) The PI must notify the R&D Governance Office within 30 days following the end of the study.
- b) The PI must submit a Trust end of Study report within 60 days of 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.(RDS014)

5 Duties

5.1 Chief Medical Officer (CMO)

The CMO is responsible for the development of the research strategy for the Trust and for overseeing its implementation and effective governance.

5.2 Site Directors and Clinical Service Leads

5.2.1 Site 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 Site, and that adequate resources are available to enable the research to take place.

5.3 Research & Innovation Management Group

5.3.1 The Research & Innovation Management Group (meeting) maintains oversight of the operations and governance of research in the Trust.

5.3.2 They are responsible for promoting and supporting high quality clinical research.

5.3.3 They are also responsible for reviewing the arrangements for the governance of research.

5.4 Head of Research & Development Governance

The Head of R&D Governance is required to:

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 UK Policy Framework for Health and Social Care Research 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 CMO
- 5.4.7 Put in place procedures to maintain effective oversight of the publication of research results for studies where the Trust is Sponsor.

5.5 Researchers

Researchers are required to:

- 5.5.1 Ensure that all potential research studies are registered with the relevant Research & Development Office (R&D) at the Queen Elizabeth Hospital or Heartlands Hospital, and that they do not proceed with the studies without authorisation.
- 5.5.2 Familiarise themselves, and comply, with the Trust's policies on research governance, the UK Policy Framework for Health and Social Care Research 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 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 the R&D Reports procedure (RDS004).
- 5.5.5 Comply with the reporting requirements of the National Research Ethics Service, the Health Research Authority 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 Implementation

- 6.1.1 The Trust's research governance policies are available on the Trust intranet and can be disseminated to all researchers via the Research & Development Office.
- 6.1.2 Researchers are required to provide annual progress reports to the Research Ethics Committee, regulatory authorities and the Trust's R&D Office.
- 6.1.3 The R&D Office maintains a forward schedule of audits and monitoring visits to check compliance with Trust policies, national guidance and relevant legislation.
- 6.1.4 The R&D Governance Office shall submit an annual report to the Board of Directors, providing an account of:
- 6.1.5 All ongoing research activity (newly registered, authorised, published and completed studies)
- 6.1.6 The progress and outcome of audits
- 6.1.7 All ongoing monitoring activity, and
- 6.1.8 Where required, matters of compliance with this policy, the protocol and relevant legislation.

6.2 Monitoring

Appendix A provides full details on how this policy will be monitored by the Trust.

7 References

Department of Health UK Policy Framework for Health and Social Care Research

8 Associated Policy and Procedural Documentation

Policy on Human Tissue in Research

Chief Investigators and Principal Investigators in Research Procedure

Safety Reporting including Adverse Events and Serious Breaches in Research Procedure

R&D Research Related Archiving (RDS014)

R&D Approvals Process (RDS012)

R&D Progress Reports (RDS004)

R&D Study Audits and Inspections Procedure (RDS005)

Appendix A

Monitoring Matrix

MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
Research Study Progress reports	Head of R&D Governance	Research Ethics Committee Regulatory authorities R and D Governance Office Research and Innovation Management Group Strategic Research and Innovation Management Group	Progress report on each research study Research Account to Board of Directors	Annually and 6 monthly Annually
Research Governance Database	Head of R&D Governance	Research and Innovation Management Group Strategic Research and Innovation Management Group	Review of records of the status of all research studies as well as details of amendments, audits, adverse incidents, agreements, investigators. Research Account to Board of Directors	Continuous Bi-Monthly & Quarterly Annually
Compliance with Trust R and D policies, national guidance and relevant legislation	R and D Quality Assurance Manager	Head of R&D Governance Director RD&I Research and Innovation Management Group Strategic Research and Innovation Management Group	Schedule of audits and monitoring visits to check compliance Research Account to Board of Directors	Audit schedule is planned quarterly in advance Bi-Monthly & Quarterly Annually
Research activity,	Head of R&D	Audit Committee	Report providing an account of:	Annually

<p>and progress and outcomes of audits</p>	<p>Governance</p>	<p>Board of Directors</p>	<ul style="list-style-type: none"> • All ongoing research activity (newly registered, authorised, published and completed studies) • Summary of research-related incidents • The progress and outcome of audits; and <p>All ongoing monitoring activity.</p>	
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Appendix 1

Definition of Research and Research Matrix

The Department of Health defines research as “*the attempt to derive generalizable (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 Investment Committee

2. *Clinical Audit*

- i. Monitoring clinical activity against established good practice guidelines

or

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- 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*

RESEARCH	SERVICE EVALUATION	CLINICAL/ NON-FINANCIAL AUDIT	USUAL PRACTICE (in public health including health protection)
<p>The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods* including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies.</p> <p>Quantitative research – can be designed to test a hypothesis as in a randomised controlled trial or can simply be descriptive as in a postal survey. Qualitative research – can be used to generate a hypothesis, usually identifies/explores themes.</p> <p>Quantitative research - addresses clearly defined questions, aims and objectives.</p> <p>Qualitative research – usually has clear aims and objectives but may not establish the exact questions to be asked until research is underway.</p> <p>Quantitative research – may involve evaluating or comparing interventions, particularly new ones. However, some quantitative research such as descriptive surveys, do not involve interventions.</p> <p>Qualitative research – seeks to understand better the perceptions and reasoning of people.</p> <p>Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care. May involve data collected from interviews, focus groups and/or observation.</p> <p>Quantitative research – study design may involve allocating patients/service users/healthy volunteers to an intervention.</p> <p>Qualitative research – does not usually involve allocating participants to an intervention.</p> <p>May involve randomisation.</p> <p>Normally requires REC review but not always. Refer to http://hra-decisiontools.org.uk/ethics/ for more information.</p>	<p>Designed and conducted solely to define or judge current care.</p> <p>Designed to answer: “What standard does this service achieve?”</p> <p>Measures current service without reference to a standard.</p> <p>Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/ service user preference.</p> <p>Usually involves analysis of existing data but may also include administration of interview(s) or questionnaire(s).</p> <p>No allocation to intervention: the care professional and patient/ service user have chosen intervention before service evaluation.</p> <p>No randomisation.</p> <p>Does not require REC review.</p>	<p>Designed and conducted to produce information to inform delivery of best care.</p> <p>Designed to answer: “Does this service reach a predetermined standard?”</p> <p>Measures against a standard.</p> <p>Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/service user preference.</p> <p>Usually involves analysis of existing data but may include administration of simple interview or questionnaire.</p> <p>No allocation to intervention: the care professional and patient/service user have chosen intervention before audit.</p> <p>No randomisation.</p> <p>Does not require REC review.</p>	<p>Designed to investigate the health issues in a population in order to improve population health</p> <p>Designed to investigate an outbreak or incident to help in disease control and prevention</p> <p>Designed to answer: “What are the health issues in this population and how do we address them?”</p> <p>Designed to answer: “What is the cause of this outbreak or incident and how do we manage it?”</p> <p>Systematic, quantitative or qualitative methods may be used.</p> <p>Involves an intervention in use only. Any choice of intervention, treatment, care or services is based on best public health evidence or professional consensus.</p> <p>May involve analysis of existing routine data supplied under license/agreement or administration of interview or questionnaire to those in the population of interest. May also require evidence review.</p> <p>No allocation to intervention.</p> <p>May involve randomisation but not for treatment/ care/ intervention.</p> <p>Does not require REC review.</p>