Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Research Governance Policy

This procedural document supersedes: CORP/COMM 14 v.2 – Research Governance Policy.

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Executive Sponsor(s):	Zoe Lintin, Chief People Officer
Author/reviewer: (this version)	Emma Adams – Research Management and Governance Manager
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Approved by:	Research & Innovation Committee
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Target audience:	Trust wide

Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
Version 3	March 2023	• Policy extensively revised, please read in full	Emma Adams
Version 2	February 2015	• Policy extensively revised, please read in full	Emma Hannaford
Version 1	June 2009	• This is a new procedural document, please read in full	Trevor Rogers

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1 INTRODUCTION

Research is an essential component of developing effective healthcare, but it can also carry elements of risk. To mitigate these risks, research studies within the NHS are required to be appropriately approved and registered within all organisations involved and, as such, it is necessary for the Trust to have a working policy relating to the way that research is undertaken in the Trust.

There are a number of activities that, although similar to research in some respects and sometimes referred to as 'research', nevertheless are not classed as research by the Department of Health and, therefore, are not subject to the provisions in this Research Policy.

1.1 Definitions

Research – Research within the NHS is defined by the Health Research Authority as 'the attempt to derive generalisable or transferable…new…knowledge to answer or refine relevant questions with scientifically sound methods'.

Please note, the UK Policy Framework for Health and Social Care 2020 covers research, as defined above, and excludes other areas of information gathering (often referred to as 'research'), for example audits, service evaluations and quality improvements; as such, this policy does not cover these areas.

2 PURPOSE

This policy aims to reflect the requirements of the UK Policy for Health and Social Care Research by developing and maintaining a culture of excellence within the Trust, providing support and guidance for those who wish to undertake a piece of research and to enable research to be undertaken to high standards, whilst meeting all necessary legislative requirements.

The aim of this policy is to provide an overview of the Trust arrangements in respect to research delivery, conduct and management for those who wish to undertake a piece of research.

Research can involve an element of risk, both in terms of return on investment (i.e. the new knowledge gained through the study might not warrant the monies, time and effort invested) and, sometimes, for the safety and well-being of the research participants. Robust governance structures are essential to ensure that patients and the public can have confidence in, and benefit from, quality research in health care. Participants have a right to expect high standards (scientific, ethical and financial), transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.

Research in the NHS is subject to a large and complex regulatory framework, composed of UK laws, regulations and other statutory requirements, and directives and guidelines issued by a number of government and non- governmental bodies, including the Health Research Authority, the Department of Health and the Medical Research Council. The requirements have been brought together within the UK Policy for Health and Social Care Research.

All research conducted within the NHS is required to meet the following fifteen statements of principle, which serve as a benchmark for good practice: safety; competence; scientific and ethical conduct; patient, service user and public involvement; quality and transparency; protocol; legibility; benefits and risks; approval; information about the research; accessible findings; choice; insurance and indemnity; respect for privacy; compliance; justified intervention; ongoing provision of treatment; integrity of the care record; and duty of care. These principles are detailed in the UK Policy for Health and Social Care Research, alongside the responsibilities of the relevant partiers involved in NHS research.

The Trust has a statutory responsibility to ensure that all research involving the Trust or Trust patients is conducted in accordance with the UK Policy for Health and Social Care Research. Trust compliance with this requirement is monitored by the Care Quality Commission. Researchers each have an individual responsibility to comply with the UK Policy for Health and Social Care Research in their own research practice. Researchers should refer to the 'Responsibilities' sections in particular of individuals and organisations, chief Investigators, research team.

2.1 Persons covered by this policy

All those who host, participate, undertake or are managing research regardless of their status within the Trust, including the following:

- all Trust employed staff
- independent contractors
- all learners
- all staff employed elsewhere covered by a Trust-issued Letter of Access or Honorary Research Contract

This policy is applicable to all research involving Trust premises or staff, NHS patients to whom the Trust has a duty of care, patient material, or patient data, conducted by Trust employees, independent contractors and other non- employees. This policy is of particular relevance to clinical research activity but applies equally to all research.

3 DUTIES AND RESPONSIBILITIES

3.1 Executive Lead

Executive level accountability for research management within the Trust lies with the Director of Education & Research, who is responsible for ensuring compliance with the UK Policy Framework for Health and Social Care Research; this includes reporting to the Trust Board.

The Executive Lead is also responsible for ensuring monitoring arrangements are undertaken and recommendations actioned.

3.2 Director of Education & Research

The Director of Education & Research is responsible for the following:

- Development and review of this policy
- Compliance with local trust policies and procedures have been considered
- Any potential conflicts of interest have been considered
- Appropriate risk review to NHS Organisation has been completed
- Risks to researcher have been assessed
- Appropriate departmental consultation has taken place to confirm the adequacy of facilities and resources
- The Trust is aware and supports the research activity detailed in this application
- Emergency/backup/support arrangements are in place

3.3 Research Support & Management (RSM) Leads

The Research Support & Management leads report to the Director of Education & Research and the Research & Innovation Committee. The role includes responsibility for:

- meets the legislative requirements for research undertaken within the NHS
- ensuring that once research studies are reported to the R&I department, they continue through the procedures outlined in the policy and the relevant Standard Operating Procedures (SOPs).
- Appropriate regulatory approvals are in place
- Appropriate informed consent process
- Suitability of local study team assessed
- Allocation of responsibilities and rights is agreed and documented
- Emergency/backup/support arrangements are in place
- Facilitation of local compliance with all applicable regulations and laws
- Appropriate Trust Divisions and department consultation has taken place

- Appropriate HR arrangements are in place for research team
- Appropriate agreements are in place
- Potential conflicts of interest have been considered
- Appropriate risk review to NHS Organisation has been completed (capacity & capability review)
- All appropriate risks are flagged to the Director or Education & Research for escalation as part of the Capacity & Capability process

3.4 The Research Support & Management (RSM) Team

Responsible for coordinating local feasibility - this is just one element of the research approvals process that is undertaken by the R&I office.

The RSM team is responsible for assessing, arranging, and confirming local Capacity and Capability for a study to take place in the Trust. The researcher must have written confirmation from the R&I Office that Confirmation of Capacity and Capability has been given before the study can begin.

The RSM Team is also responsible for monitoring and audit of active research studies, this includes annual monitoring of all studies and on-site monitoring of sponsored or high-risk studies.

The R&I Department is also responsible for ensuring that all new research is in keeping with the Trust research strategy. The R&I Department produce and maintain the information on the Trust's R&I Operational Capability Statement.

3.5 All staff undertaking research

All staff undertaking research have a responsibility to comply with the UK Policy Framework for Health and Social Research, all conditions of research approval and this policy.

All researchers must register their study with the R&I department prior to performing any protocolled procedures; the R&I staff will then review and confirm capacity & capability (C&C), as required.

All researchers must obtain a National Institute for Health Research (NIHR) accredited Good Clinical Practice (GCP) certificate and update their training every two years. The R&I Department will facilitate and support researchers in attaining this certification, where required.

In addition, all research-staff need to read comply with all relevant Standard Operating Procedures (SOPs); a full suite of these can be accessed through the R&I department.

4 PROCEDURE

All research must follow the procedures outlined within the relevant Standard Operating Procedures, if it includes human subjects (including staff) their organs, tissue, or data; or if it utilises Trust facilities or premises. To undertake research without the appropriate permissions (which include Trust Capacity & Capability assessment) and regulatory approvals may have serious consequences for all staff members involved, including possible serious implications for professional registration.

All research projects must be assessed for capacity and capability (C&C) by the Research & Innovation Team in advance of any protocolled procedures being carried out; research cannot be retrospectively approved. When a study is being considered, the Research Office should be contacted at the earliest opportunity to ensure all processes and reviews are carried out.

Audits and service evaluations do not require confirmation of C&C, but instead must be appropriately registered with the Clinical Audit department. The distinction between research and audit is not always obvious, so where there is any consideration that a project might be research, the R&I team should be contacted for advice.

4.1 Finance

All researchers must comply with the procedures of the Trust's Finance Department in planning and accounting for all expenditure, together with audit processes.

All finances coming into the Trust in relation to Research must go through the R&I lead within the Trust Finance department. Standard Operating Procedures are maintained which cover the appropriate procedures for costing, invoicing and allocation of funding for research studies.

5 TRAINING/SUPPORT

The level of information, instruction and training given to staff will be appropriate to the scale of research activity within the Trust and appropriate to their roles within it. Any courses (for example Good Clinical Practice) can be coordinated through the Research & Innovation Department. A record of the training undertaken by Trust-employed staff will be maintained within the R&I department.

All staff will have access to relevant policies and Standard Operating Procedures, as well as access formalised Trust research training sessions as they are rolled out. Standard Operating Procedures are available on the Research & Innovation page of the Trust Intranet.

6 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Ensuring GCP training is up to date	Research Management & Governance Manager	At least monthly	Research Innovation Committee
Commercial study review	External study coordinator	All commercial interventional studies	Research & Innovation Operational Governance Group

7 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix 1)

8 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

There are a number of related policies within the Trust which should be read in conjunction with this policy, these include:

- CORP/COMM 26 - Intellectual Property Policy
- CORP/RISK 15 - Serious Incidents (SI) Policy
- CORP/FIN 1 D - Fraud, Bribery and Corruption Policy and Response Plan
- CORP/ICT 9 - Information Governance Policy

9 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

10 REFERENCES

- Department of Health, 'UK Policy Framework for Health and Social Care Research', 2018, Department of Health, London
- Health and Safety at Work Act (1974)
- The Mental Capacity Act 2005
- Medicines for Human Use (Clinical Trials) Regulations 2004
- Medicines for Human Use (Clinical Trials) Amendment Regulations 2006
- Research in the NHS – HR Good Practice Resource Pack: https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx

APPENDIX 1 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Division	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Research Governance Policy	Research & Innovation (R&I)	Emma Adams Research Management & Governance Manager	Existing Policy	24 March 2026

1) Who is responsible for this policy? Name of Division/Directorate: Research and Innovation (R&I) part of Education and Research Directorate

2) Describe the purpose of the service / function / policy / project/ strategy? Who is it intended to benefit? What are the intended outcomes?

The policy has been introduced to ensure there is clarity on the governance requirements for research within the Trust

3) Are there any associated objectives? Legislation, targets national expectation, standards:

- All research receives Trust Capacity & Capability authorisation, in line with the regulatory requirements
- The key roles within research (for example Chief Investigator, Principal Investigator, Sponsor) are detailed and the responsibilities of those roles explained

4) What factors contribute or detract from achieving intended outcomes? – R&I Strategy and Trust commitment in respect to encouraging research and considering it core activity

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? Details: [see Equality Impact Assessment Guidance] - No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation] – Not applicable

6) Is there any scope for new measures which would promote equality? [any actions to be taken] Trust wide policy with no specific impact on particular groups

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	No	This policy has no specific impact on any particular group, and applies across the board to all staff equally
b) Disability	No	This policy has no specific impact on any particular group, and applies across the board to all staff equally
c) Gender	No	This policy has no specific impact on any particular group, and applies across the board to all staff equally
d) Gender Reassignment	No	This policy has no specific impact on any particular group, and applies across the board to all staff equally
e) Marriage/Civil Partnership	No	This policy has no specific impact on any particular group, and applies across the board to all staff equally
f) Maternity/Pregnancy	No	This policy has no specific impact on any particular group, and applies across the board to all staff equally
g) Race	No	This policy has no specific impact on any particular group, and applies across the board to all staff equally
h) Religion/Belief	No	This policy has no specific impact on any particular group, and applies across the board to all staff equally
i) Sexual Orientation	No	This policy has no specific impact on any particular group, and applies across the board to all staff equally

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 √	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form – see CORP/EMP 27.

Date for next review: **March 2026**

Checked by: **Emma Adams** **Date:** **24 March 2023**