



Please Note: This policy is currently under review and is still fit for purpose.

Research Governance Policy

This procedural document supersedes: CORP/COMM 14 v.1 Research Governance Policy



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Approved by:	Policy Approval and Compliance Group
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Target audience:	Trust wide

Amendment Form

Version	Date Issued	Brief Summary of Changes	Author
Version 2	5 February 2015	<ul style="list-style-type: none">• Policy extensively revised, please read in full	Emma Hannaford
Version 1	June 2009	<ul style="list-style-type: none">• This is a new procedural document, please read in full	Dr Trevor Rogers

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1. INTRODUCTION

Since the introduction of the Research Governance Framework for Health & Social Care (Department of Health, 2001) it is necessary for the Trust to have a working policy relating to the way that research is undertaken in the Trust. When an NHS body is the organisation providing care, its permission is required before a study may begin (NHS Permission for R&D involving NHS Patients DH, 2004) to enable the Trust to maintain records of and monitor the research that is taking place. Research is an essential component of developing effective health care but it can also carry elements of risk.

The Research Governance Framework states that the core principles of good research governance are secured by the achievement of key standards in five domains:

- **Ethics** – ensuring the dignity, rights, safety and well-being of research participants;
- **Science** – ensuring that the design and methods of research are subject to independent review by relevant experts;
- **Information** – ensuring full and free public access to information on the research and its findings;
- **Health and safety** – ensuring at all times the safety of research participants, researchers and other staff;
- **Finance** – ensuring financial probity and compliance with the law in the conduct of research.

All those involved in research with human participants, their organs, tissue or data must be aware of and implement the law, and the basic principles above from the Research Governance Framework. All those involved in research also have a duty to ensure that they and those they manage are appropriately qualified, both by education and experience, for the role they play in relation to any research. They must be aware of, and have ready access to, sources of information and support in undertaking that role.

This policy aims to reflect the requirements of the Research Governance Framework 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, taking into account ethical implications.

2. PURPOSE

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

The purpose of this policy is to instruct the reader in the appropriate procedures regarding the conduct of research within the Trust. Namely:

- inform staff of the appropriate procedures regarding the conduct of research within the Trust
- ensure all research undertaken by the Trust complies with statutory legislation and guidance
- provide a framework for the development of a robust research governance process across the Trust and its partner organisations
- clearly define accountability and responsibility for Research Governance
- to ensure any incidents, hazards or risks arising from Research Governance are identified and managed in accordance with Trust policies
- to promote good practice across the Trust
- to enhance ethical and scientific standards and quality.

2.1 Persons covered by this policy

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

- all Trust employed staff
- independent contractors- general practitioners, pharmacists, optometrists and dentists
- all students
- all staff employed elsewhere covered by a Letter of Access or Honorary Research Contract

3. DUTIES AND RESPONSIBILITIES

3.1 Executive Lead

Executive level accountability for Research Governance within the Trust lies with the Chief Executive who is responsible for ensuring compliance with the Research Governance Framework. This includes reporting to the Trust Board.

3.2 Research Management & Governance Lead

The Research & Development office staff report directly to the Director of R&D and the R&D Strategy Steering Committee. The role includes responsibility for:

- fulfilling the responsibilities of the organisation (Section 3.7)
- ensuring that once projects are reported, they continue through the procedures outlined in the policy.

3.3 The Research & Development Department

The Research & Development office staff (manager/ co-ordinator) has operational responsibility for Research Governance within the Trust as follows:

- working towards achieving the Health Care Commission's Research Governance Standards;
- promoting a quality research culture within the Trust;
- ensuring researchers have seen a copy of this policy and understand their responsibilities;
- ensuring the research is properly designed and that it is well managed, monitored and reported;
- taking action if misconduct or fraud is suspected;
- liaising with researchers;
- communicating research summaries or appropriate reports to staff and patients via team brief, public website, annual report etc.

3.4 The Researcher

Each researcher is accountable for their own practice and for abiding by the Research Governance Policy and others relating to it. The Principal Investigator/ lead researcher is ultimately accountable for all responsibilities below (although it may be appropriate to delegate responsibilities to other members of the research team);

- notifying the Research & Development Team of any research they are planning to undertake;
- adhering to the approved research proposal;
- informing the appropriate Research Ethics Committee and Trust Research & Development Team of any changes to the approved protocol;
- ensuring all the research is carried out in accordance with the Research Governance Framework;
- complying with legal requirements and guidance;
- ensuring that each member of the research team is qualified (education, training, experience) to discharge his/her role in the study;
- ensuring that all students and new researchers have adequate supervision, support and training;
- ensuring relevant management and clinical staff who are responsible for patients or carers taking part in the study have seen the research proposal and have been given the opportunity to comment or raise concerns;
- ensuring participants' welfare while in the study;
- reporting any adverse incidents connected to the research using the Trust's reporting system;
- to make sure that any fraud or scientific misconduct is detected;
- ensuring that procedures are in place to collect and store project data confidentially;
- arranging for the archiving of the data when the research has finished;
- ensuring that all data and documentation is available for auditing;
- submitting annual/ interim project reports, and a final project report;
- the dissemination and publication of project findings and feedback to participants, with the guidance of the Research & Development office staff.

3.5 Clinical Staff

All clinical staff members with responsibilities for patients/users/carers taking part in research have a responsibility to:

- examine the research proposal and discuss any queries/concerns with the researcher;
- ensure that research meets the standard set out in the research proposal;
- ensure there is ethical approval for all research for which they have a duty of care;
- retain responsibility for research participants' care.

3.6 Research Sponsors

All research must have a sponsor. The sponsor is the individual, or organisation (or group of individuals or organisations) that takes responsibility for confirming proper arrangements are put and kept in place for the initiation, management, monitoring, reporting and finance of the study; satisfying itself that the study meets the relevant standards. The sponsor's role is to ensure that research responsibilities are clearly and properly identified and allocated to the main parties within the research project from the outset, including ensuring:

- The research proposal respects the dignity, rights, safety and well-being of participants and the relationship with care professionals.
- An appropriate process of independent expert review has demonstrated the research proposal to be worthwhile, of high scientific quality and good value for money.
- An appropriate ethics committee or independent ethics reviewer has given a favourable opinion.
- In the case of a clinical trial involving a medicine, someone acting on behalf of the sponsor obtains a clinical trial authorisation, and the arrangements for the trial comply with the law.
- Appropriate arrangements are in place for the registration of a trial.
- The Chief Investigator, and other key researchers, including those at collaborating sites, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully.
- The arrangements and resources proposed will allow the collection of high quality, accurate data and the systems and resources proposed are those required to allow appropriate data analysis and data protection.
- Arrangements proposed for the work are consistent with the Research Governance Framework.
- Organisations and individuals involved in the research agree the division of responsibilities between them.
- There is written agreement about the arrangements for the management and monitoring of the study.
- Arrangements are in place for the sponsor and other stakeholder organisations to be alerted if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction.
- Intellectual property rights and their management are appropriately addressed in research contracts or terms of grant awards.

- Agreement has been reached about compensation in the event of harm to research participants; and if any organisation, or the sponsor itself, offers compensation without proof of negligence, it has made the necessary financial arrangements.
- There are arrangements for the conclusion of the study including appropriate plans for disseminating the findings.
- All scientific judgements made by the sponsor in relation to responsibilities set out here are based on independent and expert advice.
- Assistance is provided to any enquiry, audit, or investigation related to the funded work.

3.7 Care Organisation

- Retain responsibility for the quality of all aspects of participants' care whether or not some aspects of care are part of a research study.
- Maintain a record of all research undertaken through or within the organisation, including research students undertake as part of their training.
- Ensure patients or users and carers are provided with information on research that may affect their care.
- Be aware of current legislation relating to research and ensure that it is implemented and followed within the organisation.
- Ensure that no research with human participants, their organs, tissue or data, begins until a sponsor has confirmed it has taken responsibility.
- Require before each study begins that research involving participants for whom they are responsible has a favourable ethical opinion (and if the study is a trial of a medicine, that there is a clinical trial authorisation); and someone authorised to do so has given written permission on behalf of the organisation providing care.
- Ensure that written agreements are in place regarding responsibilities for all research involving an external partner, funder and/or sponsor, including agreement with the university or other employer in relation to supervision of student research.
- Maintain the necessary links with clinical governance and/or best value processes.
- If researchers have no contractual relationship with any NHS body and are to interact with individuals in a way that directly affects the quality of their care, ensure they hold honorary NHS contracts and there is clear accountability and understanding of responsibilities.
- Put and keep in place systems to identify, process, address and learn from errors and failures, or complaints associated with any research work undertaken through or within the organisation.
- Ensure that significant lessons learnt from errors or complaints and from internal enquiries are communicated to funders, sponsors and other partners.
- Ensure that adverse incidents in the context of research are included in reports to the Health Research Authority in line with the standard procedures of the organisation.
- Permit and assist with any monitoring, auditing or inspection required by relevant authorities.

3.8 Organisational Arrangements

The Trust Board must be kept informed of all significant developments, risks, and progress. This is carried out through the research governance office staff, who report to the Research Governance Strategy Steering Group and the R&D Director. As part of the Trust Research & Development Strategy reporting structure, quarterly reports are made to Board in response to all significant development risks and progress. These reports will be sent through by the Research Management & Governance Manager or the Clinical Research Development Manager on behalf of the R&D Director. At the twice yearly RAG group, the most recent Board Report a progress report against the R&D strategy will be presented. Contributions will be made to the Trust Annual Report and Quality Account.

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 utilising Trust facilities or premises. To undertake research without the appropriate Trust permissions and regulatory approvals may have serious consequences for all staff members involved, including possible serious implications for professional registration.

All research projects must be approved in advance with the Research & Development Team. 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.

Where studies are classed as research, the researcher must obtain approval from the Research and Development Team. Clinical Audit and Service Evaluation do not require Research Governance Approval, but 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 Research & Development 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 for dealing with fraud.

All finances coming into the Trust in relation to Research and Development must go through the R&D 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 & Development Department. A record of the training undertaken by Trust-employed staff will be maintained within the R&D department.

All staff will have access to relevant policies and Standard Operating Procedures, as well as access formalised Trust Research and Development training sessions as they are rolled out in accordance with the Trust Research and Development Strategy. Standard Operating Procedures are available on the Research & Development page of the Trust Intranet and also the external website <http://www.doncasterclinicalresearch.org/>.

6. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

Compliance against this policy will be monitored in accordance with Trust Research and Development Standard Operating Procedures in respect to all aspects of research delivery. Standard Operating Procedures are available on the Research & Development page of the Trust Intranet and also the external website <http://www.doncasterclinicalresearch.org/>.

7. DEFINITIONS

Research can be defined as the attempt to derive new knowledge by addressing clearly defined questions with systematic and rigorous methods. Research Governance comprises the systems that have been developed to provide the regulation of research and the way it is conducted in the health and social care settings by setting standards, ensuring that arrangements are in place to monitor projects, thus ensuring maintenance of research quality and providing safeguards to the public.

Additional definitions and acronyms are explained in the current version of the Standard Operating Procedure RM&G 0002 Glossary of terms and acronyms.

8. EQUALITY IMPACT ASSESSMENT

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 for details.

9. 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 13 - Policy for the Reporting and Management of Incidents and Near Misses
- 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

10. REFERENCES

- Trust R&D Strategy
- Health and Safety at Work Act (1974)
- NHS R&D Forum RM&G Toolkit (Version: March 2005)
- Policy on Adverse Event and Near Miss Management
- Research Governance Framework for Health and Social Care, Department of Health, first edition, 2002
- Research Governance Framework for Health and Social Care, Department of Health, second edition, March 2005
- 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 available from the National Institute for Health Research <http://www.nihr.ac.uk/policy-and-standards/research-passports.htm>

APENDIX 1 – EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	CSU/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Research Governance Policy	Research & Development	Emma Hannaford, Research Management & Governance Manager	Existing Policy	18 November 2014
1) Who is responsible for this policy? Name of CSU/Directorate: Research and Development				
2) Describe the purpose of the service / function / policy / project/ strategy? Who is it intended to benefit? What are the intended outcomes? The policy is being introduced to ensure there is clarity on the governance requirements for research within the Trust.				
3) Are there any associated objectives? <ul style="list-style-type: none"> • All research receives Trust approval, 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? &D 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 <ul style="list-style-type: none"> • If yes, please describe current or planned activities to address the impact [e.g. Monitoring, consultation] N/A 				
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
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**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 in Appendix 4*

Date for next review: November 2017

Checked by: Emma Hannaford, Research Management & Governance Manager

Date: 18 November 2014