Royal National Hospital for Rheumatic Diseases
NHS Foundation Trust

Research Governance Policy

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Target audience:	R&D Committee, all researchers, all researchers who are starting research at the Trust.
Related Procedural Documents:	RNHRD Code of Conduct for Employees in Respect of Confidentiality RNHRD Incident Reporting for Research Policy 2011

Document Audit Trail

Version	Date	Author; name & title	Key Changes
1.0	April 2004	Jane Carter	Original document
2.0	Jan 2008	Jane Carter	Document reviewed
3.0	Sept 2011	Jane Carter	Document format amended to comply with NHSLA requirements. Sections included to cover Research Passport system, local data protection policy, GCP training, Monitoring and Audit

Research Governance Policy

1. Purpose of this document

This document has been approved by the R&D Committee of the Royal National Hospital for Rheumatic Diseases NHS Trust and lays out the responsibilities of both the Trust, Chief/Principal Investigators and researchers when proposing to and carrying out research. This Policy is in line with the Research Governance Framework for Health and Social Care (DH 2005) Second Edition.

Summary and Contents
The Research Governance Framework sets out the necessary requirements for NHS Trusts and care providers to host research. It contains details of systems which need to be in place to ensure the quality of research, to ensure research complies with legal requirements and good practice. This document sets out the Policy of the Trust to ensure all staff are aware of their responsibilities in terms of Research Governance.

2. Policy statement

It is the policy of the Trust to ensure that all research conducted within the Trust or in conjunction with Trust staff is conducted in accordance with the Research Governance Framework for Health and Social Care (Department of Health 2001) Revised 2005 2nd Edition.

The Trust will ensure that all data collected is accurate and that the welfare and safety of all patients and staff involved in the research process is paramount.

All research:
a) must be work which is designed to provide new knowledge;
b) whose findings are potentially of value to those facing similar problems elsewhere; and
c) whose findings are planned to be open to critical examination and accessible to all who could benefit from them.

3. Scope of the policy

This Research Governance Policy applies to all individuals involved in the conduct of research either taking place within or taking place in conjunction with the Trust, its patients or staff.

4. Definition and Terms:

Researchers – those conducting the study.
Chief Investigator – the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of the study.
Principal Investigator – the person designated at the Trust to take overall responsibility for the conduct of the trial at the RNHRD eg in a multi-centre trial where the CI is based elsewhere.

5. Roles and Responsibilities

5.1 The Trust

5.1.1 To maintain an approval system for research, including collaboration with Research Ethics committees and national systems to allow the timely commencement of research projects.

5.1.2 To issue all Chief Investigators/Principal Investigators whose projects are approved by the R&D Committee as part of the system with a Trust Approval Letter, signed by the R&D Manager. No project can commence prior to receipt of this letter and full ethical committee approval where appropriate. For all Trust sponsored or non-commercially funded projects, including Trust funded projects, this approval letter acts as automatic indemnity. (See below for indemnity for commercial trials).

5.1.3 The Trust will maintain a system for reporting Adverse Events, in particular Serious Adverse Events in research with appropriate follow up procedures. All SAE must be reported to the R&D office as soon as possible and the CI/PI is responsible for completing an incident report form on Datix via the Mintranet. The Trust's R&D Committee reviews any Serious Adverse Events occurring in research participants on a monthly basis.

5.1.4 The Trust will maintain a system to allow the identification of suspected research fraud and misconduct and a procedure to deal with those found to be guilty of it.

5.1.5 The Trust will process any potential intellectual property that may result from research projects and facilitate the exploitation of the IPR in line with the Trust procedure.

5.2 The R&D Committee

5.2.1 The R&D committee will peer review all own account projects and those not previously scientifically reviewed by a recognised funding organisation.

5.2.2 The R&D committee will ensure that annual monitoring of at least 10% of all projects will take place including all RNHRD sponsored Clinical Trials as well as an audit of informed consent within these projects

5.3 The R&D Office

5.3.1 The R&D Manager will facilitate the process of agreeing research governance responsibilities with third parties eg funding organisations, collaborating centres in the form of written agreements as required by the Research Governance framework.

5.3.2 The R&D staff and Finance department will help facilitate Chief and Principal Investigators to cost research projects appropriately to make applications for external funding and will process grants and set up systems within the existing accounting system to enable expenditure of the grant and inform CI's/PI's of the budget.

5.3.3 The Research Passport system is used and all researchers applying to do

research from external organisations will be requested to use this wherever applicable. The R&D office is responsible for processing these with assistance from HR if necessary.

5.3.4 The R&D Manager in conjunction with the CI/PI will conduct a risk assessment of clinical trials before hand and ensure that in the rare exception of approving a project with an identifiable significant risk, will notify IGQUAC.

5.4 Human Resources Department

5.4.1 The Human Resources Department in conjunction with the R&D Office will facilitate the employment of new researchers and honorary researchers and those requiring a research passport/letter of access.

5.4.2 The HR Department will organise mandatory training and make it available to all researchers.

6. Responsibilities of the Principal Investigator and Researchers

6.1 R&D Approval

6.1.1 All proposed research projects developed must seek Trust approval.

6.1.2 All research projects involving patients, their data, human organs or tissue, healthy volunteers and, in some circumstances, staff members must seek NHS ethical approval as laid down by the National Research Ethics Service (NRES).

6.1.3 No Clinical Trial of an Investigational Medical Product (CTIMP) will commence without the full approval of the MHRA.

6.1.4 No project will commence without the full approval or the Trust and, where applicable, an NHS Ethics committee (MREC and /or LREC).

6.1.5 Projects will be conducted to the agreed protocol and in accordance with legal requirements and guidance.

6.1.6 Any substantial amendments to protocols will be notified to the Ethics committee giving approval and the Trust R&D committee for approval. If the RNHRD is acting as sponsor, all non-substantial amendments must also be notified to the R&D office.

6.2 Finance

6.2.1 CI's/PI's will agree all external funding applications with the Finance department prior to submission to the potential funding organisation.

6.2.2 All successful grant applications will be processed through the Finance department (except for certain joint projects hosted with other organisations). All goods and services for research will be purchased in line with the Trust purchasing procedure.

6.2.3 All projects proposed will be in line with the RNHRD R&D Strategy. PI's will comply with all monitoring, audit and final reporting mechanisms for research required by the Trust, the funding organisation and any ethical committee or other recognised regulatory organisation eg MHRA.

6.3 Incident reporting, Misconduct and Fraud

6.3.1 All adverse and serious adverse incidents will be reported according to the Trust Adverse and Serious Adverse Event SOP (2011).

6.3.2 PI's and researchers are required to report any suspected research misconduct or fraud in line with the Trust's Misconduct and Fraud Policy and taking into consideration the Trust's Whistleblowing policy.

6.4 Honorary Contracts/Letter of Access

6.4.1 All non-RNHRD staff who participate in research projects involving Trust patients, their data, human organs, tissue or staff must hold an Honorary Contract or Letter of Access from the Trust and these must be identified by the PI on the application for Trust R&D approval via the IRAS Site Specific Information Form (SSI).

6.5 Data Protection Act and Confidentiality

6.5.1 All PI's and researchers must comply with the Data Protection Act 1998 and the Caldicott Report – Protecting and Using Patient Information (Dec 1997). All patient identifiable data (paper or electronic format) must be securely stored in line with the Act. Researchers must guard against unauthorised access to; disclosure of; loss of or destruction of patient identifiable data while in their custody. Wherever possible researchers shall ensure that all basic factual data is anonymised as and when it is received and that the key to personal identities of persons involved in the research is kept in a separate and secure place.

6.5.2 All PI's and researchers must ensure they have completed a local RNHRD Data protection form authorised by the Data Protection Officer before commencing research.

6.5.3 All researchers must have read and signed to say they have understood and will abide by the Trust Code of Conduct for Confidentiality (2009).

6.5.4 Records of all participants must be maintained along with records of all participants written informed consent.

6.6 Training requirements

6.6.1 All researchers will attend mandatory training in health and safety including but not limited to infection control, fire, manual handling and CPR.

6.6.2 PI's/researchers involved in Clinical Trials of Investigational Medicinal Products (CTIMPS) must ensure they have up-to-date ICH GCP training. It is recommended that researchers for other studies also complete ICH GCP training.

6.7 Storage of medicines and drugs

6.7.1 All medicines and drugs used for research purposes will be securely stored in a locked fridge/cupboard in a locked room when unattended in the Trust or at the RUH pharmacy or by a commercial pharmacy licensed

for such purposes. Any chemicals, medicines or drugs not used for treatment purposes must be stored in a locked cabinet in accordance with the COSHH regulations (2002).

6.8 Intellectual Property

6.8.1 All PI's are responsible for notifying the R&D manager of any potential intellectual property that may result from their research projects in compliance with the Trust IPR policy and facilitate the exploitation of the IPR in line with the Trust procedure.

6.8.2 All PI's will ensure that research results are disseminated appropriately through academic journals, conferences, locally to Trust staff and that participants are given the opportunity to receive a summary of the project results where appropriate.

6.9 Completion of project

6.9.1 The PI must submit a final project report form to the R&D office on completion of a project.

6.9.2 The PI is responsible for notifying the R&D Manager if the project is terminated.

7. Commercial Clinical Trials

7.1 Externally funded commercial research is research which is undertaken in the NHS for the direct commercial gain by an external funder eg. pharmaceutical company. All commercial research should be fully funded by the commercial company except in exceptional circumstances where the research project is jointly funded with a non-commercial funder eg MRC where the Pharmaceutical company meets the cost of the drugs and placebo.

7.1.1 All Clinical Trials Agreements (CTA's) to be signed off by a Trust Finance Director or in their absence the Chief Executive. A copy must be lodged with the R&D Manager.

7.1.2 All Clinical Trials will be reviewed by the Trust's Clinical Studies Management Group.

7.1.3 All Indemnity Agreements (if separate from CTA) to be signed off by the Trust Finance Director. A copy must be lodged with the R&D Manager.

7.1.4 All trials to be costed in conjunction with the R&D Manager.

7.1.5 All finance to be agreed by the Trust Finance office and the Clinical Studies Management Group.

7.1.6 Use of services such as clinical imaging, pathology, pharmacy etc to be discussed with the relevant department during set up stage and prior to signing CTA.

7.1.7 Trials may not commence prior to signature by all parties of the CTA and Indemnity Agreements, Site Specific Information (SSI) and Data Protection Forms and NRES approval.

8. Consultation

8.1 The RNHRD Research Governance policy was first approved in April 2004 by the RNHRD R&D Committee. The document was revised in January 2008, January 2010 and September 2011 to ensure local and national changes in research policy are reflected in the document. All amendments to the policy have been approved by the RNHRD R&D Committee.

Appendix 1

References

1. Research Governance Framework for Health and Social Care (DH 2001). Updated April 2005.
2. Caldicott Report, December 1997.
3. Data Protection Act 1998.
3. National Institute for Health Research, Research in the NHS – HR Good Practice Resource Pack, September 2010.

Equality Impact Assessment Form example

	INITIAL SCREENING	Yes/No	Comments (use the back of this form if you require more space)
1.	**Does the service/ policy/procedure affect one group less or more favourably than another on the basis of:**		
	• Race	No	
	• Disability	No	
	• Gender	No	
	• Age	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation (including lesbian, gay and bisexual people)	No	
If you have answered <u>Yes</u> to any of the above in question 1, please answer questions 2 - 6. **If you have answered <u>No</u> to all of the above in question 1, please refer to the guidelines for completing the Equality Impact Assessment form.**			
	FULL IMPACT ASSESSMENT	**Yes/No**	**Comments (use the back of this form if you require more space)**
2.	**What is the evidence that some groups are affected differently?**	n/a	
3.	**Is the impact of the policy/ guidance likely to be negative?**	n/a	
4.	**If it is negative, can the impact be avoided?** **If yes, how?**	n/a	
5.	**Is the discrimination considered to be valid, legal and/or justifiable?** **If yes, how?**	n/a	

	INITIAL SCREENING	Yes/No	Comments (use the back of this form if you require more space)
6.	What actions can be taken to reduce the impact?	n/a	
When you have considered and answered questions 2 – 6 please refer to the guidelines for completing the Equality Impact Assessment form on the Mintranet for detailed guidance			

For advice in respect of answering the above questions refer to the guidelines for completing the Equality Impact Assessment form or contact the PALS co-ordinator for the Trust via switchboard.

Equality Impact Assessments (EIA) – please delete this part of the form if not used

Action plan to reduce/eliminate identified discrimination

Group / specialty / department:	
Service / Policy / function:	
Date:	

Identified discrimination from EIA:		
Action/s to be taken to reduce impact:		
Action	**Planned outcome**	**Review date**

Send a copy of this form to the Equality Lead	
Date sent:	

Review findings	Update to action plan (if necessary)	Date action completed	Outcome

Send a copy of this form to the Equality Lead	
Date sent:	

Dissemination Plan

Title of document:	Research Governance Policy
Date finalised:	

Training Plan including Timeframe:			
Training Plan Responsibility (name & role):			
Previous document already being used?	**Yes** (Please delete as appropriate)	**Dissemination lead: Print name, role and contact details**	Jane Carter R&D Manager 01225 481156
If yes, in what format and where?	Document dated January 2008, stored on Mintranet		
Proposed action to retrieve out-of-date paper copies of the document:	R&D administrator to remove and upload updated version of policy		

To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Paper or Electronic**	**Comments**
R&D Committee	R&D Secretary	Electronic	
All researchers	R&D Secretary	Electronic	Uploaded to Mintranet

Dissemination Record - to be used once document is approved.

Date put on Trust Policy Database		**Date due to be reviewed**	

Disseminated to: (either directly or via meetings, etc)	**Format (i.e. paper or electronic)**	**Date Disseminated**	**No. of Copies Sent**	**Contact Details / Comments**