Research Governance Policy
<table>
<thead>
<tr>
<th>SECTION</th>
<th>PAGE NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. INTRODUCTION</td>
<td>4</td>
</tr>
<tr>
<td>2. PURPOSE</td>
<td>4</td>
</tr>
<tr>
<td>3. SCOPE</td>
<td>4</td>
</tr>
<tr>
<td>4. RESPONSIBILITIES, ACCOUNTABILITIES AND DUTIES</td>
<td>4</td>
</tr>
<tr>
<td>5. PROCEDURE/IMPLEMENTATION</td>
<td>8</td>
</tr>
<tr>
<td>6. TRAINING IMPLICATIONS</td>
<td>11</td>
</tr>
<tr>
<td>7. MONITORING ARRANGEMENTS</td>
<td>12</td>
</tr>
<tr>
<td>8. EQUALITY IMPACT ASSESSMENT SCREENING</td>
<td></td>
</tr>
<tr>
<td>Privacy, Dignity and Respect</td>
<td>13</td>
</tr>
<tr>
<td>9. LINKS TO OTHER PROCEDURAL DOCUMENTS</td>
<td>15</td>
</tr>
<tr>
<td>10. REFERENCES</td>
<td>15</td>
</tr>
<tr>
<td>11. APPENDIX 1</td>
<td>16</td>
</tr>
</tbody>
</table>
1 INTRODUCTION

With the introduction of the Research Governance Framework for Health & Social Care (DoH 2005), it is necessary to have in place 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 can begin (DoH 2004), to enable the Trust to maintain records of and monitor the research-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.

2 PURPOSE

This policy aims to ensure that the Trust has systems in place to ensure that developing and maintaining a research culture of excellence, consistently apply the principles and requirements of the Research Governance Framework. This Trust will seek to do this by 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.

3 SCOPE

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

- Students
- Trust employed staff

Researchers not employed by the Trust but who wish to access Trust resources

4 RESPONSIBILITIES, ACCOUNTABILITIES AND DUTIES.

Overall accountability for Research Governance within the Trust lies with the Chief Executive. This responsibility is delegated to the Medical Director for management of the development and implementation of Research Governance systems and procedures. The Medical Director will act as the Trust’s authorised signatory for approving and signing off of studies.
4.1 **The Medical Director,**

Supported by the Research Office, has operational responsibilities for Research Governance within the Trust as follows:

- Approving the undertaking of trials and research studies whether or not including third parties and whether or not involving sponsorship involving sponsorship.
- Promoting a quality research culture within the Trust
- Make researchers aware of this policy and understand their responsibilities
- Confirm research is properly designed and that it is well managed, monitored and reported
- Taking action if misconduct or fraud is suspected
- Communicating research summaries or appropriate reports to staff and patients via team brief, public website, annual report, Practice Development events and Bulletins etc.
- Check staff have access to information on guidelines about research governance procedures and regulatory documentation.
- Informing staff of changes to legislation relating to research work, and ensure these changes are implemented across the organisation.
- Informing the Board of Directors of all significant developments, risks, and progress. This is carried out through the Research Panel, which reports to the Human Resources and Organisational Development Group and to the Performance and Assurance Group for policy and performance matters. These groups in turn report to the Board of Directors. Updates from the Research Panel will be provided on a regular basis and an annual report on research activity will be produced.

4.2 **The Research Panel**

- The Research Panel will monitor and develop the involvement of staff, patients and the public in all stages of research. (See appendix 1)

4.3 **The Research Lead**

- The Research Lead will chair the Research Panel on behalf of the Medical Director.
- Will contribute to the peer review process as a member of the Research Panel.

4.4 **The Research Office**

- Will advise and assist researchers through the requirements of the research governance process.
• If a complaint is received related to research activity, the effectiveness Lead in close liaison with the Medical Director will investigate this.

• The issue of research passports and letters of access for researchers have been devolved to the Research and Development Office.

• In accordance with the Research Governance Framework for Health and Social Care (DoH 2005), a random 10% of all research projects within the Trust will be audited annually by the Research Office, for compliance with the Research Governance Framework and the ethically approved protocol.

• The Trust will check that patients or users and carers are provided with information on research that may affect their care.

4.5 Researcher responsibilities

Each researcher is accountable for their own practice and for abiding by the Research Governance Policy and others relating to it. The researcher is responsible for:

• Notifying the Research Office of any research they are planning to undertake

• Adhering to the approved research proposal

• Complying with legal requirements and guidance and obtaining the prior approval of the Medical Director

• Provide relevant management and clinical staff who are responsible for patients or carers taking part in the study, the research proposal and the opportunity to comment or raise concerns

• Safeguard participants’ welfare while in the study

• Reporting any adverse incidents connected to the research in line with the Trust’s Incident Reporting Policy and electronic incident reporting system (Safeguard).

• On completion of the research project, to send a NHS Integrated Research Application System (IRAS) Completion Form with a Summary of Research to the Trust Research Office.

• The dissemination and publication of their work, with the guidance of the Research Office.

• It is the researcher’s responsibility to adhere to all Trust policies and procedures including reporting and management of adverse incidents as required by the Incident Reporting Policy.

• In addition, specific legal requirements exist to report incidents e.g. adverse reactions to medicines to the Medicines and Healthcare products Regulatory Agency (MHRA).

• It is the researcher’s responsibility to adhere to the Health and Safety at Work Act, in respect to themselves and their participants.
• All those involved in research with humans participants; their organs, tissues or data must be aware of and implement the basic principles above from the Research Governance Framework.

• The appropriate use and protection of patient information is of paramount importance to the Trust. All individuals involved in research must be aware of their legal and ethical duties and particular attention must be given to systems for ensuring confidentiality of personal information and to the security of these systems. All relevant Trust policies and procedures must be adhered to e.g. Data Protection Policy, Information Governance Policy, IM&T Security Policy, Policy for Clinical Record Keeping Standards and Clinical Records Management for and the requirements of Caldicott.

Research material such as questionnaires or raw data must be kept in accordance with NHS guidance (see Records Management Policy for retention periods).

• All those carrying out research to which the requirements of the Mental Capacity Act (2005) apply, must act in accordance with the provisions of the Act (DOH, 2007).

• 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.

4.6 External Organisations,

• Where research is externally funded, the funding organisation has the responsibility for ensuring that the funds are used in the manner they intended.

4.7 Modern matrons/Service Managers

• Modern Matrons and Service Managers are responsible for:
  
• All staff they manage being aware of how they can access copies of this policy

4.8 Clinical Staff

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

• Confirm that any research conducted is registered with the Trust’s Research Office prior to commencement

• Examine the research proposal and discuss any queries/concerns with the researcher.

• Confirm that research meets the standard set out in the research proposal.

• Confirm there is ethical approval for all research for which they have a duty of care.

• Retain responsibility for research participants’ care.
5 PROCEDURE/IMPLEMENTATION

5.1 Portfolio studies

Approval for research projects adopted onto the National portfolio. The new National Institute for Health Research (NIHR) Coordinated System for gaining NHS Permissions (CSP) has been introduced in the NHS in England for NIHR Clinical Research Network Portfolio studies.

5.2 CSP governance checks

Each participating CLRN undertakes ‘local’ governance reviews (e.g. whether the pharmacy department can undertake the study). In addition, each CLRN facilitates the contracting process and ensures that Honorary Research Contracts are in place, where appropriate. The documents that need to be submitted by the Principal Investigator, together with the SSI form, are included in the checklist in Integrated Research Application System (IRAS).

NIHR CSP is currently not available for studies outwith the NIHR Clinical Research Network Portfolio. Researchers whose study is not eligible for the Portfolio should continue to seek permission directly from the NHS Trusts involved in the study.

The study can commence at an NHS organisation (site) only after all global governance checks and local governance checks relevant to that site are completed and permission from that NHS organisation is granted, and confirmation has been sent to the CI/PI (according to local CLRN processes).

Once all the governance checks have been undertaken by the CSP Unit, the Lead CLRN and the local CLRN, the NHS Trust will be given 21 days in order to grant NHS permission. The Trust’s authorised signatory will be responsible for signing off studies at their organisation within this deadline.

Once NHS permission is confirmed, a letter will be sent to the investigator according to local systems in the CLRN.

5.3 Non Portfolio Research studies

All research must follow the procedures outlined below:

The IRAS Application Form and a research proposal must be completed, and submitted to the Trust Research Panel to check that the project is ethically and academically valid.

Approval is dependent upon:

1. Satisfactory peer review
2. Research ethics approval
3. Management approval
4. Issuing of honorary contracts (where applicable)
5. CRB and Occupational Health checks (where necessary)
All research projects that involve human subjects (including employees of the Trust or Service users), their data or organs must be submitted to an NHS Research Ethics Committee (REC) for approval.

Staff wishing to store patient identifiable information e.g. patient names, addresses, dates of birth etc on a database or spreadsheet must apply for permission from the Caldicott Guardian. Application forms can be found in the Appendix of the Data Protection Policy.

Any research involving medicines must go initially through the Trust Medicines Management Committee for approval prior to being accepted in to the Trust’s governance procedure.

5.4 External Research
Non-Trust staff who wish to conduct their research on Trust premises or access Trust facilities and or patients must have an honorary Trust contract, a research passport or a letter of access/confidentiality. The research passport system and associated procedures have been developed to ensure that the interests of all parties are considered and the safety of patients and staff are maintained. Furthermore, these procedures have been developed in parallel with other arrangements across the UK to streamline the processes for obtaining permission from NHS organisations to undertake research.

The sponsor or funder must cover all costs associated with external research.

5.5 Research passport system
Arrangements are outlined within the Research in the NHS – HR Good Practice Resource Pack (See link. http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx).

5.6 Finance and Intellectual Property
All researchers must comply with the procedures of the Trust’s Standing Financial Instructions in planning and accounting for all expenditure, together with policy and audit processes for dealing with fraud.

All researchers must comply with the Trust’s Intellectual Property Exploitation Policy. Where the research is externally funded, the findings will be subject to contractual agreement with the research funder and/or the employing organisation before commencement. The Trust must ensure that there are agreements between them and research funders/other care organisations about ownership, exploitation and income from any intellectual property that may arise from research conducted by their employees.

5.7 Involvement of consumers, service users and the public in research
Participants or their representatives should be involved wherever possible in the design, conduct, analysis and reporting of research. Social care research has a long tradition of the involvement of participants in research. “Involve”, the consumers in NHS research group, has established the principle that major advisory bodies in NHS R&D programmes should normally have at least two consumer representatives.

Once established, findings must be made available to those participating in the research (including the relatives of deceased patients who have consented to the
use of organs or tissue in the research) and to all those who could benefit from them, through publication and/or other appropriate means.

As health and social care research is conducted for the benefit of patients, users, care professionals, and the public in general, there should be free access to information both on the research being conducted and on the findings of the research, once these have been subjected to appropriate scientific review. Reports will be comprehensible and consider language and special requirements.

5.8 Health and Safety, Adverse Events and Failures
The health and safety of the research participants and researchers must be given priority at all times.

Research that involves medicines is regulated by the Medicines Act 1968 and trials of new products must be notified and given approval from the Medicines Control Agency.

5.9 Misconduct/Complaints
If the complaint is related to the behaviour or attitude of a Trust employee, this will be dealt with through the Trusts Human Resources Department.

If it is found that the researcher has not complied with the approved research protocol or their conduct is negligent in any way, and then the research project will be halted immediately.

The Research Panel will then hold an emergency meeting to implement an immediate investigation into the possible misconduct in line with Trust policies and procedures.

In the case of misconduct, professionals may be subject to disciplinary action in line with established procedures.

Each professional group is responsible to their respective regulatory body, such as the GMC, NMC and HPC.

5.10 Indemnity
All research must have a nominated sponsor who will carry non-negligent indemnity. For clinical trials involving medicines it is a legal requirement that there should be insurance or indemnity to cover the liabilities of sponsors and investigators) and if any organisation or sponsor itself, offers compensation without proof of negligence, it has made the necessary financial arrangements.

Agreements will be documented that include the responsibilities of all parties involved within the programme. This may include where there is:

- Work on more than one site
- Researchers employed by more than one organisation
- Patients, users and care professionals from more than one organisation
- More than one source of funding
For research conducted by members of Trust employed staff, the Trust will act as sponsor and provide full indemnity for that researcher, providing the research is not for an academic qualification. If the research is for an academic qualification then the Higher Education establishment will act as sponsor.

Researchers not employed by the Trust but accessing the Trust resources for the purposes of their research will have to provide their own indemnity.

Any researcher employed by the Trust who does not follow the agreed protocol for approval of their research will not be entitled to trust indemnity.

6 TRAINING IMPLICATIONS (Training Needs Analysis)

<table>
<thead>
<tr>
<th>Details of staff who will require training for the implementation of the Policy / Procedure</th>
<th>Estimate of how many staff in total</th>
<th>Frequency of training</th>
<th>Estimated number of sessions per year</th>
<th>How will the training be delivered, i.e. is the policy / procedure included in any of the training, such as Mental Health Act Training</th>
<th>Who will be responsible for the delivery of the training</th>
<th>How will the training be reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>[List by Staff Group]</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

No specific training would be required, staff to be made aware of the policy by Modern Matrons and Services Managers. The staff that would then be guided through the process by the Effectiveness Lead on an individual basis as required.

NB: Where the document identifies Mandatory Risk and Safety Training needs, please contact the Mandatory Training Manager. Where the document identifies other training needs, please contact the Head of Learning and Development.
## 7 MONITORING ARRANGEMENTS

<table>
<thead>
<tr>
<th>Area for Monitoring</th>
<th>How</th>
<th>Who by</th>
<th>Reported to</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research projects</td>
<td>Use of audit tool and progress reports.</td>
<td>Effectiveness</td>
<td>Research Panel</td>
<td>10% annually</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lead</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portfolio Studies</td>
<td>CSP</td>
<td>Effectiveness</td>
<td>CLRN SY</td>
<td>As requested</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lead</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Register of research</td>
<td>Register of all research work being</td>
<td>Effectiveness</td>
<td>Research Panel</td>
<td>Quarterly</td>
</tr>
<tr>
<td></td>
<td>undertaken through or within the Trust.</td>
<td>Lead</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research activity.</td>
<td>Annual report</td>
<td>Research Office</td>
<td>Research Panel, HR</td>
<td>Annually</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&amp; OD development</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>group, Performance</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>and Assurance Group.</td>
<td></td>
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</table>
### EQUALITY IMPACT ASSESSMENT SCREENING

For each of the seven Equality Categories opposite ask the questions in the table below:-

<table>
<thead>
<tr>
<th>Equality Category</th>
<th>Age</th>
<th>Disability</th>
<th>Race</th>
<th>Religion and Belief</th>
<th>Gender</th>
<th>Sexual Orientation</th>
<th>Other Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do different groups have different needs, experiences, issues and priorities in relation to the policy/procedure?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Is there potential for, or evidence that, the policy/procedure will affect any groups differently?</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>If different needs, experiences or issues have been identified are they met within the policy/procedure?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Could these identified different needs, experiences or issues be perceived as discriminating against any particular population or group?</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

If the answer to any of the above is ‘yes’, you will need to consider the need for a full equality impact assessment to be completed for the relevant areas.

In the event that an equality impact assessment is not felt to be necessary, please explain below the reason why.

The Mental Capacity Act (2005) addresses the issue of research on people who lack capacity to consent. This policy clearly refers researchers to the Act’s guidance and stresses the need for compliance with the Act. This will involve taking into account any additional needs relating to age, disability or race ensuring these needs are met.
<table>
<thead>
<tr>
<th>Privacy, Dignity and Respect</th>
<th>Indicate how this will be met</th>
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<tbody>
<tr>
<td>The NHS Constitution states that all patients should feel that their privacy and dignity are respected while they are in hospital. High Quality Care for All (2008), Lord Darzi's review of the NHS, identifies the need to organise care around the individual, ‘not just clinically but in terms of dignity and respect’. As a consequence the Trust is required to articulate its intent to deliver care with privacy and dignity that treats all service users with respect. Therefore, all procedural documents will be considered, if relevant, to reflect the requirement to treat everyone with privacy, dignity and respect, (when appropriate this should also include how same sex accommodation is provided).</td>
<td>The DOH Research Governance Framework states that the core principles of good research governance are secured by the achievement of key standards in five domains, the first being: Ethics – ensuring the dignity, rights, safety and well being of research participants.</td>
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</tbody>
</table>
9 LINKS TO OTHER PROCEDURAL DOCUMENTS

- Intellectual Property Exploitation Policy – General Policies
- Informatics Security Policy – Information and Knowledge Services Policies
- Policy for Clinical Record Keeping Standards and Clinical Records Management – Clinical Policies
- Data Protection Policy – General Policies
- Information Governance Policy - Information and Knowledge Services Policies
- Accident-Incident Reporting Policy – Health and Safety Policies
- Policy and Procedure Relating to the Handling of Formal Complaints – General Policies
- Standing Financial Instructions – Financial Policies

10 REFERENCES


Department of Health (2004) Research Governance in Health and Social Care, NHS permission for R&D involving NHS patients


Abbreviations used:
DOH Department of Health
R&D Research and Development
IM&T Information Management and Technology
NMC Nursing and Midwifery Council
GMC General Medical Council
HPC Health Professions Council
CRB Criminal Record Bureau
NRES National Research Ethics
CSP Coordinated System for gaining NHS Permission
IRAS Integrated Research Application System
HR & OD Human Resources and Organisational Development Group
CLRN SY Comprehensive Local Research Network. South Yorkshire
NIHR National Institute for Health Research
REC – Research Ethics Committees
Research Panel

Composition:

Consultant Psychiatrist – Research Advisor (Chair)

Executive Director with Research Portfolio

Effectiveness Lead

Research Associate

Knowledge Manager

Head of Learning and Development

2 – Medical Consultants

2 – Nurse Consultants

In addition other co-opted members