Research Governance Policy

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<th>CATEGORY:</th>
<th>Policy</th>
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<tr>
<td>CLASSIFICATION:</td>
<td>Governance</td>
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<tr>
<td>PURPOSE</td>
<td>To set out the over-arching governance policy for all research in the Trust</td>
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<td>Essential Reading for:</td>
<td>Clinical Researchers, Divisional Directors, Clinical Service Leads, Divisional Directors of Operations, Senior Trust Managers, Service Managers</td>
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<tr>
<td>Information for:</td>
<td>All staff</td>
</tr>
</tbody>
</table>
## Contents

<table>
<thead>
<tr>
<th>Paragraph</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Policy Statement</td>
</tr>
<tr>
<td>2</td>
<td>Scope</td>
</tr>
<tr>
<td>3</td>
<td>Framework</td>
</tr>
<tr>
<td>4</td>
<td>Duties</td>
</tr>
<tr>
<td>5</td>
<td>Implementation and Monitoring</td>
</tr>
<tr>
<td>6</td>
<td>References</td>
</tr>
<tr>
<td>7</td>
<td>Associated Policy and Procedural Documentation</td>
</tr>
</tbody>
</table>

### Appendices

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix A</td>
<td>Monitoring Matrix</td>
</tr>
<tr>
<td>Appendix B</td>
<td>Definition of Research</td>
</tr>
<tr>
<td>Appendix C</td>
<td>Terms of Reference of the Research Development and Innovation Strategy Group</td>
</tr>
</tbody>
</table>
1. Policy Statement

1.1 The objective of this policy is to ensure that all research undertaken by University Hospitals Birmingham NHS Foundation Trust (the ‘Trust’) complies with the Department of Health’s Research Governance Framework 2005, 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 research (as defined in Appendix B) which involves:

2.1.1 Patients of the Trust;

2.1.2 Patient data or tissue samples held by the Trust; or

2.1.3 Staff, equipment or facilities of the Trust.

3. Framework

3.1 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 (SOP’s) (see Section 7).

3.2 The Research Development (R and D) and Innovation Strategy Group 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 Development and Innovation Strategy Group.

3.3 Definitions

| Chief Investigator | 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 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. |
| Principal Investigator | 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 B) 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 Department of Health's Research Governance Framework 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 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 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. |

3.4 The Trust will ensure that all research complies with relevant legislation and the quality standards set out in the Department of Health's
Research Governance Framework. The Trust’s framework for ensuring this consists of the following stages:

3.4.1 General requirements

a) All research studies must be registered with the Trust’s Research and Development Office;

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 CI. The CI must formally request the Trust to act as Sponsor and must submit a protocol to the (R and D) Governance Office. The CI 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 PI and CI appointed in accordance with the associated Policy on Chief Investigators and Principal Investigators in Research.

3.4.2 R and D Trust Authorisation

Research cannot proceed until it has been authorised by the Trust’s R&D Governance Office. R and D Trust authorisation for any Research Study will only be given if all requirements, as detailed in the associated R and D Approvals Process (RDS012), have been met.

3.4.3 Conduct of Studies

a) All study must be conducted in accordance with the relevant legislation and protocol, this policy and all associated procedural documents.

b) All amendments to a study protocol must be registered with the R and D Governance Office and any Substantial Amendments must be approved by the R and D Governance Office before the Study can continue.

c) The PI must report all protocol breaches in accordance with the R and D Trust Approval given for the study.
d) The PI must create and maintain a study file which, as a minimum, will follow the guidance issued with the R and D Trust Approval letter.

e) Recruitment to studies will be undertaken as soon as is practicable and in order, where appropriate, to meet recruitment timescales set out by the National Institute of Health Research (NIHR) and Department of Health (DH).

f) The PI must submit to the R and D Governance Office a progress report within 60 days of each anniversary of the date of R and D Trust authorisation of the study, in accordance with the associated R and D Reports Procedure (RDS004). Templates for the annual reports are provided by the R and D Governance Office.

g) All serious adverse events must be reported in accordance with the Policy for Reporting Research Incidents and Breaches.

h) All recruitment into a study must be recorded by research staff in the master study file and, where possible, using the research tab on the Trust’s online patient information system (PICS).

3.4.4 Study Audits and Monitoring

a) The R and D Governance Office will 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 the associated Clinical Study Audits and Inspections Procedure (RDS005).

c) Progress and outcomes of audits shall be reported to the Research Development and Innovation Strategy Group.

3.4.5 Study Closure

a) The PI must notify the R and 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 associated R and D Reports Procedure (RDS004).
c) The PI must ensure appropriate arrangements are made for all study documentation to be archived in accordance with the Corporate Records and Archiving Procedure.

4. Duties

4.1 Executive Director of Delivery

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

4.2 Divisional Directors and Clinical Service Leads

Divisional Directors and Clinical Service Leads are required to ensure that they keep abreast of all research within their area of responsibility. They will 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 division, and that adequate resources are available to enable the research to take place.

4.3 Research Development and Innovation Strategy Group

4.3.1 The Research and Development and Innovation Strategy Group maintains oversight of the operations and governance of research in the Trust. Members of the Research Development and Innovation Strategy Group will be responsible for:

a) promoting and supporting high quality clinical research; and

b) reviewing the arrangements for the governance of research.

4.4 Head of Research and Development Governance

The Head of R and D Governance is required to:

4.4.1 Ensure all research projects are assessed and, when appropriate conditions have been met, duly authorised in accordance with the principles of the NHS Research Governance Framework and all relevant UK legislation;

4.4.2 Ensure that all Trust guidance and procedural documents on research governance are updated and maintained in accordance with the principles;
4.4.3 Ensure that the R and D Governance Office maintains a forward schedule of audits and monitoring visits to check compliance with Trust policies, national guidance and relevant legislation;

4.4.4 Put in place procedures to maintain effective oversight of the progress of individual research projects;

4.4.5 Oversee appropriate monitoring and auditing of individual research studies against established principles of good research practice, and to check compliance with Trust policies; and

4.4.6 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 Executive Director of Delivery.

4.5 Researchers

Researchers are required to:

4.5.1 Ensure that all potential research studies are registered with the R and D Governance Office and that they do not proceed with the studies without authorisation from the R and D Office;

4.5.2 Familiarise themselves, and comply, with the Trust’s policies on research governance, the NHS Research Governance Framework 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;

4.5.3 Cooperate with the R and D office in monitoring and auditing research studies;

4.5.4 Provide annual progress reports to the Trust’s R and D Governance Office in accordance with the Associated R and D Reports Procedure (RDS004);

4.5.5 Comply with the reporting requirements of the National Research Ethics Service and regulatory authorities;

4.5.6 Ensure that they, and other members of the research team, have appropriate expertise, training and experience to fulfil their roles in research studies; and

4.5.7 Provide evidence of suitable GCP training. The PI is responsible for ensuring all research team members are suitably qualified and supervised, including appropriate Trust authorisation for those with clinical contact.
5. Implementation and Monitoring

5.1 Implementation

5.1.1 The Trust’s research governance policies are available on the Trust intranet and can be disseminated to all researchers via the R and D Governance Office.

5.1.2 This policy will be available on the Trust’s Intranet Site. The policy will also be disseminated through the management structure within the Trust.

5.2 Monitoring

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

6. References

International Conference on Harmonisation (ICH) Guidelines on Good Clinical Practice (GCP)  

Research Governance Framework for Health and Social Care, Second edition (2005), Department of Health

7. Associated Policy and Procedural Documentation

Chief Investigators and Principal Investigators in Research Policy

Corporate Records and Archiving Procedure

Policy on Human Tissue for Research

R and D Approvals Process (RDS012)

R and D Office Procedure for Reviewing Study Amendments (RDS013)

R and D Progress Reports (RDS004)

R and D Study Audits and Inspections (RDS005)

Reporting Research Incidents and Breaches Policy

Research Passport System Policy
### Appendix A

#### Monitoring Matrix

<table>
<thead>
<tr>
<th>MONITORING OF IMPLEMENTATION</th>
<th>MONITORING LEAD</th>
<th>REPORTED TO PERSON/GROUP</th>
<th>MONITORING PROCESS</th>
<th>MONITORING FREQUENCY</th>
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<tbody>
<tr>
<td>Research Study Progress reports</td>
<td>Researchers</td>
<td>Research Ethics Committee</td>
<td>Progress report on each research study</td>
<td>Annually</td>
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<tr>
<td></td>
<td></td>
<td>Regulatory authorities R and D Office</td>
<td></td>
<td></td>
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<tr>
<td>Research Governance Database</td>
<td>R and D Governance Office</td>
<td>Head of R&amp;D Governance</td>
<td>Contains records of the status of all research studies as well as details of amendments, audits, adverse incidents, agreements, investigators.</td>
<td>Continuous</td>
</tr>
<tr>
<td>Compliance with Trust R and D policies, national guidance and relevant legislation</td>
<td>R and D Governance Office</td>
<td>Research Development and Innovation Strategy Group</td>
<td>Schedule of audits and monitoring visits to check compliance</td>
<td>Audit schedule is planned quarterly in advance</td>
</tr>
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</table>
| Research activity, and progress and outcomes of audits | R and D Governance Office | Board of Directors | Report providing an account of:  
- All ongoing research activity (newly registered, authorised, published and completed studies)  
- Summary of research-related incidents  
- The progress and outcome of audits; and  
All ongoing monitoring activity. | Annually |
Appendix B

Definition of Research

The Department of Health defines research as “the attempt to derive generalisable (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 Novel Therapies Group

2. **Clinical Audit**

i. Monitoring clinical activity against established good practice guidelines

Or

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*
Appendix C

Research and Development and Innovation Strategy Group
Terms of Reference and Framework for Operation

Reference to “the Group” shall mean the Research and Development Group
Reference to “the Trust” shall mean the University Hospitals Birmingham Foundation NHS Trust.

1. Constitution

The Group was established by the Executive Director of Delivery.

2. The purpose of the Research and Development and Innovation Management Group

2.1 The purpose of the Group is to:

2.1.1 Oversee the development and implementation of the Trust’s research strategies and ensure it is aligned to the Birmingham Health Partners (BHP) strategy.

2.1.2 Ensure assurance research conducted at the Trust adheres to applicable legislation and regulations and that all mechanisms of Trust overview are robust.

2.1.3 Oversee the development and delivery of R&D Workforce to ensure that Trust Terms & Conditions for conduct of research.

2.1.4 Ensure alignment of Trust service that upholds R&D HR research delivery performance.

2.2 The Group will bring together clinical researchers, research governance, and Trust management to support clinical research, optimise research activity and outputs and the use of resources, and manage the Trust’s research communications requirements.

3. Membership

3.1 The membership comprises the following:

3.1.1 Executive Director of Delivery (Chair)

3.1.2 Deputy Director of Delivery Research & Development Innovation

3.1.3 Associate Director of Research ADR Academic Capacity
3.1.4 Associate Director of Research (ITM)
3.1.5 Head of R&D Operations
3.1.6 Head of R&D Governance
3.1.7 Senior R&D Finance Manager
3.1.8 Commercial IP Manager
3.1.9 R&D Business Manager
3.1.10 WM GMC Project Manager
3.1.11 Lead Research Nurse Manager
3.1.12 NIHR/Wellcome Trust Clinical Research Facility - Clinical Manager
3.1.13 Senior R&D Pharmacist
3.1.14 Imaging Head of Department
3.1.15 Deputy Chief Nurse
3.1.16 R&D IT Lead

3.2 Project Managers for the NIHR hosted centres will be invited to attend the Committee on a six monthly basis to provide an update on the relevant centre.

3.3 It may be necessary to invite additional attendees to the meetings of this Group as required. The Chair will agree the requirement and extend the invitation in these cases.

4. Duties

The role of the Research and Development Innovation Management Group is set out below:

4.1 Strategic

4.1.1 Contribute to and inform the development of the Trust's/BHP research Delivery & Innovation strategy.

4.1.2 Develop and implement actions and pathways for achieving the Trust's/BHP research strategy, integrating this with other key partners.
4.1.3 Seek opportunities to enhance the portfolio of Innovation activities.

4.2 Finance & Informatics

4.2.1 Working collaboratively with Divisional Research Management Groups, develop and feedback research performance metrics to assist researchers maximise effective research outcomes.

4.2.2 Receive financial reports required by national bodies - oversee financial reports for submission - oversee use of RCF and ensure are executed in accordance with contracts and research funding in accordance with the SFI’s.

4.2.3 Recommend approaches to use of research resources. Receive financial reports on research finances.

4.2.4 Receive reports from Trust reporting systems in research performance.

4.2.5 Commission and oversee the development and implementation of Trust reporting systems on research performance.

4.3 Governance

4.3.1 Ensure that robust research governance processes are in place, and ensure that these adhere to all applicable legislation and regulations.

4.3.2 Review the R&D risk register and ensure effective controls are in place to mitigate any risks.

4.3.3 Approve all associated research and development procedural documents/SOP’s.

4.4 Communications

Oversee the communications strategy for research and development.

5. Frequency of Meetings

The Group shall meet bi-monthly.

6. Quorum

The Group will be quorate with the attendance of the Chair (or nominated deputy), a Trust Research and Development Director, Trust Director of Finance, Head of Research and Development Operations, and Head of Research and Development Governance.
7. **Agendas and Reporting**

7.1 All agenda items should be approved by the Chair prior to the meeting. Papers without this approval should not be tabled during the meeting.

7.2 Action points agreed at meetings, together with the minutes, will be circulated within 7 working days of the meeting, to the Chair and all members of the Group.

7.3 Papers for the meeting will be circulated to the Chair and the Group a minimum of three working days prior to the meeting.

7.4 Group members are expected to identify a deputy of equivalent seniority to attend in their place should they themselves be unable to attend a meeting.

7.5 The Group shall submit an annual research report to the Board of Directors and an annual Governance report will be submitted to the Audit Group.

8. **Review**

8.1 The Terms of Reference and membership of Group will be reviewed every 2 years.

8.2 Next review due in April 2017.