UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST
BOARD OF DIRECTORS
THURSDAY 25 JULY 2013

Title:	**APPROVAL OF POLICIES**
Responsible Director:	David Burbridge, Director of Corporate Affairs
Contact:	Lynda Steele, Head of Corporate Risk and Compliance Ext 13655

Purpose:	To seek Board of Directors approval of the changes to the following policies: Risk Management Strategy and Policy Policy for Research Governance	
Confidentiality Level & Reason:	None	
Annual Plan Ref:	None	
Key Issues Summary:	The documents listed above have been reviewed and amended in line with the Policy for the Development and Management of Controlled Documents. The Board of Directors' approval of the above policies is sought.	
Recommendations:	The Board is asked to consider and if thought fit, approve the amendments to: Risk Management Strategy and Policy Policy for Research Governance	
Approved by:	David Burbridge	Date: 17 July 2013

UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST

BOARD OF DIRECTORS
THURSDAY 25 July 2013

APPROVAL OF POLICIES

PRESENTED BY THE DIRECTOR OF CORPORATE AFFAIRS

1. **Risk Management Strategy and Policy**

The Risk Management Strategy and Policy has been previously approved by BOD. The policy has since passed its review date and has undergone a thorough review so as to be compliant with all NHSLA Risk Management Standards:

A Risk Management Strategy has been added which stipulates the Trust's overall strategic aim to make the effective management of risk an integral part of everyday management practice by having a comprehensive and cohesive risk management system in place which is underpinned by clear responsibility and accountability arrangements throughout the organisational structure of the Trust all which are set out in more detail in the Trust's SFIs, SOs, Corporate Governance Policy and the Chief Executive's Scheme of Delegation and Accountability.

Further changes include:

- Overall streamlining of the document by moving procedural information into the supporting procedural documents;
- Amendments to Annex B and C which detail the process in which risks are escalated from one level to the next (NHSLA requirement).
- Changes of reporting requirements of the Audit Committee to the Board of Directors (replacement of minutes by a more formal report);

2. **Policy for Research Governance**

The Policy for Research Governance has been previously approved by the Associate Medical Director and Chief Executive. Under the Trust's new Corporate Governance Policy (Annex B: Policies Reserved to the Board) this policy now requires Board approval.

<u>Framework</u>

The new framework sets out all registration and authorisation requirements for research studies to ensure the Trust keeps sufficient oversight, and explains in broad terms (details included in supporting procedures) the way in which each study has to be conducted and closed;

Monitoring section

The new monitoring section provides for annual progress reports to be made to the Trust's R&D Governance Office who maintains a forward schedule of audits and monitoring visits to check compliance with Trust policies, national guidance and relevant legislation. The R&D Governance Office shall submit an annual report to the Board of Directors, providing an account of:

- all ongoing research activity (newly registered, authorised, published and completed studies)
- the progress and outcome of audits,
- all ongoing monitoring activity, and
- where required, matters of compliance with this policy, the protocol and relevant legislation.

Further changes:

- Various definitions have been added, including 'Chief Investigator', 'Study Audit', 'Principal Investigator'**,** 'Research Study', 'Sponsor' and 'Substantial Amendments';
- The Research & Development Committee has been added to the duties section and its Terms of Reference are now set out in one of the appendices;
- Minor wording amendments throughout.

3. Recommendations

The Board of Directors is asked to consider, and if thought fit, approve the amendments to the following policies:

- Risk Management Strategy and Policy

- Policy for Research Governance

David Burbridge
Director of Corporate Affairs

University Hospitals Birmingham NHS
NHS Foundation Trust

CONTROLLED DOCUMENT

Risk Management Strategy and Policy

CATEGORY:	Strategy/Policy
CLASSIFICATION:	Governance
PURPOSE:	To set out the principles and framework for the management of risk with University Hospitals Birmingham NHS Foundation Trust.
Controlled Document Number:	**120**
Version Number:	**4**
Controlled Document Sponsor:	Director of Corporate Affairs
Controlled Document Lead:	Head of Governance
Approved By:	BOD
On:	25 July 2013
Review Date:	**July 2016**
Distribution: • **Essential Reading for:** • **Information for:**	 All Directors, Senior Managers and Department Heads All Staff

Risk Management Strategy and Policy

Contents

1 Strategy Statement

1.1 The Trust Board is committed to:

1.1.1 adopting best practice in the identification, evaluation and cost effective control of risks to ensure that they are reduced to an acceptable level or eliminated,

1.1.2 maximising opportunities to achieve the Trust's objectives and deliver core service provisions.

1.2 It is acknowledged that some risks will always exist and will never be eliminated.

1.3 The Trust's overall strategic aim is to make the effective management of risk an integral part of everyday management practice. This is achieved by having a comprehensive and cohesive risk management system in place which is underpinned by clear responsibility and accountability arrangements throughout the organisational structure of the Trust. These arrangements are set out in more detail in the Trust's SFIs, SOs, Corporate Governance Policy and the Chief Executive's Scheme of Delegation and Accountability.

1.4 The Trust takes a holistic approach to risk management, incorporating both clinical and non-clinical risks. The risk management strategy is integrated into the achievement of the Trust's business objectives and will in turn support the Trust's strategic plan. The aims and objectives are developed with consideration of the assurance framework and risk register which reflect all types of risks, including but not limited to strategic, financial, organisational, operational, external compliance, environmental, reputational risks.

1.5 The Trust has the following key risk management objectives:

- **Minimise the potential for harm to patients, all staff and visitors** to a level as low as reasonably practicable;
- **Protect everything of value** (such as high standards of patient care, staff safety, reputation and assets or income streams);
- **Anticipate and respond to** changing circumstances (social, environmental, legal financial, etc) or events.
- Maximise opportunity by **adapting and remaining resilient** to changing risk factors
- Ensure that risk management is clearly and consistently **integrated** and managed holistically and **not in silos**.
- Consider compliance with **health and safety, insurance and legal requirements as a minimum standard**.
- **Inform policy and operational decisions** by identifying risks and their likely impact.

- **Raise awareness** of the need for risk management by all those connected with the Trust's delivery of service.

1.2 These objectives will be achieved by:

- Clearly defining the roles, responsibilities and reporting lines within the Trust for risk management.
- Including risk management issues when writing reports and considering decisions.
- Continuing to demonstrate the application of risk management principles in all activities of the Trust.
- Reinforcing the importance of effective risk management as part of the everyday work of all staff employed or engaged by the Trust.
- Maintaining a comprehensive register of risks (clinical and non clinical) and reviewing the same on a periodical basis.
- Ensuring controls are in place, effective to mitigate the risk and understood by those expected to apply them.
- Ensuring gaps in control are rectified and assurances are reviewed and acted on in a timely manner.
- Maintaining documented procedures of the control of risk and provision of suitable information, training and supervision.
- Maintaining an appropriate system for recording health and safety incidents and identifying preventative measures against recurrence.
- Preparing contingency plans to secure business continuity where there is a potential for an event to have a major impact upon the Council's ability to function.
- Monitoring all arrangements continually and seeking continuous improvement.

2 Policy Statement

2.1 Risk Management is essentially the process where an organisation adopts a proactive approach to the management of future uncertainty and facilitates the evaluation and control of risk.

2.2 The Trust recognises that the provision of healthcare and the activities associated with the treatment and care of patients, employment of staff, maintenance of premises and managing finances, by their nature, incur risks. The Trust accepts its corporate responsibility to provide the highest standards of patient care and staff safety, and as such, the process of Risk Management is viewed as an essential component in maintaining and improving standards at the Trust.

2.3 The objective of this policy is to ensure that the Trust has an effective system for identifying and managing risks with the aim of:

2.3.1 achieving its objectives;

2.3.2 protecting patients, staff and members of the public; and

2.3.3 protecting assets.

3 Scope

This policy applies to all areas and activities of the Trust and to all individuals employed by the Trust including contractors, volunteers, students, locum and agency staff and staff employed on honorary contracts.

4 Framework

4.1 This section describes the broad framework for the management of risk. Operational instructions for risk management, investigation of incidents, and learning from incidents are detailed in separate procedural documents which are approved by the Director of Corporate Affairs.

4.2 Definitions

4.2.1 Hazard - A hazard is something (e.g. an object, a property of a substance, a phenomenon or an activity) that can cause adverse effects

4.2.2 Risk is the likelihood of a hazard resulting in an incident set against the severity of that incident if it does occur. In terms of the healthcare environment risk means the possibility of injury, harm or loss to patients, staff, visitors or the structural/financial integrity of the organisation.

4.2.3 Control is the mitigating action put in place to reduce the risk.

4.3 Risk Management Structure

4.3.1 Appendix B provides the Risk Management Reporting Framework; this framework identifies organisation's risk management structure, detailing all those committees and groups which have some responsibility for risk. This also provides assurance to the Board that Risk Management processes are in place and effective.

4.3.2 The Executive Director Risk Registers and the Board Assurance Framework Risk Register combined, form the organisation wide risk register. The Board Assurance Framework is reviewed at the Board of Directors Meeting on a quarterly basis.

4.3.3 The Board of Directors shall conduct an annual review of the effectiveness of the Trust's system of internal controls, which shall be reflected in the Annual Governance Statement (AGS) that is published in the Annual Report. The Board will receive the Audit Committee minutes and an Audit Committee annual report which provides assurance to the Board on the risk management process in the Trust.

4.3.4 The Board has delegated authority to the Audit Committee to oversee risk management on its behalf. The Audit Committee will receive quarterly Risk Management Reports which include trends data in relation to incidents including Serious Incidents Requiring Investigation; as well as results of the quarterly Risk Register compliance audit.

4.3.5 The Terms of Reference for the Audit Committee identify the role of the Audit Committee and its responsibility for risk management within the organisation.

4.4 Managing Risks within the Trust

4.4.1 The risks in a health care environment are significant and ever changing. Risk must be managed through the systematic analysis of actual and potential risks and the development and implementation of measures to counteract those risks.

4.4.2 There are corporate risks inherent in the financial and contractual stability of the Trust; the Trust must seek to manage risks that threaten its ability to achieve its business objectives.

4.5 Risk Management is made up of three stages:

4.5.1 Risk identification

4.5.2 Risk analysis

4.5.3 Risk control

4.6 Risk identification

4.6.1 Risks can be identified from a number of the following sources (this list is not exhaustive):

a) Incidents;

b) Complaints;

c) Claims; and

d) General observations

4.6.2 The Procedure for the Assessment of Risks and Management of Risk Registers details the process of reviewing the organisational wide risk register through to the local management of risks by Division/Specialty/Ward/Department.

4.6.3 Once a risk has been identified the risk must be assessed and reviewed in accordance with the Procedure for the Assessment of Risks and Management of Risk Registers.

4.6.4 All identified risks must be recorded on the appropriate risk register in accordance with the Procedure for the Assessment of Risks and Management of Risk Registers.

4.6.5 All risks will be escalated from the relevant risk register in accordance with the Procedure for the Assessment of Risks and Management of Risk Registers.

4.7 Risk analysis

4.7.1 For each risk identified, a reasonable estimate must be made of its likely occurrence and its likely consequences[1] with no controls in place. This analysis will identify the "Initial Risk".

4.7.2 Any risk identified must be assessed to identify the likely consequences for patients, staff, visitors or the Trust.

4.7.3 Analysis of consequence and likelihood provides the risk significance enabling a list of prioritised risks to be developed. The Procedure for the Assessment of Risks and Management of Risk Registers provide further detail.

4.8 Risk Control

4.8.1 The Board of Directors shall determine the level of risk tolerance that is deemed to be acceptable to the Trust and review this as required.

[1] The method of analysing risk is based on an adaptation of the Australian/New Zealand Risk Management Standard AS/NZ 4360:1999.

4.8.2 The level of acceptable risk is set out in the Procedure for the Assessment of Risks and Management of Risk Registers.

4.8.3 Any risk deemed to be above the acceptable level will be considered for escalation. Significant and high risks will be escalated from Ward/Department to Specialty to Division to Executive Directors and finally to the Board. Appendix C details the overarching process for escalating risks.

4.8.4 All risks above this level must have controls set up that will eliminate the risk or reduce the risk. Divisional Management Teams must also ensure that any risks quantified as high should have controls and action plans in place.

4.9 Incident Reporting

4.9.1 For Risk Management to be effective, staff must report all adverse incidents and near misses that they have been involved in or witnessed. If all incidents including near misses are reported, areas of potential risk can be identified and any trends analysed.

4.9.2 The Policy for the Reporting and Management of Incidents including Serious Incidents Requiring Investigation, the Procedure for the Assessment of Risks and Management of Risk Registers and, the Procedure for the Reporting and Management of Incidents including Serious Incidents Requiring Investigation provide further details.

4.10 Training

4.10.1 All Board members, including Non-Executive Directors and Senior Managers (which, for the purpose of this policy means those directors reporting directly to the Chief Executive and their deputies, Divisional Directors, Directors of Operations and Associate Directors of Nursing) will be provided with risk awareness training within 6 months of the commencement of their role. An individual who has undergone this training before is not required to repeat it on a move to a new role.

4.10.2 The process for ensuring compliance with this training requirement, including recording of attendance and following up of non-attendance is set out in the Board/Senior Manager Risk Awareness Training Procedure.

4.10.3 Risk awareness training for all other staff shall be provided as set out in the Trust's Training Catalogue (Training Needs Analysis).

4.10.4 Where there are changes to risk management standards further refresher training will be provided as appropriate.

5 Duties

5.1 Chief Executive

The Chief Executive is the Accountable Officer with overall responsibility for Risk Management, including Health and Safety. As such, the Chief Executive must take assurance from the systems and processes for Risk management and ensure these meet statutory requirements and the requirements of the regulators.

5.2 Director of Corporate Affairs

The Director of Corporate Affairs is responsible for ensuring that the Trust's obligations for Risk Management and Health and Safety Policy are discharged accordingly and that Risk Management principles are embedded throughout the Trust. This includes compliance with the NHS Litigation Authority Risk Management Standards and UK law and compliance with Health and Safety Executive (HSE) guidance and UK legislation.

5.3 Chief Financial Officer

The Director of Finance is responsible for ensuring the effective operational management and strategic development of all financial risks. This includes the Standing Financial Instructions.

5.3 Chief Operating Officer

The Chief Operating Officer is responsible for ensuring that effective operational arrangements are in place throughout the Trust and across both sites. This includes the management of operational risks.

5.4 Executive Director of Delivery

The Director of Delivery has responsibility for ensuring the effective operational management of all Human Resources and Occupational Health and Safety.

5.5 **Medical Director**

The Medical Director has responsibility for ensuring the effective operational management of all relevant professional risks.

5.6 **Executive Chief Nurse**

The Chief Nurse has responsibility for ensuring the effective operational management of all relevant professional risks. The Chief Nurse also has responsibility for the management of infection control, patient involvement, and Patient Relations.

5.7 **New Hospital Project Director**

The New Hospital Project Director has responsibility for the risks associated with the real estate, new hospital and retained estate.

All the above directors are responsible for ensuring that the members of the Board of Directors are informed of the appropriate risks.

5.8 **All Managers**

5.8.1 All managers must:

a) Ensure all necessary risk assessments are carried out within the Division/Group/Department and appropriate control measures are implemented and monitored.

b) Ensure all employees are aware of the risks within their work environment and of their personal responsibilities. They must also be given the necessary information, instruction, supervision and training to enable them to work safely. These responsibilities extend to anyone affected by the Trust's operations including sub-contractors, members of the public, visitors etc.

c) Ensure that inspection, testing and maintenance of equipment used within their areas of managerial control is carried out in accordance with legislative requirement and are responsible for ensuring all risks identified are minimised as far as is reasonably practicable.

d) Ensuring risks identified are populated within the relevant risk register according to the management level. See the Procedure for the Development and Management of Risk Registers.

5.9 **Head of Risk and Compliance**

The Head of Risk and Compliance responsibility for implementation of all aspects of governance, clinical effectiveness and risk management.

5.10 **Risk and Compliance Unit**

5.10.1 The Risk and Compliance Unit is responsible for achieving high standards of risk management for the Trust, including the implementation of the Trust's Risk Management Policy. They are responsible for the continuing development of a proactive risk management culture and practice throughout the Trust; actively promoting and ensuring good risk management practices, an open, just and fair culture.

5.10.2 The Risk and Compliance Unit has responsibility for supporting the implementation of risk management activities throughout the Trust providing a support role to Divisional management. They also provide support for other committees within the Trust as required.

5.10.3 The Risk and Compliance Unit undertakes an audit of compliance with the Risk Register process on a quarterly basis.

5.11 **All Employees**

5.11.1 All employees must:

a) comply with all Trust rules, regulations and instructions;

b) work in a manner which is safe and secure for themselves, colleagues, patients and visitors.

c) take reasonable care for their own safety and the safety of others who may be affected by their acts or omissions;

d) undertake safe clinical practice in diagnosis and treatment;

e) comply with Divisional/Group/Departmental clinical procedures; and

f) neither intentionally or recklessly interfere with or misuse any equipment provided for the protection of health and safety.

5.11.2 Any employee who fails to comply with the Trust or local policies or guidelines on risk, or recklessly interferes with or misuses any equipment, provided for the protection of health and safety, will be subject to disciplinary action.

6 Implementation and Monitoring

6.1 The Policy and the associated procedural documents will be available on the Trust intranet. The policy will also be disseminated through the management structure within the Trust.

6.2 The Risk and Compliance Unit will provide consistent advice and guidance to managers and staff on the application of this policy and its procedures.

6.3 See Appendix A for details of monitoring.

7 References

7.1 Australian/New Zealand Risk Management Standard AS/NZ 4360:1999

7.2 NHSLA Risk Management Standards

7.3 Care Quality Commission Essential Standards of Quality and Safety

8 Associated Policy and Documentation

8.1 Policy for the Reporting and Management of incidents including Serious Incidents Requiring Investigation

8.2 Procedure for the Assessment of Risks and Management of Risk Registers

8.3 Procedure for the Reporting and Management of Incidents Including Serious Incidents Requiring Investigation

8.4 Board/Senior Manager Risk Awareness Training Procedure

8.5 Policy for the Management of External Agency Visits, Inspections and Accreditation

8.6 Training Catalogue (Training Needs Analysis)

8.7 Trust's SFIs and SOs

8.8 Corporate Governance Policy

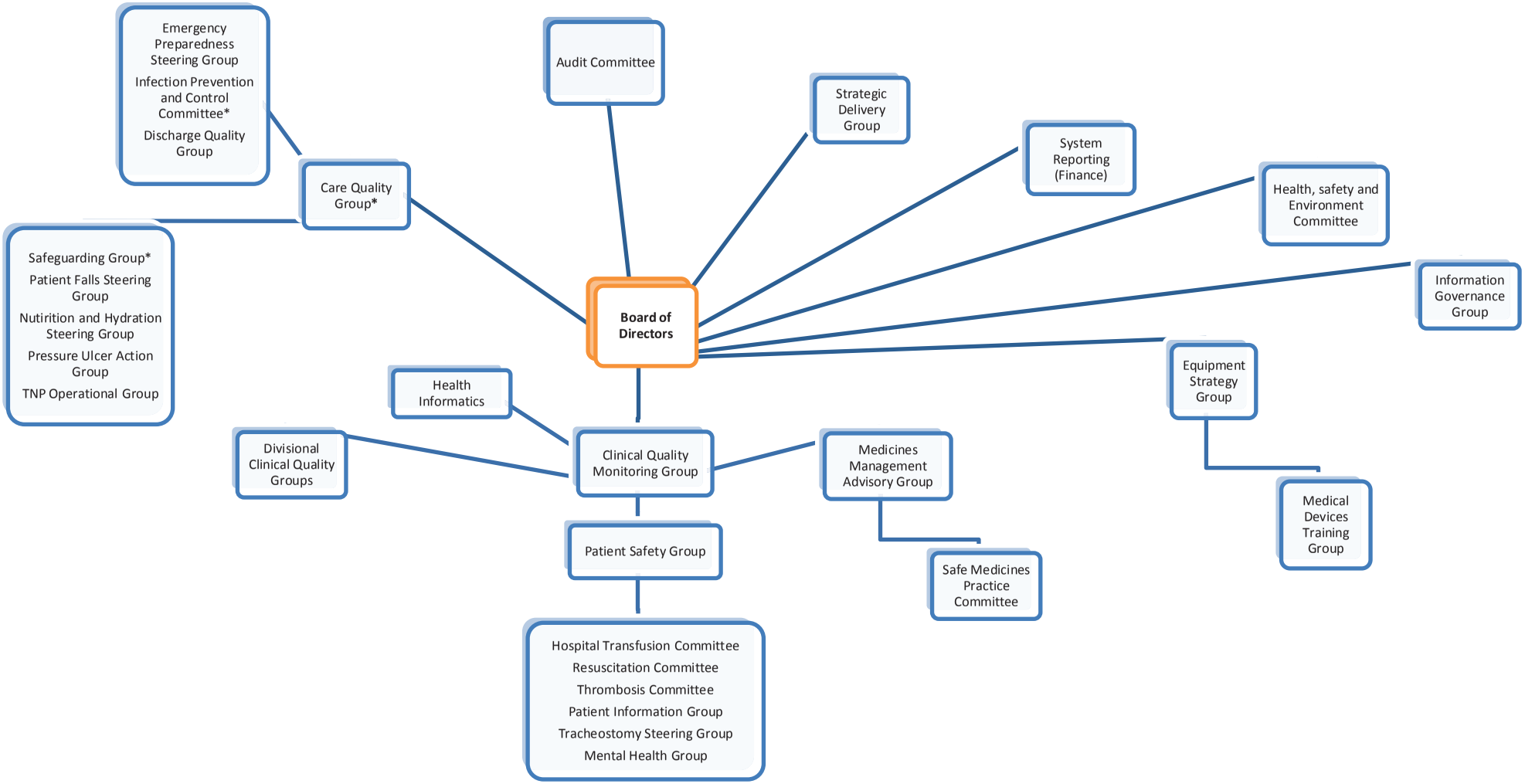
8.9 Chief Executive's Scheme of Delegation and Accountability

Appendix A - Monitoring

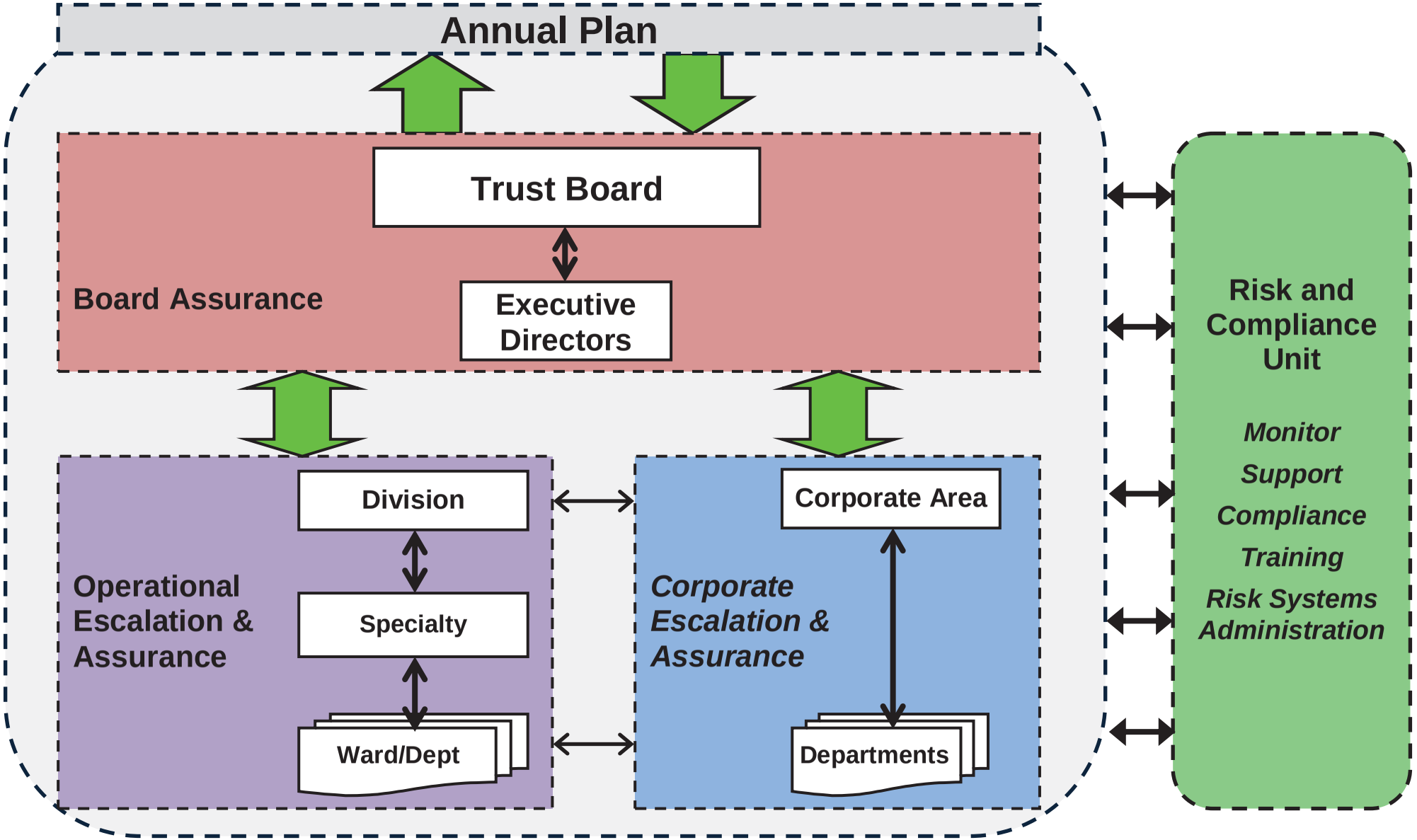
MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
Senior Managers and BoD members receive the relevant training as per the Board/Senior Manager Risk Awareness training	Risk and Compliance Unit	DCA Governance Group	Any exceptions to the training provided to Senior Managers will be reported as required.	Quarterly
Internal Auditors carry out an audit programme to provide assurance regarding elements of the risk management process	Director of Corporate Affairs	Audit Committee	Internal audit report is presented to the Audit Committee	Annual
Compliance with the Risk Register and Risk Register Process is monitored.	Risk and Compliance Unit	Audit Committee	Report of Specialty and Divisional compliance is presented to the Audit Committee.	Quarterly
Local risk registers* are monitored by the Divisional Management Teams via by the Risk Management Team	Risk and Compliance Unit	Divisional Clinical Quality Groups	A local risk register tracker is in place, held by the Risk Management Team, that details all areas of each division that require a risk register. Quarterly reports are presented to the Divisional Clinical Quality Groups detailing compliance with the process.	Quarterly
The Board of Directors via the Audit Committee monitor the organisation-wide risk register	Head of Risk and Compliance	Audit Committee	The organisation-wide (Board Assurance Framework) risk register is reviewed on a quarterly basis by each Executive Director and reported to the Audit Committee for assurance. The Audit Committee then report exceptions to the Board of Directors.	Quarterly
Compliance with the Risk Management Process	Risk and Compliance Unit	Audit Committee	An audit of a sample of local areas to ensure risks are assessed, managed and escalated in line with the Procedure for the Risk Assessment and Management of Risk Registers.	Annual

* ***Local Risk registers -*** *A subdivision of the organisation, for example, division, directorate, specialty, or business unit.*

Appendix B – Committees with Responsibility for Risk Management



Appendix C - Risk Escalation



CONTROLLED DOCUMENT

University Hospitals Birmingham NHS
NHS Foundation Trust

Policy for Research Governance

CATEGORY:	Policy
CLASSIFICATION:	Research Governance
PURPOSE	To set out the over-arching governance policy for all research in the Trust
Controlled Document Number:	**48**
Version Number:	**2**
Controlled Document Sponsor:	Executive Director of Delivery
Controlled Document Lead:	Head of Research and Development Governance
Approved By:	Board of Directors
On:	25 July 2013
Review Date:	**July 2016**
Distribution: • **Essential Reading for:** • **Information for:**	 Clinical Researchers, Divisional Directors, Clinical Service Leads, Divisional Directors of Operations, Senior Trust Managers, Service Managers All staff

Contents

1 Policy Statement

1.1 The objective of this policy is to ensure that all research undertaken in the Trust complies with the Department of Health's Research Governance Framework, 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 1) that 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 Definitions

3.1 **Chief Investigator (CI):** 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.

3.2 **Monitoring**: Is a quality control (QC) 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.

3.3 **Principal Investigator (PI):** 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.

3.4 **Research Study:** A research study is a formal piece of work that uses research methods (see Appendix 1) 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.

3.5 **Sponsor:** The Sponsor of a clinical research study is defined in the Research Governance Framework as the organisation who takes responsibility for securing arrangements to initiate, manage and finance the study.

3.6 **Study Audit**: A study audit is a quality assurance (QA) 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.

3.7 **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.

4 Framework

4.1 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 SOPs (see section 8).

4.2 The Research and Development Committee (R&D Committee) 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 R&D Committee.

4.3 The Trust will ensure that all research complies with all relevant legislation and the quality standards set out in the Department of Health's Research Governance Framework[1]. The Trust's framework for ensuring this consists of the following stages**:**

4.3.1 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 Chief Investigator. The Chief Investigator must formally request the Trust to act as sponsor and must submit a protocol to the R&D Governance Office. The Chief Investigator will be asked to complete a Sponsorship Request Form and Chief Investigator Agreement before the Trust can confirm sponsorship.

[1] Research Governance Framework, version 2. Department of Health (2004). Copies available from the Trust's R&D Office.

d) The study must have an identified Principal Investigator (PI) and Chief Investigator (CI) appointed in accordance with the Policy on Chief Investigators and Principal Investigators in Research.

4.3.2 R&D Trust Authorisation

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

4.3.3 Conduct of Studies

a) All studies 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&D Governance Office and any Substantial Amendments must be approved by the R&D Governance Office before the Study can continue.

c) The PI must report all protocol breaches in accordance with the R&D Trust Approval given for the study.

d) The PI must create and maintain a study file which, as a minimum, should follow the guidance issued with the R&D Trust Approval letter.

e) Recruitment to studies should be undertaken as soon as is practicable and in order, where appropriate, to meet NIHR/DH recruitment timescales.

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

4.3.4 Study Audits and Monitoring

a) The R&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 Clinical Study Audits and Inspections procedures (RDS005).

c) Progress and outcomes of audits shall be reported to the R&D Committee.

4.3.5 **Study Closure**

a) The PI must notify the R&D Governance Office when the study has finished within [30] days following the end of the study.

b) The PI must submit a Trust end of study report within [60] days following the end of the study in accordance with the R&D Reports procedure (RDS004)

c) The PI must ensure appropriate arrangements are made for all study documentation to be archived in accordance with the Document Archiving Procedure.

5 Duties

5.1 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 in accordance with this Policy.

5.2 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 should 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.

5.3 R&D Committee

5.3.1 The R&D Committee maintains oversight of the operations and governance of research in the Trust.

5.3.2 It is responsible for promoting and supporting high quality clinical research.

5.3.3 It is also responsible for reviewing the arrangements for the governance of research.

5.3.4 The terms of reference of the R&D Committee are set out in Appendix 2. Amendments to these Terms of Reference may be approved by the Executive Director of Delivery.

5.4 Head of Research & Development Governance

The Head of R&D Governance will:

5.4.1 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;

5.4.2 Ensure that all Trust guidance and procedural documents on research governance are updated and maintained in accordance with the principles;

5.4.3 Ensure that the R&D Governance Office maintains a forward schedule of audits and monitoring visits to check compliance with Trust policies, national guidance and relevant legislation.

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

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

5.4.6 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.

5.5 Researchers

Researchers are required to:

5.5.1 Ensure that all potential research studies are registered with the Research & Development Office (R&D) and that they do not proceed with the studies without authorisation from the R&D Governance Office.

5.5.2 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.

5.5.3 Cooperate with the R&D Governance Office in monitoring and auditing research studies.

5.5.4 Provide annual progress reports to theTrust's R&D Governance Office in accordance with [ ]

5.5.5 Comply with the reporting requirements of the National Research Ethics Service and regulatory authorities.

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

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

6 Implementation and Monitoring

6.1 The Trust's research governance policies are available on the Trust intranet and will be disseminated to all researchers via the R&D Governance Office.

6.2 Researchers are required to provide annual progress reports to the Trust's R&D Governance Office.

6.3 The R&D Governance Office maintains a forward schedule of audits and monitoring visits to check compliance with Trust policies, national guidance and relevant legislation.

6.4 The R&D Governance Office shall submit an annual report to the Board of Directors, providing an account of :

6.4.1 all ongoing research activity (newly registered, authorised, published and completed studies)

6.4.2 the progress and outcome of audits,

6.4.3 all ongoing monitoring activity, and

6.4.4 where required, matters of compliance with this policy, the protocol and relevant legislation.

7 References

Department of Health — Research Governance Framework, version 2 (2004)

8 Associated Policy and Procedural Documentation

Policy on the Collection and Use of Human Tissue for Research

Policy on Chief and Principal Investigators

Research Passport System Policy

Policy on Scientific Misconduct

Policy on Reporting Research Incidents and Breaches

Document Archiving Procedure

R&D Governance Office Procedures

R&D Approvals Process (RDS012)

R&D Reports procedure (RDS004)

Clinical Study Audits and Inspections procedure (RDS005)

Appendix 1

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 Clinical Innovations Committee

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 2

University Hospital Birmingham NHS Foundation Trust

Research and Development Committee (R&D Committee)

Terms of Reference

Reference to "the Committee" shall mean the Research and Development Committee.
Reference to "the Trust" shall mean the University Hospital Birmingham Foundation NHS Trust.

1. Purpose

The purpose of this Committee is to drive the Trust's research agenda forward and embed it into daily Trust working. The Committee will support bringing together "research champions" and research resources, and ensure that a robust communications strategy is in place to publicise Trust research activity.

2. Scope

The scope of the Committee is to:

- Review divisional research performance against agreed key performance indicators
- Ensure that a robust research governance framework is in place to support research undertaken by divisions
- Receive financial reports on divisional research finances
- Recommend approaches to use of research resources
- Oversee the communications strategy for research and development

3. Membership

The membership comprises the following:

Chair: Executive Director of Delivery

Members:

- Trust Research and Development Co-Director
- Trust Research and Development Co-Director
- Trust Deputy Director of Finance
- Head of Clinical Redesign
- Head of Research and Development (Operations)
- Head of Research and Development Governance
- Nursing Research Fellow
- A nominated Research Nurse
- A nominated Research Pharmacist(s)
- 5 nominated Divisional Research Management Group Leads
- A representative for Education

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

5. Quorum

The Committee will be deemed quorate with the attendance of the Chair (or nominated deputy), a Trust Research and Development Director, Trust Deputy Director of Finance, Head of Research and Development Operations and Head of Research and Development Governance.

6. Frequency of Meetings

Meetings shall be held not less than four times a year. The Executive Director of Delivery may call additional meetings where considered necessary.

7. Agenda and reporting

a. Agendas and briefing papers should be prepared and circulated in sufficient time for Committee Members to give them due consideration. All agenda items should be approved by the Chair prior to the meeting. Additional papers shall only be tabled at the meeting with authorisation by the Chair.

b. Action points agreed at meetings, together with the minutes, will be circulated by the individual nominated by the Chair within 7 working days of the meeting, to the Chair and all members of the Committee.

c. An annual report from the Committee to the Board of Directors should be produced to demonstrate the Committee's effective discharge of its duties. The report should include comment on the Committee's work in relation to study registrations and authorisation, progress and outcome of research audits and any monitoring activity, and shall provide a

generic overview of the efficacy of the Research Governance Assurance Framework.

8. Review

The Terms of Reference and membership of this Committee shall be reviewed on a yearly basis.