Research Governance Policy and Procedure

Version: 5
Name of originator/author: Dr Lisa Austin - University of Bath
Name of executive lead: Dr Ian Orpen, Clinical Chair
Date ratified: Tbc
Review date: Three years from ratification

APPLICABLE TO:
All staff.

EXECUTIVE SUMMARY
The purpose of this policy is to ensure that NHS Bath & North East Somerset Clinical Commissioning Group (Hereinafter called “the CCG”) complies with the standards and principles set out in the Government’s Research Governance Framework, thus ensuring the quality, safety, and good conduct of all research activity led or hosted by the CCG.

The policy and procedure describes the corporate and individual responsibilities and necessary procedures to support research governance within the CCG.

IMPLEMENTATION
Implementation by managers. Key points for implementation are to ensure that:

- all proposed research involving either the CCG staff or patients/service users complies with the research governance framework outlined in the policy;
- research studies are registered with the CCG and do not proceed without explicit written approval of the Clinical Chair

This document can only be considered valid when viewed via the CCG’s intranet site. If this document is printed into hard copy or saved to another location you must check that the version number on your copy matches that of the one on-line. The document applies equally to full and part time employees, bank and agency employees.
CONSULTATION PROCESS

Key individuals involved in developing this document (main authors)

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Ian Orpen</td>
<td>Clinical Chair</td>
</tr>
</tbody>
</table>

Circulated to the following individuals for consultation

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dawn Clarke</td>
<td>Director of Nursing and Quality</td>
</tr>
<tr>
<td>Dr Lisa Austin</td>
<td>R&amp;D Manager, BRD</td>
</tr>
<tr>
<td>CCG</td>
<td>Quality Committee Members</td>
</tr>
</tbody>
</table>

Circulated to the following groups for ratification

<table>
<thead>
<tr>
<th>Name of Group</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Committee</td>
<td>8th June 2017</td>
</tr>
</tbody>
</table>

VERSION CONTROL

<table>
<thead>
<tr>
<th>Version No</th>
<th>Updated By</th>
<th>Updated On</th>
<th>Description of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>BANES</td>
<td>May 2017</td>
<td>Update to policy approved by Board in 2014</td>
</tr>
</tbody>
</table>
## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultation process</td>
<td>2</td>
</tr>
<tr>
<td>Contents</td>
<td>3</td>
</tr>
<tr>
<td>A</td>
<td></td>
</tr>
<tr>
<td>1. Introduction</td>
<td>4</td>
</tr>
<tr>
<td>2. Definitions</td>
<td>4</td>
</tr>
<tr>
<td>3. Aims and Objectives</td>
<td>4</td>
</tr>
<tr>
<td>4. Responsibilities</td>
<td>5</td>
</tr>
<tr>
<td>5. Approvals</td>
<td>5</td>
</tr>
<tr>
<td>6. Resources</td>
<td>5</td>
</tr>
<tr>
<td>7. Indemnity</td>
<td>6</td>
</tr>
<tr>
<td>8. Dissemination</td>
<td>6</td>
</tr>
<tr>
<td>B</td>
<td></td>
</tr>
<tr>
<td>9. Procedure</td>
<td>7</td>
</tr>
<tr>
<td>i. For Non Commercial (Academic) Research</td>
<td>7</td>
</tr>
<tr>
<td>ii. For Commercial Research</td>
<td>9</td>
</tr>
<tr>
<td>Appendices</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>3</td>
<td>12</td>
</tr>
</tbody>
</table>

### A

1. **Introduction**
   - Page 4
2. **Definitions**
   - Page 4
3. **Aims and Objectives**
   - Page 4
4. **Responsibilities**
   - Page 5
5. **Approvals**
   - Page 5
6. **Resources**
   - Page 5
7. **Indemnity**
   - Page 6
8. **Dissemination**
   - Page 6

### B

9. **Procedure**
   - Page 7
   - i. For Non Commercial (Academic) Research
     - Page 7
   - ii. For Commercial Research
     - Page 9

### Appendices

1. **Research Governance Framework**
   - Page 10
2. **Research Registration Flowchart for Commercial Research**
   - Page 11
3. **Research Registration Flowchart for Non Commercial/Academic Research**
   - Page 12
Section A: Policy

1 INTRODUCTION

NHS Bath & North East Somerset Clinical Commissioning Group promotes, supports and encourages the conduct of high quality research and the use of research evidence to inform practice. It also encourages relevant training to create a workforce able to contribute to research in health and social care and to make use of research evidence appropriately.

In April 2005 the Department of Health published the Second Edition of the Research Governance Framework for Health & Social Care which sets out standards of best practice in research. Research Governance aims to provide a quality assurance framework for all health-related organisations, individuals and stakeholders involved in research.

The purpose of this policy is to ensure that the CCG complies with the standards and principles as set out in the Government’s Research Governance Framework 2nd Edition, thus ensuring the quality, safety, and good conduct of all research activity led or hosted by the CCG; and that the dignity, rights, safety and well-being of research participants are protected.

2 DEFINITIONS

Research may be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. This excludes activities such as clinical audit and patient satisfaction surveys which are concerned with evaluating local service planning and delivery against evidence based standards. If in doubt as to whether a planned activity constitutes research and therefore falls within the terms of the policy advice should be sought from Bath Research and Development (BRD).

Research governance is a system whereby research is critically assessed against relevant standards, principles and guidelines to ensure that it is conducted to high scientific and ethical standards. A core standard for health care organisations is that they have such systems in place to ensure the principles and requirements of the Department of Health’s Research Governance Framework for Health and Social Care (RGF) 2nd Ed., are consistently applied. The framework consolidates legislation, standards and good practice guidelines for conducting high quality research and presents them under five domains: Ethics; Science; Information; Health, Safety and employment; Finance and intellectual property.

3 AIMS AND OBJECTIVES

The aim of this policy is to set out the standards that relate to the conduct of research to ensure that all research conducted within the CCG meets research governance requirements. Its objectives are:

- To set out the CCG corporate responsibilities for ensuring that research governance standards are met
- To set out the responsibilities of researchers to ensure that their research meets research governance standards
- To describe the procedures that researchers are required to follow to obtain research governance and legal compliance approval from the Health Research Authority (HRA), favourable opinion from a Research Ethic Committee (REC) and assurance from their local R&D office (Bath Research and Development).
RESPONSIBILITIES

Research and Development in the CCG is overseen by the Clinical Chair.

The strategic direction for R&D as set out in Best Research for Best Health (Department of Health, 2006) and implemented by Bath Research and Development (BRD). BRD is a partnership that was formed in April 2005 between the Department for Health, University of Bath and BaNES, Swindon and Wiltshire Clinical Commissioning Groups. BRD currently receives funding from the Department of Health to support high quality research. This money is spent on supporting NIHR research and sustaining a research workforce. It offers a research management and governance support service to local researchers.

This policy is potentially of relevance to all members of staff. Even staff who are not directly involved in the conduct of research may have responsibilities if they are providing clinical care to patients enrolled into research studies. The policy applies to all research, whether it is initiated by an employee of the CCG as the principal investigator (i.e. the CCG is the investigator site) or the employee is participating in research led from elsewhere.

It is the responsibility of researchers to be familiar with research standards and guidance and to comply with all legal requirements and those of the Department of Health.

APPROVALS

All proposed research involving patients, patient data, staff or facilities of the CCG or its provider organisations must comply with the research governance framework. Research studies must be registered with the CCG and can only proceed once HRA Approval and assurance from BRD (the local R&D office) has been issued, confirming that the research application complies with the relevant legislation and meets an acceptable standard. In addition, where a research ethics committee (REC) favourable opinion is required, written approval must be received before the study can commence. Guidance on obtaining HRA approval and REC favourable opining is available at www.hra.nhs.uk. RECs give an opinion about proposed participant involvement and whether the research is ethical. HRA Approval considers the wider issues of scientific quality, financial arrangements, data protection, medicines management issues and legal compliance. The research governance review procedure is detailed in Section B.

If CCG staff are approached by researchers requesting information regarding patients they have a responsibility to check with the Information Governance Manager or the Research Governance Lead to confirm whether the research study has been ethically approved and that the flow of information requested is in line with the research protocol.

RESOURCES

Research should not be undertaken without identification of the resource requirements and the sources to be used for provision of those resources. The funding arrangements for the study must be explicit and agreed by all relevant parties and seen to offer the taxpayer value for money. There are four basic types of cost:

- Research costs specifically associated with the running of the study (including staff appointed expressly for the purpose of the study).
- Service support costs – additional patient care costs which will end when the study's complete (e.g. extra blood tests).
- Excess treatment costs – the extra cost of a new intervention or service under investigation compared with current practice.
- Indirect costs – infrastructure and general overheads

Staff engaged in research other than within the terms of their contract of employment should ensure that such involvement is not to the detriment of their clinical or other contractual workload. The written approval of their line manager needs to be secured for their participation in research activity and a copy of this approval provided as part of the HRA Approval application. Where the research may affect routine clinical sessions appropriate cover needs to be secured and funding provided for this. If there are any resource implications for any department arising from a study these should be made known to the department(s) and financial agreements made where necessary and confirmed in writing as part of the application for HRA Approval.

For commercial projects all costs must be met by the sponsor company. A levy is raised by the CCG for hosting commercial research to cover infrastructure and overhead costs.

7 INDEMNITY

All research should have appropriate arrangements for the provision of compensation in the event of harm arising from participation.

All commercially sponsored studies must provide the standard indemnity conforming to the most recent guidelines of the Association of the British Pharmaceutical Industry. A signed copy of the indemnity agreement should be submitted with HRA Approval and REC review application.

For NHS-sponsored research Health Service Guidance HSG (96)48 applies. Both sponsors and investigators must have insurance or indemnity cover to meet their potential liabilities arising from research. Under the Research Governance Framework, the research sponsor is responsible for ensuring that appropriate insurance and indemnity are in place for the research. This includes ensuring that research participants who are NHS patients are covered by NHS indemnity in respect of negligent harm.

Individual investigators may have NHS indemnity arrangements extended to them through NHS contracts of employment. Where a researcher is not a NHS employee and their research has a bearing on the participants’ care, an honorary research contract may need to be issued by BRD. Independent contractors, including GPs and pharmacists, and the staff they employ, are not covered by NHS indemnity so must have their own professional indemnity arrangements.

8 DISSEMINATION

Appropriate details of ongoing research should be made available to relevant research registers. Randomised trials should be registered on an appropriate trials register.

The results of a study should be made widely available in an accessible form to all those with the potential to derive benefit, including patients, carers and healthcare professionals. This normally includes publication in peer-reviewed journals and presentations at national and international meetings. There should be particular attention paid to making the research results known to research participants, and innovative approaches to reaching this audience should be pursued, e.g. publications in patient groups’ newsletters, presentations to patient groups etc.
Section B: Procedure

PROCEDURE

The following procedures have been developed in conjunction with BRD to facilitate efficient review and approval of research studies with regards to research governance. Flow charts illustrating these procedures are shown in Appendices 2 and 3.

i. For Non-Commercial (Academic) Research

Firstly, the manager/director of the proposed site where the research will be conducted must agree to the proposal going forward.

The Principal Investigator (PI) and/or research team apply for HRA Approval and, for studies that require review by an NHS Research Ethics Committee (REC), a coordinated REC review.

The application is made via the Integrated Research Application System (IRAS: https://www.myresearchproject.org.uk/) and should be made in accordance with the HRA’s guidance: http://www.hra.nhs.uk/research-community/applying-for-approvals/hra-approval/ N.B. For NIHR Portfolio eligible studies the Portfolio Application Form (PAF) is generated via IRAS.

The application package for HRA Approval and REC review comprises a single, combined IRAS form and study document set that are submitted electronically. So, instead of having to submit both REC and R&D IRAS forms and upload study document sets for both, there is now just one submission.

Application packages to the HRA for non-commercial studies will also require Statement of Activities (SoA) and Schedule of Events (SoE) forms. One SoA is submitted for each site type. So, if a study includes patient identification sites (PICs) and research sites, a SoA would be completed for each type.

The SoA provides key information to allow HRA assessment to take place and it also provides information for participating organisations to help them arrange their capacity and capability to undertake the study (where necessary). The SoA can also act as the agreement between the Sponsor and participating organisations in place of any other form of site agreement/contract.

The SoE details local activities and their cost attribution. HRA Approval will not be conditional on correct attribution or full research cost coverage but information will be passed to sites.

To submit the application (IRAS Form and supporting study document set), the instructions provided on the E-submission tab for the IRAS Form should be followed. The application is booked and submitted for REC submissions using the Central Booking System (CBS). If REC review isn’t required, the CBS is still contacted before submitting the application.

After the application for HRA Approval has been submitted an initial assessment letter will be issued, which should be sent, along with study document set (including the IRAS form), to BRD and the NHS participating organisations in England.

On completion of a satisfactory assessment, the HRA will issue an approval letter to the Principal Investigator which confirms that the study meets recommended research governance standards and legal compliance, and for those studies that require REC review, the REC will issue a favorable opinion letter. The PI should send these to BRD and the NHS participating organisations in England.
Upon receipt BRD will review the study document set, ensuring that each research site covered by the CCG has been recorded correctly on the IRAS form, if they haven’t BRD liaise with the PI to advise on the actions that need to be taken to amend this so the study can start. BRD will also check the HRA Approval letter and issue Letters of Access or Honorary Research Contracts if necessary.

Once BRD have reviewed the study document set and are satisfied that all requirements are met, they will provide assurance to the PI that the research site covered by the CCG should have no issues conducting the study (based on their previous experience) and abiding by the terms and conditions of the SoA.

The HRA Approval, REC favorable opinion and BRD assurance are sent to the CCG Research Governance Lead along with a brief outline of the aims of the study and its implications for the participants and proposed site. The study details are entered in the CCG research register.
ii. For Commercial Research

The Sponsor Study Coordinator applies for HRA Approval and, for studies that require review by an NHS Research Ethics Committee (REC), REC review.

The application is made via the Integrated Research Application System (IRAS: https://www.myresearchproject.org.uk/) and should be made in accordance with the HRA’s guidance: http://www.hra.nhs.uk/research-community/applying-for-approvals/hra-approval/ N.B. For NIHR Portfolio eligible studies the Portfolio Application Form (PAF) is generated via the IRAS application form.

The application package for HRA approval and REC review comprises a single, combined IRAS form and study document set that are submitted electronically. So, instead of having to submit both REC and R&D IRAS forms and upload study document sets for both, there is now just one submission.

Application packages to the HRA for commercial studies will also require a completed NIHR Industry Costing Template and the template agreement(s) that the Sponsor intends to use with host NHS organisations.

To submit the application (IRAS Form and supporting study document set), the instructions provided on the E-submission tab for the IRAS Form should be followed. The application is booked and submitted for REC submissions using the Central Booking System (CBS). If REC review isn’t required, the CBS is still contacted before submitting the application.

After the application for HRA Approval has been submitted an initial assessment letter will be issued, which should be sent, along with study document set (including the IRAS form), to BRD and the NHS participating organisations in England.

On completion of a satisfactory assessment, the HRA will issue an approval letter to the Sponsor Study Coordinator which confirms that the study meets recommended research governance standards and legal compliance, and for those studies that require REC review, the REC will issue a favorable opinion letter. The Sponsor Study Coordinator should these to BRD and the NHS participating organisations.

Upon receipt BRD will review the study document set, ensuring that each research site covered by the CCG has been recorded correctly on the IRAS form, if they haven’t BRD will liaise with the Sponsor Study Coordinator to advise on the actions that need to be taken to amend this so the study can start. BRD will also check the HRA Approval letter and issue Letters of Access or Honorary Research Contracts if necessary.

Once BRD have reviewed the study document set and are satisfied that all requirements are met, they will provide assurance to the Sponsor Study Coordinator that the research site covered by the CCG should have no issues conducting the study (based on their previous experience) and abiding by the terms and conditions of the site agreement/contract.

The HRA Approval, REC favorable opinion and BRD assurance are sent to the CCG Research Governance Lead along with a brief outline of the aims of the study and its implications for the participants and proposed site. The study details are entered in the CCG research register.
Appendix 1

Research Governance Framework

Research governance aims to continuously improve the quality of research activity within the NHS and to reduce variations in research practice. The research governance framework identifies the five following domains which attempt to capture the range of standards, legislation, and guidelines associated with conducting high quality research.

Ethics

All research that involves patients, users, care professionals, volunteers, or their organs, tissue, or data, must be referred to independent ethical review and approved by an NHS ethics committee, prior to commencement of the research project. Ethical approval aims to ensure that the dignity, rights, safety, and well-being of participants are paramount when planning, conducting, analysing, or reporting on any research project. All studies must have appropriate arrangements for obtaining and recording of informed consent. Risk must be kept to a minimum and carefully and clearly explained.

Science

All research must have undergone and responded to independent scientific peer review prior to commencement of the research study – i.e. the study must have been subjected to review by experts in the relevant field who are able to offer independent advice on its quality. Researchers should demonstrate how they will ensure protocol compliance and prevent research misconduct or fraud. Research involving medicines must be authorised by the Medicines and Healthcare Products Regulatory Agency and the conduct of the research must comply with the Medicines for Human Use (Clinical Trials) Regulations 2004.

Information

Information is available on all research being undertaken in the organisation. The findings from research studies (once subjected to scientific review) must be accessible to those participating in the research and to those who may benefit from such research. These findings must be disseminated in a format that is understandable.

Health, Safety and Employment

The safety of employees, contractors, patients and carers must be carefully considered when planning and conducting research in a way that minimises risks and ensures compliance with the Health & Safety policy of the CCG and UK law. All adverse incidents must be reported to the CCG and any other mandatory body as applicable, in a timely manner.

Finance and Intellectual Property

The CCG is expected to demonstrate financial probity and compliance with the law and the rules of HM Treasury with respect to research studies. All research proposals must be carefully scrutinised in order to establish if the stated funding is adequate and robust and to ensure that the conduct of the research does not have an adverse impact on the organisation’s care arrangements. The CCG will establish if the indemnity for negligent harm is suitable for the type of research being proposed and consideration will be given to how best to protect any intellectual property that is anticipated from research studies.
Principal Investigator (PI) and/or research team apply for HRA Approval, and if required, REC review via IRAS. The application package, which comprises of a single submission for both HRA and REC, includes:

- IRAS Form
- Research Protocol
- Participant information sheet & consent form
- SoA & SoE
- CVs of Chief Investigator and Principal Investigator
- Evidence of Indemnity
- Any other relevant study documents

Once the HRA have received the application package, they issue an initial assessment letter. This should be sent along with the study document set (including the IRAS form) to BRD and NHS participating organisations, so local assurance and capacity & capability checks can begin.

On completion of a satisfactory assessment in relation to research governance and legal compliance, the HRA will issue an approval letter to the Principal Investigator.

The HRA and/or REC may have questions and require additional information.

For those studies that required REC review, on completion of a satisfactory review the REC will issue a favorable opinion letter to the Principal Investigator.

The Principal Investigator sends the HRA Approval and REC favorable opinion letter to BRD and NHS participating organisations. BRD review the study document package, and on completion of a satisfactory review, provide assurance to the Principal Investigator that the research site/s covered by the CCG should have no issues conducting the study and abiding by the terms and conditions of the SoA.

Start study
Appendix 3

Commercial Research Approval Flowchart for Wiltshire, BaNES and Swindon CCGs

Sponsor Study Coordinator applies for HRA Approval, and if required, REC review via IRAS. The application package, which comprises of a single submission for both HRA and REC, includes:

- IRAS Form
- Research Protocol
- Participant information sheet & consent form
- NIHR industry costing template (validated by the CRN) & template agreement
- CVs of Chief Investigator and Principal Investigator
- Evidence of Indemnity
- Any other relevant study documents

Once the HRA have received the application package, they issue an initial assessment letter. This should be sent along with the study document set (including the IRAS form) to BRD and NHS participating organisations, so local assurance and capacity & capability checks can begin.

On completion of a satisfactory assessment in relation to research governance and legal compliance, the HRA will issue an approval letter to the Sponsor Study Coordinator.

The HRA and/or REC may have questions and require additional information.

For those studies that required REC review, on completion of a satisfactory review the REC will issue a favorable opinion letter to the Sponsor Study Coordinator.

The Sponsor Study Coordinator sends the HRA Approval and REC favorable opinion letter to BRD and NHS participating organisations. BRD review the study document package, and on completion of a satisfactory review, provide assurance to the Sponsor Study Coordinator that the research site/s covered by the CCG should have no issues conducting the study and abiding by the terms and conditions of the site agreement/contract.

Start study