Research Policy

Document Data		
Subject:	Research Policy	
Document Type:	Policy	
Document Status:	Approved	
Document Owner:	Diana Benton, Head of Research & Innovation	
Executive Lead:	Medical Director	
Approval Authority:	Trust Research Group	
Estimated Reading Time:	10 minutes	
Review Cycle:	12	
Next Review Date:	**Date of First Issue:**	**Date Version Effective From:**
28/01/2020	24/02/2012	12/02/2019

Document Abstract

This policy describes the framework for research undertaken within this Trust. It is to be used by all staff (including those with honorary contracts or other HR arrangements in place) who are undertaking research at UH Bristol.

Document Change Control

Date of Version	Version Number	Lead for Revisions	Type of Revision	Description of Revision
24/02/2012	0.5	David Wynick	Minor	First draft
25/03/2013	0.6	David Wynick	Minor	Reformat of Policy
21/02/2014	0.7	David Wynick	Minor	Minor updates
24/02/2015	0.8	Diana Benton	Minor	Minor updates
30/10/2015	0.9	Diana Benton	Minor	To reflect new SOPs and processes in UK research environment
28/01/2019	0.10	Jess Bisset	Minor	Minor update

Table of Contents

1. Introduction

1.1 This policy describes the framework for research undertaken within this Trust. It is to be used by all staff (including those with honorary contracts or other HR arrangements in place) who are undertaking research at UH Bristol.

2. Purpose and Scope

2.1 The purpose of this policy is to describe the framework for research taking place within this trust. Procedural details are described in the SOP and procedural documents referenced in the Associated Documents section.

2.2 The scope of the policy is research falling under the UK Policy Framework for Health & Social Care Research and the Medicines for Human Use (Clinical Trials) Regulations.

3. Definitions & Abbreviations

3.1 ***Sponsor***

See section 4.1.

3.2 ***Researcher***

Individual conducting research.

3.3 ***Chief/ Principal Investigator (CI/PI)***

Researcher responsible for the overall conduct of a research project (chief) or for the conduct of a research project at a particular site (principal).

3.4 ***Trust Research Group and Research Leads***

See below.

3.5 ***ICH GCP***

International Conference on Harmonisation for Good Clinical Practice.

3.6 ***R&I***

Research & Innovation.

3.7 ***SLA***

Service Level Agreement.

3.8 ***NIHR***

National Institute for Health Research

3.9 *ATIMP*

Advanced Therapy Investigational Medicinal Product – as defined by the NIHR Clinical Trials Toolkit as an ATMP as defined in Article 2(1) of Regulation 1394/2007 which is tested or used in a clinical trial (in accordance with Article 2(d) of Directive 2001/20/EC).

http://www.ct-toolkit.ac.uk/glossary/

Regulation (EC) No 1394/2007 defines 'Advanced therapy medicinal product' as any of the following medicinal products for human use:

— a gene therapy medicinal product as defined in Part IV of Annex I to Directive 2001/83/EC,

— a somatic cell therapy medicinal product as defined in Part IV of Annex I to Directive 2001/83/EC

— a tissue engineered product.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF

4. Duties, Roles and Responsibilities

4.1 *Sponsor*

(a) Under the UK Policy Framework for Health and Social Care and the Medicines for Human Use (Clinical Trials) Regulations 2004 (Clinical Trials Regulations) the trust is required to have oversight of research it sponsors and hosts.

(b) The sponsor is defined differently for Clinical Trials of Investigational Medicinal Products (CTIMPs) and non CTIMPs:

(i) CTIMP "sponsor" means, in relation to a clinical trial, 'the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial'
http://www.legislation.gov.uk/uksi/2004/1031/regulation/3/made

(ii) Non CTIMP Sponsor: 'Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study'
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf

4.2 *Researcher*

(a) The roles and responsibilities of researchers are described within the documents listed under point six.

(b) For studies sponsored by UH Bristol, certain tasks are delegated to the Chief/Principal Investigator (CI/PI) at UH Bristol or other departments within the trust e.g. pharmacy, research units etc. For each UH Bristol CTIMP or complex interventional sponsored trial at the point sponsorship is issued a document is provided to the Chief Investigator for signature entitled TMPL_023 'Statement of Responsibilities'. The document will be signed by the CI to indicate agreement with the contents.

(c) For studies sponsored by other organisations, tasks accepted by the trust as the responsibility of the trust and the PI are documented in the agreement with the sponsor. The PI is expected to conduct the research in accordance with the relevant guidance and legislation documented in the trust's Research SOPs. Support department agreement to carry out specific activities is documented by the use of locally developed pro-formas and/or by means of authorisation on the Research Management System 'EDGE'.

4.3 *Research Team*

(a) The PI may delegate certain tasks to members of the research team if they are appropriately qualified. Appropriate qualification must be documented by means of a current curriculum vitae before the tasks commence. Delegated tasks are documented and agreed in the site file using the delegation log. Correct use of the logs and delegation to appropriately trained staff is one of the elements of study conduct that may be checked by the R&I department during routine monitoring under SOP_010 Monitoring & Oversight of Research Activity.

4.4 *Trust Research Group and Research Leads*

(a) Trust Research Group has a trust wide remit for research. The terms of reference describe the membership and responsibilities of the group. The Research Leads, members of the Group, have a role description and lead research within the divisions.

4.5 *UH Bristol ATIMP Committee*

Its role is to consider all Advanced Therapy Investigational Medicinal product research protocols including those which fall under the GMO (Contained Use) Regulations 2014 and/or the Genetically Modified (Deliberate Release) Regulations 2002 and amendments which have activity within University Hospitals Bristol (UH Bristol) premises and make recommendations to deliver the research safely and in line with the Trust's mission statement to improve the health of the people we serve by delivering exceptional care, teaching and research every day.

4.6 *Partner Organisations*

(a) UH Bristol staff collaborate to develop and deliver research with experts located locally, regionally and nationally. Collaboration agreements document the roles and responsibilities of the collaborators. Drafting/review of collaboration agreements is supported by the research contracts advisor.

(b) Certain activities cannot be carried out by the trust, and arrangements are made for

these to be carried out by other organisations, such as partner universities, trusts or laboratories. These are usually carried out under a service level agreement (SLA) signed by both parties and are study-specific, unless other overarching arrangements are in place. Drafting/review of SLAs is carried out by the trust's solicitor with responsibility for research or research contracts advisor.

5. Policy Statement and Provisions

University Hospitals Bristol's research vision (as stated in our research strategy) is to improve patient health through our excellence in world-class translational research and our culture of innovation.

5.1 *Patient safety and data integrity*

Through our commitment to high quality research we will:

(a) Ensure that the dignity, rights, safety and well-being of participants lies at the heart of all research conducted in this trust.

(b) Prioritise and deliver research of the highest scientific quality where we have, or have the potential to be, world leaders.

(c) Enable our patients to access high quality clinical trials, developing and maintaining robust research governance systems.

(d) Tackle the challenges of disease and ill-health and contribute to the effective delivery of health care services by generating evidence and contributing to the knowledge economy of the UK.

5.2 *Values and professional standards:*

Our Trust's values and the professional standards of all our staff will be maintained in the conduct of research to prioritise patient safety and data integrity by:

(a) Treating patients and colleagues with respect, keeping our research participants fully informed and respecting personal data and confidentiality.

(b) Striving to ensure that each individual involved in research understands his or her responsibility for knowing and following good practice, identifying where accountabilities and responsibilities lie and taking responsibility for one's actions.

(c) Supporting and promoting openness and rigour to ensure data integrity and high scientific quality.

(d) Ensuring that all allegations of misconduct or fraud in research are treated seriously and fairly.

(e) Endeavouring to identify and resolve conflicts of interest appropriately.

6. Standards and Key Performance Indicators

(a) The Research Policy is supported and driven by the UK and EU legal and regulatory framework for research, notably by:

(i) ICH GCP Guidelines – May 1996.

(ii) UK Policy Framework for Health & Social Care Research 2017.

(iii) Medicines for Human Use (Clinical Trials) Regulations 2004 (S1031) and amendments.

(iv) In addition to this the national requirements for NHS Trusts to report their research activity levels and performance to the Department of Health (Care Quality Commission) and National Institute for Health Research drive the governance and reporting requirements described within this framework.

(v) Other regulations which have a bearing on the conduct of research are referenced in relevant trust policies and procedures.

6.2 Applicable Standards

The Trust relies on a variety of measures to define and maintain quality standards, including but not limited to:

- National Guidance, Legislation and reporting requirements: Medicines for Human Use (Clinical Trials) Regulations 2004, ICH GCP, UK Policy Framework for Health and Social Care Research , Department of Health and National Institute for Health Research requirements.
- Trust-wide Policies and Procedures: Research Policy and Research Standard Operating Procedures, R&I Templates, Guidance Documents and Work Instructions, Capacity and Capability review checks, and other trust-wide policies and procedures.
- Methodological support and from members of the NIHR Research Design Service, accredited Trials Units, Bristol Biomedical Research Centre and CLAHRC (ARC) West, and other university expert collaborators
- Training Programmes provided by the organisation and other partners including the NIHR Clinical Research Network West of England.

6.3 Measurement and Key Performance Indicators

Key performance indicators (KPI) are defined and agreed by the Director of Research in consultation with relevant trust groups and committees. Performance against KPIs and standards is monitored in accordance with the table in section 9.

7. References

- ICH GCP Guidelines – May 1996.
- UK Policy Framework for Health and Social Care Research v3.3 07/11/17 and

any amendments.

- Medicines for Human Use (Clinical Trials) Regulations 2004 (SI031) and amendments.
- Regulation(EC) No 1394/2007 of the European Parliament and of The Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004
- NIHR Clinical Trials Toolkit

8. Associated Documentation

This policy should be read in conjunction with the following research specific documents:

- Research & Innovation Strategy
- Research & Innovation SOPs
  - SOP_001 Authorship Review Revision Approval ProcDocs
  - SOP_002 Sponsorship
  - SOP_003 Developing and Designing your study
  - SOP_004 Writing a Research Protocol
  - SOP_005 Gaining & Maintaining Authorisations
  - SOP_006 Investigational Medicinal Products
  - SOP_007 Research Training
  - SOP_008 Investigator Oversight of Research
  - SOP_009 Research Safety Reporting
  - SOP_010 Monitoring and Oversight of Clinical Trials
  - SOP_011Validation and backup of computer systems used in research
  - SOP_012 Study data
  - SOP_013 Research Study Samples SOP
  - SOP_014 Essential Research Documents
  - SOP_015 Archiving
  - SOP_016 Research Contracts and Vendor Selection SOP
  - SOP_017 Capacity and Capability Review UH Bristol SOP
  - SOP_018 Managing Breaches UH Bristol
  - SOP_019 UH Bristol sponsored research amendments
  - SOP_020 UH Bristol hosted research amendments
  - SOP_021 UH Bristol review of clinical trials involving ATIMPs
  - SOP_022 Extended roles of non-medical clinicians

Research is part of the core business of the trust. Research policies and procedures should be read in conjunction with trust policies and procedures.

9. Appendix A – Monitoring Table for this Policy

9.1 A range of monitoring systems are in place to oversee the conduct of research within the organisation for individual research programmes

Item	Method	Written by	Frequency	For whom
Key Performance Indicators & standards associated with research projects	Report	Research Management Office	Quarterly	Trust Research Group
KPI exception report	Report	Director of Research	Monthly	Senior Leadership Team
Board report	Report	Director of Research	Biannual	Trust Board
Board report	Presentation	Director of Research	Biannual	Trust Board
Adherence to quality standards	Monitoring visits for individual research projects	Research Management Facilitator responsible	Ad hoc	Research Management Office
Adherence to quality standards	Self-monitoring for individual research projects	Principal Investigator/ nominated team member	Ad hoc	Research Management office
KPI review	Presentation of key performance indicators against plan	R&I Operations Team	Monthly	(Deputy) Director of Research
Financial information (spend against budget)	Report	Finance department	Annual	National Institute for Health Research
Adherence to national benchmarks set by the National Institute for Health Research	Report	R&I Information Officer	Quarterly	National Institute for Health Research

10. Appendix B – Dissemination, Implementation and Training Plan

10.1 The following table sets out the dissemination, implementation and training provisions associated with this Policy.

Plan Elements	Plan Details
The Dissemination Lead is:	Research Operations Manager
This document replaces existing documentation:	Yes
Existing documentation will be replaced by:	V0.10 28/01/19
This document is to be disseminated to:	Divisional Boards via Divisional Directors and Clinical Chairs Research staff Clinical and non-clinical staff supporting research within the trust.
Training is required:	No
The Training Lead is:	Not applicable

Additional Comments

11. Appendix C – Document Checklist

11.1 The checklist set out in the following table confirms the status of 'diligence actions' required of the 'Document Owner' to meet the standards required of University Hospitals Bristol NHS Foundation Trust Procedural Documents. The 'Approval Authority' will refer to this checklist, and the Equality Impact Assessment, when considering the draft Procedural Document for approval. All criteria must be met.

Checklist Subject	Checklist Requirement	Document Owner's Confirmation
Title	The title is clear and unambiguous:	Yes
	The document type is correct (i.e. Strategy, Policy, Protocol, Procedure, etc.):	Yes
Content	The document uses the approved template:	Yes
	The document contains data protected by any legislation (e.g. 'Personal Data' as defined in the Data Protection Act 2018):	No
	All terms used are explained in the 'Definitions' section:	Yes
	Acronyms are kept to the minimum possible:	Yes
	The 'target group' is clear and unambiguous:	Yes
	The 'purpose and scope' of the document is clear:	Yes
Document Owner	The 'Document Owner' is identified:	Yes
Consultation	Consultation with stakeholders (including Staff-side) can be evidenced where appropriate:	Not Applicable
	The following were consulted:	Not Applicable
	Suitable 'expert advice' has been sought where necessary:	Not Applicable
Evidence Base	References are cited:	Yes
Trust Objectives	The document relates to the following Strategic or Corporate Objectives:	Not Applicable
Equality	The appropriate 'Equality Impact Assessment' or 'Equality Impact Screen' has been conducted for this document:	Yes
Monitoring	Monitoring provisions are defined:	Yes
	There is an audit plan to assess compliance with the provisions set out in this procedural document:	Yes
	The frequency of reviews, and the next review date are	Yes

Checklist Subject	Checklist Requirement	Document Owner's Confirmation
	appropriate for this procedural document:	
Approval	The correct 'Approval Authority' has been selected for this procedural document:	Yes
