Research Policy

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What is in this policy?
This policy describes the framework for research undertaken within University Hospitals Bristol and Weston NHS Foundation Trust (the 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 or on behalf of UHBW.

Document Change Control				
Date of Version	**Version Number**	**Lead for Revisions**	**Type of Revision**	**Description of Revision**
24/02/2012	1.5	Joint Director of Research	Minor	First draft
25/03/2013	1.6	Joint Director of Research	Minor	Reformat of Policy
21/02/2014	1.7	Joint Director of Research	Minor	Minor updates
24/02/2015	1.8	Head of Research and Innovation	Minor	Minor updates
30/10/2015	1.9	Head of Research and Innovation	Minor	To reflect new SOPs and processes in UK research environment
28/01/2019	1.10	Research Operations Manager	Minor	Minor update
05/03/2020	1.11	Head of Research and Innovation	Minor	Minor update to revise: Review cycle, updated Definitions section, updated Monitoring Table and transfer to updated template

Sign off Process and Dates	
Groups consulted	**Date agreed**
Senior Leadership Team	07/05/2020 (Medical Director outside of SLT due to COVID-19 pandemic)
Policy Assurance Group	21/01/2020

- **Stakeholder Group** can include any group that has been consulted over the content or requirement for this policy.
- **Steering Group** can include any meeting of professionals who has been involved in agreeing specific content relating to this policy.
- **Other Groups** include any meetings consulted over this policy.
- **Policy Assurance Group** must agree this document before it is sent to the **Approval Authority** for final sign off before upload to the DMS.

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Do I need to read this Policy?

All Staff (including those with honorary contracts or other HR arrangements in place) who are undertaking research at UHBW must be aware of the Policy.

Sections 6 and 7 of this Policy should be read by all managers with oversight and responsibility for the research function.

All research staff must also read Research Standard Operating Procedures 1-22 where applicable to their role.

1. Introduction

This policy describes the framework for research undertaken within the Trust.

2. Purpose

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

The policy relates to all research falling under the UK Policy Framework for Health & Social Care Research and the Medicines for Human Use (Clinical Trials) Regulations.

3. Scope

This policy is to be used by all staff (including those with honorary contracts or other HR arrangements in place) who are undertaking research at the Trust.

4. Definitions

4.1 Sponsor

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

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

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

4.2 Researcher

Individual conducting research.

4.3 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).

4.4 Advanced Therapy Investigational Medicinal Product (ATIMP)

Advanced Therapy Investigational Medicinal Product – as defined by the NIHR Clinical Trials Toolkit as an ATIMP 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

4.5 Delegation Log

The purpose of a delegation log is to record all study staff members' study related duties. It should provide a list of study staff members and the duties that have been delegated to them by the PI. A delegation log is required for observational and interventional clinical research studies.

5. Duties, Roles and Responsibilities

5.1 Sponsor

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.

5.2 Researcher

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

(b) For studies sponsored by the Trust, certain tasks are delegated to the Chief/Principal Investigator (CI/PI) at UHBW or other departments within the Trust e.g. pharmacy, research units etc. For each UHBW CTIMP or complex interventional sponsored trial at the point sponsorship is issued a document is provided to the CI 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.

(d) 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'.

5.3 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 current curriculum vitae before the tasks commence.

(b) 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.

5.4 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.

(b) The Research Leads and members of the group have a role description and lead research within the divisions.

5.5 UHBW ATIMP Committee

(a) 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 Trust 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.

5.6 Partner Organisations

(a) UHBW staff collaborate to develop and deliver research with experts located locally, regionally and nationally.

(b) Collaboration agreements document the roles and responsibilities of the collaborators. Drafting/review of collaboration agreements is supported by the research contracts advisor.

(c) 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.

6. Policy Statement and Provisions

The Trust'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.

6.1 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) 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.

(e) Ensure all research complies with applicable information governance standards.

6.2 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 rigor 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.

7. Standards and Key Performance Indicators

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

(a) ICH GCP Guidelines – May 1996 and amendments.

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

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

(d) 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.

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

7.1 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 West, and other university expert collaborators
- Training Programmes provided by the organisation and other partners including the NIHR Clinical Research Network West of England.

7.2 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.

8. References

ICH GCP Guidelines – May 1996 and amendments.

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

9. Associated Internal Documentation

Research & Innovation SOPs available from the DMS or from our website: http://www.uhbristol.nhs.uk/research-innovation/

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

10. Appendix A – Monitoring Table for this Policy

The following table sets out the monitoring provisions associated with this policy. Please ensure any possible means of monitoring this policy to ensure all parts are fulfilled are included in this table.

Objective	Evidence	Method	Frequency	Responsible	Committee
To assess whether governance standards are being met and whether we are meeting performance standards.	Key Performance Indicators & standards associated with research projects	Report	Quarterly	Research Management Office	Trust Research Group
To advise SLT where KPIs are not being met	KPI exception report	Report	Monthly	Director of Research	Senior Leadership Team
To inform Trust Board of research activity and performance	Board report	Report	Biannual	Director of Research	Trust Board
To assure the trust of adherence to quality standards	Monitoring reports	Monitoring visits for individual research projects	Ad hoc	Research Management Facilitator responsible	Research Management Office
To assure the trust of adherence to quality standards	Monitoring reports	Self-monitoring for individual research projects	Ad hoc	Principal Investigator/ nominated team member	Research Management office
To maintain oversight of performance against KPIs	KPI review	Presentation of key performance indicators against plan	Monthly	R&I Operations Team	(Deputy) Director of Research
To assure NIHR	Financial	Report	Annual	Finance	National

Objective	Evidence	Method	Frequency	Responsible	Committee
of sound management of awarded funds	information (spend against budget)			department	Institute for Health Research

11. Appendix B – Dissemination, Implementation and Training Plan

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
Is this document: A – replacing the same titled, expired policy, B – replacing an alternative policy, C – a new policy:	A
If answer above is B: Alternative documentation this policy will replace (if applicable):	[DITP - Existing documents to be replaced by]
This document is to be disseminated to:	Research & Innovation staff
Method of dissemination:	The Policy will be hosted on the Trust's intranet (via DMS) and internet site available to all staff who are undertaking research at UHBW
Is Training required:	No
The Training Lead is:	N/A

Additional Comments
[DITP - Additional Comments]

12. Appendix C – Equality Impact Assessment (EIA) Screening Tool

Further information and guidance about Equality Impact Assessments is available here:
http://nww.avon.nhs.uk/dms/download.aspx?did=17833

Query	Response
What is the main purpose of the document?	To describe the framework for research taking place within the Trust.
Who is the target audience of the document? Who is it likely to impact on? (Please	Add ☑ or ☒ **Staff Patients ~~Visitors Carers Others~~**

Query	Response
What is the main purpose of the document?	To describe the framework for research taking place within the Trust.
tick all that apply.)	

Could the document have a significant negative impact on equality in relation to each of these characteristics?	YES	NO	Please explain why, and what evidence supports this assessment in relation to your response.
Age (including younger and older people)		√	No detriment identified
Disability (including physical and sensory impairments, learning disabilities, mental health)		√	No detriment identified
Gender reassignment		√	No detriment identified
Pregnancy and maternity		√	No detriment identified
Race (includes ethnicity as well as gypsy travelers)		√	No detriment identified
Religion and belief (includes non-belief)		√	No detriment identified
Sex (male and female)		√	No detriment identified
Sexual Orientation (lesbian, gay, bisexual, other)		√	No detriment identified
Groups at risk of stigma or social exclusion (e.g. offenders, homeless people)		√	No detriment identified
Human Rights (particularly rights to privacy, dignity, liberty and non-degrading treatment)		√	No detriment identified

Will the document create any problems or barriers to any community or group? NO

Will any group be excluded because of this document? NO

Will the document result in discrimination against any group? NO

If the answer to any of these questions is YES, you must complete a full Equality Impact Assessment.

Could the document have a significant positive impact on inclusion by reducing inequalities?	YES	NO	If yes, please explain why, and what evidence supports this assessment.
Will it promote equal opportunities for people from all groups?		√	
Will it help to get rid of discrimination?		√	
Will it help to get rid of harassment?		√	

Will it promote good relations between people from all groups?		√	
Will it promote and protect human rights?		√	

On the basis of the information/evidence so far, do you believe that the document will have a positive or negative impact on equality? (Please rate by circling the level of impact, below.)

Positive impact				**Negative Impact**		
Significant	Some	Very Little	**NONE**	Very Little	Some	Significant

Is a full equality impact assessment required? NO

Date assessment completed: 13th December 2019

Person completing the assessment: Research Operations Manager