# Research Framework Policy

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**Contribution List**
Key individuals involved in developing this version of the document

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| Fiona Smith | Associate Director, R&D |
| | |

**Change of History**

| Version | Date | Author | Reason for change |
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**Abbreviations and Acronyms**

| Abbreviations and Acronyms | Description |
|---|---|
| MDT | Multidisciplinary Team |
| PGRG | Policy & Guideline Review Group |
| QSG | Quality & Safety Group |
| | |

**Contents**

## 1. Introduction

This policy supports the national ambition to make the UK a great place to do research where more people have the opportunity to participate in health and social care research and continue to feel safe when they do.

Developing a research-active culture can bring a host of benefits for patients, clinicians and the NHS, driving innovation, giving rise to better and more cost-effective treatments, and creating opportunities for staff development. Growing evidence supports this:

- Research-active Trusts appear to do better in overall performance[1]
- Academic output correlates with better mortality rates.[2]
- Treatment of patients on clinical trials is associated with considerable cost savings.[3]

## 2. Objectives

The aim of this policy is to provide guidance and support for those undertaking research and to promote high standards of quality, ethics and research governance in all areas of research activity in line with the requirements of the UK policy framework for health and social care published by the Health Research Authority (HRA) in October 2017[4]

The Trust is committed, and has put in place a structure and processes, to develop and support an environment where:

- patients, service users and the public are given, and take, the opportunity to participate in health and social care research, and are confident about doing so;
- safer, more efficient or more effective treatments, care and other services are developed through ethical and scientifically sound research for the benefit of patients, service users and the public;
- applying to do research is simple and getting a decision is quick and with predictable timelines;
- researchers find it straightforward to do high-quality, ethical research;
- commissioners and providers of health and social care appreciate how health and social care research benefits patients, service users, staff and the public, and make their resources available for research;
- industry sees WHTH as a great place to do health and social care research and increases its investment for the benefit of patients and service users;
- income from charities and other research funders goes into carrying out research, not into navigating needless bureaucracy or duplicating previous work;
- research projects get registered, the data and tissue they collect can be made available for future analysis, where appropriate and with adequate consent and safeguards and research findings;
- transparency is demonstrated - research findings are summarised and published

The framework sets out the principles of good practice in the management and conduct of health and social care research that take appropriate account of legal requirements and other standards[4].These principles protect and promote the interests of patients, services users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.

The contents of this Policy are consistent with the principles of the UK policy framework for health and social care research and describe the responsibilities of those involved in research including Chief Investigators (CI), Principal Investigators (PI), research nurses and trial practitioners, sponsors, research sites, regulators, employers and health and social care providers.

## 3. Definitions

| TERM | DEFINITION |
|---|---|
| **Chief Investigator (CI)** | The CI is the overall lead researcher for a project and is responsible for the overall conduct of the project. |
| **Clinical Research Network (CRN)** | Support clinical research infrastructure throughout England, which is working towards increased access for patients to new and better treatments in the NHS. There are 15 local CRNs and we are a member of the North Thames network hosted by Barts Health NHS Trust. |
| **Commercial Research** | Research that is sponsored by a commercial organisation. Full costs of the research activity are recovered from the company. |
| **Confirmation of Capacity and Capability (R&D Approval)** | Formally known as NHS Permission. R&D can only review a study once it has received a valid application. No research activity may commence before R&D confirmation has been received. |
| **Employers** | The employer is the body or bodies that employ the investigators and research teams for a research project. |
| **Funder** | The funder is the body or bodies that fund a research project. |
| **Good Clinical Practice (GCP)** | GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials |
| **Health and social care providers** | Organisations that provide health or social care. Providers' involvement is generally as research sites, when they are also the employer of members of the research team and responsible for research participants' care. In addition to their responsibilities as a research site, employer and/or sponsor, providers should recognise the importance of research |
| **Health Research Authority (HRA)** | The HRA was established in December 2011. Its main purposes, in accordance with the Care Act 2014, are to protect and promote the interest of patients and the public in health and social care research. |
| **HRA Approval** | HRA Approval is the process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK research ethics service |
| **HRA Assessment** | Research governance and legal compliance checks undertaken by the HRA |
| **Investigator** | Person responsible, individually or as leader of the researchers at a site, for the conduct of a study at that site. For clinical trials involving medicines, an investigator must be an authorised health professional. |
| **Non-commercial/academic research** | Research that has grant funding to meet the R&Ds costs and sometimes the research, service support costs associated with the study can be met by the NIHR if the study is adopted. |
| **National Institute of Health Research (NIHR)** | Created in April 2006 under the 2005 Government strategy for health research: Best Research for Best Health to improve the health and wealth of the nation through research |

| | |
|---|---|
| **Participant** | Patient, service user, carer, relative of the deceased, professional carer, other employee, or member of the public, who consents to take part in a study. |
| **Participant Identification Centres (PICs)** | An organisation that identifies potential participants for participation in studies not open at their site |
| **Portfolio Adopted Research** | Research that is funded by a recognised funding partner or commercial company that is adopted onto the NIHR portfolio.<br>Locally the research is supported by NIHR funded staff. |
| **Public Involvement** | Working in collaboration with patients, service users or the public in the design, management, conduct or dissemination of research. |
| **Principal Investigator (PI)** | The lead researcher for a research project at a particular site. Has responsibility for the conduct of the project at that site. |
| **Research** | The attempt to derive generalisable or transferable new knowledge. |
| **Researchers** | Those conducting the research. |
| **Research Ethics Committee (REC)** | Committee established to provide participants, researchers, funders, sponsors, employers, care organisations and professionals with an independent opinion on the extent to which proposals for a study comply with recognised ethical standards. For clinical trials involving medicines, the ethics committee must be one recognised by the United Kingdom Ethics Committee Authority. |
| **Research Sponsor** | The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. |
| **Research Team** | The people involved in the conduct of a research project. There may be different research teams for the project at different sites. |
| **Responsible care professional** | Doctor, nurse, social worker or other practitioner formally responsible for the care of participants while they are taking part in the study. |
| **Student Research** | Any research which is undertaken in fulfilment of a qualification; students can be internal or external |

## 4. Scope

This policy describes the framework for all research taking place in the Trust to ensure compliance with good practice in research[5] without restricting the freedom of individual researchers to develop ideas which can improve clinical care.

The policy is relevant to all staff holding a contract of employment issued by WHTH who undertake, support or manage clinical research including chief and principal investigators, care professionals, researchers, research nurses, managers and support staff and should be used in conjunction with research Standard Operating Procedures.

The policy applies to all research activity involving the Trust including:

- Research where the Trust is a lead organisation
- Research where the Trust is a participating site in research
- Research where participants are patients, carers, volunteers and members of Trust staff
- Research using patient tissue, organs or data

- Research taking place on Trust premises
- Research involving Trust resources
- Research that is non-clinical or laboratory base
- Research being undertaken as part of an educational qualification

All staff are contractually obligated to follow this Policy as well as any relevant Trust Standard Operating Procedures. Non-compliance with this Policy will be managed in accordance with other Trust Policies.

This policy is available for all staff and is required reading in Induction Training for new staff involved in Research. All R&D policies and SOPs are available on the intranet.

## 5. Responsibilities

Roles & Responsibilities within the Trust

The RDSG are responsible for receiving compliance reports and escalating issues where required [see Appendix 1 – escalation plan]

- The RDSG are responsible for implementation and monitoring of research standard operating procedures and reporting to the People, Education and Research Committee [PERC]

R&D is responsible for:

- demonstrating to relevant approval bodies and sponsors that the location is suitable for the research;
- being aware of all research activity being undertaken in or through the site;
- ensuring that the roles and responsibilities of individuals at the site and any collaborating parties are agreed and documented for individual research projects; and
- satisfying themselves that, if expected or required, the research has approval from a research ethics committee and any other relevant approval bodies before research participants take part;
- ensuring that the research activities are conducted in accordance with their applicable legal obligations
- ensuring employees are supported in and held to account for conducting research in a professional manner, including research integrity, and
- ensuring effective management of employees and their work, including employees' safety, well-being, work environment and facilities,
- making information available about their capacity and capability to support different types of research so that sponsors can tell quickly and easily where they should place their studies to best effect;
- ensuring they are in a position to be able promptly, efficiently and proportionately to assess their ability to take part in an individual research project;
- ensuring that in cases where a site needs to put in place additional arrangements to support a specific research project at the intended location, that process should take into account the views of the sponsor and research team about the timetable for starting the research at that location, particularly for multicentre projects
- accepting assurances about the ethics and safety of the research project, its compliance with the law and other standards (e.g. confidentiality), the suitability of contracts and costings and the competence, character and indemnification of members of the research team who are not substantively employed at the site, including patients, service users and the public from others in apposition to provide this information;

- taking steps to avoid disproportionate ‘one size fits all’ processes and duplication of effort, especially in requesting and assessing information;
- ensuring that where there is an urgent need or small window of opportunity for relevant ethical research, such as public health emergencies, quick co-operation among relevant parties to facilitate the research is expected;
- ensuring agreement with their partners and employees about accountability and division of responsibilities, including arrangements for any intellectual property arising from research;
- ensuring researchers understand and discharge their responsibilities;
- following good HR practice
- providing written procedures, supervision and training that support accountability and effective collaboration
- ensuring research income is appropriately managed
- raising awareness of the wider environment within which health and social care research is conducted
- taking proportionate, effective action in the event of errors and breaches or if misconduct or fraud are suspected.
- ensuring appropriate individual learning and competence.

The **Director of Research and Development** is responsible for providing assurance to the Chief Executive, through the approved governance structure.

The **Associate Director of Research and Development** is responsible for ensuring all members of the research team are aware of this policy and R&D standard operating procedures and reporting compliance to RDSG

**Line Managers** are responsible for ensuring their staffs, where appropriate, are aware of this policy

**Trust Staff** are responsible for implementing and complying with this policy within the areas of their control.

**The Chief Investigator (CI)** is the overall lead researcher for a project and is responsible for the overall conduct of the project.

**The Research Team** is the group of people involved in the conduct of the research project. It may include care professionals, academics, patients and service users, research professionals, scientists and students. Research team members’ accountability should be clearly agreed between them and their employer and documented.

**The Sponsor** is the individual or organisation that takes overall responsibility for proportionate, effective arrangements being in place to set up, run and report the research project. All health and social care research requires a sponsor and for non-commercial research it is usually the employer of the CI.

**Research Sites** are the organisations that have the day-to-day responsibility for the locations where the research is taking place.

**Regulators of professions** such as General Medical Council, Nursing and Midwifery Council are responsible for professional standards and ensuring compliance with the standards of the UK policy framework e.g. assessing fitness to practice.

**Other Regulators** are statutory bodies that oversee particular activities set out in legislation. There are a number of regulators in the UK with a remit for activities associated with health and social care research; the Health Research Authority (HRA) the Human Fertilisation and Embryology Authority, the human Tissue Authority (HTA) and the Medicines and Healthcare products Regulatory Agency (MHRA)

### 5.1 Chief Investigator, Investigators, Other Researchers

- Developing proposals that are scientifically sound and ethical (CI)
- Submitting the design for independent expert review (CI)
- Submitting the study (or proposal) for independent ethical review (CI)
- Conducting a study to the agreed protocol (or proposal), in accordance with legal requirements, guidance and accepted standards of good practice
- Preparing and providing information for participants in a suitable format and is clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research
- Adhering to the agreed arrangements for making information about the research publicly available before it starts (CI)
- Adhering to the agreed arrangements (paragraph 8.11) for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after the research has finished (CI)
- Starting the research only once the sponsor has confirmed that everything is ready for it to begin
- Ensuring participants' welfare while in the study
- Arranging to make findings and data accessible following expert review.
- Feeding back results of research to participants

### 5.2 Main Funder

Assessing the scientific quality of the research as proposed

- Reviewing information about the attribution of costs to confirm that costs to all parties (including excess treatment costs) have been identified and described in accordance with national guidance
- Considering whether the research is really achievable within the settings as a whole in which it is intended to be carried out, particularly in view of the priorities and constraints in health and social care if the research will have an impact on care provision
- Requiring that a sponsor takes on responsibility before the research begins
- Using contracts (e.g. model agreements, where applicable) for making information about research publicly available before it starts and for retaining and making accurate findings, data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished.

### 5.3 Sponsor

The sponsor has overall responsibility for the research, including:

- Identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols or applications and ensuring that research proposals and protocols:
- Satisfying itself the research protocol, research team and research environment have passed appropriate scientific quality assurance;
- Ensuring that roles and responsibilities of the parties involved in the research and any delegation by the sponsor of its tasks are agreed and documented;
- Satisfying itself the study has ethical approval before it begins;

- Ensuring adequate (provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project;
- ensuring appropriate arrangements are made for making information about the research publicly available before it starts, agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished; and ensuring arrangements for information about the findings of the research to be made available, including, where appropriate, to participants;
- ensuring that, where expected or required, the research has approval from a research ethics committee and any other relevant approval bodies before it begins;
- verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner;
- putting and keeping in place arrangements for adequate finance and management of the research project, including its competent risk management and data management;
- ensuring that effective procedures and arrangements are kept in place and adhered to for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments;
- For clinical trials of investigational medicinal products, their legal duties are followed (i.e. seeking a clinical trial authorisation and making arrangements for investigational medicinal products) and that they ensure that the trial complies with the legislation and GCP.

### 5.4 Employing Organisation

Encourage a high-quality research culture

- Ensuring researchers understand and discharge their responsibilities
- Follow good HR practice, including in the provision of assurances about researchers' suitability, provide written procedures, supervision and training that support accountability and effective collaboration; encourage care with financial resources; raise awareness of the wider environment within which health and social care research is conducted; and bridge any gap between employees' current competence and the competence needed for their work;
- Ensuring appropriate individual learning and competence.
- Encourage open and honest reporting
- Ensuring studies are properly designed and submitted for independent review
- Ensuring studies are managed, monitored and reported as agreed according to the protocol. .
- Taking action if misconduct or fraud is suspected.

### 5.5 Organisation Providing Care / Responsible Care Professional

Promoting opportunities to take part in health and social care research

- Retaining responsibility for the care of their patients and service users as research participants, including agreeing any associated excess NHS tariff treatment costs
- Having regard to the UK Policy Framework for health and social care research according to their legal duty and contributing to the fulfilment of their commissioners' legal duties to promote research under the Health and Social Care Act 2012.
- Arranging for an appropriate person to give permission for research involving their patients, service users, carers or staff, before the research starts.

- Ensuring any such research is conducted to the standards set out in the research governance framework.
- Requiring evidence of ethical review before recruitment to any research that affects their duty of care.
- Before recruitment to trials with medicines, requiring evidence of a positive ethical opinion and a clinical trials authorisation.
- Retaining responsibility for the care of participants to whom they have a duty.

## 6. Procedure

### 6.1 Legal requirements

The following items are legal requirements and are included in standing NHS procedures. Ensuring compliance is the responsibility of general performance management.

- Systems to ensure researchers are aware of the Data Protection Act and other legal provisions and guidance on handling information
- Systems to ensure financial probity
- Arrangements to make researchers aware of their responsibilities under the Health and Safety Act both in respect of themselves and participants.

- Where tissue samples are involved, the study must be carried out in accordance with the Human Tissue Act 2004 available at
- https://www.hta.gov.uk/guidance-professionals/hta-legislation/human-tissue-act-2004
- the Codes of Practice from the Human Tissue Authority available at https://www.hta.gov.uk/guidance-professionals/codes-practice
- Bribery Act 2010 available at https://www.legislation.gov.uk/ukpga/2010/23/contents

### 6.2 Confirmation of Capability and Capacity for research projects

**All research projects require Confirmation of Capability and Capacity before commencement**

All research projects [including pre-protocol and educational research projects] require regulatory approvals, HRA approval and Confirmation of Capability and Capacity before the study can commence. All relevant guidance is available on the intranet/website or from the R&D offices (for contact information please see final page of this document).

Clinical Directors are asked to examine the proposal and ensure that the project is compatible with the direction and workload of the directorate, sets out to answer a question of value and interest, and is adequately supported financially so that routine patient care funds are not jeopardised.

All research requires a nominated ‘sponsor’. If there is no external sponsor, this can be the NHS Trust. Please contact the Associate Director, R&D for advice about this requirement. Investigators with limited experience in research should obtain a supervisor, a senior member of staff with research experience, within the Trust who will oversee the running of the project.

## 6.3 Ethical Practice

The dignity, rights, safety and wellbeing of participants must be the primary consideration in any research study. Research involving patients, service users, care professionals or volunteers, or their organs, tissue or data must be reviewed independently to ensure it meets ethical standards.

For all research which falls within the remit of the Governance Arrangements for Research Ethics Committees (GafREC) review from a recognised NHS Research Ethics Committee (REC) is required. Guidance is available at http://www.hra.nhs.uk/

All research at the Trust must be submitted for regulatory review via the Integrated Research Application System (IRAS) https://www.myresearchproject.org.uk/. This is a single system for applying for the permissions and approvals for health and social care / community care research in the UK.

IRAS captures the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Confidentiality Advisory Group (CAG)
- Gene Therapy Advisory Committee (GTAC)
- Health Research Authority (HRA) for projects seeking HRA Approval
- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS / HSC Research Offices
- NHS / HSC Research Ethics Committees

For many studies, informed consent from participants is essential and consent must be sought in the way agreed during ethical review.

All clinical trials, given a favourable opinion by a REC within the Health Departments' Research Ethics Service and currently in active recruitment in the UK, have been registered on a publicly accessible register (clinicaltrials.gov) [6].

## 6.4 Financial management and Costing of Research

**Systems to ensure financial probity are a legal requirement for all projects. Researchers are required to liaise with R&D to agree costing and budgetary management of projects.**

The research costs of all projects funded via external grant applications, commercial agreements or the internal funding system will be calculated according to a standardised and robust model. This is to ensure that the true costs to the Trusts are known, and there is no cross subsidisation between service budgets and research.

The Attributing the Costs of Health and Social Care Research and Development[7] provides a framework for the NHS and its partners to identify, attribute and recover the various costs associated with research in the NHS in a transparent, robust and consistent manner.

The research costs of all projects funded via external grant applications, commercial agreements or the internal funding system will be calculated using the NIHR Industry Costing Template by the R&D department. This is to ensure that the financial risks to R&D and the Trust can be anticipated and managed.

An overhead is included in commercial research contracts to cover the cost of R&D management and general associated Trust costs. Any surplus is available to support and promote high quality research activity in the Trust.

### 6.5 Data Protection

The Data Protection Act requires that confidential patient data is only accessed by researchers who have obtained ethical and HRA approval for their study and who understand their responsibilities with regard to data protection regulations, particularly ensuring patient anonymity and confidentiality.

The General Data Protection Regulations (GDPR) introduced the requirement for explicit consent, which is in line with good research practice. Questionnaire research studies that collect personal and/or sensitive data by means of implicit consent will be discussed with the Trust's Data Protection Officer.

The SOP "Management of source data" is available for researchers. Researchers are required to have read the guidance and made arrangements for appropriate storage of research documentation.

The SOP SOP-17 "Archiving of essential documents" requires that there are appropriate arrangements in place to archive the data when the research has finished and to make it accessible.

### 6.6 Good Clinical Practice (GCP)

Everyone involved in the conduct of clinical research must have training to ensure they are best prepared to carry out their duties. It is the responsibility of the Principal Investigator to be satisfied that the local research team are trained to deliver the study

The principles of GCP state that "*Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s*)".

The Medicines for Human Use (Clinical Trials) (2004) regulations [8] require that all staff are trained to carry out their duties on each study they are working on. All staff involved in clinical trials of medicinal products (CTIMPS) must have a valid GCP training certificate and this policy recommends staff involved in non-interventional studies also hold a valid GCP certificate. GCP training can be accessed online through e-learning.

### 6.7 Indemnity

The Trust participates in the NHS risk pooling scheme administered by the NHS Litigation Authority "Clinical Negligence Scheme for NHS Trusts" for medical professional and/or medical malpractice liability, and general liability

All commercial companies sponsoring research must have a contract in place including an indemnity agreement accepting responsibility for any claims for compensation arising following inclusion in the study.

### 6.8 Partner organisations

Research cannot be carried out with partner organisations unless a documented agreement is in place allocating responsibilities.

For commercial CTIMPs or commercial studies involving medical devices the Trust expects that commercial companies will use the national model Clinical Trial Agreements for pharmaceutical companies working with the NHS.

When the Trust conducts research involving non-commercial partner organisations the allocation of responsibilities should be clearly documented.

### 6.9 Research Personnel

All staff involved in research require a substantive or honorary contract of employment with the Trust or must have a research passport / letter of access for the study.

### 6.10 Peer Review

All research where the Trust is Sponsor should be subjected to review by independent recognised experts in the relevant fields.

All non-commercial research that is externally funded via grants from research councils or major charities will have already been subject to peer review.

All internally funded projects go through informal peer review by discussion with the head of department, Clinical Director, members of the R&D Steering Group as appropriate. Projects with funding in excess of £10,000 will require an external peer review if not provided by the external funding body. This review must be independent, expert and recorded

### 6.11 Project Management

Guidance is available from the R&D offices regarding best practice in research project management. The lead researcher in each project is responsible for efficient and ethical management of all aspects of the project and is required to ensure all trial documentation is in order and available for internal and external audit and inspection

### 6.12 Medical Devices

Any piece of electrical equipment supplied as part of the trial must be notified to Clinical Engineering (WGH ext 7558). Before placement on any ward/department the equipment must be checked for electrical safety by Clinical Engineering for the relevant site, and full documentation provided for its safe operation.
Any item of analytical electrical equipment or any screening kits (e.g. d-Dimer, pregnancy testing, drugs of abuse etc) must be notified to the Point of Care Manager (01923-217998) for suitability, and also to the Medical Devices Group. Any item deemed unsuitable analytically will be referred back to the trials organiser with recommendations for suitable alternatives.

### 6.13 Fraud & Misconduct in Research

A clinician or health professional is available at each hospital site to deal with any concerns. Any issue can be discussed with these staff members in complete confidence. The Director of R&D, or deputy, will then assess appropriate action, following discussion with the lead researcher of the project involved and the Caldicott Guardian if appropriate.
The General Medical Council recommends that action should be taken promptly, including:

- taking account of participants' safety,
- establishing the facts as far as possible, separating genuine concerns from those made mischievously or maliciously

- protecting the person who has made the allegations and the person about whom the allegation is made from harmful criticisms or actions
- having a system in place to deal fairly and promptly with complaints and allegations of fraud and misconduct.

The R&D Steering Group has the power to suspend projects while investigations are being made. If there is proven cause for concern, the sponsors of the study would be informed and the disciplinary procedure for misconduct would be commenced.

### 6.14 Involving Consumers in Research

The Trust actively encourages CIs to involve patients, service users and public appropriately in the design, management, conduct and dissemination of research.

### 6.15 Intellectual Property (IP) Rights

All projects are reviewed to consider the potential intellectual property rights before approval is given. The IP Policy outlines the principles of IP Management in the Trust.

At WHTH the IP Lead is the Associate Director, R&D.

The Trust has membership of Health Enterprise East, a regional IP organisation that offers independent advice to NHS Trusts.

### 6.16 Transparency

There is the expectation, by WHTH and under the terms of the ethics application, that all WHTH sponsored research will be published, whether a positive or negative outcome was demonstrated. All publications from research studies sponsored by the Trust should be copied to the R&D Department prior to submission for publication

R&D will actively support and encourage dissemination of research findings at local, regional, national and international meetings in accordance with the national transparency requirements.

## 7. Monitoring & Compliance

| | | | |
|---|---|---|---|
| 1 | Following local and national policies and guidelines, what key elements require monitoring? | List elements to be monitored | a. Adherence to regulations and guidance |
| 2 | Who will lead/be accountable for monitoring? | Lead title and/or MDT | Research & Development Steering group (RDSG) |
| 3 | Describe how the key elements will be monitored? | List tools to evidence compliance | a. Non-compliance issues discussed with the RDSG and documented in the RDSG minutes<br>b. Project Review<br>c. Annual R&D Review<br>d. Audit plans for Trust Sponsored projects<br>e. Annual Report submitted to Trust Board<br>f. Involvement in external/internal audit/inspection |

| | | | |
|---|---|---|---|
| 4 | How frequently will each element be monitored? | List frequency of monitoring for each element | a. As required |
| 5 | Explain the protocols for escalation in the event of problems? | List the processes of escalation | a. RDSG to People, Education and Research Committee (PERC) and Quality and Safety Group (Q&S) |
| 6 | Which Committee/ Panel/ Group will reports go to? | List the Committee/Panel/ Group/Peer Review that the reports will go to | a. RDSG<br>b. PERC<br>c. Q&S |
| 7 | Explain how the policy/guideline will be disseminated within the Trust? | List ways identifying how this document will be shared and how it will be recorded that appropriate staff have been made aware of the document and where to find it | a. Intranet<br>b. Researcher discussions |

## 8. Safeguarding

Does this document have any impact on safeguarding issues for adults and/or children?
n/a

## 9. Patient & Carer Involvement

Reference any group/individual patient/carer involvement in developing this document
n/a

## 10. References


1. Based on clinical trial data published in: Downing A, Morris EJ, Corrigan N et al. High hospital research participation and improved colorectal cancer survival outcomes: a population-based study. Gut 2017;66:89–96. High hospital research participation and improved colorectal cancer survival outcomes: a population-based study | Gut (bmj.com)
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5. HRA- Improving Research Policies https://www.hra.nhs.uk/planning-and-improving-research/policiesstandards-legislation/good-clinical-practice/
6. Clinical Trial.gov (Find a study) https://clinicaltrials.gov/
7. Attributing costs of health and social care research https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-careresearch
8. The Medicines for Human Use ( Clinical Trials) Legislations http://www.legislation.gov.uk/uksi/2004/1031/contents/made

### 10.1 Research and Development Contact Details

R&D office info Tel: 01923 217854
R&D box: westherts.rdapplications@nhs.net
Email: fiona.smith8@nhs.net
Website: www.westhertshospitals.nhs.uk

### 10.2 Ethics Committee Contact Details

For further information regarding Ethics Committee submissions please contact: Health Research Authority
Skipton House
80 London Road
London
SE1 6LH
Tel: 020 797 22545
General enquiries: contact.hra@nhs.net
RES/research queries: HRA.Queries@nhs.net

## 11. Related Policies and Guidelines

Intellectual Property Policy
R&D SOP's
Appendix 1: Serious Breaches of GCP and Critical Audit Findings in Clinical Research

## 12. Equality Impact Statement (EIA)

What is an equality impact assessment?

There are many benefits in conducting an equality impact assessment (EIA) prior to making business decisions about policies, clinical guidelines or any other work that may potentially impact on a wide range of people with protected characteristics. Equality impact assessments should not be seen as an afterthought once decisions have already been made.

Benefits:

- Improved capacity to consider equality, diversity and inclusion as part of business management
- Reduced costs as a result of not having to revisit a policy/project
- Take into account a diverse range of views and needs
- Enhanced reputation as a Trust that is seen to understand and respond positively and proactively to diversity.

Whatever approach you take to an equality impact assessment, case law has established that you should keep an accurate, dated, written record of the steps you have taken to analyse the impact on equality. This will help you to check whether you are complying with the duty and it will be useful if your decisions are challenged.

When completing an equality impact assessment you should consider:

- Treating a person worse than someone else because of a protected characteristic (known as direct discrimination)
- Putting in place a rule or way of doing things that has a worse impact on someone with a protected characteristic than someone without one, when this cannot be objectively justified (known as indirect discrimination)
- Treating a disabled person unfavourably because of something connected with their disability when this cannot be justified (known as discrimination arising from disability)
- Failing to make reasonable adjustments for disabled people.

**Equality impact assessment process**
Stage 1 (Screening)

This stage provides an opportunity to explore whether the policy decision may have a negative, neutral or positive impact on different groups of people.

- If yes, use the ‘comments’ column to describe what this impact could be.

- If no, outline how have you arrived at this conclusion.

- If unsure use the ‘comments’ column to describe what you need to do to find out.

Stage 2 (Full Assessment)
This should be carried out in compliance with policy HR028 Equality & Human Rights Policy.

| Does this policy/guideline affect one group less or more favourably than another on the basis of: | | | |
|---|---|---|---|
| | | | Comments |
| 1 | Age<br>(younger people & children& older people) | no | |
| 2 | Gender<br>(men & women) | no | |
| 3 | Race<br>(include gypsies and travellers) | no | |
| 4 | Disability<br>(LD, hearing/visual impairment, physical disability, mental illness) | no | |
| 5 | Religion/Belief | no | |
| 6 | Sexual Orientation<br>(Gay, Lesbian, Bisexual) | no | |
| 7 | Gender Re-assignment | no | |
| 8 | Marriage & Civil Partnership | no | |
| 9 | Pregnancy & Maternity | no | |
| | Is there any evidence that some groups maybe affected differently? | no | |
| | Could this document have an impact on other groups not covered by a protected characteristic? (e.g.: low wage earners or carers) | no | |
| | If '**NO IMPACT'** is identified for any of the above protected characteristics then no further action is required. | | |
| | If '**YES IMPACT**' is identified a full impact assessment should be carried out in compliance with HR028 Equality & Human Rights Policy and linked to this document | | |

| **Any other comments:** |
|---|
| *Please use this box to add any additional comments relevant to the assessment* |

| Assessment completed by: | *Fiona Smith, Associate Director, R&D* | Date completed: | 02/02/2023 |
|---|---|---|---|

If you have any queries or concerns about completing the EIA form, contact the Trust's Inclusion & Diversity Team at WestHerts.Inclusion@nhs.net

**Appendix 1**

**Serious Breaches of GCP and Critical Audit Findings in Clinical Research**

**Summary**

This paper summarises the process for escalating findings of non-compliance relating to the governance of clinical research activity.

**Contents**



## 1. Identification of non-compliance in clinical research

- Non-compliance in clinical research may be identified through one of 3 routes:
- By the clinical research study team conducting the trial
- Through monitoring or auditing conducted by the R&D Department
- Through monitoring or auditing conducted by partners

## 2. Categories of non-compliance in clinical research

**Serious breach**: A breach in compliance with clinical trial protocol or GCP regulations which is likely to affect to a significant degree the safety of the trial participant or the scientific validity of the trial.

**Critical Finding**: Where evidence exists through audit that significant and unjustified departure(s) from applicable legislative requirements has occurred with evidence that;

- the safety or well-being of trial subjects either has been or has significant potential to be jeopardised, and/or,
- the clinical trial data is unreliable and/or,
- there are a number of Major non-compliances across areas of responsibility, indicating a systematic quality assurance failure, and/or,
- where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported Major non-compliances.

## 3. Reporting of non-compliance in clinical research

Reports of serious breaches and critical findings will be provided to the R&D Steering Group and the Quality & Safety Committee.

All potential serious breaches of GCP in Trust sponsored studies are reported to the R&D Dept in accordance with the SOP on Notification of Serious Breaches of GCP.
All confirmed serious breaches of GCP in hosted studies must be reported as required by the sponsor and in accordance with the SOP. It is the sponsor's responsibility to inform the PI.

In all cases, potentially serious breaches and critical audit findings are escalated to a governance review panel comprised of the following:

- Associate Medical Director
- Director of R&D
- Associate Director of R&D

This panel may choose to consult further with the Medical Director.
If any panel member is involved in the trial being reviewed, the next most senior clinician within the management structure will be called upon for their professional opinion.

The panel is responsible for reviewing non compliance reports, agreeing and taking the appropriate managerial action and if necessary notifying the relevant regulatory authority within the appropriate period. Where notification to a regulatory authority is required, a copy of this notification will also be sent to the Medical Director.

If a risk to organisational reputation is identified, the Medical Director is responsible for alerting the communications teams as appropriate.
Additionally the R&D Department will review all clinical trial audit reports and escalate any issues as required.

Incidents relating to all clinical trials are also reported to the Trust via the risk reporting process and to the RDSG. Quarterly oversight of these incidents will be undertaken by the RDSG.