Trust Policy

Worcestershire Acute Hospitals NHS Trust

Research Governance Policy

Department / Service:	Research and Innovation
Originator:	Anna Walker, Head of Research Operations
Accountable Director:	Dr Jules Walton, Chief Medical Officer
Approved by:	Research and Innovation Committee 07/04/2025 Clinical Audit and Effectiveness Group 29/04/2025
Approved by Medicines Safety Committee:	Not applicable
Date of approval:	07/04/2025
Revision Due: **This is the most current document and should be used until a revised version is in place**	07/04/2028
Target Organisation(s):	Worcestershire Acute Hospitals NHS Trust
Target Departments:	All departments
Target staff categories:	All staff

Policy Overview:

Worcestershire Acute Hospitals NHS Trust has a duty to oversee standards in research to ensure that patients have confidence in, and benefit from, quality research. This includes scientific and ethical standards to respect the dignity, rights, safety and well-being of participants.

As such, the purpose of the policy is to:
- Clearly define the responsibilities of all those involved in the research process
- Set standards of operations and conduct
- Define the mechanisms to ensure standards are being met
- Protect the wellbeing of research participants, researchers and the Trust.

In this way, the Trust aims to develop and maintain a research culture of excellence.

All individuals involved in research at Worcestershire Acute Hospitals NHS Trust should read this document.

This is a controlled document and should only be accessed from the WAHNHST Key Documents portal via The Source.

Key amendments to this document

Date	Amendment	Approved by:
February 2021	Document extended for 6 months as per Trust agreement 11.02.2021	Trust agreement
June 2021	Amendments to dates Changes to name to Research and Innovation to reflect branding Minor amendments to ease reading Addition of outline of quality processes Clarification around some processes Inclusion of Information Governance and GDPR Addition of information about the EDGE database	Research and Innovation Committee
April 2025	Changes to staff titles to reflect role changes Changes to SOP numbers and titles Updates to titles and versions of national policy documents and legislation Addition of requirement for a local co/sub PI Addition of ability of staff employed on Honorary Contracts to take on PI responsibility Updates to GCP training Addition of requirement for research CV Updates to archiving information Clarification around reporting of research misconduct and fraud	Research and Innovation Committee Clinical Audit and Effectiveness Group

Contents page:

1. Introduction

Research is core business to the NHS as it plays a vital role in improving health outcomes and quality of care to our patients. Worcestershire Acute Hospitals NHS Trust is committed to the development of a strong research culture. As part of this commitment, we must ensure that research is conducted safely, and to the highest standards, protecting research participants at all times.

Research Governance is the term used to describe the duties, standards and regulations of good practice that exist to safeguard the public and improve research quality and reliability. There are various laws and standards for clinical research, underpinned by the UK Policy Framework for Health and Social Care Research for which the Trust must have due regard. This policy interprets these laws and standards to collectively provide guidance to:

- Safeguard the wellbeing of research participants and potential research participants, which can include patients, relatives, carers, staff, healthy volunteers and other members of the public
- Protect researchers and the Trust with a clear set of principles to work towards, preventing poor performance and misconduct

- Set standards for the conduct of research to enhance ethical and scientific quality
- Define mechanisms and systems to ensure standards are being met
- Minimise risks associated with research and promote good practice
- Monitor practice to oversee ethical and scientific quality
- Develop and maintain a culture of excellence, quality improvement and ensure lessons are learned.

2. Scope of this document

2.1 Projects within the scope of this policy

Research may be defined as the attempt to derive generalizable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods. It may involve:

- Direct intervention (medicines, devices, surgical procedures)
- Taking or using samples (tissues, fluids, organs), whether specifically for research, or using material that would typically be discarded
- Additional diagnostic, physical or psychological tests
- Completing questionnaires
- Undertaking interviews
- Access to patient records
- Use of Trust resources

Research may affect any of the following:

- Current or past patients
- Relatives of current or past patients
- The recently deceased
- Members of staff
- Healthy volunteers

2.2 Projects outside the scope of this policy

Audit, service evaluation and improvement, patient surveys, and innovation projects are excluded from the activities laid out in this policy.

It is the responsibility of the researcher to determine whether or not their project falls within the scope of this policy. They can do this in conjunction with the R&I Department. To assist, the Health Research Authority provide this definitive decision making tool.

2.3 Who does the Policy apply to?

This policy applies to all individuals involved in research, including contractors and students where Worcestershire Acute Hospitals NHS Trust is acting as the host authority. This a broad term to cover a range of scenarios, and may include, but is not limited to:

- Trust staff developing their own research project
- Clinical staff approaching patients about a research project
- Staff employed for research roles
- Staff entering the Trust to carry out research duties as part of an external project
- Those with a responsibility for management of staff who are research active

2.4 Who is excluded from this Policy?

This policy does not apply to research carried out by practitioners in roles where they are employed by, and operating in, other private or NHS organisations. These organisations will have their own research policies.

3. Definitions – see Appendix 1

4. Responsibility and Duties

The UK Policy Framework for Health and Social Care Research documents the responsibilities for:

- Chief Investigators
- Research teams
- Funders
- Sponsors
- Contract Research Organisations
- Research sites
- Regulators of professions
- Other regulators
- Employers

Therefore, there are a number of sections applicable to staff working on research within the Trust. The Framework should be read in conjunction with this Policy.

- **The Chief Medical Officer** takes executive responsibility for the management for all research on behalf of the Trust. A delegation of authority is in place from the Chief Medical Officer to the Associate Medical Director of Research and Innovation and the Head of Research Operations for the Trust.
- **The Research and Innovation Committee** - main body overseeing Research and Innovation for the Trust with delegated authority from the Clinical Audit and Effectiveness Group / Quality Governance Committee. Governance concerns are escalated through these committees.
- **The Research and Innovation Department** – responsible for implementing Standard Operating Procedures for research processes so that they are compliant with this policy and other applicable laws and guidance. These are managed locally within the department. Copies must be retained and full archiving and auditing processes in place for the purposes of quality and inspection. The Research and Innovation Department holds responsibility for the review of studies and other procedures as set out in Section 8 for the oversight of this policy.

- **All Trust employees and external staff conducting research within the Trust** are responsible for complying with the requirements of this policy and the relevant standard operating procedures that are referenced, highlighting poor practice, misconduct or fraud pertaining to research as required.
- **Chief Investigator** – the appropriately qualified investigator that leads on the conduct of an individual study. They may be external to the organisation. There is one Chief Investigator for every study, of which must be in UK for clinical trials.
- **Principal Investigators** - responsible for the individual study at site level whereby they have agreed to take on this role, including ensuring research staff working on these studies are aware and compliant with this policy. There must be a Principal Investigator for every study and every site. Principal Investigators must hold a substantive or honorary contract of employment with the Trust.
- **Individual researchers and research staff** – anyone who has duties delegated to them by the Principal Investigator to carry out research activities.
- **The Chief Executive** is the Accountable Officer

5. Policy Detail

5.1 Standards required by the Trust

The Trust requires all staff, students, and contractors to observe the highest standards in the conduct of research. In pursuing high standards, it is expected that they will:

- Ensure the dignity, rights, safety and wellbeing of participants are the primary consideration in any research study.
- Adhere to the UK Policy Framework for Health and Social Care Research and all applicable legislation
- Maintain professional standards
- Follow the Trust's research project approval and monitoring processes, submitting all research projects to the R&I Department prior to commencing any activities on these
- Adhere to all relevant Trust policies and Standard Operating Procedures
- Maintain research quality in accordance with Good Clinical Practice (Appendix 2)
- Be aware of their legal duties in respect of protection of patient data.
- Accurately and comprehensively document and disseminate results
- Attribute honestly the contribution of others
- Ensure valid informed consent is taken from all participants recorded and stored appropriately
- Secure and store all data, including archiving requirements
- Report any conflicts of interest to the R&I Department and Ethics Committee
- Keep clear and accurate records that are subject to audit

5.2 Prior to applying for approvals: What needs to be in place?

Research Sponsorship: Every study conducted in the Trust must have a sponsor that is agreed and documented prior to the study commencing. The Sponsor is responsible for overseeing the initiation, management and financing of the study. For educational projects, this should be the academic organisation responsible for the educational programme. For non-commercial research, this should be the employing organisation of the Chief Investigator. For commercially initiated

research, this should be the company initiating the study. The Sponsor must have documented arrangements for insurance and indemnity prior to the study commencing. The Trust should be notified of any changes to the sponsor via the amendments process.

The Trust can act as Sponsor on behalf of Trust staff or patient-initiated research projects, and follows the relevant Standard Operating Procedures for Sponsorship. NHS Indemnity is provided as standard for this. Prior to agreeing to act as Sponsor, the Trust will ensure that a literature review has been carried out, including unpublished / active studies so that there is no duplication. It also requires that two peer reviewers have reviewed the protocol, one of which must be external, for further details see the Peer Review Standard Operating Procedure.

Funding: If funding is required for a research project, it is essential that this is identified prior to starting applications. Signposting can be provided by the R&I Department.

Documentation: For further advice on documents required prior to the approvals process, visit the HRA website, IRAS website or the R&I Department.

5.3 Reviews and Approvals required prior to research commencing

It is the responsibility of the Chief Investigator and Sponsor to determine and obtain the necessary approvals prior to a study commencing. Every individual working on a research study should ensure approvals are in place prior to performing any study activity. Copies of approvals should be stored in the Investigator Site File. These approvals include:

Health Research Authority (HRA) Approval: A single, streamlined approval to provide NHS indemnity for research. All research in the NHS requires HRA approval. The only exception to this are single-site, non-portfolio, student, staff-only studies (see guidance for students). Applications to the HRA are made centrally by submitting documents via the Integrated Research Application System (IRAS). Approval will include review from the REC, should this also be required and other relevant approvals (e.g. Confidentiality Advisory Group).

Research Ethics Review: An independent review of a study to ensure it meets ethical standards, in order to protect the dignity, rights, safety and wellbeing of participants. All research involving patients in the NHS fall under the Governance Arrangements for Research Ethics Committee (GafREC) (Department of Health, 2011). This will be obtained through application to the HRA. Only one NHS REC approval (favourable opinion) is required per project. Research that does not require a favourable opinion under GafREC, such as research conducted on staff, may have separate Ethical Review from an academic institution.

Confidentiality Advisory Group Approval: There are certain circumstances where it is not possible to obtain consent prior to the disclosure of identifiable information. Approval must be provided by the HRA Confidentiality Advisory Group with a Section 251 approval. No identifiable information should ever be disclosed for the purposes of research without consent outside of this approval.

Trust Authorisation: Prior to any study commencing, the R&I Department will review the study in one of the following approaches, determined by the Sponsor (and confirmed by the HRA).

Assessing, Arranging and Confirming Capability and Capacity Review: In these circumstances, a full review must be undertaken following the relevant Assessing, Arranging and Confirming capability

and capacity readiness to recruit SOP. The R&I Department has a target of 30 days to complete this process, so early engagement is advised. Help and information on research and the application process are posted on the R&I Intranet site. This review will include arrangements set out in 5.4 of this policy. All research studies are recorded onto the EDGE database. Sign off can only be provided by those in the SOP with authority to do so. Confirmation will only be provided if all national approvals are in place, and usually after the Site Initiation Visit.

Issuing of No objection: Studies that do not require a full capability and capacity review will be assessed for any local implications. If there are no objections, sign off is required for the Trust Head of Research Operations. On receipt, the R&I Department will issue an email no objection to the study. The R&I Department will record this study onto EDGE.

Approvals for CTIMPs: It is against the law to start a clinical trial, including the approach and consent of participants without a favourable ethical opinion or without a Clinical Trials Authorisation from the regulatory body, the Medicines and Healthcare products Regulatory Agency (MHRA). Every CTIMP must also be registered on the European Clinical Trials Database (EudraCT) (Medicines for Human Use (Clinical Trials) Regulations, 2004, SI 1031).

Medical device clinical investigations: Clinical Investigations of Medical Devices must be notified to the MHRA. For further details on the regulation and approvals for medical devices, visit the MHRA website and contact the R&I Department https://www.gov.uk/government/collections/regulatory-guidance-for-medical-devices

Studies Involving Radiation: The Ionising Radiation (Medical Exposure) Regulations (IRMER) (SI 2017/1322 and SI 2018/121) governs the exposure to ionising radiation of participants in research. A “research exposure” is defined as “any exposure required by the research protocol following initial consent from the participant.” Clinical Radiation Expert (CRE) and Medical Physics Expert (MPE) approval must be sought prior to agreeing to take part in research involving research exposures. This will be identified in the set-up process.

ARSAC Certificate: It is a requirement of the Medicines (Administration of Radioactive Substances) Regulations (SI 2006/2806) that administrations of radioactive medicinal products to humans in research studies above standard care should be conducted under an ARSAC research certificate.

Green Light: Once all approvals are in place, the Sponsor will issue the Green Light. This should be the final confirmation that all arrangements are in place and the study can commence recruiting.

5.4 Contractual agreements required prior to research commencing

Contracts and Organisation Information Documents (OID): Responsibilities for research must be set out between the Sponsor (and contracting organisation) and the site. This should be documented on either a model contract or organisation information document, dependent on the type of study. Any pass through of payments should be documented on one of these documents. Only those with delegated authority can act as signatory on these. All contracts will be reviewed by the Head of Research Operations prior to approval. Further review by Contracting or Finance is only required where non-model versions of contracts are to be used or exceed limits in the Standing Financial Instructions. For most types of studies, signatories are identified through the Standing Financial Instructions.

5.5 Internal agreements prior to study commencing

As part of the Assess, Arrange and Confirming Capability and Capacity Process, the Research and Innovation Department will ensure that local approvals are sought prior to the study commencing.

Pharmacy: For studies involving medicines, pharmacy need to review arrangements for procurement, storage, dispensing, maintaining drug accountability records, disposal of medicines and archiving prior to agreeing to take part. This will happen as part of the review. They will write standard operating procedures governing these processes for the trial. It is the responsibility of pharmacy to identify any resource implications including excess treatment costs.

Supporting Departments: Agreement for the capacity and capability of any department involved with the study must be sought prior to a study commencing, e.g. radiology, cardiac investigations, laboratories etc.

Medical devices: Research involving medical devices should be reviewed by the Medical Devices Group via the R&I Department. If devices are to be supplied, then arrangements should be documented within the Contract or OID.

Information Governance: All studies are reviewed for their compliance with Data Protection Legislation and UK GDPR by the HRA. Local arrangements are reviewed as part of the AAC process. Where processes for the governance of data or information do not follow standard processes, advice and agreement will be sought from the Trust Information Governance department, and Caldicott Guardian Approval may be required.

Costings: All research should demonstrate value for money and make the best use of resources. A full costing of the study to demonstrate its cost effectiveness should be carried out as early as possible.

Site Recruitment Targets: A target should be agreed for all studies to monitor progress in the study and assess feasibility. This is usually agreed with the Sponsor and documented in the Contract and on EDGE.

Site Initiation Visit: It is standard practice to hold a site initiation visit prior to a study commencing. This is usually hosted by the Sponsor or Trials Unit and ensures that all site personnel are trained in study procedures.

Principal Investigator: All studies must have a named and suitably qualified Principal Investigator. They should confirm in writing they have agreed to take on the responsibilities of this role. A co / sub – investigator must be identified to provide support in the absence of the Principal Investigator.

Directorate Support: The directorate where the research to take place should authorise the department's involvement unless there are specific arrangements with the directorate that this is not necessary.

External Researchers: It is common for researchers to need to access the Trust for the purposes of research. Anybody entering on site, or who has access to patients or patient information should not do so until they have been issued with the appropriate HR arrangements (Research Passport and / or Honorary Research Contract / Letter of Access.) Processes for this are documented in the Research Passport and HR Arrangements for Research Standard Operating Procedure. This follows the Department of Health and Social Care Good Practice Guidelines.

Material Transfer Agreements (MTA): Arrangements for transfer of human tissue for the purposes of research must have written processes. This is documented in a Material Transfer Agreement. The MTA may form part of the Contract / OID, or may be provided as a separate document. This must be signed and agreed before the transfer of any tissue to another organisation.

Conflict of Interests: Any conflicts of interest by the investigator or other researcher should be declared at the start of the study. Any new conflicts of interest should be reported to the R&I Department.

5.6 General Standards

Standard Operating Procedures: The R&I Department oversees the development of standard operating procedures that provide guidance on how research is conducted from expression of interest to close out. These should be followed by all Trust personnel.

Good Clinical Practice Training: GCP Training provides an introduction to the scientific and ethical standards in research. GCP training is a mandatory requirement for all staff involved in the management and delivery of research. A pragmatic approach to refresher training should be taken, and it is generally considered that two years is an appropriate interval for refresher training. However this is not mandated by the Trust, three or more years is an acceptable time period where a researcher can demonstrate significant experience and attendance at other relevant training (e.g. initiation visit.) If a significant period has lapsed since initial GCP training then it may be necessary to repeat the Introduction course. GCP Consolidation training is available to support understanding of the application of GCP in practice. Further training requirements should be considered on an individual and study level.

Research CV: Staff involved in the management and delivery of research must be appropriately trained and qualified, and must provide a copy of a signed and dated research CV.

Other Training: To be competent to fulfil their duties, including compliance with GCP, all researchers must complete relevant training. This should be suited to the involvement and level of the researcher. The researcher is responsible for identifying their training needs and developing the relevant skills to competently carry out their duties. Individual studies will have training requirements that the research team must also comply with. Formal training is available such as Principal Investigator, Site File Management, Consent, Adults Lacking Capacity and Paediatric Research. Informal training such as observations, coaching and shadowing should be documented as evidence towards research.

Essential Documents: All research studies should have an investigator site file and follow the Site File and Essential Document SOPs. Assistance with this can be obtained from the R&I Department. The Site File must contain all essential documents, including a Delegation of Duties log.

Delegation of Duties Log: This provides a comprehensive list of study staff members and the duties that have been delegated to them by the Principal Investigator, prior to beginning work on a study. It is a Trust requirement that a Delegation of Duties Log is maintained for all research that is hosted within the Trust, even if this is not a Sponsor requirement.

Human Tissue samples: All samples classed as relevant material used for research are regulated by the Human Tissue Act (UK, 2004), overseen by the Human Tissue Authority. This states specific

consent must be sought for its collection and use, and the Patient Information Sheet must be explicit in explaining where samples will be stored. If a sample is being transferred outside of the European Union, specific consent must be sought for this.

Recording of Patient Recruitment: All participants in a research project, whether patients, carers or staff must be recorded on the EDGE database. The person recruiting that participant is responsible for this, however this can be delegated out in certain circumstances. The Research and Innovation Department can be contacted for guidance and support with this.

Amendments: Any changes made to the research project or research documentation after approvals have been provided will be classed as an amendment. Depending on the nature of the amendment, separate review may be required by the HRA, REC, R&I and MHRA, and cannot be implemented until the relevant approvals have been received. The exception to this is urgent safety measures, which can be implemented immediately.

End of Study Notification: It is the responsibility of the principal investigator to inform the Trust when a study has ended. Further information can be found in the Study Closedown SOP.

Archiving: The Principal Investigator has a duty to ensure that all essential documents are stored for the length of time specified in the study protocol. For clinical trials, there are legal periods. documents should be stored in a locked filing cabinet, or electronic equivalent with restricted access. This should be free from the risk of environmental damage. R&I utilises the services of Restore Records Management, Ashchurch Parkway, Tewkesbury, GL20 8TU for archiving of essential documents. Further information can be found in the Archiving SOP.

Internal Audit, Monitoring and Inspection: All researchers in the Trust have a duty to comply with requirements for monitoring, internal audit and inspection. Monitoring may be instigated by an external study team. For studies Sponsored by the Trust, a monitoring plan will be set up at the start of the study. Internal audits can be carried by the R&I department or by the Sponsor, and are carried out by those independent of the study. An inspection is for clinical trials or investigations and is carried out by the MHRA. These can be on an individual study, or organisation level. The R&I department should be provided with copies of any monitoring, auditing or inspection reports provided externally.

Patient identifiable information in research: Research is considered to be a ‘task in the public interest’ under the General Data Protection Regulation and associated Data Protection Act. Appropriate actions are in place to inform patients that their data may be used for the purposes of research, and further information is available on the HRA website. Confidentiality of patient identifiable information should be maintained at all times to comply with Trust policies and UK legislation. The use of patient data should be respected, and recorded and handled to allow for rigorous data integrity. Use of patient data for purposes of research requires consent, which usually includes a general statement about further research studies so as to avoid duplication of data collection. There are some exceptions that fall under section 251 of the NHS Act 2006 under the power of Health Service (Control of Patient Information) Regulations (2002, SI 1438). Any research accessing identifiable patient information without consent must be reviewed by the R&I Department and have approval from the Health Research Authority (HRA) Confidentiality Advisory Body (CAG) and Trust Caldicott Guardian.

Safety Reporting: All those with patient contact in trials have a responsibility to identify adverse events to oversee the safety of all research participants. Researchers are required to report Adverse Events (AE), Serious Adverse Events (SAE) and Serious Unexpected Suspected Adverse Reactions

(SUSARs) as per the study protocol. Serious Adverse Events must be sent to the R&I Department as per the SOP. Where appropriate these should also be reported in line with the Trust Incident Reporting Policy. See the Safety Reporting SOP for further detail. The R&I Department monitor SAE reporting at the R&I Committee.

Protocol Deviations: The protocol, and its supporting documents, provide the guide for how every procedure for an individual research study should be carried out. Any deviation from this, regardless of whether it is within the researcher's control is a protocol deviation. These must be reported to the Sponsor as per the protocol. Those that could have been avoided internally should also be reported to the R&I department as evidence of lessons learned form a quality monitoring activity. A root cause analysis (RCA) and corrective action / preventative action (CAPA) is applied to these.

Serious Breaches: Serious breaches are those where there is a persistent or systematic failure to adhere to the protocol or Good Clinical Practice. For CTIMPs, these must be reported to the MHRA, usually via the Sponsor. Principal Investigator and R&I department must be documented as well as RCA and CAPA.

Intellectual Property: Research that derives new intellectual property should be protected and follow the Trust protection of Intellectual Property Policy. The Trust's policy is to encourage and enable staff to participate in the generation of IP as part of its commitment to deliver the best possible patient care. However, the Trust is entitled to receive benefits from intellectual property rights (IPR) and must be able to protect and exploit these wherever possible. For the development of partnerships about new ideas, the Company Secretary and R&I department should be involved to ensure that IP is protected.

Informed Consent Procedures: All studies should have a documented process for consenting participants that involve patients, service users, employees, volunteers, their organs, tissue or data, unless the approved protocol has the relevant approvals that override this. In obtaining and documenting informed consent, the investigator should comply with the protocol requirements, the Trust Policy for Consent to Examination or Treatment, and the relevant research Consent SOPs. Particular care is needed in the consent from adults considered under the Mental Capacity Act (2005) and follow the SOP, and Trust Policy for Assessing Mental Capacity Act and Complying with Mental Capacity Act 2005. Documentation must be approved by the HRA / REC and R&I prior to using. Copies of the signed Informed Consent Form and Participant Information sheet should be uploaded to patient medical notes.

Informed consent in a Paediatric Setting: A minor for the purposes of research is classed as a person under the age of 16. Researchers involved in research in a paediatric setting should have a full understanding of informed consent and parental responsibility prior to being involved in this process, and follow the SOP.

Pre-screening notes: Trust-employed research staff are bound by the same confidentiality code as clinical staff and should be seen as part of the clinical team for the purposes of screening notes prior to consent in a research study. Activities including the provision of approved posters and leaflets may be utilised to inform patients that their information may be accessed for research.

Dissemination of Results: All proposals for research must state how dissemination of results will take place. Every effort must be made to disseminate results as widely as possible. This should include ways to inform both patients and staff involved in the study of the results. The R&I Department should be informed of all papers and reports resulting from local and national studies.

5.7 Research Misconduct and Fraud

Research misconduct at any level is unacceptable. It is dishonest in itself, and is contrary to the core values of the NHS and those who work within it. It jeopardises scientific integrity, endangers research participants, and erodes trust and confidence in research and the wider NHS.

It is important that staff feel able to report their concerns to someone with whom they feel comfortable and without fear of recrimination. Suspected research misconduct should be reported to the Head of Research Operations as a matter of urgency, who will inform the Associate Medical Director for Research and Innovation. Other acceptable reporting routes could include to a Line Manager, or to the Trust Freedom to Speak Up Guardian.

Research misconduct includes, but is not limited to:

- Breach of this policy
- Serious Breaches of Good Clinical Practice
- Wilful destruction of research materials
- Failure to work in a way which adequately controls risks
- Colluding in, or concealing, the misconduct of others
- Failure to obtain appropriate approvals to conduct research
- Not obtaining informed consent from research subjects
- Unauthorised use of information which was acquired confidentially
- Deliberate or negligent deviations from the protocol in carrying out research
- Fraud as defined below

Fraud includes, but is not limited to:

- Invention of data (falsification)
- Misuse of research funds or research equipment
- Misrepresentation of research results (fabrication)
- Plagiarism (the copying of ideas, data or text, or any combinations of the three, without permission or acknowledgement)
- Piracy (the deliberate exploitation of ideas or work of others without acknowledgement)
- Deception in proposing, carrying out or reporting the results of research
- Deliberate omission of data that do not fit expected results
- Publication of data known to be false or misleading
- Deliberate maligning of another's research reputation based on false information

Misconduct in research does not include honest and reasonable error or differences in interpretation. Misconduct is managed through Trust disciplinary procedures, whereas honest error or difference in interpretation is managed through the R&I Department with support and guidance. All Trust employed staff, including those holding honorary contracts and other visiting staff have a responsibility to report any incident of fraud or misconduct whether this has been witnessed or for which there are reasonable grounds for suspicion.

The Associate Medical Director for Research and Innovation reserves the right to suspend research activities relating to any concerns raised, while those concerns are investigated. In the case of misconduct, the Sponsor will be informed and will be responsible for reporting the misconduct to REC/HRA, if it is appropriate to do so.

Suspicion of fraud should be reported promptly to the Trust Local Counter Fraud Specialist or Director of Finance in accordance with Trust Fraud, Bribery and Corruption Policy. These individuals will notify the R&I Department. Reports can also be made to the R&I Department, or via the online reporting forum https://www.cfa.nhs.uk/report-fraud

5.8 Responsibilities for involving patients and public in research

It is well regarded that an active partnership between researchers and users creates research that is more relevant and of a higher quality. It is the responsibility of the researcher to involve patients and the public in the research process wherever possible, including the planning and design process. Researchers must ensure that all information provided for patients or the public is presented in a format and language which is suitable for the intended audience. Actions to include patients and the public in research will include, but are not limited to:

- Activities to raise the profile of research locally
- A Patient Research Ambassador programme
- Consultation with relevant patient groups for identified agenda items of the R&I Committee

5.9 Internal Auditing of Research

In accordance with R&I SOPs, a selection of all projects will be subject to internal audit each year. Non-commercial projects will prioritised due to the fact there are fewer monitoring arrangements. Studies must have recruited at least one research participant.
Projects requiring special attention may be selected at the discretion of the R&I Department. Such projects include those:

- With higher / lower numbers of adverse event reports than expected
- Where a serious breach has been filed
- Where suspicions of research misconduct or fraud have been raised
- Which have potential to represent higher risk to the Trust
- Involve vulnerable groups

Feedback will be provided to each member of the research team as a detailed report and a series of action points required for improvement. Results of all audits will be combined and key areas for improvement will be highlighted to the R&I Committee and escalated as appropriate. These key areas will also be highlighted to all researchers to enable them to improve their practice. Training will be provided as required.

5.10 Finance

Rules set out by HM Treasury (2023) for Managing Public Money should be applied to research as for any other department. Therefore, transparency and accountability of research income and expenditure is paramount. All researchers must comply with the procedures of the Standing Financial Instructions in planning and accounting for all expenditure.

The Attributing the Costs of Health and Social Care Research (AcoRD, DoH, 2024) sets out the responsibilities of financing research across the NHS and its academic partners in National Institute for Health Research (NIHR) Portfolio research. As part of the approval process, researchers are required to provide detailed cost information as to the likely financial impact of the study to participating sites. The Trust will only agree to host projects that are not detrimental to the service currently provided to patients.

Commercial studies are usually costed through the NIHR National Contract Value Review. This tariff standardises research activity costs within the NHS, whilst ensuring overheads and capacity building elements are included. The R&I Manager must review these costs prior to the study commencing and agree to these.

All monies obtained from R&I activities must be paid into the R&I budget because the R&I budget can be carried forward across financial years. R&I budgets are subject to the usual NHS accounting procedures as the funds ultimately belong to the Trust. In all cases, if funds can be claimed for a specific project, R&I must be made aware of this during the approval process, and as the project and patients progress, to ensure that funds owed are claimed in a timely manner. Funds claimed against commercial projects will be subject to distribution through an agreed Income Distribution Policy.

Should costs be higher than initially calculated then R&I can approach the Sponsor for additional funding.

6. Implementation

6.1 Plan for implementation

This is a long-standing policy and as such is already implemented. Implementation is predominantly carried out through GCP training, and adherence to Trust R&I Standard Operating Procedures.

6.2 Dissemination

This policy will be placed on the R&I page of the Trust's Intranet, through the WAHT Key Documents platform, and will be available in the R&I Research Governance and SOPs Teams File.

6.3 Training and awareness

This policy will be available to new staff within the R&I department, who will document training to the policy in their Competencies Log. New Principal Investigators will be sent a copy of the policy to their Trust email account.
This policy is referred to in GCP training, and in Honorary Research Contracts and Letters of Access.

7. Monitoring and compliance

Monitoring and compliance against this policy will be the responsibility of the Head of Research Operations and the R&I Committee.

The table below details the process for the monitoring and ensures that research is conducted in line with this policy.

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the Policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
5.3	R&I Capacity and Capability Review	Review of study procedures to assess compliance with SOP	At start of study	R&I Facilitators	Trust signatories	Once per study
5.6	Training in GCP and SOPs	GCP and SOP training and assessments to be undertaken	Ongoing programme	Head of Research Operations	N/A	N/A
5.6	Monitoring of Trust-Sponsored studies	Document checks and interviews	Determined per study	Monitors	Head of Research Operations	Determined per study
5.6	Monitoring from external Sponsors	External monitors assess study for compliance with protocol and GCP	Determined per study	Sponsor	R&I department	Determined per study
5.9	Internal Auditing of research studies	12 studies to be selected per year for audit	Annual	Research Team Leads	Head of Research Operations	Annual
5.6	MHRA inspections	On either individual study or organisation level	Risk-based, no timelines	MHRA	Head of Research Operations	Undefined
5.6	Amendments submitted to R&I department for review	Documentation reviewed for compliance with policy	Determined per study	R&I Facilitators	Head of Research Operations	Undefined
7	Monitoring questionnaire	Questionnaire sent out to identify breaches to this policy	Annual per study	R&I Facilitators	Head of Research Operations / AMDR&I	Annual
5.7	Reporting of breaches, misconduct and fraud	Investigations, disciplinary and fraud procedures followed	On identification	All staff	Head of Research Operations / AMDR&I	On identification
5.6	Reporting SAEs	Reported to R&I via EDGE for review	On identification	All staff	R&I Committee	On identification
5.10	R&I budget subject to financial audit	Reviewed for compliance with SFIs and CRN reporting	Annual	Finance	Head of Research Operations	Annual

8. Policy Review

This policy will be reviewed two years from the date of approval, or earlier if necessary, depending on changes to the research landscape.

9. References

Internal Trust Policies	Code
Novel therapeutic interventions policy	TBC
Policy for consent to examination or treatment	WAHT-CG-075
WAHT standing orders	WAHT-TWI-032
Health and safety policy	WAHT-CG-125
Risk management strategy	WAHT-CG-007
Clinical audit policy	WAHT-CG-107
Code of conduct for employees in respect of confidentiality	WAHT-IG-001
Information governance policy	WAHT-CG-579
Concerns and complaints policy and procedure	WAHT-PS-005
Disciplinary policy	WAHT-HR-017
Fraud, bribery and corruption policy	WAHT-CG-456
Freedom to speak up policy for the NHS	N/A
Standards of business conduct policy – Appendix 3 - declaration of gifts, hospitality and sponsorship	N/A
Patient safety incident reporting policy	WAHT-CG-008
Income distribution policy	N/A
R&I Standard Operating Procedures (SOPs)	
Expressions of interest	R&ISOP02
Confirmation of capacity not required (non-AAC studies)	R&ISOP03
Confirmation of capacity required (Recruiting site)	R&ISOP04
Confirmation of capacity required (PIC site)	R&ISOP05
Confirmation of capacity required (Continuing Care site)	R&ISOP06
Managing site files and study documentation	R&ISOP07
Delegation of duties	R&ISOP08
Screening and informed consent	R&ISOP09
Alerts for research participants	R&ISOP10
Randomisation of research participants	R&ISOP11
Research participant expenses	R&ISOP12
Adverse events and safety reporting	R&ISOP13
Amendments	R&ISOP14
Change of Principal Investigator	R&ISOP15
Serious breaches	R&ISOP16
Research passports and HR arrangements	R&ISOP17
Training for research staff	R&ISOP18
Close out of research projects	R&ISOP19

Archiving	R&ISOP20
NHS Digital opt out	R&ISOP21
Out of hours	R&ISOP22
Principal Investigator oversight and engagement	R&ISOP23
EDGE	R&ISOP24
Monitoring	R&ISOP25
Urgent Safety Measures	R&ISOP26
Trust Sponsorship - Peer Review	R&ISOP27
Research Sponsorship	R&ISOP28

External References:

Department of Health. (2011). Governance arrangements for research ethics committees: a harmonised edition (updated April 2012). Published 9 May 2011.

Department of Health. (2012). Attributing The Costs of Health & Social Care Research & Development (AcoRD). Published: 4th May 2012.

HM Treasury. (2015). Managing Public Money. July 2013, republished with revised annexes 2015.

International Conference of Harmonisation. (1996). “ICH Harmonised Tripartite Guideline for Good Clinical Practice E6 (R1).” Published: 10th June 1996.

Medicines (Administration of Radioactive Substances) Amendment Regulations. (2006). Statutory Instrument No. 2806. Final: 17th November 2006

Medicines for Human Use (Clinical Trials) Regulations. (2004). Statutory Instrument No. 1031. Final: 1st May 2004.

National Health Service, England and Wales, The Health Service (Control of Patient Information) Regulations. (2002). Statutory Instrument No. 1438. Final: 1st June 2002.

National Institute for Health Research. (2012). Research in the NHS – HR Good Practice Resource Pack. HR Good Practice: Information for researchers, R&D and HR staff in Higher Education Institutions and the NHS. Version 2.1. September 2012.

The Ionising (Medical Exposure) Regulations 2017. Statutory Instrument No. 1322. Final: 6th February 2018.

The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018. Statutory Instrument No.121. Final: Coming into force in accordance with regulation 1(2)

UK Health Departments. (2011). Governance Arrangements For Research Ethics Committees: A Harmonised Edition. Published: May 2011, Updated 2012.

UK Policy Framework for Health and Social Care Research (2016)

United Kingdom (1998). Data Protection Act. Reprinted Incorporating Corrections 2005. London: Stationery Office.

United Kingdom. (2004). Human Tissue Act. London: Stationery Office.

United Kingdom. (2005). Mental Capacity Act. London: Stationery Office.

10. Background

10.1 Consultation

This document has been circulated for consultation to those designees listed below.

Contribution List

This key document has been circulated to the following individuals for consultation;

Designation
Associate Medical Director for Research and Innovation
Lead Research Nurse

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Research and Innovation Committee

10.2 Approval Process

This policy has been reviewed and approved by the WAHT Research and Innovation Committee, and WAHT Clinical Audit and Effectiveness Group.

Appendix 1: Definitions

a. Caldicott Guardian: a senior person responsible for protecting the confidentiality of people's health and care information and making sure it is used properly**.**

b. Chief Investigator (CI): The lead researcher for the project with overall responsibility for the conduct of research on a particular named study. In a multi-site study the CI has the co-ordinating responsibility for the research at all sites, thus might not be based at the Trust**.**

c. Clinical Audit: A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria/standards, followed by the implementation of change where shown to be relevant. This includes routine data collection for monitoring of clinical performance. Monitoring clinical activity against established good practice guidelines or developing guidelines from accepted research evidence. This includes routine data collection for monitoring of clinical performance.

d. Clinical Trial of an Investigational Medicinal Product (CTIMP): An investigation in human subjects which is intended to "discover or verify the clinical, pharmacological or other pharmacodynamics effects of one of more medicinal products, to identify any adverse reactions to one or more such products, or to study absorption, distribution, metabolism and excretion of one or more products, with the object of ascertaining the safety and efficacy of those products" (Regulation 2 of SI 2004/1031).

e. Employer: The body or bodies that employ the investigators and research teams for a research project.

f. Funder: The organisation, or organisations supplying financing or resources for the study, which may be from academic, charitable of commercial sources, or a combination of these.

g. Interventional research: Research involving a change in treatment, care or other services made for the purpose of the research. Does not refer to research involving other methodological 'interventions', e.g. issuing a postal survey.

h. Investigator Site File: The Investigator Site File contains all essential documents held by the Principal Investigator conducting a trial which individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced.

i. Non-CTIMP: Trials that do not involve an Investigational Medicinal Product (IMP) as defined by the MHRA and therefore do not fall within the scope of the Medicines for Human Use (Clinical Trials) Regulations 2004.

j. Participant: A patient, service, user, care, relative of the deceased, professional care, other employee or member of the public who consents to take part in a study (DoH, 2005).

k. Participant Identification Centres (PICs): Organisations from which clinicians or clinical units refer potential participants to a research team based in another Trust Policy Research Governance Policy WAHT-CG-597 Page 22 of 25 Version 8 organisation, for assessment and possible recruitment to a study but do not carry out any other research activities themselves.

l. Participating Site: A site authorised by the Sponsor perform research activity as part of a protocol. This is an organisation with day-to-day responsibility for the location where a research project is carried out.

m. Principal Investigator (PI): The person responsible for the study at a particular research site. If the study is conducted by a team of individuals, the PI is the responsible leader of the team. The PI is ultimately responsible for the running of the study within the Trust and accountable to the Trust, the research sponsor and their employing organisation (if that is not the Trust). For a single site study, the PI may also be the CI.

n. Public: Includes carers, relatives of patients and service users and healthy volunteers.

o. Public Involvement: Working in collaboration with patients, service users or the public in the design, management, conduct or dissemination of research.

p. Research: within the NHS Research Governance Framework is defined as 'the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods' (DoH, 2005, para 1.10, pg. 3).

q. Research Site: The organisation with day-to-day responsibility for the location where a research project is carried out.

r. Researcher: anyone performing activities as part of a research study, regardless of their employment status.

s. Research Team: The people involved in the conduct of a research project. There may be different research teams for the project at different sites.

t. Research Ethics Committee (REC): Committee responsible for reviewing research with the purpose of safeguarding the rights, dignity and welfare of people participating in research in the NHS. Each REC is entirely independent of the researcher and the organisations funding and hosting the research.

u. Service Evaluation: Patient or staff satisfaction surveys that relate to aspects of the routine functioning of established services of the Trust.

v. Service Users: Recipients of health care, social care or other services or support provided by or on behalf of health or social care organisations, such as NHS patients and social care service users.

w. Sponsor: The organisation that takes the lead in confirming arrangements for the initiation, management, monitoring and financing of a study. 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.

x. Trust: Worcestershire Acute Hospitals NHS Trust (WAHT).

Appendix 2: Good Clinical Practice (GCP)

The International Conference on Harmonisation Good Clinical Practice (ICH - GCP) produced an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well–being of trial subjects are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The Principles of GCP:

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s)
2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial and subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
3. The rights, safety, and well -being of the trial subjects are the most important considerations and should prevail over interests of science and society.
4. The available non-clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
6. A trial should be conducted in compliance with the protocol that has received prior Institutional Review Board (IRB) / Independent Ethics Committee (IEC) approval / favourable opinion.
7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
9. Freely given informed consent should be obtained from every subject prior to clinical participation.
10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
12. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
13. Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Supporting Document 1 – Equality Impact Assessment form

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

NHS Worcestershire Acute Hospitals NHS Trust

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	✓	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	Anna Walker

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Anna Walker	Head of Research Operations	anna.walker7@nhs.net
Date assessment completed	12.02.2025		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:** Research Governance Policy
What is the aim, purpose and/or intended outcomes of this Activity?	The purpose of the Policy is to: • Clearly define the responsibilities of all those involved in the research process • Set standards of operations and conduct • Define the mechanisms to ensure standards are being met • Protect the wellbeing of research participants, researchers and the Trust

Who will be affected by the development & implementation of this activity?	✓ ✓ ✓ ❑	Service User Patient Carers Visitors	✓ ❑ ❑ ❑	Staff Communities Other _____	
Is this:	✓ Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?				
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	UK Policy Framework for Health and Social Care Research, 2023 Similar policy at other organisations (Tees, Esk and Wear Valleys NHS Foundation Trust; East London NHS Foundation Trust; Oxford Health NHS Foundation Trust)				
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	The policy has been reviewed by the Research and Innovation Committee, with members of the group having protected characteristics.				
Summary of relevant findings	The impact is neutral for all those staff and patients to whom the policy applies.				

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		X		
Disability		X		
Gender Reassignment		X		
Marriage & Civil Partnerships		X		
Pregnancy & Maternity		X		
Race including Traveling Communities		X		
Religion & Belief		X		
Sex		X		

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Sexual Orientation		X		
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		X		
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		X		

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
		.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	Annually			

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.
1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Anna Walker
Date signed	12/02/2025
Comments:	
Signature of person the Leader Person for this activity	Anna Walker
Date signed	12/02/2025
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval