| Trust Policy | NHS Worcestershire Acute Hospitals NHS Trust |
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# Research Governance Policy

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| **Department / Service:** | Research & Innovation |
| **Originator:** | Emma Rowan |
| **Accountable Director:** | Mr Mike Hallissey (Chief Medical Officer) |
| **Approved by:** | Research and Innovation Committee |
| **Date of Approval:** | 30th June 2021 |
| **Review Date:**<br>**This is the most current document and should be used until a revised version is in place** | 3rd June 2025 |
| **Target Organisation(s)** | Worcestershire Acute Hospitals NHS Trust |
| **Target Departments** | All departments |
| **Target staff categories** | All staff |

**Purpose of this document:**

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:**
http://www.treatmentpathways.worcsacute.nhs.uk/key-documents/

**Key Amendments to this document:**

| Date | Amendment | By: |
|---|---|---|
| February 2021 | Document extended for 6 months as per Trust agreement 11.02.2021 | Trust agreement |
| June 2021 | Amendments to dates<br>Changes to name to R&I Department to reflect branding<br>Minor amendments to ease reading | Research and Innovation Committee |

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| | Addition of outline of quality processes<br>Clarification around some processes<br>Inclusion of Information Governance and GDPR<br>Addition of information about the EDGE database | |
| 3rd December, 2024 | Document review date extended to 3rd June, 2025, awaiting governance. | Anna Walker |

## 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 make sure that research is conducted safely and to the highest quality, 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 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 the 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 Policy

### 2.1 Projects within the scope of this policy

Research can be defined as systematic activity that provides generalisable new knowledge. It can involve:

- Direct intervention (drugs, 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:

- Past or present patients
- Relatives of past or present patients
- The recently deceased

- Members of staff
- Healthy volunteers

### 2.2 Projects outside the scope of this policy

*Clinical Audit, service evaluation, patient surveys, improvement and innovation projects are excluded from the procedures laid out in this policy.*
It is the responsibility of the researcher to clarify 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
www.hra-decisiontools.org.uk/research

### 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. This is not an inclusive list but may include:

- 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 3

## 4. Responsibility and Duties

The UK Policy Framework for Health and Social Care 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. This should be read in conjunction with this document.

- **The Medical Director** takes executive responsibility for the management for all research on behalf of the Trust. A delegation of authority is in place from the Medical Director to the Associate Medical Director of Research and Development and the Research Operations Lead for the Trust.
- **The Research and Innovation Committee**- main body overseeing Research and Innovation for the Trust with delegated authority from the Clinical Governance 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.
- **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 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 1)
- 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. Assistance 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 organisation.

**Confidentiality Advisory Group Approval:** There are certain circumstances where it is not possible to obtain consent prior to the disclosure of identifiable information. These studies are rare, and approval must be provided by the 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,).

As*sessing, 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 40 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 Research Operations Lead. 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 exposure. 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 arragenemts are in place and the study can commence recruiting.

### 5.4. Contractual Agreements required prior to research commencing

**Contracts and** Organisation Information Documents: 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 from the Research Contracting Standard Operating Procedure can act as signatory on these. All contracts will be reviewed by the Research Operations Lead 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 for the device to be

**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. Caldicott Guardian Approval will be in place for this.

**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 initation 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.

**Directorate Support:** The directorate where the research to take place should authorise the department's involvement unless there is 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:** Arrangements for transfer of human tissue for the purposes of research must have written processes. This is documented in a Material Transfer Agreement. 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.

### 5.5. 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.

**GCP Training** - GCP Training provides an introduction to the scientific and ethical standards in research. GCP training is a mandatory requirement, the level of which can be determined by the NIHR decision tree in agreement with the R&I Department. 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. Fundamentals training may be more appropriate for those working under strict Standard Operating Procedures with minimal involvement in the study. This can be replaced by study training if deemed by the R&I Department to cover the core content. Further training requirements should be considered on an individual and study level.

**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 -** All staff working on a study including should be listed on the Delegation of Duties log (or Signed Authorised Persons Record) prior to working on a study.

**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. This should be stored in a locked filing cabinet, or electronic equivalent with restricted access. This should be free from the risk of environmental damage. Further information can be found in the Archiving SOP.

**Audit, Monitoring and Inspection** – All researchers in the Trust have a duty to comply with requirements for monitoring, 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. 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 a study basis or as an organisation. The R&I department should be provided with copied 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 laws. 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 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 protocol. Serious Adverse Events must be sent to the R&I Department as per the SOPWhere appropriate these should also be reported in line with the Trust Incident Reporting PolicySee the Safety Reporting SOP for further detail. The R&I Department monitor SAE reporting at 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 need reporting 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 as a quality monitoring activity. A root cause analysis (RCA) and corrective action / preventative action 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 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, the Trust Consent to Examination or Treatment Policy and the relevant research Consent SOPs. Particular care is needed in the consent from adults considered under the Mental Capacity Act (DoH, 2005), and

follow the SOP. See further detail in Appendix 3. Documentation must be approved by the HRA / REC and R&I prior to using.

**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 are undertaken 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.

### 5.6. Research Misconduct and Fraud

*Research misconduct* includes, but is not limited to, the following:

- 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, the following:

- 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 a scientist's research reputation based on false information

Suspicion of research misconduct that does not involve fraud should be reported promptly to the R&I Department.

Misconduct in research does not include honest and reasonable error or differences in interpretation. Misconduct is managed through Trust disciplinary procedures, whereas honest error and difference 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.

Suspicion of fraud should be reported promptly to the Trust Local Counter Fraud Specialist or Director of Finance in accordance with Trust 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.reportnhsfraud.nhs.uk/

### 5.7. 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 Research Expert Forum

### 5.8. Auditing Research

In accordance with the Trusts SOP “Research Governance Audit”, a selection of all projects will be subject to audit each year. Non-commercial projects will prioritised due to the fact there are less monitoring arrangements. Studies must have recruited at least one research participant and the Principal Investigator must be based at the Trust.

Projects requiring special attention may be selected at the discretion of the R&IR&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 for improvement. Results of all audits will be combined and key areas for improvement

will be highlighted to the Research Expert Forum 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.

### 5.9. Finance

Rules set out by HM Treasury (2015) for the use of public funds 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 for Research and Development (AcoRD, DoH, 2012) 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 impact of the study to the Trust. Worcestershire Acute Hospitals NHS Trust will only agree to host projects that are not detrimental to the service currently provided to patients.

Commercial studies are usually costed using the NIHR Industry Costing Template. This template 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 between 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 money can be claimed for a specific project then R&I must be made aware of this during the approval process, and informed as the project and patients progress to ensure that R&I finance. Money 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 funder for additional money.

## 6. Implementation of Key document

### 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 following of Trust Standard Operating Procedures for new members of staff.

### 6.2 Dissemination

This policy will be placed on the Trust's Intranet and all staff made aware through the use of Trust wide e-mail processes and in regular Trust communications. PIs will be sent a copy to their Trust email account.

### 6.3 Training and Awareness

This policy is referred to in GCP training, in Honorary Research Contracts and Letters of Access.

## 7. Monitoring and Compliance

Monitoring and compliance against this policy will be the responsibility of the Research Operations Lead and Research Expert Forum as per the table in Appendix 4. The process will ensure that research is conducted in line with this policy

## 8. Policy Review

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

## 9. References:

### a. Internal

| Policy | Code: |
|---|---|
| • Novel Therapeutic Interventions Policy | WAHT-CG-515 |
| • Policy for Consent to Examination or Treatment | WAHT-CG-075 |
| • Standing Orders, Reservation and Delegation of Powers and Standing Financial Instructions | WAHT-CG-463 |
| • Health & 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-01 |
| • Information Security Policy | |
| • Complaints Policy and Procedure | WAHT-PS-01 |
| • Disciplinary Policy and Procedure | WAHT-HR-017 |
| • Public Interest Disclosure (whistleblowing) Policy | WAHT-HR-015 |
| • Standards of Business Conduct Guidelines – Declaration of Interests and Acceptance of Gifts and Hospitality | WAHT-HR-525 |
| • Incident Reporting Policy | WAHT-CG-008 |
| • Income Distribution Policy | TBC |

| Standard Operating Procedure | |
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| Sponsorship | |
| Peer Review | |
| Assess, Arrange and Confirming C&C | |
| Safety Reporting | |
| Research Misconduct and Fraud | |
| Research Governance Audit | |
| Streamlined HR Processes for Research Policy | |
| Consent in a paediatric setting | |
| Consent and the mental capacity act | |

### b. External

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## 10. Background

### 10.1 Equality Requirements

The assessment conducted for this policy revels no equality issues. The record of the assessment is appended (Supporting Document 1)

### 10.2 Financial Risk Assessment

A financial risk assessment has been performed and appended and reveals that there are no immediate financial implications to this policy (Supporting Document 2).

### 10.3 Consultation Process

This document will be circulated to the Chair of the Research Expert Forum, the Key Document Approval Group, Divisional Management Teams, Corporate Heads, and the Clinical Governance Group.

## 11. Approval Process

This policy will be approved by the Trust Leadership Group / Clinical Governance Group

## 12. Version Control

| Date | Amendment | By: |
|---|---|---|
| January 2008 | Mental Capacity Act information included in consent section | Amanda Jones |
| October 2012 | Minor revisions to incorporate "Governance arrangements for research ethics committees: a harmonised edition" effective from September 2011.<br>Update to finance section 5, to include use of national commercial costing templates | Kelly Spencer |
| January 2016 | Minor revisions and updates | Charlotte Passingham |
| June 2016 | Revisions to bring the policy in line with HRA requirements | Charlotte Passingham |
| June 2018 | Revisions to bring policy in line with Trust Policy Template, GDPR and UK Policy Framework for Health and Social Care. Clarified sections, and made some clearer | Emma Rowan |
| June 2021 | Amendments to dates<br>Changes to name to R&I Department to reflect branding<br>Minor amendments to ease reading<br>Addition of outline of quality processes<br>Clarification around some processes<br>Inclusion of Information Governance and GDPR<br>Addition of information about the EDGE database | |
| 3rd December, 2024 | Document review date extended to 3rd June, 2025, awaiting governance. | Anna Walker |

## 13. Appendices

**Appendix 1: Good Clinical Practice**
**Appendix 2: Implications of the Mental Capacity Act on Research**
**Appendix 3: Definitions**
**Appendix 4: Monitoring**

## Appendix 1: Good Clinical Practice

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.

## Appendix 2: Implications of the Mental Capacity Act on Research

The Mental Capacity Act[1] was developed to assist and support people who may lack capacity, but still allow them to participate in research studies.

1. The Act does not have a strict definition of research, therefore, research may:
   - Provide information that can be applied to an illness, disorder of condition
   - Demonstrate how effective and safe a new treatment is
   - Add to evidence that one from of treatment works better than another
   - Add to evidence that one from of treatment is safer than another
   - Examine wider issues (i.e. capacity issues)

2. Researchers should assume that a person has capacity; unless there is proof that they lack capacity to make a specific decision. The person should receive support to try to help them make their own decision. The person whose capacity is in question has the right to make decisions that others might not agree with, and they have the right not to take part in research.

3. The Act mainly covers medical and social care research, but this can be extended to other areas:
   - Is 'intrusive' – if the research is 'intrusive', it would normally require the consent of a person with Capacity in order for it to be lawful; this must be undertaken involving the person who lacks the capacity to consent at all times without exception
   - Involves people with an impairment of, or a disturbance in the functioning of their mind or brain, which makes them unable to decide whether or not to agree to take part.
   - Is not a clinical trial covered under MHRA.

4. The responsibility of meeting the requirements of the Act lies with the 'appropriate body'; this is an organisation that can approve research projects. In England and Wales this would be the Research Ethics Committee, supported by the researchers conducting the research.

5. Potential benefits of research for a person who lacks capacity could include (these may be direct or indirect benefits):
   - Developing more effective ways of treating a person or managing their condition
   - Improving the quality of healthcare, social care or other services they have access to
   - Discovering the cause of their condition
   - Reducing the risk of harm

6. Before starting the research the research team must endeavour to:
   - Obtain approval from the 'appropriate body'
   - As a matter of good practice, seek views of carers and other relevant people before involving a person who lacks capacity in research (this individual must not be acting in a professional or paid capacity (person's solicitor))
   - Respect the objections, wishes and feelings of the person involved
   - Place more importance on the person's interests than those of science and society

[1] *Mental Capacity Act 2005 (c.9.) Office of Public Sector Information.*

## Appendix 3: 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

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 4: Monitoring

| Key control: | Checks to be carried out to confirm compliance with the Policy: | How often check carried out: | Respons-ible for check: | Results check reported to: | Frequency of reporting: |
|---|---|---|---|---|---|
| R&I Capability and Capacity Review | Review of study procedures to assess compliance with SOP | At start of study | R&I Facilitators | Trust signatories | Once per study |
| Training in GCP and SOPs | GCP training and SOP training and assessments to be carried out | Ongoing programme | Research Operations Lead | N/A | N/A |
| Monitoring of Trust-sponsored studies | Document checks and interviews | Determined per study | Monitors | Research Operations Lead | On identification |
| Monitoring from external Sponsors / Trials units | External monitors assess study for compliance with protocol and GCP | Determined per study | Sponsor | R&IR&I Department R&I Department | Determined per study |
| Auditing of research studies | 4 studies to be selected a year for auditing | Annual | Auditors | Research Operations Lead | Annual |
| MHRA inspections | Can be on individual studies or organisation | Risk-based, no timelines | MHRA | Research Operations Lead | Undefined |
| CQC Inspections | TBC – defining metrics for reporting | TBC | TBC | TBC | TBC |
| Amendments submitted to R&I Department for review | Documentation reviewed for compliance with policy | Determined per study | Research Facilitators | Research Operations Lead | Undefined |
| Monitoring questionnaire | Questionnaire sent out to identify breaches to this policy | Annual per study | Research Facilitators | Research Operations Lead | Annual |
| Reporting of breaches, misconduct and fraud | Investigations, disciplinary and fraud procedures followed | On identification | All staff | Research Operations Lead / AMD | On identification |
| Reporting of SAEs | Reported to R&I Department for review | As identified | Research Facilitators | Escalated to Research Operations Lead / AMD | On identification |
| R&I budget subject to financial audit | Reviewed for compliance with SFIs and CRN reporting | Annual | Finance | Research Operations Lead | Annual |

## 14 Supporting Documents

*Supporting Document 1* *Equality Impact Assessment*
*Supporting Document 2* *Financial Risk Assessment*

## Supporting Document 1 - Equality Impact Assessment Tool

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

| | | Yes/No | Comments |
|---|---|---|---|
| **1.** | **Does the Policy/guidance affect one group less or more favourably than another on the basis of:** | | |
| | • Race | No | |
| | • Ethnic origins (including gypsies and travellers) | No | |
| | • Nationality | No | |
| | • Gender | No | |
| | • Culture | No | |
| | • Religion or belief | No | |
| | • Sexual orientation including lesbian, gay and bisexual people | No | |
| | • Age | No | |
| **2.** | **Is there any evidence that some groups are affected differently?** | No | |
| **3.** | **If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?** | N/A | |
| **4.** | **Is the impact of the Policy/guidance likely to be negative?** | N/A | |
| **5.** | **If so can the impact be avoided?** | N/A | |
| **6.** | **What alternatives are there to achieving the Policy/guidance without the impact?** | N/A | |
| **7.** | **Can we reduce the impact by taking different action?** | N/A | |

If you have identified a potential discriminatory impact of this key document, please refer it to Assistant Manager of Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Assistant Manager of Human Resources.

## 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