journey to change

NHS
Tees, Esk and Wear Valleys
NHS Foundation Trust

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Contents

1 Introduction

The Tees, Esk & Wear Valleys NHS Foundation Trust (TEWV NHS FT) recognise the importance of research for the successful promotion and protection of health and wellbeing. However, research can involve an element of risk, both in terms of return on investment and sometimes for the safety and wellbeing of the research participants. Therefore, correct governance of research is essential to ensure that the public can have confidence in, and benefit from, high quality research in health and social care.

The *UK Policy Framework for Health and Social Care Research* sets out principles of good practice in the management and conduct of health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research. This is to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public. This policy framework replaces the Research Governance Framework (DoH, 2005) previously issued in each of the four UK countries and sets out 19 principles serving as a benchmark for good practice that the management and conduct of all health and social care research in the UK are expected to meet. The principles are as follows:

- Safety
- Competence
- Scientific and Ethical Conduct
- Patient, Service User and Public Involvement
- Integrity, Quality and Transparency
- Protocol
- Legality
- Benefits and Risks
- Approval
- Information about the Research
- Accessible Findings
- Choice
- Insurance and Indemnity
- Respect for Privacy
- Compliance
- Justified Intervention*
- Ongoing Provision of Treatment*
- Integrity of the Care Record*
- Duty of Care*

*These apply to interventional research only, where a change in treatment, care of other services is made for the purpose of research.

All NHS organisations must comply with the *UK Policy Framework for Health and Social Care Research*. Research governance is one of the core standards for health care

requiring NHS organisations to have systems in place to ensure the principles and requirements of the framework are consistently applied. Further details on each of these principles are documented in Appendix 1. Health care organisations have to take this standard into account in discharging their duty of quality under *Section 45 of the Health and Social Care (Community Health Standards) Act 2003*[2].

TEWV is a partner organisation of the National Institute for Health Research (NIHR) Clinical Research Network: North East and North Cumbria (CRN NENC). TEWV is committed via the Partnership Agreement with the CRN to streamline study set up with a view to increase the amount of NIHR portfolio research carried out locally and in the UK as a whole.

This policy is critical to the delivery of Our Journey To Change and our ambition to co-create safe and personalised care that improves the lives of people with mental health needs, a learning disability or autism. It helps us deliver our three strategic goals as follows:

This policy supports the trust to co-create a great experience for all patients, carers, and families from its diverse population by inviting members of the patient and public involvement team to provide insight and feedback. With this support the research ensures accessibility to relevant populations with the aim to provide outstanding and compassionate care whilst delivering research.

This policy supports the trust to co-create a great experience for our colleagues by supporting them to be involved in research. This can be as participants, as researchers themselves or as facilitators of research by promoting research to service users. Being involved, colleagues can feel as though they are making a meaningful contribution to care through research.

This policy supports the trust to be a great partner with the National Institute of Health Research (NIHR) and Health Research Authority (HRA) by sharing an understanding of the needs and strengths of our communities. We would like to be widely recognised for improving people's health and wellbeing and working innovatively to protect and promote the interests of patients and the public in health and social care research.

2 Why we need this policy

2.1 Purpose

This policy provides a framework for the conduct and management of research across TEWV which is formulated with reference to the standards and guidelines outlined in the *UK Policy Framework for Health and Social Care Research.*

This policy facilitates a safe system of high quality research that enables improvements in patient care and greater organisational efficiency and effectiveness by:

- Enhancing ethical and scientific standards and promote good research practice

- Clearly defining accountability and responsibility for research governance
- Informing all staff of the appropriate procedures for conducting research within the NHS

2.2 Objectives

- The policy is needed to safeguard participants in research, protect researchers/investigators (by providing a clear framework within which to work), enhance ethical and scientific quality, mitigate risk, monitor practice and performance, promote good practice and ensure that lessons are learned.

3 Scope

This policy and procedure applies to all staff and external researchers who wish to undertake research within the Trust. This policy does not apply to audit or service evaluations. For guidance on the differentiation between research, audit and service evaluations, please refer to the **definitions**.

3.1 Who this policy applies to

- This policy and procedure applies to all staff and external researchers who wish to undertake research within the Trust. This policy does not apply to audit or service evaluations. For guidance on the differentiation between research, audit and service evaluations, please refer to the definitions.
- The policy is reviewed and approved by the Research Governance Group which consists of service users, staff and lay members of the public, with members of the group having protected characteristics

Respect
- Listening
- Inclusive

Compassion
- Kind
- Supportive

Responsibility
- Honest
- Learning

- Working in partnership
- Recognising and Celebrating
- Ambitious

3.2 Roles and responsibilities

All organisations conducting, sponsoring, funding or hosting health and social care research must have systems to ensure that they and their staff understand and follow the standards set out in the framework. A summary of the key responsibilities of people and organisations accountable for the conduct of research has been provided in Appendix 2.

The Chief Executive has overall responsibility for the strategic direction and operational management of TEWV, including ensuring that the Trust policies comply with all legal, statutory and good practice guidance requirements.

The Trust Board has responsibility for setting the strategic context in which organisational policies and procedures are developed, and for establishing a scheme of governance for the formal review and approval of policies.

Role	Responsibility
Clinical Director for R&D supported by the Research Governance Group	• To ensure that the Trust's services fully implement the NHS UK Policy Framework for Health and Social Care Research. • To establish appropriate working relationships with a range of Trust corporate and clinical departments and external partners critical to good research governance (including the NIHR Clinical Research Network). • To ensure increasing user and carer involvement in all stages of the research process. • To report to the Quality Assurance Committee on research governance matters. • To contribute to the development of the R&D strategy and monitor its implementation
Head of Research	• To lead the development of the R&D strategy and monitor its implementation • To establish appropriate working relationships with a range of Trust corporate and clinical departments and external partners critical to good research governance (including the NIHR Clinical Research Network). • To facilitate partnership working with Higher Education Institutes and other organisations to support the development of new research grants relevant to our Trust population and needs. • To contribute to the development of an innovations service in the Trust

R&D Manager	• Ensuring efficient systems are in place within the Trust to support the research process • Research management and governance • Streamlining research approvals procedures • To manage implementation of R&D Strategy • Day-to-day management of research activity
Researchers	• Ensure compliance with the UK Policy Framework for Health and Social Care Research • Ensure all research has been approved by an appropriate Research Ethics Committee (REC) where appropriate. However, NHS staff research only requires HRA approval • Comply with any current legislation and policy requirements relating to research and implement effectively • Comply with Trust R&D Standard Operating Procedures • Ensure patients, users and carers are provided with information on research that may affect their care • Maintain a record of their research activity being undertaken in the Trust • Notify the R&D department of any amendments, adverse incidents or complaints arising from the research • Assist with monitoring and auditing when approached • Submit progress and final reports to aid research monitoring • Promote a quality research culture in the Trust

4 Policy

4.1 Equality and diversity statement

The Trust is committed to providing equality of opportunity, not only in its employment practices but also in the services for which it is responsible. As such, this document has been screened, and an Equality Impact Assessment has been carried out on this document, to identify any potential discriminatory impact. If relevant, recommendations from the assessment have been incorporated into the document and have been considered by the approving committee. The Trust also values and respects the diversity of its employees and the communities it serves. In applying this policy, the Trust will have due regard for the need to:

- Eliminate unlawful discrimination
- Promote equality of opportunity
- Provide for good relations between people of diverse groups

4.2 Legal and professional obligations

Approval for all research projects is required through the Health Research Authority (HRA). The HRA developed the UK Policy Framework for Health and Social Care Research. The document outlines principles of good governance that apply to all research within the remit of the Secretary of State for Health and Social Care

4.3 HRA Approval and R&D confirmation for research to commence

All research projects taking place within the NHS must have HRA (Health Research Authority) Approval before any research activity can commence, this is to ensure high quality health and social care research is being conducted to improve people's health and well-being. Their core purpose is to protect and promote the interests of patients and the public in health and social care research. HRA system brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee so that only one application needs to be submitted.

The dignity, rights, safety and wellbeing of participants must be the primary consideration in any research study. The Department of Health requires that research involving patients, service users, care professionals or volunteers, or their organs, tissue or data is reviewed independently to ensure it meets ethical standards. The NHS (REC) is not accountable in any way to NHS Trusts, and in particular is separate from Trust Research Departments in respect of the accountability for their operational processes and decision-making. The REC is part of the HRA Assessment and is only required for studies including service users, patients and carers, for studies involving NHS staff only REC is not needed. All studies must have appropriate arrangements for gaining consent. Particular care is needed for obtaining consent for children and vulnerable adults such as those with mental health problems or learning disabilities. Where ethical approval is obtained for research with participants lacking capacity to consent, the requirements of the Mental Capacity Act 2005 must be followed (see definition).

This process allows the Trust R&D team to focus on assessing, arranging and confirming the capacity and capability to deliver a study.

The R&D manager will ensure that the process of research confirmation is as streamlined as possible, and work with corporate departments to deal with barriers in the system which delay opening studies.

Research applications for all approvals must be made using the Integrated Research Applications Service (IRAS) via http://www.myresearchproject.org.uk/ and further guidance can be found on the HRA website or by contacting the TEWV R&D office

Once research approvals are in place, significant changes or developments to research proposals, such as change in protocol, must be communicated to the HRA, through a notice of substantial amendment (see definition). The amendment is applied for under the amendment tab on the IRAS page. The notice of substantial amendment should be emailed to the Research Ethics Committee (REC). With regard to a non-substantial amendment (see definition) you are required to notify the NHS/HSC participating organisations and use the template form. More information can be found via http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/.

The Trust has an established organisational structure for managing R&D. The Research Governance Group (RGG) provides assurance to the Quality Assurance Committee that all research projects have adequate consideration of; sponsorship, ethical review, scientific review, evidence of funding, safety of participants, researchers and other staff, Trust resource requirements, data protection and intellectual property.

4.4 Scientific review

All existing sources of evidence must be considered carefully before undertaking research. Research which duplicates other work unnecessarily, or which is not of sufficient quality to contribute something useful to existing knowledge, is unethical.

Every proposal must be subjected to review by experts in the relevant fields able to offer independent advice on its quality. It is the research sponsor's responsibility to ensure adequate peer review is in place which is proportional to the scale of the research. For example:

- Portfolio research has been peer reviewed as part of the adoption process.
- Externally funded research (i.e. from a research council or charity) - it is expected that peer review would have been undertaken as part of the application process.
- Commercial sponsored projects - it is the responsibility of the commercial sponsor to arrange peer review.

- Student projects - the peer review processes of the university involved should normally be adequate.
- Self-funded/ own account research where the Trust is to act as the research sponsor - the R&D department will arrange an independent peer review.

Evidence of a favourable peer review must be in place before applying for HRA approval.

4.5 Research funding

The R&D department does not directly fund research and funding for projects must be identified prior to HRA application. It is recognised that some non-portfolio studies, particularly conducted as part of postgraduate education, will not be externally funded, but any costs to services as a result of hosting such research should be acknowledged and minimised. All externally funded research projects should contain clear financial arrangements and should be realistically costed with support of the R&D Office in liaison with Trust Finance Department. Research funding types (service support, research costs and treatment costs) definitions are found in section 5. The Trust R&D Office will advise and facilitate costing including allocation of an appropriate overhead.

Funding for commercially contracted research (funded and sponsored by a commercial company) should cover the full costs incurred including appropriate Trust overheads. For all commercial research at TEWV there will also be a non-refundable R&D fee.

All research income will be managed in separate research accounts within the R&D department. Trust budget holders are required to authorise all expenditure from the research accounts and all credits to budget accounts. The Trust Finance Department will monitor and report on accounts for research purposes in accordance with Trust finance policies.

The Trust receives NHS service support funding via the Clinical Research Network North East and North Cumbria (NIHR CRN NENC) in relation to its activity on NIHR portfolio studies. The R&D Manager will work together with the Trust Finance Department to allocate CRN funding appropriately for research delivery, and will report back to the CRN on use of resources.

The R&D Office must be informed of all external grant funding applications which Trust staff are involved in, either as lead or co-applicants. This should occur before the application is submitted to allow assessment of whether the Trust can host the proposed research. R&D Office support is required for all external grant funding applications by Trust staff. The R&D Office will consult with the Finance Department as part of this process. Where external funding applications include Trust costs, costings should be obtained through the R&D Department.

Where a NIHR portfolio study requires Excess Treatment Costs to be met locally, discussions should take place as early as possible with the R&D Manager so that mechanisms can be put in place to plan the reimbursement of such costs.

4.6 Clinical Trials of investigational medicinal product

There is a strict legal framework within which clinical trials of Investigational Medicinal Products (ctIMPs) must be conducted. The EU Clinical Trials Directive and GCP Directive (transposed in UK Law through the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031) and Amendment Regulations 2006 (SI 1928), state that clinical trials must

be carried out to the principles of Good Clinical Practice (GCP) based on Article 2 to 5 of the GCP Directive.

This legislation states it is against the law to start or conduct, or to recruit participants to a clinical trial involving a medicinal product until there is HRA approval which involves a Clinical Trials Authorisation from the licensing authority, the Medicines and Healthcare products Regulatory Agency (MHRA).

The Trust will not issue Trust R&D confirmation for a ctIMP study without evidence of HRA approval for the study and evidence that a Clinical Trials Authorisation has been obtained from MHRA. During risk assessment for ctIMP studies the Trust will also consider issues regarding the long-term management of patients at the end of the trial in terms of appropriate exit strategies relevant to each study. The Trust will also require confirmation that monitoring arrangements are in place for ctIMP studies (see Audit and Monitoring) and confirmation of arrangements for safety reporting before Trust R&D approval will be granted.

4.7 Use of patient data

4.7.1 In Specific Research Projects

Data and information collected in the course of research must be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification to ensure data integrity. Furthermore, the appropriate use and protection of patient data should be paramount and particular attention must be given to systems for ensuring confidentiality of personal information.

The handling of personal information in research must be compliant with Trust information governance policies in relation to the General Data Protection Regulation (GDPR) introduced in May 2018 and any data or confidentiality breaches must be reported using relevant Trust policy.

To ensure the security of systems used in research for data collection, storage and transfer of data, all uses of patient-identifiable data for research purposes must be reviewed by the Trust Caldicott Guardian. Evidence of Caldicott approval must be provided for studies where patient identifiable information is required to be used in the research before HRA approval is granted. If data is to be used for research without consent then evidence of approval from NIGB must also be provided to Trust R&D before confirmation will be granted.

All use of patient data for research purposes requires the consent of the patient. There are some exceptions where patient data can be used without consent under Section 60 of the Health and Social Care Act 2001. Requests for this go through the Confidentiality Advisory Group (CAG). CAG is in place to protect and promote the interests of patients and the public whilst at the same time facilitating appropriate use of confidential patient information for purposes beyond direct patient care. Applications to CAG must be booked for review prior to HRA submission. To find more information on the application process, please refer to http://www.hra.nhs.uk/research-community/applying-for-approvals/confidentiality-advisory-group-cag/

National Data Opt Out - using confidential information for national research and planning purposes

The National Data Opt Out (NDO) prevents NHS Digital from sharing identifiable patient data for planning and research purposes.

When screening service user records for research purposes, we will comply with the NDO by using the MESH system to check NHS numbers against those with national data opt-outs registered. The records of those who have opted out will not be screened for research purposes.

4.8 Patient and carer involvement

Service users and carers, where possible, should be involved in the design, conduct, analysis and reporting of research. National organisations, such as INVOLVE (see http:www.invo.org.uk/), are working to support and promote active public involvement in the NHS and this includes involvement in research. Chief and principal investigators will be encouraged to consider PPI, as appropriate, in their research. We actively seek studies that cover a broad range of conditions within the mental health spectrum with the aim to be as inclusive as possible. Whilst we strive to ensure inclusivity it is not something we can ensure as it is dependent upon the study at hand and/or who chooses to participate.

Trust policies and procedures regarding PPI should be followed, including the provision of appropriate expenses.

The R&D Office will encourage investigators to include service user and carer representation on any steering groups in relation to research studies.

Appropriate training will be provided for service users and carers who become significantly involved in Trust R&D.

4.9 Study agreements and contracts

Before a piece of research can start, sponsors and host institutions need to have appropriate agreement in place which set out the responsibilities of the parties involved in research. The UK Clinical Research collaboration (UKCRC) and stakeholders have developed a suite of model agreements as follows:

- Commercial ctIMP studies: Commercial companies are expected to use the national model Clinical Trial Agreement (mCTA or CRO mCTA) for pharmaceutical companies working in the NHS.
- Commercial studies involving medical devices: Commercial companies are expected to use the national model Devices Clinical Trials Agreements (Devices mCTA).
- Non-commercial studies: non-commercial partners are expected to use the national non-commercial Clinical Trial Agreement (mNCA)

The model agreements can be found at:

https://www.nihr.ac.uk/documents/model-site-agreements-model-contracts-standard-research-agreements/11612

Appropriate employment arrangements must also be in place for research staff. For NHS staff, evidence of their employment status will be required. Researchers not employed by

any NHS organisation and requiring access to the Trust will be required to complete a Research Passport form, and when completed send to the R&D office. More information, including the form can be found via https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx#HR-Good-Practice-Resource-Pack

It is the responsibility of the Chief Investigator or Principal Investigator to ensure staff have the necessary contracts or letters of access in place before staff begin research work within the Trust.

All externally funded research will have contractual arrangements in place. All contracts must be signed by the Chief Executive unless delegated to Directors or the Clinical Director for R&D.

4.10 Risk assessment and management

Research can involve increased risks arising from the research activity as opposed to the baseline level of risk arising from normal clinical practice.

Risk should be assessed during protocol development to manage risk with patient autonomy and safety as paramount concerns. Risk will be controlled by systems in place to ensure that:

- Projects have a sponsor
- Projects are peer-reviewed
- Projects are approved by the HRA and confirmed by R&D
- Research proposals are taken through a staged approach of approval before the research can commence
- Sponsors and Researchers act within the Research Governance Framework
- Staff have appropriate training
- Research is appropriately audited and monitored

All proposals will be assessed for risk by the R&D Office. Where serious risks are identified which are anticipated to persist despite the above controls, a proposal will be formally discussed at the Research Governance Group and the Quality Assurance Committee as appropriate. R&D confirmation may in some circumstances not be granted until such discussions have taken place and agreement achieved.

Researchers should immediately notify the R&D Manager, the study sponsor and the HRA that originally approved the study of any unanticipated problems involving risks to subjects or others. In addition, all adverse incidents should be reported as documented in the appropriate Trust policies and procedures.

For ctIMP studies, the Research Sponsor is required to report unexpected serious adverse reactions to the Medicines and Healthcare Products Regulatory Agency (MHRA) within its deadlines, and, Researchers should follow the conditions of ethical approval (see Monitoring and Audit section for reporting ctIMPs).

The responsibility for project management of research lies with the chief or principal investigator, with appropriate delegation to other members of the research team (research assistants, clinical studies officers and other clinical colleagues). The R&D Office will offer support and advice on project management matters, and coordinate local steering groups for large-scale NIHR portfolio studies as appropriate.

4.11 Audit and Monitoring

Organisations and individuals involved in research are expected to be able to demonstrate compliance with the *UK Policy Framework for Health and Social Care Research* and the requirements in legislation and regulations described within the Framework. Systems are required that should include a risk-based programme of routine and random monitoring and audit.

It is a statutory requirement that ctIMP studies are conducted in accordance with the principles of Good Clinical Practice (GCP). GCP is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting ctIMPs that involve the participation of human subjects. Compliance with GCP provides assurance that the rights, safety and well-being of trial subjects are protected and that the results of clinical trial are credible and accurate. Working to GCP standards involves meeting stringent criteria in respect of study documentation, safety monitoring and reporting, data capture and management, study monitoring, training of study personnel and study conduct in general. Meeting these standards has significant resource implications in terms of time, personnel, equipment, software etc. It is imperative that investigators plan and budget for meeting these obligations of regular monitoring. More information on GCP can be found on the Trust intranet page.

Safety reporting to MHRA is also a legal requirement which allows the authority to identify when trial participants are at increased risk and where to assess when a trial should be modified or stopped. Chief Investigators, Principal Investigators and Research Sponsors have responsibilities for the recording and reporting of adverse events or reactions within a ctIMP study. Certain types of events, (Suspected, Unexpected, Serious Adverse Reactions –SUSARs) have particularly strict requirements with expedited reporting of 7 days (fatal and life-threatening) and 15 days (non-fatal or non -life threatening). All ctIMP studies must have appropriate arrangements for safety reporting clearly outlined in the study protocol.

A percentage of randomly selected research projects taking place across the Trust will be monitored and audited each year for compliance with the agreed research proposal and the standards in accordance with the *UK Policy Framework for Health and Social Care Research*. The Trust will ensure that all data, records and other materials are kept confidential. All Principal Investigators should maintain a Trial Site File with all relevant research documents and approvals. This must, on reasonable notice, be available for inspection.

Guidance on how to prepare for an internal monitoring and audit inspection is provided on the Trust intranet page in the form of a R&D standard operating procedure.

4.12 Indemnity

TEWV provides standard NHS indemnity to compensate anyone harmed by negligence by its employees. The Trust does not provide compensation for non-negligent harm. NHS Indemnity may be extended to research partners, e.g., academic researchers, who are not directly employed by the NHS through honorary research contracts where appropriate (i.e., where the researcher has a direct bearing on the care on the Trust's patients). For non-commercial university-sponsored studies, the university may provide additional indemnity for non-negligent harm via its own insurance arrangements

For commercial ctIMP studies, commercial companies will be expected to provide cover for negligent and non-negligent harm under the standard Clinical Trial Compensation Guidelines recommended by the Association of the British Pharmaceutical Industry. This should be clearly outlined in the Clinical Trial Agreement.

4.13 Research Misconduct

Research misconduct includes, but is not limited to, the following, whether deliberate, reckless or negligent.

4.13.1 Misconduct in relation to grant applications and fund utilisation:

- Failure to obtain appropriate permission to conduct research
- Deception in relation to research proposals
- Fraud or other misuse of research funds or research equipment

4.13.2 Misconduct in relation to treatment of/ dealing with experimental subjects:

- Unethical behaviour in the conduct of research, e.g. in relation to research subjects
- Unauthorised use of information which was acquired confidentially
- Deviation from good research practice, where this results in unreasonable risk of harm to humans, animals or the environment

4.13.3 Misconduct in relation to analysis and reporting of findings:

- Fabrication, falsification or corruption of research data
- Distortion of research outcomes by distortion or omission of data
- Dishonest misinterpretation of results
- Publication of data known or believed to be false or misleading
- Plagiarism, or dishonest use of unacknowledged sources
- Misquotation or misrepresentation of other authors
- Inappropriate attribution of authorship

4.13.4 Misconduct in relation to misconduct of others:

- Attempting, planning or conspiring to be involved in research misconduct
- Inciting others to be involved in research misconduct
- Collusion in or concealment of research misconduct by others

The Trust's system for monitoring and auditing provides a mechanism for detecting any evidence of mismanagement, fraud or other scientific or professional conduct. Suspected fraud or misconduct will be investigated using the Trust's policies and disciplinary procedures. Further details on the management of suspected research fraud or misconduct is outlined in the R&D Standard Operating Procedure available on the Trust intranet pages.

4.14 Research Dissemination

It is expected and good practice of researchers to disseminate established findings (positive or negative), published in a way that allows critical review and dissemination through the accepted scientific and professional channels. Information on research being conducted in the Trust must be accessible most importantly to those who participated, staff, the public and to all those who could benefit from the findings.

Information about what research is being conducted and what research has been completed will be made available to all staff through the Trusts intranet site. In addition, internal communications such as the Trust's internal magazine will be used to inform staff of research developments.

Research findings will be published in peer-review journals or other relevant publications where possible. The format will be subject to the specific journal requirements. Researchers are required to share their publication plans through the IRAS form and to submit a copy of any accepted papers to the Trust Library service, so evidence of dissemination is held by the organisation.

4.15 Intellectual property

NHS Trusts are required by the Department of Health to protect and manage intellectual property arising from R&D funded by the NHS. A Trust policy is available with detailed information outlining the effective identification, protection and management of intellectual property within TEWV

The potential for generation of intellectual property will be considered by the R&D Office as part of the research approval process, and all intellectual property outputs from the Researcher's research activity in the Trust, should be declared to the R&D department for our records, e.g. peer-reviewed papers. Advice should be sought from the R&D Manager and the Innovations Coordinator before publicly disclosing any work where there may be likelihood of intellectual property.

4.16 Staff training and development

Appropriate staff training and development will be provided to improve knowledge of the research process, systems, guidance and support available so as to develop capacity, expertise and skills required to undertake research.

To ensure that all studies are carried out in accordance with the principles of GCP, staff must receive GCP training on a regular basis. The Trust requires that GCP training is updated at least every three years. GCP courses are available through the NIHR CRN. The R&D office can facilitate the identification of GCP courses either the online or face to face version.

5 Definitions

Term	Definition
Adverse Effects	Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment.
Caldicott Guardian	Responsible for agreeing and reviewing internal protocols governing the protection and use of patient-identifiable information by the staff of their organisations.
Chief Investigator	The authorised health professional who takes primary responsibility for the design, conduct and reporting of a study.
Clinical Audit	'A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change' (Standards for Better Health, DH, 2004). Accessed from: http://webarchive.nationalarchives.gov.uk/20121206105212/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4132991.pdf
Clinical Research Network (CRN)	The CRN supports patients, the public and health and care organisations across England to participate in high-quality research, thereby advancing knowledge and improving care. The CRN is comprised of 15 Local Clinical Research Networks and 30 Specialties who coordinate and support the delivery of high-quality research both by geography and therapy area. National leadership and coordination is provided through the CRN Coordinating Centre.
Costs	Costs relating to research in the NHS are defined in the guidance note 'Attributing the costs of health and social care research' (https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research) (Last updated in August 2019) Three costs are distinguished; • Research costs - attributable directly to the research activity and met by research grant funding, • NHS support costs - the costs to the NHS of hosting the research, now met by Trusts via research network funding and • Treatment costs - the patient care costs, which would continue to be incurred if the patient care service in question continued to be provided after the R&D study had stopped.
Health Research Authority	A governing body established to promote and protect the interests of patients, streamline regulation and promote transparency in health and social care research. We aim, with partners, to make the UK a great place to do health research, to build confidence and participation and so improve the nation's health. See http://www.hra.nhs.uk/about-the-hra/who-we-are/

Indemnity	Provides protection against any action by an individual, a group or an organisation that believe they received bad or negligent services, and incurred a loss as a result. Most professional bodies have professional indemnity cover; in some cases it is compulsory. The limit of an indemnity policy relates to the maximum amount of money that an individual or organisation will pay out in the event of a claim being made.
Integrated Research Application System (IRAS)	A single system for applying for the permission and approvals for health and social care research in the UK. See http://www.myresearchproject.org.uk
International Conference on Harmonization Good Clinical Practice	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 clinical trial data are credible. See https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
Medicines and Healthcare products Regulatory Agency (MHRA)	The Executive Agency of the Department of Health protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely. See http://www.mhra.gov.uk
Mental Capacity Act 2005	Places clear responsibilities on researchers seeking participants lacking in capacity (see Trust MCA guidance)
National Institute of Health Research (NIHR)	The NIHR is the nation's largest funder of health and care research. Working with experts across healthcare research and the NHS, NIHR identifies which illnesses and conditions need more research to help improve people's lives.
NIHR Portfolio	A national database of high quality studies which have been deemed eligible to receive NHS support.
Non substantial Amendment	Where small changes have been adopted to your research, that is not due to have significant effect on the study for example; minor changes to the protocol or other study documentation, e.g. correcting errors, updating contact points, minor clarifications; changes to the chief investigator's research team; changes in funding arrangements; inclusion of new sites and investigators in studies other than CTIMPs.
Research	'An attempt to devise generalisable or transferable new knowledge' (UK policy framework for health and social care research 2017).

Researchers	Those conducting the study and bear day-to-day responsibility for the conduct of the research at the trial site
Service Evaluation	Designed and conducted solely to define or judge current care (HRA decision tool 2017)
Substantial Amendment	An amendment to the terms of the application, or to the protocol or any other supporting documentation, that is likely to affect to a significant degree, including; the safety or physical or mental integrity of the subjects of the study; the scientific value of the study; the conduct or management of the study; or the quality or safety of any investigational medicinal product used in the trial.
Suspected Unexpected Serious Adverse Reaction (SUSAR):	All adverse events that are suspected to be related to an investigational medicinal product and that are both unexpected and serious are considered to be SUSARs.

6 Related documents

[References to the procedures that are linked to this policy, and any other policies and procedures that the reader may need to refer to.]

Intellectual Property Policy

7 How this policy will be implemented

The policy will be implemented by;

- Being published on the Trust's intranet and external website.
- Disseminated through Line Management to all Trust employees through a line management briefing.

7.1 Implementation action plan

Activity	Expected outcome	Timescale	Responsibility	Means of verification/ measurement
n/a				

7.2 Training needs analysis

Staff/Professional Group	Type of Training	Duration	Frequency of Training
All staff conducting research	Bespoke on request, may include GCP training or procedures in R&D SOP's		As required

8 How the implementation of this policy will be monitored

Number	Auditable Standard/Key Performance Indicators	Frequency/Method/Person Responsible	Where results and any Associate Action Plan will be reported to, implemented and monitored; (this will usually be via the relevant Governance Group).
1	A percentage of research studies will be audited annually and reported back to the research governance group	Research Facilitator	Research Governance Group
2	Internal audit of the effectiveness of controls over research activity in the Trust	Audit One	Research Governance group

9 References

All Trust involved in research must ensure they have read and understood the UK Policy Framework for Health & Social Care v3.3

- UK Policy Framework for Health & Social Care V3.3 7/11/2017. Accessed from: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- Responsibilities of conducting research. Accessed from:
    - Roles and responsibilities - Health Research Authority (hra.nhs.uk)
- Office of Public Sector Information. (2003) Health and Social Care (Community Health Standards) Act 2003. Accessed from: http://www.opsiof .gov.uk/acts/acts2003/ukpga_20030043_en_
- Department of Health (2005). Mental Capacity Act. London, HMSO. Accessed from: http://www.legislation.gov.uk/ukpga/2005/9
- Department of Health (2018. Data Protection Act. London: Stationery Office. Accessed from: Data Protection Act 2018 (legislation.gov.uk)
- Department of Health (2001). Health and Social Care Act. Accessed from http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted

10 Document control (external)

To be recorded on the policy register by Policy Coordinator

Date of approval	18 May 2022
Next review date	18 May 2025
This document replaces	Research Governance Policy CORP-0050-v4
This document was approved by	Research Governance Group
This document was approved	10 March 2022
This document was ratified by	Management Group
This document was ratified	18 May 2022
An equality analysis was completed on this policy on	20 April 2022
Document type	Public
FOI Clause (Private documents only)	Not applicable

Change record

Version	Date	Amendment details	Status
3	26 August 2015	Amendment to Trust approval, Ethical review and minor changes throughout.	Withdrawn
4	01 October 2018	Updated Research Governance Framework (DoH, 2005) to UK Policy Framework for Health and Social Care Research (November, 2017). Additional information regarding training needs and how the policy will be monitored.	Withdrawn
5	18 May 2022	Full three year review with minor changes. Updated to Trust 'Our Journey to Change' template and hyperlinks updated. Links to SOPs removed as intranet updated. Amended the research approval process to include both Health Research Authority (HRA) and NHS Research Ethics Committee (REC) under one section.	Published

Appendix 1 - Equality Analysis Screening Form

Please note: The Equality Analysis Policy and Equality Analysis Guidance can be found on the policy pages of the intranet

Section 1	Scope
Name of service area/directorate/department	Research and Development
Title	Research Governance Policy
Type	Policy
Geographical area covered	Across Tees, Esk and Wear Valleys NHS Foundation Trust
Aims and objectives	To safeguard participants in research, protect researchers/investigators (by providing a clear framework within which to work), enhance ethical and scientific quality, mitigate risk, monitor practice and performance, promote good practice and ensure that lessons are learned.
Start date of Equality Analysis Screening	21/10/2021
End date of Equality Analysis Screening	04/03/2022

Section 2	Impacts
Who does the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan benefit?	The policy benefits all members of TEWV staff, and potential investigators by providing a clear guidance on how ethical approval is applied for and obtained.
Will the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan impact negatively on any of the protected characteristic groups?	• **Race** (including Gypsy and Traveller) **/NO** • **Disability** (includes physical, learning, mental health, sensory and medical disabilities) **NO** • **Sex** (Men, women and gender neutral etc.) **NO**

	• **Gender reassignment** (Transgender and gender identity) **NO** • **Sexual Orientation** (Lesbian, Gay, Bisexual and Heterosexual etc.) **NO** • **Age** (includes, young people, older people – people of all ages) **NO** • **Religion or Belief** (includes faith groups, atheism and philosophical beliefs) **NO** • **Pregnancy and Maternity** (includes pregnancy, women who are breastfeeding and women on maternity leave) **NO** • **Marriage and Civil Partnership** (includes opposite and same sex couples who are married or civil partners) **NO**
Describe any negative impacts	No negative implications will be felt by those who have protected characteristic, as the Policy is the same for all applicants.
Describe any positive impacts	

Section 3	**Research and involvement**
What sources of information have you considered? (e.g. legislation, codes of practice, best practice, nice guidelines, CQC reports or feedback etc.)	UK Policy Framework for Health & Social Care V3.3
Have you engaged or consulted with service users, carers, staff and other stakeholders including people from the protected groups?	Yes
If you answered Yes above, describe the engagement and involvement that has taken place	Yes - the policy was taken to the Research Governance Group which consists of service users, TEWV staff and lay members of the public, with members of the group having protected characteristics.
If you answered No above, describe future plans that you may have to engage and involve people from different groups	n/a

Section 4	Training needs
As part of this equality analysis have any training needs/service needs been identified?	No
Describe any training needs for Trust staff	None
Describe any training needs for patients	None
Describe any training needs for contractors or other outside agencies	None

Check the information you have provided and ensure additional evidence can be provided if asked

Appendix 2 – Approval checklist

To be completed by lead and attached to any document which guides practice when submitted to the appropriate committee/group for consideration and approval.

	Title of document being reviewed:	Yes / No / Not applicable	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Are people involved in the development identified?	Yes	
	Has relevant expertise has been sought/used?	Not applicable	
	Is there evidence of consultation with stakeholders and users?	Yes	
	Have any related documents or documents that are impacted by this change been identified and updated?	Not applicable	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
	Are supporting documents referenced?	Yes	
6.	**Training**		
	Have training needs been considered?	Yes	
	Are training needs included in the document?	yes	
7.	**Implementation and monitoring**		

	Title of document being reviewed:	Yes / No / Not applicable	Comments
	Does the document identify how it will be implemented and monitored?	Yes	
8.	**Equality analysis**		
	Has an equality analysis been completed for the document?	yes	
	Have Equality and Diversity reviewed and approved the equality analysis?	yes	E&D have reviewed and approved the Policy & appended Equality Impact Assessment on date 20/04/2022
9.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	approved by Research Governance Group on date 10/03/2022
10.	**Publication**		
	Has the policy been reviewed for harm?	Yes	
	Does the document identify whether it is private or public?	Yes	Public
	If private, does the document identify which clause of the Freedom of Information Act 2000 applies?	Not applicable	