

Research & Innovation Policy

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Status	LIVE		
Target Audience- who does the document apply to and who should be using it.	<p>This policy must be adhered to by research active employees including those holding an honorary contract, research passport or letter of access and covers all NIHR portfolio research activity, both commercial and non-commercial involving all clinical specialities across the Trust including:</p> <p>Research using patients, carers, volunteers and employees at the Trust</p> <p>Research using patient tissue, organs or data, even if obtained for clinical purposes and/or used for research purposes elsewhere, or obtained from elsewhere but used for research purposes involving the Trust Research taking place on Trust premises or involving Trust resources, including non clinical and laboratory based</p>		
Accountable Director	Research & Innovation Director/Clinical Lead		
Author/originator – Any Comments on this document should be addressed to the author	Research & Innovation Manager		
Division and Department	Corporate, Research & Innovation		
Implementation Lead	Research & Innovation Manager		
If developed in partnership with another agency ratification details of the relevant agency			

Equality Impact

Great Western Hospitals NHS Foundation Trust strives to ensure equality of opportunity for all service users, local people and the workforce. As an employer and a provider of health care, the Trust aims to ensure that none are placed at a disadvantage as a result of its policies and procedures. This document has therefore been equality impact assessed in line with current legislation to ensure fairness and consistency for all those covered by it regardless of their individuality. This means all our services are accessible, appropriate and sensitive to the needs of the individual.

Special Cases

There are no identified special cases for this policy.

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1 Document Details

1.1 Introduction and Purpose of the Document

To ensure all Great Western Hospitals NHS Foundation Trust (the Trust) employees actively involved in Research are aware of and comply with all Research and Innovation (R&I) standard operating procedures and adhere to the management and governance of research in line with the appropriate legislation and guidance provided by the Department of Health (DH) and other regulatory authorities.

It also identifies and instructs those participating in research to the Trusts expectations of conduct when carrying out research alongside recognised codes of practice including International Conference for Harmonisation Good Clinical Practice (ICH GCP) (Ref 3)

1.2 Glossary/Definitions

The following terms and acronyms are used within the document:

CI	Chief Investigator
CRN WoE	Clinical Research Network West of England
DH	Department of Health
GP	General Practitioner
HRA	Health Research Authority
HRA	Health Research Authority
ICH GCP	International Conference for Harmonisation Good Clinical Practice
IMP	Investigational Medicinal Product
IMP	Investigational Medicinal Product
ISF	Investigator site file
IVF	In vitro fertilisation
MHRA	Medicines and Healthcare Products Regulatory Agency
NHS	National Health Service
NHS	National Health Service
NIHR	National Institute of Health Research
NIHR LCRN	The National Institute for Health Research Clinical Research Network
PI	Principal Investigator
R & I	Research and Innovation
RM&G	Research Management and Governance
SOP	Standard Operating Procedure

Research – An attempt to derive generalisable or transferable new knowledge by addressing clearly defined questions with systematic and rigorous methods. Research may be aimed at understanding the basis and mechanism of disease, improving the diagnosis and treatment of a disease or designing better ways of delivering healthcare.

Participant – Patient, service user, carer, relative of the deceased, professional carer, other employee, or member of the public, who consents to take part in a study. In law, participants in clinical trials involving Investigational Medicinal Product (IMP) are known as subjects.

Chief Investigator (CI) – The person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design, conduct and reporting of the study, whether or not that person is an investigator at any particular site

Principal Investigator (PI) – The leader responsible for a team of individuals conducting a study at a site.

Sponsor – Individual, organisation or group taking responsibility for securing the arrangements to

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initiate, manage and finance a study. (A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all responsibilities in the UK Policy Framework for Health and Social Care Research that are relevant to the study.

Student Research – Research performed by a student as part of an educational qualification.

Investigational Medicinal Product (IMP) – A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial including a medicinal product which has a marketing authorisation but is, for the purposes of the trial, being used or assembled (formulated or packaged) in a way different from the approved form, or being used for an unapproved indication or when used to gain further information about an approved use.

Researchers – Those conducting the research.

2 Main Policy Content Details

2.1 Principles

Research falling under the scope of this policy must have explicit written authorisation from the R & I Manager or delegated authority prior to commencing. It is the R&I Manager's responsibility to ensure that all research conducted throughout the Trust has been through the feasibility process and has met all the necessary Trust and regulatory approvals. Any proposed site selection visits, site initiation visits, sponsor led monitoring and potential study closures must be communicated to the R&I department.

All research must be conducted in accordance with the UK Policy Framework for Health and Social Care Research and applicable regulations and guidance including the Medicines for Human Use (Clinical Trials) Regulations and International Conference for Harmonisation Good Clinical Practice (ICH GCP) (Ref 3) .

All employees actively involved in research must adhere to R & I standard operating procedures (Ref 4) and work instructions concerning the set up and delivery of research within the Trust.

All research must be carried out in accordance with the contractual agreements in place and follow the study protocol (pertaining to specific research projects). Where a study Protocol deviates from Trust Operating Procedures it will be escalated to the Medical Director, Director of Governance and Assurance and Chief Nurse for risk assessment and approval before authorisation to run the Trial can be given by the R&I Manager or delegate.

All **Investigational Medicinal Products** (IMPs) must be ordered, stored and dispensed by the Clinical Trials Pharmacy Team. Any exceptions/deviations from the Trust Medicines Control and Administration Policy (Ref 5) must be reviewed by the Director of Pharmacy and Medicines Optimisation and appropriate action taken. This may include a risk assessment and escalation to the Medical Director, Director of Governance and Assurance and the Chief Nurse for approval where appropriate.

This requirement relates to any research involving:

- Patients and users of the National Health Service (NHS). This includes all potential research participants recruited by virtue of the patient's or user's past or present treatment by, or use of, the NHS.
- NHS patients treated under contracts with private sector institutions.
- Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above.

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- Access to data, organs or other bodily material of past and present NHS patients.
- Foetal material and In vitro fertilisation (IVF) involving NHS patients.
- The recently deceased in NHS premises.
- The use of or potential access to NHS premises or facilities.
- NHS employee recruited as research participants by virtue of their professional role.

3 Protected Characteristics Provision

This policy does not discriminate against any of the protected characteristics.

4 Duties and Responsibilities of Individuals and Groups

4.1 Chief Executive / Medical Director

The Chief Executive is ultimately responsible for the implementation of this document. The Medical Director has board responsibility for Research.

4.2 Associate Medical Directors

Associate Medical Directors authorisation is required by the R&I Department as part of the approval process for research to be conducted. This enables oversight of consultant workload within directorates.

4.3 Document Author and Document Implementation Lead

The document Author and the document Implementation Lead are responsible for identifying the need for a change in this document as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and resubmitting the document for approval and republication if changes are required.

4.4 Target Audience – As indicated on the Cover Page of this Document

All research active employees including those holding an honorary contract, research passport or letter of access, have the responsibility to ensure their compliance with this document by:

- Ensuring any training required is attended and kept up to date including GCP.
- Ensuring any competencies required are maintained.
- Co-operating with the development and implementation of policies, standard operating procedures and work instructions as part of their normal duties and responsibilities.
- Satisfying themselves that the research has been granted the appropriate approvals and authorisations before approaching their patients/service users.

4.5 Researchers

Researchers who do not hold a substantive employment contract with the Trust must obtain either an NHS to NHS proforma confirmation of pre-engagement checks or a Research Passport from their own substantive NHS or University employer. These must be provided to the R&I department in order that either an honorary contract or letter of access can be issued, whichever is appropriate.

The research is conducted in accordance with:

- Health Research Authority (HRA) approval and Trust approved protocol (Ref 7).
- ICH GCP (Ref 3)
- UK Policy Framework for Health and Social Care Research (Ref1)

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The integrity and confidentiality of clinical and other records and data generated by the research is protected in accordance with general data protection regulation (GDPR) (Ref 8) and the Caldicott Principles. (Ref 9)

- Any failure in conducting the study in accordance with the above must be reported in the first instance to the R&I Manager who will take the appropriate action and escalate as required. .
- Pharmacy must be informed very early in the set up process of any trials involving IMP's.
- All adverse events are recorded and reported in accordance with the Safety Reporting SOP (Ref 4).

4.6 Chief Investigator

The Chief Investigator (CI) must be a senior individual with appropriate experience, expertise and training to either:

- 4 Undertake the design, conduct, analyses and reporting of the study to the standards set out in the UK Policy Framework for Health and Social Care Research (Ref 1).
- 5 Lead and manage others who have been delegated responsibility for some of these aspects.

The CI has overall responsibility for the conduct of the research and is accountable for it to their employer, and through them, to the sponsor(s) of the research.

The CI is also directly accountable to the care organisation(s) where the research takes place (or through which the research team has access to participants, their organs, tissue or data). If the research is taking place at more than one site, the CI takes on personal responsibility for the design, management and reporting of the study, and coordinating the Principal Investigators (PI).

The Chief Investigator is responsible for ensuring that:

- The research team gives priority at all times to the dignity, rights, safety and wellbeing of participants.
- The study complies with all legal and ethical requirements.
- The research is carried out to the standards in the UK Policy Framework for Health and Social Care Research (Ref 1).
- Each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge their role in the study, and their qualifications are documented and retained in the Investigator Site Files (ISF) at site.
- All researchers involved in a clinical trial of an IMP are aware of their responsibilities as set out in the Protocol, delegation log and ICH GCP.
- All researchers involved in trials on medicines can provide proof of ICH GCP training within the last three years.
- Students and new researchers have adequate supervision, support and training.
- A suitable sponsor(s) is secured and agreements are in place for Clinical Trials on IMP's detailing the responsibilities of all parties involved in the research.
- R&I authorisation is obtained from each care organisation involved prior to commencing the study at that care organisation.
- The protocol is submitted for ethics review and HRA approval, the study does not start without a favourable opinion and the research team acts on any conditions attached to the ethics opinion.
- Unless urgent safety measures are necessary the research follows the protocol or proposal agreed by the relevant ethics committee, by the Trust R&I department and by the sponsor(s)
- Substantive changes to the protocol or proposal are submitted for review, for the sponsor(s) agreement and for the Trust R&I authorisation, with the exception of urgent safety measures, these amendments are implemented only when approved
- When a study involves participants under the care of a Doctor, GP or other health or social care professional for the condition to which the study relates, those health and social care

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professionals are informed that their patients or users are being invited to participate and agree to retain overall responsibility for their care.

- When the research involves a service user or carer or a child looked after or receiving services under the auspices of the local authority, the agency director or their deputy agrees to the person (and/or their carer) being invited to participate and is fully aware of the arrangements for dealing with any disclosures or other relevant information.
- Potential participants and other service users and carers are involved in the design and management of the study whenever possible.
- Unless participants or the ethics opinion says otherwise, participants' health or social care professionals are given any information directly relevant to their care that arises in the research as appropriate and outlined in the Data Protection Act.2018 (Ref 10)
- For clinical trials involving IMP, the research follows any conditions imposed by the Medicines and Healthcare products Regulatory Agency (MHRA). (Ref 6)
- Procedures are in place to ensure collection of high quality, accurate data and to maintain the integrity and confidentiality of data during processing and storage adhering to all relevant codes of practice.
- Arrangements are in place for the management of financial and other resources provided for the study, including for the management of any intellectual property arising.
- Reports on the progress and outcomes of the research are required by the Trust R&I department, the sponsor(s), funders, MHRA or others with a legitimate interest which must be produced on time and to an acceptable standard.
- The findings from the research are open to critical review through the accepted scientific and professional channels.
- The CI accepts a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs.
- Once established, findings from the research are disseminated promptly and fed back as appropriate to participants.
- There are appropriate arrangements to archive the data when the research has finished and to ensure it is still accessible. Study documents and source data must be retained in accordance with the study protocol or sponsor(s) instructions.
- All data and documentation associated with the study are available at the request of the inspection and auditing authorities.

Where the CI delegates responsibilities to members of the research team this must be clearly documented in a delegation log or similar and kept in the ISF or similar for each study. The CI remains accountable for the actions of his/her research team.

4.7 Principal Investigator (PI)

The PI and the CI may be the same person. In this case the CI must assume the PI responsibilities detailed in this policy in addition to the CI responsibilities.

The PI is responsible for the conduct of a study within the Trust and must ensure that:

The research team give priority at all times to the dignity, rights, safety and wellbeing of participants.

The study complies with all legal and ethical requirements, approvals and authorisations.

The research is carried out to the standards in the UK Policy Framework for Health and Social Care Research (Ref 1)

Each member of the local research team is qualified by education, training and experience to discharge his / her role in the study and their qualifications are documented and retained in the ISF.

Ensure all involved employees are fully briefed at the start of studies and at appropriate intervals during the study.

All local researchers involved in a clinical trial of an IMP are aware of their legal duties.

All researchers involved in trials on medicines can provide proof of ICH GCP training within the last three years.

Students and researchers have adequate supervision, support and training.

Assessment of capacity and capability has been conducted and the study is feasible to run within the Trust.

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R&I authorisation is obtained prior to commencing the study.

Unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant ethics committee, by Trust R&I Department and by the Sponsor.

Substantive changes to the protocol or proposal are submitted for ethical review, for the sponsor(s) agreement and for the Trust R&I authorisation.

With the exception of urgent safety measures these amendments are implemented only when approved.

When a study involves participants under the care of a doctor, GP or Health and social care professional for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate and they agree to retain overall responsibility for their care.

When the research involves a service user or carer or a child looked after or receiving services under the auspices of the local authority, the agency director or their deputy agrees to the person (and / or their carer) being invited to participate and is fully aware of the arrangements for dealing with any disclosures or other relevant information.

Unless participants or the ethics opinion says otherwise, participants' health and social care professionals are given information directly relevant to their care that arises in the research.

For clinical trials involving medicines, the research follows any conditions imposed by the MHRA.

Procedures are in place to ensure collection of high quality, accurate data and for the integrity and confidentiality of data during processing and storage.

Arrangements are in place for the management of financial and other resources provided for the study.

Arrangements are in place for the management of any intellectual property arising from the research.

Reports on progress and outcomes of the research are required by the CI, R&I, the sponsor(s), funders, MHRA or others with a legitimate interest. These must be produced on time and to an acceptable standard.

The findings from the research are open to critical review through the accepted scientific and professional channels.

Once established, findings from the research are disseminated promptly and fed back as appropriate to participants.

There are appropriate arrangements to archive the data when the research has finished and to ensure it is still accessible. Study documents and source data must be retained in accordance with the R&I Archiving Standard Operating Procedure (Ref 4)

In the event that the PI leaves the Trust, the PI must hand over all site study documentation to the R&I office.

All data and documentation associated with the study are available at the request of study monitors and the MHRA.

In the event that the PI's position in the Trust is terminated, an appropriate individual assumes the role of PI and the sponsor(s), ethics committee, MHRA, CI and the R&I department are informed.

The PI must ensure that the R&I department is involved in arranging agreements relating to the Trusts responsibilities in conducting non-commercial research involving external partner(s), funder(s) and / or sponsor(s).

In relation to commercial research the PI must:

Refer all commercial research to the R&I department at the earliest opportunity prior to the research commencing.

Ensure that commercial research is performed under a written agreement between the Trust and the commercial company. This agreement must be signed by the Chief Executive of the Trust or delegated authority from the Research and Innovation Department

4.8 The R&I Department are responsible for:

- Developing and establishing systems for the management of research involving the Trust including systems to ensure that it can meet the responsibilities of a research sponsor [if and when appropriate] under the Medicines for Human use (clinical trials) Regulations (Ref 2) and the UK Policy Framework for Health and Social Care Research (ref 1) [or revised framework].
- Maintaining a record of all research being conducted within the Trust.
- Ensuring that research has the appropriate HRA approvals and that a full feasibility assessment has been conducted in the line with the HRA's requirement to assess, arrange and confirm capacity and capability.
- Assessing applications for the Trust to act as research sponsor, or co-sponsor with appropriate universities or Trusts as appropriate
- Arranging for written agreements to be put in place for all research involving an external partner, funder and / or sponsor, including agreement with universities or other employers in relation to student supervision.

In relation to commercial /non-commercial research:

- Negotiating contracts and or statement of activities..
- Developing and establishing systems to ensure financial probity.
- Providing training in research governance in conjunction with the The National Institute for Health Research Clinical Research Network (NIHR CRN's).
- Regular monitoring and audit of research delivered in the Trust.
- Permitting and assisting with any monitoring, auditing or inspection by relevant authorities.
- Developing a Trust R&I Strategy in consultation with researchers.
- Promoting strategies for consumer involvement in research in conjunction with local Patient and Public Involvement groups.
- Promoting the dissemination of research findings.
- Assisting with the identification and management of intellectual property arising from research and development.
- Compiling and submitting Trust returns, as required, to the CRN West of England and Trust Board.
- Investigate and take appropriate action on receipt of any report of suspected research misconduct.
- Take action in accordance with the Safety Reporting (SOP) (Ref 4) on receipt of any serious adverse event report.
- In the event of the PI leaving the Trust, if a no other PI can be identified R&I must make appropriate arrangements to close the study at the site and to archive the study documents and data for closed studies ensuring it is all accessible. Study documents and source data must be retained in accordance with the the R&I Archiving SOP(Ref4)
- To ensure that this policy is implemented fully therefore ensuring that indemnity insurance cover is provided.

4.9 Research and Innovation Director/Clinical Lead

The Director of R&I has a delegated responsibility from the Chief Executive for the conduct, governance and strategic direction of research within the Trust which includes but is not limited to:

- Signing, on behalf of the Trust, all contracts for commercially sponsored research.
- Ensuring that the R&I Department meets the responsibilities detailed in section (4.8)

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5 Monitoring Compliance and Effectiveness of Implementation

The arrangements for monitoring compliance are outlined in the table below: -

Measurable policy objectives	Monitoring / audit method	Monitoring responsibility (individual / group /committee)	Frequency of monitoring	Reporting arrangements (committee / group to which monitoring results are presented)	What action will be taken if gaps are identified?
Evidence of GCP training	Monthly check of GCP certificates held on file	RM&G Team	Reviewed on a monthly basis	R&I Manager is notified of any non compliance with GCP requirement and will follow up	If the R&I Manager receives no response to request for updated GCP they will suspend the researcher from research participation and escalate to R&I director/clinical lead for resolution

6 Review Date, Arrangements and Other Document Details

6.1 Review Date

This document will be fully reviewed every three years in accordance with the Trust's agreed process for reviewing Trust -wide documents. Changes in practice, to statutory requirements, revised professional or clinical standards and/or local/national directives are to be made as and when the change is identified.

6.2 Regulatory Position

International Conference for Harmonisation Good Clinical Practice Guidelines (Ref 3)
 UK Policy Framework for Health and Social Care Research (Ref 1)
 Medicines for Human Use (Clinical Trials) Regulations (Ref 2)
 General Data Protection Regulation (GDPR) (Ref 8)

6.3 References, Further Reading and Links to Other Policies

The following is a list of other policies, procedural documents or guidance documents (internal or external) which employees should refer to for further details:

Ref. No.	Document Title	Document Location
1	UK Policy Framework for Health and Social Care Research	https://www.hra.nhs.uk
2	Medicines for Human Use (Clinical Trials) Regulations	http://www.legislation.gov.uk

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Ref. No.	Document Title	Document Location
3	International Conference for Harmonisation Good Clinical Practice	http://ichgcp.net/
4	Research and Innovation standard operating procedures	http://gwh-intranet
5	GWH – Medicines Control and Administration Policy	http://gwh-intranet
6	Medicines and Healthcare Products Regulatory Agency	https://www.gov.uk
7	Health Research Authority	https://www.hra.nhs.uk
8	General Data Protection Regulation (GDPR)	https://local.gov.uk
9	Caldicott Principles	https://www.igt.hscic.gov.uk
10	Data Protection Act 2018	http://www.legislation.gov.uk

6.4 Consultation Process

The following is a list of consultees in formulating this document and the date that they approved the document:

Job Title / Department.	Date Consultee Agreed Document Contents
Medical Director	19.08.2018
R and I Director	16.08.2018
R and I Manager	16.08.2018
Chief Nurse	10/10.2018
Director of Governance and Assurance	16.10.2018
Pharmacy Clinical Trial Lead	21.08.2018

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Appendix A – Equality Impact Assessment

Equality Impact Assessment

Are we Treating Everyone Equally?

Define the document. What is the document about? What outcomes are expected?

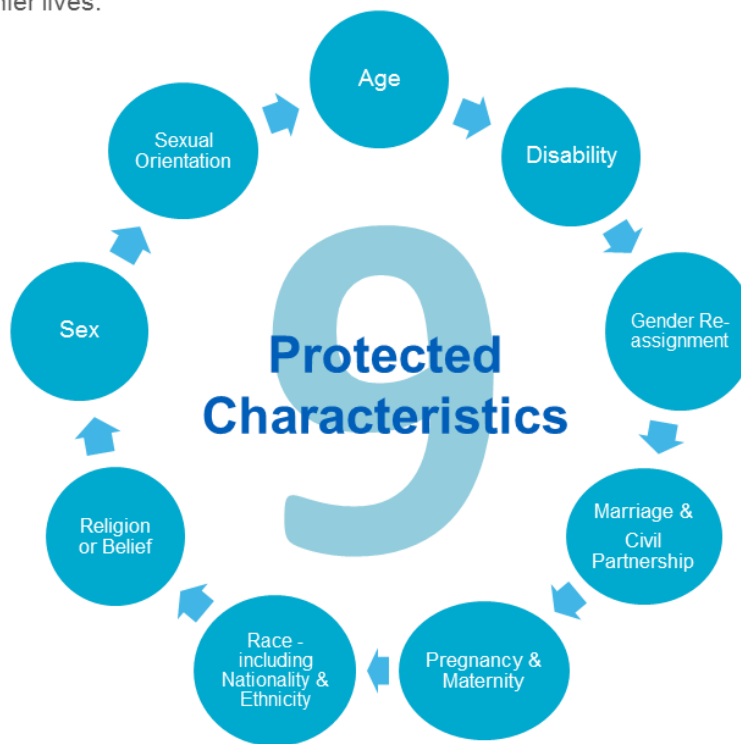
Consider if your document/proposal affects any persons (Patients, Employees, Carers, Visitors, Volunteers and Members) with protected characteristics? Back up your considerations by local or national data, service information, audits, complaints and compliments, Friends & Family Test results, Staff Survey, etc.

If an adverse impact is identified what can be done to change this? Are there any barriers? Focus on outcomes and improvements. Plan and create actions that will mitigate against any identified inequalities.

If the document upon assessment is identified as having a positive impact, how can this be shared to maximise the benefits universally?

Our Vision

Working together with our partners in health and social care, we will deliver accessible, personalised and integrated services for local people whether at home, in the community or in hospital empowering people to lead independent and healthier lives.



Trust Equality and Diversity Objectives

Better health outcomes for all	Improved patient access & experience	Empowered engaged & included staff	Inclusive leadership at all levels
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Appendix B – Quality Impact Assessment Tool

<p>Purpose - To assess the impact of individual policies and procedural documents on the quality of care provided to patients by the Trust both in acute settings and in the community.</p>		
<p>Process -The impact assessment is to be completed by the document author. In the case of clinical policies and documents, this should be in consultation with Clinical Leads and other relevant clinician representatives.</p> <p>Risks identified from the quality impact assessment must be specified on this form and the reasons for acceptance of those risks or mitigation measures explained.</p>		
<p>Monitoring the Level of Risk - The mitigating actions and level of risk should be monitored by the author of the policy or procedural document or such other specified person.</p> <p>High Risks must be reported to the relevant Executive Lead.</p>		
<p>Impact Assessment</p> <p>Please explain or describe as applicable.</p>		
1.	Consider the impact that your document will have on our ability to deliver high quality care.	<i>R&I oversight of Research carried out at this Trust helps to ensure all studies are conducted as per the ethically approved protocol.</i>
2.	The impact might be positive (an improvement) or negative (a risk to our ability to deliver high quality care).	N/A
3.	Consider the overall service - for example: compromise in one area may be mitigated by higher standard of care overall.	N/A
4.	Where you identify a risk, you must include identify the mitigating actions you will put in place. Specify who the lead for this risk is.	N/A
<p>Impact on Clinical Effectiveness & Patient Safety</p>		
5.	Describe the impact of the document on clinical effectiveness. Consider issues such as our ability to deliver safe care; our ability to deliver effective care; and our ability to prevent avoidable harm.	This document ensures research active staff are aware of responsibilities in order to conduct high quality research whilst ensuring patient safety.
<p>Impact on Patient & Carer Experience</p>		
6.	Describe the impact of the policy or procedural document on patient / carer experience. Consider issues such as our ability to treat patients with dignity and respect; our ability to deliver an efficient service; our ability to deliver personalised care; and our ability to care for patients in an appropriate physical environment.	N/A

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Impact on Inequalities	
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7.	Describe the impact of the document on inequalities in our community. Consider whether the document will have a differential impact on certain groups of patients (such as those with a hearing impairment or those where English is not their first language).
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N/A

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