# Corporate

## Research Governance Policy

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1. Introduction
The Trust’s ambition is to be a global leader in research and innovation, delivering benefit to patients at pace and scale to make a real and lasting difference to the quality of care provided by the Trust. We must ensure that research we undertake is carried out safely and to the highest quality standards.

This policy sets out the requirements for conducting research within the Trust to ensure that research activity complies with the principles of the Research Governance Framework for Health and Social care (DH, 2005). It provides a framework for research which complies with good practice without restricting the freedom of individual researchers to develop ideas which can improve clinical care.

Research governance 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

The policy is relevant to all staff who undertake, support or manage clinical and non clinical research including chief and principal investigators, care professionals, researchers, research nurses, managers and support staff.

The policy applies to research activity where research is defined as:

“...the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods” (Research Governance Framework, DH, 2005, para 1.10, pg. 3)

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

- Research where the Trust is a lead organisation
- Research where the Trust is a participating site in research
2. Purpose

This policy provides a framework of standards and requirements for the conduct and management of research in the Trust to ensure that all research activity complies with the principles of the Research Governance Framework for Health and Social Care (Department of Health, 2005).

NOTE: Failure to follow this policy could result in the instigation of disciplinary procedures.

As a research active NHS organisation, the Trust is required to demonstrate that it has implemented effective systems to manage and administer that activity. The Trust is committed to a high standard of practice in the administration of its research activity; this policy is designed to ensure that those charged with achieving these standards have available to them a suitable operational framework.

This policy and associated SOPS (standard operating procedures situated on the Research & Innovation (R&I) intranet page are designed to ensure there is clear guidance for managers/supervisors and research active staff in relation to requirements issued in the following main documents:

- Department of Health (2000) Research & Development for a First Class Service
- Medicines for Human Use (Clinical Trials) Regulations 2004

3. Scope

South Staffordshire and Shropshire Healthcare NHS Foundation Trust recognises the importance of research to ensure 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 occasionally for the safety and wellbeing of the research participants. Therefore, 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 public...
has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust quality assurance in place.

The Research Governance Framework for Health and Social Care (DH, 2005) sets out core standards that apply to the conduct of all clinical research. It was developed by the Department of Health as a framework for the governance of research and applies to all research that relates to the responsibilities of the Secretary of State for Health. This includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services.

All NHS Organisations must comply with the Research Governance Framework (RGF) when getting involved with any research, additionally organisations must have systems to ensure the principles and requirements of the framework are consistently applied.

4. Policy Effect

4.1 Requirements for Trust R&I Approval (NHS Permission)

All research taking place within the Trust must have Trust R&I approval before any research activity begins. The Trust will only extend NHS Indemnity cover (for negligent harm) to its employees taking part in research studies that have been registered and approved by the R&I department. The Trust will not accept liability for research that has not been registered and approved.

4.2 Research Sponsorship

All research must have an identified sponsor. The sponsor is the institution that takes overall responsibility for the initiation, financing, management and monitoring of a study. The Trust have stipulated that the research sponsor organisation should be the substantive employer of the chief investigator of the study. For commercially initiated research, the commercial company would be expected to act as research sponsor. Evidence of research sponsorship will be required before Trust R&I approval is granted.

4.3 Research Ethics Review

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

For all research which falls within the remit of the Governance Arrangements for Research Ethics Committees (GaFREC) paragraph 3.1, review from a recognised NHS Research Ethics Committee (REC) is required (see GaFREC guidance at: http://www.hra.nhs.uk/resources/research- legislature-and-governance/governance-arrangements-for-research-ethics-committees/

Applications for NHS REC review are processed via the Integrated Research Application System (IRAS) at https://www.myresearchproject.org.uk/
Where required evidence of a full favourable opinion from an NHS REC, including confirmation that the participant information sheet and informed consent forms have been reviewed, is required before the Trust will grant Trust R&I approval.

All clinical trials, given a favourable opinion by a Research Ethics Committee (REC) within the Health Departments’ Research Ethics Service and currently in active recruitment in the UK, have been registered on a publically accessible register in compliance with existing duties of sponsors and the Health Research Authority (HRA) requirements and extended compliance checks.

4.4 Scientific Review

All existing sources of evidence, especially systematic reviews, 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 or protocol must be subjected to review by relevant experts who are 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 externally funded research, for example from a research council or a charity, it is expected that peer review would have been undertaken as part of the application for funding process. For commercially sponsored projects, it is the responsibility of the commercial sponsor to arrange peer review. For student projects, peer review by the individual’s supervisor should normally be adequate. For self-funded or own account research, peer review must be undertaken/arranged by the R&I Lead, Associate Director and relevant member of the R&I committee. For further guidance please see peer review flow chart on R&I intranet page.

4.5 Consent

All studies must demonstrate appropriate arrangements regarding consent. Informed consent is the process by which a participant voluntarily confirms willingness to participate in a particular study, having been informed of all aspects of the study that are relevant to their decision to participate. This should be documented by means of a written, signed and dated consent form, updated on Rio and in the investigator site file. SOP 4 details the requirements of informed consent including that for a CTIMP Trial (Clinical Trial Investigational Medicinal Products)

4.6 Finance

Financial probity and compliance with the law and with the rules set out by HM Treasury for the use of public funds are as important in research as in any other area. There must be transparency and accountability of all research income and expenditure.

The Attributing the Costs of Health and Social Care Research and Development (AcoRD, DH, 2012) provides a framework for the NHS and its partners to identify, attribute and recover the various costs associated with research in the NHS in a transparent, robust and consistent manner.

When considering a study for R&I approval, the Head of R&I and finance accountant must be satisfied that all costs for the research are fully covered. For all commercial research within the Trust there is also a non-refundable R&I Set up Fee.
4.7 Conducting clinical trials of investigational medicinal products (CTIMPs)

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 subsequent amendments, state that clinical trials must be carried out according to 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 CTIMPs are credible and accurate.

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 a favourable opinion from an ethics committee and a clinical trials authorisation from the licensing authority, the Medicines and Healthcare products Regulatory Agency (MHRA).

4.8 Good Clinical Practice (GCP) Training

All staff working on research studies in the Trust should be working to the standards of Good Clinical Practice described in the Research Governance Framework (2005) and, for CTIMPs, as described in UK law in the Medicines for Human Use (Clinical Trials) Regulations 2004. The standards of GCP described in these two documents are the same but are legally binding for CTIMPs and form the basis of audit or inspection.

GCP training is available through online training and the Clinical Research Network West Midlands Academy. Further information can be accessed via the R&I department and R&I intranet page.

4.9 Use of patient data

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 policies in relation to the Data Protection Act 1998 and any data/confidentiality breaches must be reported using the Trust’s policy.

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 251 of the NHS Act 2006. Requests for this use are made through the Confidentiality and Advisory Group (CAG). [http://www.hra.nhs.uk/resources/confidentiality-advisory-group/](http://www.hra.nhs.uk/resources/confidentiality-advisory-group/)

If data is to be used for research without consent then evidence of approval from CAG must be provided as part of the submission for Trust R&I approval before confirmation of approval will be granted.
4.10 Health, Safety and Employment/Honorary Status

The safety of research participants and research staff must be given priority at all times. Health and Safety Regulations and Trust policies or employing organisation’s Health and Safety policies must be strictly observed during the course of the research. This is particularly important if the research involves the use of potentially dangerous or harmful equipment, substances or organisms.

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 who interact with research participants in a way that has a direct bearing on the quality of their care will be issued honorary research contracts via the Research passport System.

Other arrangements will be made for non-NHS staff where their research does not have a bearing on the quality of patient care. It is the responsibility of the Chief Investigator or Principal Investigator at each site, to work with the governance team within R&I to ensure staff have the necessary contracts or letters of access in place before staff begin research work within the Trust.

When an honorary contract is not required a letter of access may be provided. SSSFT R&I department will process applications for research passports and letters of access in accordance with the national institute for health (NIHR) research in the NHS – HR good practice resource pack.

4.11 Definitions

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 (DH 2005).

Principal Investigator (PI): The leader responsible for a team of individuals conducting a study at a site (DH 2005).

Investigator: Person responsible, individually or as leader of the researchers at a site, for the conduct of a study at that site. For clinical trials involving medicines, an investigator must be an authorised health professional.

Researchers: Those conducting the research (DH 2005)

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. (DH 2005)

Research Sponsor: Individual, organisation or group taking on responsibility for securing the arrangements to 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 the responsibilities in the research governance framework that are relevant to the study). (DH 2005)
**Employing organisation:** Organisation employing the chief investigator, investigators or other researchers. Employers remain liable for the work of their employees. The organisation employing the chief investigator normally holds the contract or grant agreement with the funder of the study. Organisations holding contracts with funders remain responsible for the management of the funds provided. (DH 2005)

**Organisation providing care:** Organisation responsible for providing health or social care to patients and/or service users and carers participating in a study. Health and social care organisations remain liable for the quality of care, and for their duty towards anyone who might be harmed by a study. (DH 2005)

**Responsible care professional:** Doctor, nurse, social worker or other practitioner formally responsible for the care of participants while they are taking part in the study. (DH 2005)

**Research Ethics Committee:** Committee established to provide participants, researchers, funders, sponsors, employers, care organisations and professionals with an independent opinion on the extent to which proposals for a study comply with recognised ethical standards. For clinical trials involving medicines, the ethics committee must be one recognised by the United Kingdom Ethics Committee Authority. (DH 2005)

**Funder:** Organisation providing funding for a study (through contracts, grants or donations to an authorised member of the employing and/or care organisation). The main funder typically has a key role in scientific quality assurance. In any case, it remains responsible for securing value for money. (DH 2005)

5. **Process For Monitoring Compliance And Effectiveness**

5.1 **Organisations Providing Care**

The Trust must be made aware of all research undertaken within the organisation, or involving participants’ organs, tissue or data obtained through the organisation and this is done through research governance.

The Head of Research and Innovation oversees the governance processes adopted by the Trust and is supported by one research governance facilitator. It is the responsibility of the R&I office to:

- Ensure that research involving participants for whom it is responsible has ethical approval and has been given permission before the study starts
- Ensure that non-NHS employed researchers hold honorary NHS contracts
- Permit and assist with any monitoring, audit or inspection as required
- Ensure that all research meets the standards set out in the Research Governance Framework
- Ensure that all research is reviewed by clinical leads to assess any potential risks associated with the conduct of the work within the clinical directorate.
- Place latest versions of all SOPs outlining the approval and conduct of CTIMPs on the Trust intranet R&I page, and retain hard copies within the R&I office for reference.
• Support the PI to ensure that all CTIMPs conducted within SSSFT are set up then monitored as per SOP 5 (SOP 5: set up and management of CTIMPs)

• Liaise with the support team and research teams as necessary during the approval of CTIMPs.

• Implement an audit programme to quality assure all process/protocols and applicable regulatory requirements are adhered to.

5.2 Care Professionals
Health and social care staff will retain responsibility for the care of their patients or service users, when they are participating in research.

Before agreeing to patients, service users or carers being approached, care professionals must satisfy themselves that the chief investigator has the permission of the appropriate authorities within their organisation. Advice should be sought from the R&I Office.

5.3 Equality and Diversity
This policy has been impact assessed to ensure it complies with the principles of equality, diversity and human rights.

5.4 Involvement of Consumers, Service Users and the Public in Research
Participants or their representatives will be involved wherever possible in the design, conduct, analysis and reporting of research.

Once established, findings must be made available via the Chief investigator to those participating in the research and to all those who could benefit, through publication and/or other appropriate means.

Prior to permission being granted, all researchers are asked to provide their proposed methods of dissemination, and an early invitation to participate in the Trust’s Research Seminar Series is provided.

5.5 Intellectual Property
NHS organisations are required to manage the intellectual property (IP) arising from their activities. Ideas arising out of routine work as well as research may lead to improvements in patient care through new innovations and financial benefits to the inventor or the NHS.

All staff should be aware of and abide by Trust IP policy.

5.6 Monitoring and Audit
Organisations and individuals involved in research are expected to be able to demonstrate compliance with the requirements of the Research Governance Framework (DH, 2005) and the Medicines for Human Use (Clinical Trials) Regulations 2004. It is a statutory requirement that CTIMPs are conducted in accordance with the principles of GCP. Working to GCP principles 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. If a study has a commercial sponsor, the
commercial company (or a delegated Clinical Research Organisation) would conduct and monitor the CTIMP in accordance with GCP guidelines.

5.7 Study Agreements/Contracts

Before a research study can start, sponsors and host institutions need to have appropriate agreements in place which set out the responsibilities of the parties involved in the research.

**Commercial Studies**

For commercial CTIMPs the Trust expects that commercial companies will use the national model Clinical Trial Agreement (mCTA or CRO mCTA) for pharmaceutical companies working with the NHS.

**Non-commercial Studies**

For non-commercial studies the Trust expects that other non-commercial partners will use the national model Non-Commercial Agreement (mNCA).

The model agreements can be found at:


5.8 Indemnity

NHS indemnity for negligent harm is extended to researchers with an employment contract (substantive or honorary) with the Trust. The Trust only accepts liability for research activity that has been managerially approved by the R&I Department.

For commercial CTIMP studies, commercial companies will 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 and patient information sheet and consent form supplied to study participants.

5.9 Research Misconduct and Fraud

The Trust is committed to maintaining the integrity and probity of research undertaken in the Trust and will thoroughly investigate any allegations of misconduct in research made against employees of the Trust.

5.10 Dissemination of Results and Information

When established, findings (including negative findings) should be published in a way that allows critical review and dissemination through the accepted scientific and professional channels. Published findings must be made accessible to those participating in research and to those who could benefit from them.

Other researchers should have access to the data on which the findings are based. The information should address different media and writing styles for different audiences and
unless the research ethics committee agrees otherwise, those consenting to be involved in a study should have ready access to the findings at the end of the study.

5.11 End of Study Notification and Archiving

It is the responsibility of the principal investigator to inform the Trust when a study has ended. The definition of end of trial or study should be included in the study protocol.

For CTIMPs it is a statutory requirement that the MHRA as the Competent Authority is notified of the end of the trial within 90 days or within 15 days if the Trial is terminated early.

Once completed, study documentation should be archived according to Trust/Sponsor CTIMP Archiving policy and Trust Health Records Management Policy.

6. References

- Department of Health (2000) Research & Development for a First Class Service
- Medicines for Human Use (Clinical Trials) Regulations 2004
- International Conference on Harmonisation Good Clinical Practice (ICH GCP)
- Attributing the costs of health & social care Research & Development (AcoRD) (Department of Health, 2012)