Southern Health
NHS Foundation Trust

SH NCP 8

General Policy on Conducting Research within Southern Health NHS Foundation Trust

Version: 3

Summary:	This policy provides a framework for research-active staff that complies with good practice	
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General Policy on Conducting Research & Development
Southern Health NHS Foundation Trust

Executive Summary

High quality clinical and non-clinical research is essential to providing sound, evidenced based health and social care. The aim of Southern Health NHS Foundation Trust is integration of a comprehensive research strategy into day to day practice as part of the culture, policies and procedures of the organisation, and the organisation aims to maximise patient and clinician participation in research. To this effect our vision is that every patient and clinician in the organisation has the opportunity to participate in research.

Clinical research is defined as any research involving human subjects or tissues, including healthy volunteers. Following a number of high-profile problems, clinical research became subject to the Research Governance Framework, first written in 2001 and the second edition appearing in 2005. The research governance frameworks were subsequently replaced by the UK Policy Framework for Health and Social Care Research in November 2017. This new policy framework aims to help make the UK a better place to do research. It is aimed at all those responsible for health and social care research in the UK.

Research Governance affects all NHS staff and patients. Anyone connected with research which involves NHS patients, samples, information, facilities, staff or services is covered by the Framework. This includes staff with full or honorary NHS contracts, students and part-time staff or those on short term attachments.

This policy sets out the landscape for the ethical and legal conduct of research in Southern Health, detailing the levels of responsibility for various groups of staff involved in research.

1. Introduction

1.1 Background

Research is essential to the successful promotion and protection of health and wellbeing, and also to modern, effective health and social care services. At the same time, 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. Having a policy framework that sets out principles and responsibilities, and that takes into account relevant legislation in the UK, is essential to ensure that the public can have confidence in, and benefit from, 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 monitoring arrangements.

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 that take account of legal requirements and other standards. These principles protect and promote the interests of patients, service users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.

All NHS organisations must comply with the UK policy Framework when participating in any research activity.

1.2 Aims and Outcomes

The aim of this policy is to ensure that all research hosted by Southern Health NHS Foundation Trust meets all the requirements of the UK Policy Framework for Health and Social Care research (v3, Oct 2017). This policy provides a framework for research that complies with good clinical practice, yet does not unnecessarily restrict the freedom of the individual researchers to develop ideas which can improve clinical care. In line with our vision to "*enable every patient and staff the opportunity to participate in research*", this policy aims to safeguard the rights and interests of patients and public involvement in research.

2. Scope

This policy sets out the requirements for all research within Southern Health NHS Foundation Trust to ensure that research activity complies with the principles of The UK Policy Framework for Health and Social Care Research and satisfies the fundamental standards for healthcare required by the healthcare regulator, the Care Quality Commission.

The policy applies to research activity where research is defined within the UK policy framework as:

"…the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods."

This policy covers all research activity, both commercial and non-commercial involving Southern Health NHS Foundation Trust including:

- Research where Southern Health NHS Foundation Trust is the Sponsor

- Research where Southern Health is a participating site in research
- Research using patients, carers, volunteers and members of staff at Southern Health
- 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 Southern Health
- Research taking place on Trust premises or involving Trust resources, including non-clinical and laboratory based research
- Research being undertaken as part of an educational qualification
- Research being undertaken using Southern Health premises or staff where the subjects are not Southern Health patients

The policy does not apply to audit or service evaluations. For guidance on the differentiation between research, audit and service evaluation, please refer to http://www.hra-decisiontools.org.uk/research/

3. Definitions

Audit
An audit is not research and does not involve testing new or gaining further evidence on a hypothesis. Audits assess how well a pre-set standard is met. See relevant Trust policy for requirements to register and conduct an audit.

Advanced Therapy Medicinal Product (ATMP)
ATMPs are medicinal products which are prepared industrially or manufactured by a method involving an industrial process. ATMPs fall into three categories; Gene Therapies, Somatic Cell Therapies and Tissue Engineered Products. For further information please visit:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000294.jsp&mid=WC0b01ac05800241e0

Investigator
An individual who conducts an investigation (i.e., under whose immediate direction the study is managed). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team.

Chief Investigator (CI)
A Chief Investigator is an individual who initiates and conducts an investigation, leading the study as well as fulfilling the requirements applicable to a sponsor. The CI 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)
A Principal Investigator is an individual who both initiates and conducts an investigation and under whose immediate direction the study is managed at a local site but is not leading multicentre study within the United Kingdom.

Co-Investigator
Any study is allowed to have named co-investigators as per agreement with the local team. These individuals will need to be listed in a delegation log and authorized by the local PI.

Clinical Trial of Investigational Medicinal Product (CTIMP)
Clinical trials during which a pharmaceutical form of an active substance or placebo is being tested or used. This includes 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.

Employing organisation
An 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 the contracts with funders remain responsible for the management of the funds.

Intellectual Property (IP)
IP means intellectual property of any description including but not limited to all inventions, designs, information, specification, formulae, improvements, discoveries, know-how, data, processes, methods, techniques and the intellectual property rights therein, including but not limited to patents, copyrights, database rights, design rights (registered and unregistered), trademarks, trade names and service marks, applications for any of the above.

Medicines and Healthcare products Regulatory Agency (MHRA)
The MHRA is an executive agency of the Department of Health that assesses compliance with the requirements of Good Clinical Practice (GCP) guidelines and applicable regulations. It is the UK competent authority which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.

Health Research Authority (HRA)
HRA /REC are convened to provide independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals comply with recognised ethical standards.

Organisation providing care (Participating Site)
An organisation responsible for providing health or social care to patients and/or service users and carers who participate 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.

Research
Research can be defined as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound 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. Research within Southern Health NHS Foundation Trust must fit with the overall research strategy.

Researchers
Researchers are the staff helping the Chief Investigator to conduct the study at site.

Responsible care professional
These are staff including doctors, nurses, social workers or other practitioners formally responsible for the care of participants whilst they are taking part in a study.

Research Ethics Committee (REC)
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.

Research Sponsor
An 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 UK Policy Framework that are relevant to the study). The sponsor is usually, but does not have to be, the main funder. Where research has no external sponsor, the NHS organisation must accept the responsibility of sponsor.

Serious Breach
A breach of Good Clinical practice (GCP) or the protocol which is likely to affect to a significant degree the mental or physical integrity of the subject/participant or the scientific validity of the trial.

Service Evaluation
A service evaluation assesses an existing service or established practice, whether it is worth continuing and how it can be improved. The service is not measured against a standard (which makes it distinct from audit).

SUSAR
A suspected unexpected serious adverse reaction

4. Duties / Responsibilities

4.1 Responsibilities - All Staff

All staff, including those holding an honorary contract, have the responsibility of being familiar with the principles of Good Clinical Practice (GCP), that is, the international ethical, scientific and practical standard to which all clinical research is conducted.
The HRA, MHRA Joint Statement on the Application of Good Clinical Practice to Training for Researchers advocates a proportionate approach to the application of GCP training to researchers. Those conducting clinical trials of investigational medicinal products (CTIMPs) must comply with the high level conditions and principles of GCP, but there is no legal requirement for other types of research to do so.

The Southern Health policy on GCP requirements and expectations for researchers and staff in in line with the HRA/MHRA guidance:

CTIMPs
All staff working on a CTIMP, ATMP or Medical Device Investigation requiring Competent Authority/MHRA approval must have completed their GCP training before they have any participant contact or data collection/entry.

Other types of research
Southern Health research department highly recommends training in relevant aspects of GCP for anyone involved in conducting non-CTIMP research. Such research should be conducted in a manner that provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data is reliable - this can be achieved through means that are appropriate and proportionate to the activities being

undertaken. Whilst members of the research team in such studies are expected to be qualified by education, training or experience, there is no legal requirement for non-CTIMP research to be conducted in accordance with the conditions and principles of GCP. Whether members of staff require GCP training for a particular research project will be determined by Band 7 Portfolio Delivery Leads during study feasibility.

GCP Training
The frequency of GCP training is not defined in the regulations. How often this training is repeated is a business decision for the organisation concerned. Southern Health recommends that staff update their GCP training every 2 years.

GCP training can be provided in a range of formats, including face-to-face or web-based. On inspection, MHRA GCP inspectors will look for evidence that individuals involved in the conduct of CTIMPs have received adequate training in GCP and appropriate legislative requirements commensurate with their roles and responsibilities. GCP certificates and dates of completion are checked during research approval for each study and during research department monitoring / audit.

Before agreeing to their patients or users being approached, all staff must satisfy themselves that the research has been approved by the Trust Research Department.

4.2 Responsibilities – Research sites

Research sites are the organisations with day-to-day responsibility for the locations where a research project is carried out. In health and social care research, they are often providers of health or social care and/or the employer of members of the research team. Research sites are responsible for:

a. demonstrating to relevant approval bodies and sponsors that the location is suitable for the research;

b. being aware of all research activity being undertaken in or through the site;

c. ensuring that the roles and responsibilities of individuals at the site and any collaborating parties are agreed and documented for individual research projects; and

d. satisfying themselves (e.g. by taking assurances from others in a position to give them) that, if expected or required, the research has approval from a research ethics committee and any other relevant approval bodies before research participants take part (including indirectly, through the involvement of data or tissue that is likely to identify them).

4.3 Responsibilities – Research teams

The research team is the group of people involved in the conduct of a research project. It may include care professionals, academics, patients and service users, members of the public, research professionals, students and/or scientists. Research teams are responsible for:

a. demonstrating to chief investigators and sponsors their suitability to conduct the research;

b. acquiring any particular knowledge and skills in order to conduct the research;

c. conducting the research according to the approved research proposal or protocol and any complementary information (such as the research ethics committee application form), in compliance with any applicable regulatory standards and guidance;

d. providing information in a suitable format for potential participants that is clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research; and

e. ensuring participants' safety and well-being in relation to their participation in the research (e.g. by asking questions about the patient's experience with the research intervention) and reporting adverse events where expected or required.

Where consent is sought:

f. potential research participants should be provided, normally by the research team, with the information they need to help them decide whether they wish to take part in research or not, and should be given reasonable time to reach their decision. The information should be provided in a suitable format. Unless otherwise justified (e.g. by feedback from public involvement), the information should include a concise explanation of relevant research evidence and research in progress that shows why the proposed research is justified;

g. a permanent and accessible copy of any information sheet should normally be made available to all participants; and

h. consent should be documented and available for inspection by relevant regulators.

4.4 Responsibilities - Chief Investigator (CI)

With the exception of student research, the Chief Investigator must be a senior individual, with appropriate experience, expertise and training to either:

- Undertake the design, conduct, analyses and reporting of the study to the standards set out in the UK Policy Framework
- Lead and manage others who have been delegated responsibility for some of these aspects where appropriate

Students should not normally take the role of chief investigator at any level of study, as this function should be undertaken by supervisors or course leaders. An exception may be made for an experienced care practitioner or a manager undertaking an educational qualification for continuing professional development or a doctoral-level study while employed by a health or social care provider or a university, or for a researcher undertaking a doctoral-level study in receipt of a fellowship.

The chief investigator is the overall lead researcher for a research project. In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project, including:

a. satisfying themselves that the research proposal or protocol takes into account any relevant systematic reviews, other research evidence and research in progress, that it makes effective use of patient, service user and public involvement where appropriate and that it is scientifically sound, safe, ethical, legal and feasible and remains so for the duration of the research, taking account of developments while the research is ongoing;

b. satisfying themselves that the research proposal or protocol has been submitted for appropriate independent expert ('peer') review and revised in light of that review;

c. satisfying themselves that, if expected or required, the proposal has been submitted for review by and obtained approval from a research ethics committee and any other relevant approval bodies;

d. satisfying themselves that everyone involved in the conduct of the research is qualified by education, training and experience, or otherwise competent, to discharge their roles in the project;

e. satisfying themselves that the information given to potential participants is in a suitable format and is clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research;

f. adhering to the agreed arrangements for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee);

g. adhering to the agreed arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after the research has finished

h. starting the research only once the sponsor has confirmed that everything is ready for it to begin;

i. adhering to the agreed procedures and arrangements for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct, the participants' safety and well-being and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments; and

j. adhering to the agreed arrangements for making information about the findings of the research available, including, where appropriate, to participants.

4.5 Responsibilities - Principal Investigator (PI)

In the case of single centre studies 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 the study **at Southern Health** and must ensure that:

a. The research team give priority at all times to the dignity, rights, safety and well-being of participants

b. The study complies with all legal and ethical requirements

c. The PI understands he/she must personally supervise the study and maintain oversight

d. PI allows direct access to all trial data and source data to monitors, auditors and inspectors as appropriate

e. The research is carried out to the standards in the UK Policy Framework

f. 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 Investigator Site File (ISF)

g. Any changes to the research team at Southern Health are notified to the research department Office prior to the individuals commencing in their role on the study to ensure that all appropriate checks are in place

h. Students and new researchers have adequate supervision, support and training.

i. For each participant the research study involvement must be documented into the patient medical records

j. Southern Health R&D approval is obtained prior to commencing the study.

k. When a study involves participants under the care of a doctor, nurse or social worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate, and agree to retain overall responsibility for their care, unless this is agreed as inappropriate by the ethics committee

l. 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 this is agreed as inappropriate by the ethics committee

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

n. Unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant ethics committee, by the Trust research department and by the sponsor

o. Urgent safety measures must be notified to Sponsor and hosting research departments

p. Reports to the Sponsor for all adverse events related to a research project should be copied to Southern Health research department to ensure adequate oversight

q. Any event falling under the definition of Trust Incident must be also reported according to Southern Health Procedure for Reporting and the Management of Serious Incidents

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

s. Reports on the progress and outcomes of the work required by the CI, Southern Health research department, the Sponsor(s), funders, MHRA or others with a legitimate interest are produced on time and to an acceptable standard

t. All breaches of GCP (e.g. deviation from the protocol, adding new/omitting tests/interventions, delaying dates for visits, insufficiently trained staff working on procedures) must be recorded in the Investigator Site File and as appropriate notified to the sponsor according to the research protocol. Copies of any such reports should be held by Southern Health R&D Office

u. All serious breaches of GCP must be expedited to Sponsor and hosting research departments within 24 hrs of becoming aware of them. The same escalation reporting applies for persistent breaches of GCP (i.e. 3 occurrences of the same type of event are defined as "serious")

v. Once established, findings from the work are disseminated promptly and fed back in line with the REC approval for that particular study

w. There are appropriate arrangements to archive the data when the research has finished, or the PI leaves Southern Health in line with the Trust research department SOP - NCP/R&D004 (Closing and Archiving a Study)

x. Study documents and source data must be retained in accordance with the Southern Health Information Lifecycle Policy or the protocol whichever is the longest

y. Appropriately qualified and experienced PI cover must be put in place by the study PI if he/she is absent for a prolonged period at any time (e.g. annual leave, sabbaticals, international meetings, etc.). This should be notified to Southern Health research department in advance of the cover being activated

z. All data and documentation associated with the study are available at the request of the inspection and auditing authorities

The PI must ensure that the research department is involved in arranging agreements relating to the Trusts responsibilities in conducting all research involving an external partner, funder and/or sponsor.

In relation to commercial research the PI must:

a. Refer all commercial research to the research department at the earliest opportunity prior to the research commencing

b. 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

4.6 Responsibilities – Research Sponsor

The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research has a sponsor. The sponsor is normally expected to be the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial research12. The sponsor has overall responsibility for the research, including:

a. identifying and addressing poorly designed or planned research and poor quality research proposals, protocols or applications and ensuring that research proposals and protocols:

- take into account systematic reviews of relevant existing research evidence and other relevant research in progress
- make appropriate use of patient, service user and public involvement and
- are scientifically sound (e.g. through independent expert review), safe, ethical, legal and feasible and remain so for the duration of the research, taking account of developments while the research is ongoing;

b. satisfying itself that the investigators, research team and research sites are suitable;

c. ensuring that roles and responsibilities of the parties involved in the research and any delegation by the sponsor of its tasks are agreed and documented;

d. ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project; and

e. ensuring appropriate arrangements are made for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee); agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished; and ensuring arrangements for information about the findings of the research to be made available, including, where appropriate, to participants;

f. ensuring that, where expected or required, the research has approval from a research ethics committee and any other relevant approval bodies before it begins;

g. verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner;

h. putting and keeping in place arrangements for adequate finance and management of the research project, including its competent risk management and data management;

i. ensuring that effective procedures and arrangements are kept in place and adhered to for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.

4.7 Responsibilities – Department Management

Managers can assist in meeting responsibilities by:

a. Ensuring adequate line management of researcher(s)

b. Allowing access to appropriate training

4.8 Responsibilities - Research and Development Department

The Southern Health research department is responsible for:

a. Developing and maintaining systems for the management of research involving Southern Health in line with the UK Policy Framework for Health and Social Care Research

b. Developing and maintaining the Southern Health research approval process to meet the requirements of the Department of Health

c. Maintaining a record of all research being conducted within Southern Health, including student research

d. Ensuring, where necessary, that an appropriate NHS research ethics committee has approved the research

e. 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

f. Ensuring that researchers not employed by Southern Health obtain appropriate honorary contracts or letters of access

g. Negotiating contracts

h. Developing and maintaining systems to ensure financial probity

i. Regular monitoring and audit of research will be undertaken in line with the appropriate SOPs

j. Permitting and assisting with any monitoring, auditing or inspection required by relevant authorities

k. Escalate any relevant monitoring / audit findings to the Clinical Teams that need to be aware (ensuring that incidents have been reported via the Trust incident reporting system) and; as well as the Sponsor and/or relevant authorising bodies such as REC and MHRA where necessary

l. Developing the Southern Health research strategy in consultation with researchers, clinicians and managers and input from patient and public involvement

m. Promoting strategies for consumer involvement in research

n. Promoting the dissemination of research findings

o. Assisting with the identification and management of intellectual property arising from research and development

p. Compiling and submitting Southern Health returns/reports as required by the NIHR Clinical Research Network Wessex

q. Investigate and take appropriate action on receipt of any report of suspected research misconduct in line with the relevant Trust policy

r. Take action in accordance with the Research Related Adverse Event Reporting Policy and the Procedure for Reporting and the Management of Serious Incidents on receipt of any serious adverse event report

s. Make appropriate arrangements to archive study documents and data for closed studies ensuring it is still accessible, including where investigators have left. Study documents and source data must be retained in accordance with the Southern Health Information Lifecycle Policy or the protocol whichever is the longest.

4.9 Responsibilities - Director of Research and Development

The Director of Research has delegated responsibility from the Chief Executive for the conduct, governance and strategic direction of research within Southern Health NHS Foundation Trust which includes but is not limited to:

a. Safety and wellbeing of Trust participants in research.

b. The approval of all research involving the Southern Health NHS Foundation Trust.

c. Signing, on behalf of the Trust, all contracts for commercially sponsored research. Ensuring that the research department meets the responsibilities detailed in section 4.8.

4.10 Service user, Carer and Public Involvement

The Trust strongly supports and encourages the principle that NHS service users, carers and public should be involved in decision-making process relating to research strategy, policy and activity.

The research department works closely with the Patient, Carer and Public Involvement and Engagement Co-ordinator on research and engagement and involvement. Researchers should seek to involve service users, carers and public in the design, conduct, analysis and reporting of individual projects. Where it is not possible expert organisations like INVOLVE, CAST may be consulted.

4.11 Participants

The participants are the people who use Trust services; relatives, professional carers, other staff or members of the public agreeing to take part in the study. Responsibilities of participants include:

a. Giving serious consideration to agree to be notified of, and to participate in, research undertaken in the Trust

b. Not hesitating to ask if they do not understand the explanations and information given

c. To withdraw their consent at any time during the period of the research

d. Reporting any adverse events to the researcher, health care professional or the research office

4.11 Health Research Authority

The Health Research Authority (HRA) is an executive non-departmental public body of the Department of Health. The HRA protects and promotes the interests of patients and the public in health and social care research. The HRA achieves this by:

a. Ensuring research is ethically reviewed and approved. HRA Approval brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee (REC). It applies where the NHS organisation has a duty of care to participants, either as patients/service users or NHS staff/volunteers.

b. Promoting transparency in research to ensure that participants are protected from unnecessary research and patients benefit from improved outcomes and care informed by high quality studies. The HRA encourages and facilitates the use of evidence in order to reduce research waste.

c. Overseeing a range of committees and services that help protect and promote the interests of patients and the public in health research, and to streamline the regulation of research.

d. Providing independent recommendations on the processing of identifiable patient information where it is not always practical to obtain consent, for research and non-research projects.

4.12 Intellectual Property Rights

Staff will be expected to honour Intellectual property rights in accordance with the Collaboration Agreement (e.g. Brunswick Academic Collaboration Agreement / or sponsor specific collaborator agreement (e.g. in commercial trials)

4.13 Responsibilities - Chief Executive

The overall responsibility for this policy rests with the Chief Executive.

5. Training Requirements

Trust-wide launch of the Policy, through the research department, will ensure that research-active personnel are aware of the Policy and implications for their practice. The availability of the Policy will be highlighted to Principal Investigators via the packs sent with approval letters for all studies. The PIs will be responsible for identifying the existence of the Policy to all members of his/her research teams.

The existence of the Policy and its implications for researchers will be covered during Trust research training events and through induction packs for PIs.

On-going support for the research staff in Southern Health will be provided by the Trust research office.

For GCP training requirements, see section 4.1 of this policy.

6. Financial and Resource Implications

To come in line with the Government's Plan for Growth the Trust needs to ensure that it complies with the requirement of the National Institute for Health Research (NIHR) that all research is managed in accordance with the UK Policy Framework for Health and Social Care Research and other associated legislation. A failure to comply with this will result in a reduction of income to support research from the Wessex LCRN allocation.

In order to recruit and retain experienced members of staff with a commitment to evidenced based practice a positive research culture is required at all levels within the organisation.

7. Study Misconduct

Principal Investigator (PI) is the person at a single site designated as taking responsibility within the research team for the conduct of the study. Researchers are responsible for ensuring that suspected fraud or misconduct is reported in accordance with the appropriate Trust policy document (management action when a concern arises).

Any fraud and study misconduct is monitored by the Trust's research department which has a responsibility to ensure that research studies conducted within Southern Health or where Southern Health is acting as a research sponsor are in accordance with the Department of Health's UK Policy Framework for Health and Social Care Research and the International Conference on Harmonisation (ICH) Harmonised Tripartite Guideline for Good Clinical Practice ((ICH)-GCP). This monitoring also ensures that the conduct of the study is in compliance with the current approved protocol/protocol amendment(s) and with the applicable regulatory requirements. Should the results of any research site visit cause concern that misconduct or fraud has taken place, the study will be referred to the research manager and then if needed escalated to the Director of Research.

Should the Sponsor, CI, PI or any member of site staff feel that the research department visit report does not accurately represent the conduct of the study they may request further consultation with the research department. This request should be made in writing to the research department within two weeks of site receiving the report. The request should state the reason for request and be directed to those research department staff involved in the original visit(s).

Upon receipt of the request for consultation the primary action of the research department will be to confirm receipt and to schedule a meeting between the individual making the request and those members of the research department in the initial visit(s). The purpose of this meeting will be to discuss the findings of the visit and ascertain where the differences of opinion lie with the aim of ultimately resolving these differences.

Where differences of opinion are not resolved by this process the matter(s) will be referred to the research manager and Director of Research who will review the matter and seek advice from the appropriate regulatory authorities and experts in the field of research governance. The conclusions will be reported back to the Sponsor, CI/PI as applicable and recommended actions will be advised as necessary. As far as possible all communications relating to the matter will be kept confidential.

The findings of research department monitoring visits will only be made available to the research staff active on the study, copied to sponsor and staff in the research department with the exception of a matter being referred for dispute fraud, misconduct or resolution by the research department, the sponsor or escalated to the Trust HQ.

The monitoring can also be requested by staff concerned about study conduct or compliance of a study with GCP/Regulatory requirements. They may request monitoring of a study by contacting the research department. Staff may relay any request to the research department via telephone, email or in person. In all cases communications will be treated as confidential.

The trust whistle blowing policy also applies to any member of Southern Health involved in research and can be reported in confidence to the research manager and Director of Research.

Once a concern has been raised about any member of Southern Health involved in research, this will be dealt with under the appropriate trust policy.

8. Monitoring Compliance

The Trust research department is responsible for the oversight of Research Governance in the Trust and for providing necessary assurance of robust Research Governance arrangements.

It will be necessary to ensure that research studies hosted by the Trust are being carried out in accordance with the terms of this Policy document.

The monitoring/auditing of studies will be carried out by the Trust research office to ensure that all processes comply with the Policy. The decision of which studies and the frequency of monitoring/auditing will be decided on a risk-based assessment of the individual studies. Similarly, regular Clinical Trial monitoring will assess awareness of, and compliance with, the Policy.

It should be noted that non-compliance with a Trust Policy, Procedure, protocol or participant information standard may result in disciplinary action.

9. General Data Protection Regulation

The General Data Protection Regulations (GDPR) came into force on 25th May 2018.

GDPR brings in a new “principle” of “transparency and accountability”. This means that Data Controllers (i.e. the Trust) has to ensure that Data Subjects (i.e. public; patients; staff) are aware of the processing of their personal data – and this information is readily available to them.

As a public authority (i.e. NHS), the Trust does not rely upon a Data Subject’s consent for Researchers to access information the Trust has collected about them. However, the Trust does rely upon a Data Subject’s consent for them to actively take part in a research study.

Staff must respect a Data Subject’s right to confidentiality and must not access patient or staff information on any system (electronic or paper) that relates to family (including spouses; children; parents etc.) or friends, even if it is considered to be within their role in the organisation. Failure to comply could result in disciplinary action.

All project based research within the Trust must comply with the Data Protection & Caldicott Guardian Principles as set out within the Trust’s Data Protection & Confidentiality Policy, be registered by the Research and Development Department and undergo review through the NHS Health Research Authority (HRA) approval process to provide assurance to the Trust, the patients of the Trust and the public that all research meets the necessary legal and compliance standards.

The research department will log and retain as appropriate, all relevant data protection agreements and HRA approvals for research studies, as evidence for compliance with the General Data Protection Regulation 2018.

All staff must complete annual Information Governance Training – which covers Data Protection and Confidentiality.

10. Support Available

The Research Design Service (RDS), funded by the National Institute for Health Research (NIHR), provides free support and advice to health and social care professionals, NHS and social care organisations, people who use our services and academics who wish to develop applications to national, peer reviewed funding streams. The RDS advisory panel aims to increase individual’s proposals chances of success by providing input from experienced professionals working across clinical and academic disciplines. The service has a particular focus on (but is not restricted to) the NIHR funding programmes. The relevant RDS centre for Southern Health NHS Foundation Trust is the Research Design Service South Central.

Further information on the RDS can be found on their website: www.rds-sc.nihr.ac.uk

11. Policy Review

As this is an existing Policy, it will follow the Policy review cycle, which is every four years, or sooner if applicable, in line with Southern Health policy review schedules. The review is conducted by the research department.

12. Associated Documents

- The Policy on Reporting Research Related Adverse Incidents (SH NCP 33)
- Policy for Managing Incidents and Serious Incidents (SI) (NCP 16)

13. Supporting References

UK Framework for Health and Social Care Research Version3.3 07/11/17

Health and Social Care Act 2008.
http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/HealthandSocialCareBill/DH_080604

Health and Social Care Act 2012
http://www.legislation.gov.uk/ukpga/2012/7/pdfs/ukpga_20120007_en.pdf

Medicines for Human Use (Clinical Trials) Regulations 2004, Statutory Instrument2004/1031 http://www.opsi.gov.uk/si/si2004/20041031.htm#33

Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, Statutory Instrument 2006/1928 http://www.hmso.gov.uk/si/si2006/20061928.htm

Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006, Statutory Instrument 2006/2984
http://www.legislation.gov.uk/uksi/2006/2984/contents/made

Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008, Statutory Instrument 2008/941
http://www.legislation.gov.uk/uksi/2008/941/pdfs/uksi_20080941_en.pdf

Medicines for Human Use (Marketing Authorisations Etc) Amendment Regulations 2008, Statutory Instrument 2008/3097

http://www.mhra.gov.uk/home/groups/clin/documents/websiteresources/con033682.pdf

Medicines for Human Use (Advanced Therapy and Miscellaneous Amendments) Regulations 2010, Statutory Instrument 2010/1882
http://www.legislation.gov.uk/uksi/2010/1882/pdfs/uksi_20101882_en.pdf

Medicines and Healthcare products Regulatory Agency - Serious Breaches Guidance: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/News/CON084915

Medical Devices Regulations 2002, Statutory Instrument 2002:0618;
http://www.opsi.gov.uk/si/si2002/20020618.htm

UK Data Protection Act (2018):
http://www.legislation.gov.uk/ukpga/2018/12/pdfs/ukpga_20180012_en.pdf

The Human Tissue Act (2004);
http://www.legislation.gov.uk/ukpga/2004/30/contents

The Mental Capacity Act (2005):
https://www.legislation.gov.uk/ukpga/2005/9/contents

Research in the NHS – Human Resources (HR) Good Practice Resource Pack:

https://www.nihr.ac.uk/02-documents/policy-and-standards/Faster-easier-clinical-research/Research-passports/Hr%20Good%20Practice%20Resource%20Pack/HR-Good-Practice-Info-for-researchers-RD-and-HR-staff-in-the-NHS-and-HEIs.pdf

ICH Harmonised Tripartite Guideline for Good Clinical Practice. Reprinted with permission of the ICH by the Institute for Clinical Research. Marlow. Bucks www.instituteofclinicalresearch.org
www.ich.org

Appendix 1: Southern Health NHS Foundation Trust:
Equality Impact Analysis Screening Tool

Equality Impact Assessment (or 'Equality Analysis') is a process of systematically analysing a new or existing policy/practice or service to identify what impact or likely impact it will have on protected groups.

It involves using equality information, and the results of engagement with protected groups and others, to understand the actual effect or the potential effect of your functions, policies or decisions. The form is a written record that demonstrates that you have shown *due regard* to the need to **eliminate unlawful discrimination**, **advance equality of opportunity** and **foster good relations** with respect to the characteristics protected by equality law.

For guidance and support in completing this form please contact a member of the Equality and Diversity team

Name of policy/service/project/plan:	General Policy on Conducting Research and Development within Southern Health NHS Foundation Trust
Policy Number:	SH CP 8
Department:	Research and Development Department
Lead officer for assessment:	Prof Shanaya Rathod
Date Assessment Carried Out:	17 September 2018

1. Identify the aims of the policy and how it is implemented.	
Key Questions	**Answers / Notes**
Briefly describe purpose of the policy including: - How the policy is delivered and by whom - Intended outcomes	The aim of Southern health NHS Foundation Trust is integration of a comprehensive research strategy into day to day practice as part of the culture, policies and procedures of the organisation. Trust vision: to provide high quality, safe services which improve the health, wellbeing and independence of the people we serve. Our Vision: Enabling every patient and clinician the opportunity to participate in research. The organisation aims to maximise patient and clinician participation in research. High quality clinical and non-clinical research is essential to providing sound, evidenced based health and social care. Clinical research is defined as any research involving human subjects or tissues, including healthy volunteers. Following a number of high-profile problems, clinical research became subject to the Research Governance Framework, first written in 2001 and the second edition appearing in 2005. The research governance frameworks were subsequently replaced by the UK Policy Framework For Health And Social Care Research

	in November 2017. This new policy framework aims to help make the UK an even better place to do research. It is aimed at all those responsible for health and social care research in the UK.

2. Consideration of available data, research and information

Monitoring data and other information involves using equality information, and the results of engagement with protected groups and others, to understand the actual effect or the potential effect of your functions, policies or decisions. It can help you to identify practical steps to tackle any negative effects or discrimination, to advance equality and to foster good relations.

Please consider the availability of the following as potential sources:

- Demographic data and other statistics, including census findings
- Recent research findings (local and national)
- Results from consultation or engagement you have undertaken
- Service user monitoring data
- Information from relevant groups or agencies, for example trade unions and voluntary/community organisations
- Analysis of records of enquiries about your service, or complaints or compliments about them
- Recommendations of external inspections or audit reports

Key questions		**Data, research and information that you can refer to**
2.1	What is the equalities profile of the team delivering the service/policy?	This policy provides a framework for research- active staff that it complies with good practice: The Trust Equality and Diversity team report on equality data profiling
2.2	What equalities training has staff received?	SHFT provides a range of E&D training that includes: Induction training, Respect and Values and E-Learning/Assessments
2.3	What is the equalities profile of service users?	The Trust Equality and Diversity team report on equality data profiling
2.4	What other data do you have in terms of service users or staff? (E.g. results of customer satisfaction surveys, consultation findings). Are there any gaps? **Cultural Competency** A necessary overarching theme among research and human services is cultural competency. In terms of human services is cultural competency. In terms of research; cultural competency is broadly defined as "Involving the recognition and understanding of the diverse values, norms, and needs of a community and integrating the knowledge about service [and research] that are accessible and relevant to that community"(Prado & DeRoche, 2008, p.20). **General equality considerations:**	There a number of ethical principles that should underpin the conduct of all research undertaken by SHFT: - No harm to individuals - Confidentiality and Anonymity - Informed Consent - Culturally sensitive methodologies - Language requirements - Remuneration

	- Explore a variety of research methodologies, seeking to identify approaches that are most likely to yield accurate, in-depth outcomes related to all target audiences. Consider a blend of qualitative and quantitative approaches. - Use sampling techniques that provide for adequate representation among all targeted audiences, and address appropriate subpopulations, not merely broad racial or ethnic categories. - Researchers should endeavour to ensure that research participants are protected from undue intrusion, distress, indignity, physical discomfort, personal embarrassment, or psychological or other harm.	
2.5	What internal engagement or consultation has been undertaken as part of this EIA and with whom? What were the results? Service users/carers/Staff	
2.6	What external engagement or consultation has been undertaken as part of this EIA and with whom? What were the results? General Public/Commissioners/Local Authority/Voluntary Organisations	

In the table below, please describe how the proposals will have a positive impact on service users or staff.
Please also record any potential negative impact on equality of opportunity for the target:
In the case of negative impact, please indicate any measures planned to mitigate against this:

	Positive Impact (including examples of what the policy/service has done to promote equality)	**Negative Impact**	**Action Plan to address negative impact**			
			Actions to overcome problem/barrier	**Resources required**	**Responsibility**	**1.3 Target date**
Age	Informed consent: is a vital aspect of research with people of all ages. SHFT will ensure that participants will understand the negative as well as positive consequences of consenting to participation in the research process. R&D policy is inclusive of all ages as is the nature of research. We will seek and promote projects and research ideas from all service groups including children, young people, adults of working age, older people services and corporate.	Researchers should be aware that power issues could arise (e.g. people feeling obligated to participate). Access to ethically approved research not researching target population.	Presentations at Trust inductions and to services across the organisation Promoting research on Trust media outlets and platforms Trust research website and research app Posters and research material at team bases notice boards Presentation of research at Trust Board. Distributing current studies to services.	Trust Exec support. Divisional support. Clinical staff engagement in research.	Director of Research	Ongoing

Disability	**Minimizing Risk:** The Trust will provide reasonable adjustments to ensure the full participation of disabled people	Not making the research accessible to people with disabilities: e.g. Not providing information in alternative formats for participants: Easy Read, BSL, Braile	Continued presentations to services, to promote the benefits of research both from the			

			participant, staff and organisation's perspective. Ensuring study material is adapted accordingly. Depending on study protocol, try to undertake home visits to research participants to enable them to participate in studies where they may be otherwise excluded. To provide transport to enable those with disabilities to attend study specific visits.			
Gender Reassignment	The Trust will take appropriate measures to ensure that the privacy of participants is not invaded: Researchers should be aware of the potential impact of sensitive topics on the community being researched. Researchers should be non-judgemental and objective at all times.	By what means can it be ensured that different groups are properly represented in research studies, and if not, that this is due to considered rationale rather than omission or accident? Research studies, in coding sex, conventionally allow only for the options	Equality and Diversity Team. We actively seek research projects that align with all population groups.			

	The research department recognises all diverse groups within SHFT and the wider population.	of male and female. This may exclude people who are 'intersex' (born with elements of both male and female sexual organs and biology), transgendered (people engaged in identity, physical or behavioural changes to what was their gender assignment at birth), or transsexuals (people who have undergone sex change surgery and other forms of treatment).				

Marriage and Civil Partnership	A World Health Organization (WHO) report, Putting Women First: Ethical and Safety Recommendations for Research on Domestic Violence Against Women, highlights the need for specific precautions in undertaking research.		The policy applies to all equally.			
Pregnancy and Maternity	The Trust will ensure equality of opportunity by supporting researchers during maternity, paternity or adoption leave: Note that maternity leave may have an impact on an individual's ability to conduct research in addition to the defined period of maternity leave itself.	Impacts related to pregnancy or maternity may include but are not limited to: Medical issues associated with pregnancy or maternity;	Exceptions to inclusion of pregnant patients are on specific studies with an exclusion criteria that would exclude individuals as per favourable opinion of the HRA/REC.			

		Health and safety restrictions in field work during pregnancy or breastfeeding; Constraints on the ability to travel to undertake fieldwork due to pregnancy or breastfeeding.				

Race	The Trust provides Interpreting and Translation services. Researchers must have an understanding of the culture of the BME community being studied: The Trust E&D team will provide support, advice and signposting to relevant agencies to promote understanding and awareness. SHFT will ensure that racist or xenophobic language and concepts are not concepts are not included in any aspect of the research design, conduct or reporting.	Providing information in a format that the participant will not understand: Specific consideration should be given when using interpreters in BME communities as some of these communities tend to be small and are sensitive to issues of confidentiality. Researchers should be aware that some groups may be sensitive to certain issues and should therefore ensure that the research experience is not a distressing one. Particular research methodologies that discriminate against people from different racial, ethnic, religious and cultural	Policy is inclusive We actively seek participation in research projects across a range of topics from the NIHR portfolio. In line with our vision to enable every patient an opportunity to take part in research', we actively engage all without discrimination			

		backgrounds? By what means can it be ensured that different groups are properly represented in research studies, and if not, that this is due to considered rationale rather than omission or accident.				
Religion or Belief	The Trust will engage and ensure that the religious requirements of participants will be respected: for example, Prayer facilities; dietary requirements etc.	Research events planned and scheduled on days that may exclude certain groups.	Equality and Diversity Team. Trust Diversity Calendar.			
Sex	Researchers must pay attention to, and respect, gender differences: attention must be paid to the way people are treated, the use of gendered language, issues of inclusion in research, and the different impact of various methodologies on women and men. When conducting focus groups on sensitive such as GBV, it is often preferable that participants are relatively similar to one another in terms of protected characteristics: By attempting to create a more homogeneous profile of participants within each focus group, you may be able to	Research methodologies that discriminate against women or men?	We welcome robust good quality research projects regardless of sex or gender. We continue to recruit to current studies from both groups with the exception of specific study criteria.			

	increase group comfort level when discussing sensitive topics.					

Sexual Orientation	The Trust will ensure the privacy, dignity and respect of all research participants and avoid using terms that may cause offence.	It is recognised that lesbian, gay and bisexual (LGB) 1 people experience various forms of discrimination and harassment because of their sexual orientation.	Equality and Diversity Team. We welcome interest from all diverse groups in the Trust to contribute towards research projects.			

Appendix 2: Research Department Strategic Direction

Strategic direction for 2018/20 and plan to support High Level Objectives (HLO):

- Be seen as a leader in research in mental and physical health, learning disability and community care regionally and at national level (develop capability and capacity)
- Attract national and regional research funding
- Develop the infrastructure to be able to participate in more commercial trials in accordance with national agenda
- Embed research and the use of evidence in every day clinical practice in every clinical team (improve standards)
- Expand on the number of studies so that we have the ability to offer research in every service that southern health offers
- Offer research training – PhDs, research fellows

In order to deliver to the HLO we aim to:

- Promote greater awareness and engagement internally, raise the profile of research and continue increasing its reach across integrated services, thereby increasing research activity across divisions.
- Foster collaborations with academic institutions to increase scope for home grown research trials.
- Championing research by engaging the board and clinicians of Southern Health through reports to Medical Director and presentation at meetings etc., to facilitate a culture where staff will consider recruitment to trials important.
- Publicity of research through our communication outlets including Research App, website, posters in clinical areas that we are a research active organisation.
- Engage clinicians and ensure clinical areas have relevant information of ongoing trials.
- Dedicated pharmacy support, a critical factor in delivery of commercial trials and building capacity.
- Develop capacity to sponsor more trials.

APPENDIX 3 – HRA WORKFLOW						Metrics	
Step	**Name**	**STEP START**	**Actions**	**STEP ENDS**	**Recording**	**CRN**	**DH / NHIR**
1.	**IDENTIFY**	Horizon Scan CRN Notification Direct approach from study team	Band 7's conduct initial feasibility: • PI • Population • Pharmacy • Funding	Expression of Interest email sent Or reject if not feasible citing reasons	Where applicable, Governance administrative team records EOI dashboard and add 'response required by' date Band 7's to: • Enter onto E.O.I. dashboard • Add to SIF Folder (if SIF completed) • Notify management team		N/a

Commercial Studies → CDA sent to PI and R&D manager → CDA reviewed and signed → Completed CDA returned (Copy to CRN) → CDA recorded on CDA tracker

CRN records response time

2. ASSESS	**Date Site Invited** Date on the Sponsor email received by the site providing the protocol in the version to be submitted for regulatory review	**Assess capacity and capability** **Governance Team with Band 7's** to: Assess requirement for facilities support • requirement for third party contracts Assess Finance arrangements: • Attached funding –model Clinical Trial Agreements/Site agreements • Subvention • ETCs Detailed pharmacy discussion/review Confirm with PI Band 7 - Complete: • Risk assessment • Recruitment strategy • Monitoring plan Band 7 assigns project Co-ordinator	Email reply sent to sponsor Or reject if not feasible citing reasons	**Admin team**: Create study record within Research Database and EDGE **Project Coordinator**: set up study folder (spine information and appropriate contents page)		N/a

3. STUDY SET UP	**Date Site Selected** Date on the Sponsor email received by the site providing the minimum defined documents to enable site to commence arrangement and/or confirmation of local capacity and capability as applicable representing that the site has been selected to take part in the study. Where the Sponsor is also the site, this is the date of the HRA initial assessment letter. Receipt of **"Local Information Pack"** from Sponsor: • HRA Initial Assessment Letter • Statement of Activities **(non-commercial)** • Schedule of Events **(non-commercial)** • Costing Template and mCTA **(commercial)** **HRA Approval Letter** received from Sponsor ---------- **Date Site Confirmed by Sponsor**	Start of arranging capacity and capability: Review SoA Review SoE Review Costings / mCTA / Agreements, etc. Complete / Authorise SoA First Party signs mCTA / Agreement Or Sponsor emails final version of the SoA ---------- Site confirmation cannot take place **prior to HRA Approval**.	---------- **Receive:** the FIRST (Sponsor) signature on mCTA/Agreement (x3 copies) REC approval letter HRA approval letter (to include approval of SOA & SOE) MHRA approval (for CTIMP) ARSAC certificate (if required) Other regulatory approvals required	**Record "Participating Site Selected" date on EDGE and the Research Database** **Record "Date of HRA Approval Letter" on EDGE and the Research Database** **Record "Date Participating Organisation Confirmed by Sponsor" on Edge and the Research Database**	Start of "Selected to Site Confirmation" metric **40 DAYS**

4. CONFIRM	**Date Site Confirmed**	Fully Executed mCTA / Agreement received Or Email confirmation of acceptance of SoA from both Sponsor and Site,	Admin to arrange sign off: SOA,SOE, mCTA and other Contracts. E-mail to CI/Sponsor	**Record "Date Participating Organisation Confirmed" on EDGE and the Research Database** *Ensure all data fields are completed in EDGE and the Research Database*		
	Date Site ready to start	SIV date and/ or Confirmation received from Sponsor that recruitment can begin at site (email)		**Record "Open to Recruitment" date on EDGE and the Research Database**	Start of "Confirmed by Sponsor to First Patient" metric **30 DAYS**	RTT
	Non-Confirmation	Sponsor declines site or site confirms "No Capacity and Capability"	Site unable to participate in study	**Record "Non-Confirmation" on EDGE and the Research Database**		
5. FIRST PATIENT RECRUITED	**First patient is recruited at Site**	Where a participant consents to both screening and participation into a study and they then fail to pass screening, their consent date cannot be used. The next date of consent to participate of an eligible participant will be defined as the first participant. The confirmation of the first participant will be a retrospective verification as will require the outcome of screening to ensure the participant is eligible for the study before this data point can be captured.	Record Screened patients – add note to explain screening period. At next CTP report review and update	**Record "First Patient Recruited" date on EDGE and the Research Database**	End of 30-days to "First Patient" metric	

	During Recruitment Window	**Patients recruited at Site**	PI / Research Team to maintain recruitment record on EDGE Ongoing Monitoring (either internal or external) Reporting of Events to CI/PI/sponsor – Governance team and Trust reporting if required Band 7's and Admin to keep monitoring dashboard up to date Audits and spot checks Weekly feedback in staff meeting Continuing review of plans and strategies Amendments processed		R&D to ensure recruitment uploads being completed Amendments recorded on EDGE	RTT Continued
6. LAST PATIENT RECRUITED		**Last patient is recruited at Site**	Ensure last patient last visit is recorded on EDGE		Record "Last Patient Recruited" date on EDGE	
7. END OF STUDY		Confirmation from Sponsor that study will/has ended	Follow-up if applicable Archiving study folders/documents Dissemination of findings	**Request sponsor opportunity to monitor site file ready for archiving** **OR: Final site file monitoring review in-house**	Update on EDGE Archive Site file Archive Governance folder according to Trust policy.	

DEFINITIONS	
Date Site Invited	Date on the Sponsor email received by the site providing the protocol in the version to be submitted for regulatory review
Date Site Selected	Date on the Sponsor email received by the site providing the minimum defined documents to enable site to commence arrangement and/or confirmation of local capacity and capability as applicable representing that the site has been selected to take part in the study.
HRA Approval Date	Date of HRA Approval for study as per HRA Approval Letter
HRA Approval Letter	A letter confirming that HRA Approval has been given for a study, on the basis described in the application form, protocol, supporting documentation (and any clarifications noted in the Approval letter).
HRA Initial Assessment Letter	
Site Initiation Visit	Once NHS Permission has been granted for a commercial study and the study contract has been signed, the sponsor will usually need to perform a Site Initation Visit with the Investigator and study team prior to providing any study drug to site and giving the Investigator authorisation to start recruiting patients (often referred to as the 'Green Light') The sponsor will usually have a checklist of items they will need to go through to make sure the Investigator and study team are ready to start recruiting to the study. The Site Initiation Visit can take several hours, and the sponsor will expect the Investigator, members of the study team and representatives from any support departments, such as Pharmacy, to be available.
Date Site Confirmed by Sponsor	Date of the first contract signature of all the organisations involved (i.e. sponsor, site, 3rd party) or Date on the email received from Sponsor providing the final statement of activity ready for final agreement.
Date Site Confirmed	Date of the last contract signature of all the organisations involved (i.e. sponsor, site, 3rd party) or date of final written agreement of statement of activity (as applicable)
Non-Confirmation Status	Record reason for non-confirmation of a site to start the study
Date Site ready to start	Date that the site is ready to start (i.e .recruit study participants, provide data or tissue) defined by all other requirements to start, additional to contract signature and/or Statement of Activity agreement, are satisfied
First Participant Recruited Date	The date of consent to participate for an eligible participant
Recruitment to Time and Target **(RTT)** (commercial contact studies)	The target number of participants (which is suitably documented to be recruited to participate in the study), have been recruited to study by the agreed target date
Statement of activities (Non-commercial)	The HRA Statement of Activities (along with the SoE) is part of the document submission pack, to be submitted via IRAS for non-commercial studies applying for HRA Approval. The SoE and SoA aim to capture all information around study activities being undertaken at a local level. Non-commercial sponsors may propose to the HRA that the Statement of Activities is used with

	participating organisations as a form of site agreement, in line with the criteria and standards published by the HRA. Where the sponsor does not intend to use the Statement of Activities as the site agreement, or where the HRA indicates that this is appropriate, the template(s) of the agreement(s) that the sponsor does intend to use with participating organisations should be submitted to the HRA as part of the submission checklist from IRAS.
Schedule of Events (non-commercial)	The HRA Schedule of Events (along with the SoA) is part of the document submission pack, to be submitted via IRAS for non-commercial studies applying for HRA Approval. The SoE and SoA aim to capture all information around study activities being undertaken at a local level. It also forms part of the local document pack that sponsors should provide to participating organisations once the template submitted to the HRA have been agreed and this agreement recorded in the HRA Initial Assessment Letter (or HRA Approval Letter where no Initial Letter is issued).
NIHR Industry Costing Template	For commercially sponsored studies Schedule of Events and Statement of Activities templates are not used. Instead, a completed NIHR Industry Costing Template should be submitted to the HRA, along with the template agreement(s) that the sponsor intends to use with host organisations.
Subventions	In very exceptional circumstances, where the volume or concentration of Excess Treatment Costs associated with a particular piece of externally funded R&D impacts unfairly on a very small number of NHS organisations and would risk serious disruption to NHS services locally, DH may make available a subvention to cover part of the Excess Treatment Costs. DH will determine the level of subvention offered in discussion with the Chief Investigator(s). A subvention will not cover the full Excess Treatment Costs, part of which will be expected to be borne through normal commissioning arrangements. Only non-commercial research studies entered onto the NIHR Clinical Research Network Portfolio database or studies funded through the NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs), Biomedical Research Centre and Biomedical Research Unit funding schemes are eligible to apply for subvention funding. Applications must be made by the study Chief Investigator