Research Governance Policy

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1. Statement of Aims and Objectives

1.1. Introduction

1.2. South East Coast Ambulance Service NHS Foundation Trust (the Trust) is committed to being a research active organisation that is recognised as a world-class provider of emergency unscheduled and urgent care by improving clinical outcomes and patient experience through the safe implementation of innovation, service evaluation and research findings.

1.3. This policy identifies the requirements for conducting research within the Trust, thereby ensuring that all studies comply with the current UK Policy Framework for Health and Social Care Research (2023). This ensures that all research undertaken is conducted in a safe and consistent manner.

1.4. Scope

1.5. This policy is relevant to all aspects of research undertaken within the Trust and applies to those studies where the Trust has been identified as a study site, Participant Identification Centre and, or where the Trust is leading the study. Furthermore, any study where Trust premises, Trust resources, Trust staff, Trust collaborators or service users are involved are also subject to this policy.

1.6. All aspects of this policy comply with the UK Policy Framework for Health and Social Care Research (2023) and incorporate the five domains of health and social care research, including all legislation, standards, and good practice guidelines:

- Ethics
- Science
- Information
- Health, Safety and Employment
- Finance and Intellectual property

1.7. Areas of service evaluation, quality improvement and clinical audit are not encompassed by this policy, instead those are managed by either the staff members head of department, Quality Improvement Department, Audit Department, or relevant service provider. Where there are areas of cross-over the Research and Development Department may act in a representative capacity on behalf of other departments and on behalf of the Trust.

1.8. Aims and Objectives

1.9. The Trust has recognised research as essential in the delivery and sustainability of high-quality care provision. To meet this level of effectiveness, achievement of key objectives is sought as part of all new and ongoing studies.

- Ensure that high quality research is undertaken.
- To involve patients and the public in research at all levels.
- Maintain a support and governance function for Trust staff undertaking research.
- Seek collaborations leading to development of appropriate research projects and grant applications.
- To develop and build on a research culture that enables established and aspiring researchers to develop capacity and capability.
- To contribute to the evidence base that informs paramedics' and other ambulance clinicians' practice and the provision of urgent and emergency. unscheduled healthcare.
- To ensure a high quality and sustainable research and development infrastructure with dedicated research staff to facilitate the management and expansion of these activities.
- To ensure that research and development links with other clinical delivery strategies such as Clinical Audit, Quality Improvement, Clinical Risk and Clinical Governance.
- To ensure that innovations and all new practices introduced by SECAmb are evidence based.
- To generate research income from various sources to ensure research activities become self-funding in the long-term.
- To enhance publication and research output from SECAmb staff in both quality and quantity.
- To ensure that research, innovation, and service evaluation are integral to the Trust's Annual Plan Review (APR).

2. Principles

2.1. Use of patient data

2.1.1. All data and information accessed and collected during research activities must be managed in accordance with the Trust's Information Governance Policy and in accordance with the General Data Protection Regulation (GDPR) / Data Protection Act 2018.

2.1.2. Consent must be sought from any individual providing data for use within a research study. 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 Health Research Authority (HRA) Confidentiality and Advisory Group (CAG).

2.1.3. The lawful basis for which data is collected, collated, and stored must be specified to all participants and internally recorded. This is required to illustrate the legal basis for processing information (Articles) within the GDPR.

2.1.4. Where Trust data is viewed, collected, collated, or analysed for the purpose of research activities a Data Protection Impact Assessment (DPIA) **MUST** be completed and approved by the Trust's Information Governance Department. This is in addition to national and local research governance/ethical approvals. *(see section 2.6)*

2.2. Conducting clinical trials of investigational medicinal products (CTIMPs)

2.2.1. Clinical Trials of Investigational Medicinal Products (CTIMPs) must adhere to the EU Clinical Trials Directive 2004 (transposed in UK Law through the Medicines for Human Use (Clinical Trials) Regulations 2004. CTIMP studies must also be conducted according to Good Clinical Practice (GCP) and all individuals undertaking this research must be compliant with current GCP training. *(see section 5)*

2.2.2. Prior to commencement all CTIMP trials must have in place a favourable opinion from a recognised ethics committee and an authorisation from the Medicines and Healthcare Products Regulatory Agency (MHRA).

2.3. Clinical trials of Medical Devices

2.4. Authorisation from the MHRA is required for all clinical trials of medical devices whether non-CE Marked (e.g. a new device) or CE Marked and being used for a purpose other than that originally intended.

2.5. Consent

2.5.1. All research studies must demonstrate that suitable arrangements have been made relating to consent. All elements of the consent process must be documented as appropriate to the study and relevant individuals.

2.5.2. Appropriate adjustments should be made where the requirements of the study involve elements of the Mental Capacity Act 2005. These adjustments must provide suitable protection for individuals participating in the study so as to provide a safe environment for them. The Mental Capacity Act 2005 provides clear information as to how varying approaches can be made with people who are unable to make their own decisions.

2.6. Regulatory and Ethical Approval

2.6.1. 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.

2.6.2. All studies involving recruitment of NHS patients and staff, use of premises, resources, or data, **MUST** have HRA regulatory approval in place as a minimum.

2.6.3. Some research studies will require ethical approval to be in place prior to commencement. Where this is the case approval must be obtained from a recognised Research Ethics Committee. Depending on the type of study this may be required nationally via the HRA, from a Higher Education institution, or both.

2.7. Trust Approvals

2.7.1. All research studies being undertaken within the Trust must have received approval from the Research and Development Department prior to commencement. Indemnity cover is only valid once the Research and Development Department have approved the study. The Trust will not be liable for any study undertaken within the Trust that has not first been approved by the Research and Development Department.

2.7.2. All applicants seeking Research and Development Department approval, and confirmation of Capacity and Capability must follow the Trust's approval process that is outlined in the document ***'A brief guide to gaining Research Governance and Ethics approvals'*** available on the Research and Development Department pages of The Zone.

2.8. Science

2.8.1. Prior to commencing any study, an appropriate level of preparation is required in order to ascertain the viability, effectiveness, and quality of the proposed work. This is to reduce the possibility of replication of previous studies and maximise the ability for it to inform future practice/literature.

2.8.2. All proposals or protocols need to be reviewed by appropriate individuals who have specialist knowledge in both the application of research and the field being studied. These individuals should provide feedback to the researcher in order to advise as to the studies' quality and overall viability. This review should take place prior to submission for HRA review and Trust approval.

2.9. Health and Safety

2.9.1. Researchers must be aware of their responsibilities according to Health and Safety policies and ensure the safety of all study participants and associated staff.

2.9.2. All areas of the study must be assessed to identify any potential breaches of policy/procedure, and these must be addressed prior to Trust approval is sought and or provided.

2.9.3. Should any adverse event occur as part of the study, it is imperative that this is reported and recorded in line with Trust procedures.

2.10. Finance

2.10.1. All studies must comply with the Trust's finance arrangements as overseen by the Finance Department.

2.10.2. Where funding is required for a study, it is the researcher's responsibility to make sure that this has been secured and confirmed prior to application for Trust approval.

2.10.3. Funding for studies is secured against a clear framework and so there must be a clear transparency of all research income and expenditure. Accountability of all finances within the study sits with the named research team.

2.10.4. All external research studies must meet the financial implication as set out within the Research Administration and Data Charging Policy.

2.11. Intellectual Property

2.11.1. All studies must adhere to the Trust's terms and conditions around intellectual property (IP). All IP generated from research activities where the Trust acts as the sponsor will remain the property of the Trust and may be reproduced or used to aid service improvement, inclusive of patient care.

2.11.2. Where studies result in output that is published as part of academic journals, or presented through developmental events (e.g. conferences), it is accepted that copyright may be assigned to the author of those published items. In these circumstances the aforementioned author holds IP rights as identified by the relevant outlet (e.g. publisher, organiser).

2.12. Sponsorship

2.12.1. All research studies undertaken within the Trust must have a sponsor. The sponsor or sponsoring institution/organisation will take overall responsibility for all aspects of the study (e.g. finance, monitoring).

2.12.2. All studies must identify their sponsor as part of the Trust's research governance approval process.

2.12.3. Where the Trust is to be the nominated sponsor it is important to gain advice from the Research and Development Department early in the process. The Research and Development Department must be informed of all agreements of sponsorship by the Trust.

2.13. Fraud/Misconduct

2.14. Allegations of fraud and/or misconduct within any research activity undertaken within the Trust and/or where the Trust is named as a participant will be fully investigated in line with the Trust's current Anti-Fraud and Bribery, Complaints and Grievance policies.

2.15. Indemnity

2.15.1. Where appropriate all studies must have indemnity arrangements in place. These must be detailed within your approval application and must encompass both the duration of study and all impacted elements of the trust.

2.14.2. Where studies are conducted by external research teams, all indemnity arrangements are subject to details specified within either the Letter of Access or Honorary Research Contract issued by the SECAmb Human Resources Department.

2.16. Public/Patient Involvement and Engagement (PPIE)

2.16.1. All research should include public/patient representation in the design, conduct, analysis, and reporting of findings. There may be circumstances where PPIE representation is not appropriate, and these should be discussed with the Research and Development Department at the earliest opportunity.

2.17. Research Completion

2.17.1. Upon completion of a study the Research and Development Department will be informed (preferably by the same investigator who requested initial Trust approval). The research team may then be asked to report on their study at the next available Research and Development Group meeting.

2.17.2. All studies identified as being completed within the Trust will be reviewed by the Research and Development Department to identify any potential developmental areas relevant to the Trust. Where suitable areas are identified, information will be fed back to the directorate head responsible for that work stream along with details of the respective research team.

2.17.3. Studies conducted within the Trust should be considered for presentation or publication. This could involve, but is not limited to, peer reviewed journals, conferences, articles, letters, and Trust magazines.

2.17.4. All published materials using Trust sought data **MUST** be reviewed by the Research and Development Department prior to submission. Where findings are to be submitted for publication, it is the responsibility of the research team to consult with the Research and Development Department to ascertain suitability of content.

2.17.5. Suitable support on the preparation and submission of papers for publication can be sought from the Research and Development Department.

2.17.6. All study materials must be archived according to the sponsor/Trust's current policies.

3. Definitions

3.1. **Audit:** Work undertaken to ascertain whether the quality of a process meets a predetermined standard with the aim of ascertaining how close it is to best practice. (E.g. Do all unconscious patients receive a blood glucose test?).

3.2. **Chief Investigator (CI):** Takes responsibility for the conduct of the proposed research. The CI supervises the research and is available to communicate with the Research Ethics Committee (REC) and other review bodies during the application process and, where necessary, during the conduct of the research.

3.3. **Confidentiality and Advisory Group (CAG):** An NHS group set up to protect and promote the interests of patients and the public whilst at the same time facilitating appropriate use of confidential patient information for purposes beyond direct patient care. https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/

3.4. **Good Clinical Practice (GCP):** An international ethical, scientific, and practical standard to which all clinical research is conducted.

3.5. **Health Research Authority (HRA):** The HRA is a body that regulates different aspects of health and social care research throughout the NHS in England. It brings together the assessment of governance and legal compliance and replaces the need for local checks of legal compliance and related matters by each participating organisation. http://www.hra.nhs.uk/research-community/hra-approval-the-new-process-for-the-nhs-in-england/

3.6. **Higher Education Institution (HEI):** Organisations providing higher, postsecondary, and tertiary education, i.e. University.

3.7. **Innovation:** The application of knowledge or ideas for the development of products, services, or processes in order to create a new solution to an existing problem or take an existing solution and make it better.

3.8. **Integrated Research Application System (IRAS):** A UK-wide system that streamlines the process for applying for permissions and approvals to conduct health and social care research. IRAS allows researchers to enter the information for the relevant permissions and approvals once, instead of having to complete several separate application forms for each review body. http://www.hra.nhs.uk/resources/applying-for-reviews/integrated-research-application-system-iras/

3.9. **Medicines and Healthcare Products Regulatory Agency (MHRA):** A regulatory agency that regulates medicines, medical devices, and blood components for transfusion in the UK. https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

3.10. **Principal Investigator (PI):** The investigator responsible for the research site where the study is being undertaken. In the case of a single-site study, the chief investigator and the PI will normally be the same person.

3.11. **Proposal:** An initial document putting forward the idea for a research study. This is usually undertaken to gain agreements around sponsorship, funding, ethics, etc.

3.12. **Protocol:** A full description of the research study that acts as a 'manual' for members of the research team to ensure adherence to the methods outlined.

3.13. **Quality Improvement:** A collaborative process of continuous evaluation and improvement of healthcare delivery to achieve better patient outcomes.

3.14. **Research:** Work undertaken to generate new knowledge and change current practice (e.g. What effect does adrenaline have on resuscitation outcomes?).

3.15. **Research Ethics Committee (REC):** A group responsible for ensuring that all research undertaken is conducted in an ethical manner and in accordance with local, national, and international policy.

3.16. **Service Evaluation:** Service evaluation seeks to identify the standards being achieved by a given process in order to help inform the development, and improvement of a service, process, or practice (e.g. Do clinicians find the new PCR layout helpful?)

3.17. **Service User:** Anyone who uses a component of the trust. For example, a patient and/or their family and friends, a care facility (i.e. care home, hospital) or members of trust staff.

3.18. **Sponsor:** The individual, company, institution, or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research.

4. Responsibilities

4.1. The Chief Executive has overall responsibility for the strategic direction and operational management of the Trust.

4.2. The Chief Medical Officer has responsibility for identifying, developing, and implementing a Research Governance Policy that supports the Chief Executive in his responsibility.

4.3. It is the responsibility of the Research Manager to draft, implement and update this policy.

4.4. It is the responsibility of the Joint Partnership Forum and Senior Management Team to approve this policy.

4.5. It is the responsibility of the Head of Research to ensure the Research and Development Department collaborates with colleagues across the Trust to embed this policy in daily practice.

4.6. It is the responsibility of all Trust staff to identify the need for any change to this policy as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising their line manager accordingly.

5. Competence

5.1. All staff employed by the Trust for the sole purpose of undertaking research roles must be able to demonstrate an understanding of current national and local policies and procedures. This will be further supported

through the demonstration of engagement with academic development in the area of research and its associated practices.

5.2. All staff undertaking research activities in line with the scope of this policy must be able to demonstrate that they have received suitable training relevant to their identified roles and responsibilities.

5.3. All external researchers wishing to work with the Trust for the purpose of data collection must confirm upon application that they have the required knowledge and expertise to complete the requested tasks. This will form part of their contract with the Trust.

5.4. Individuals working on a Clinical Trials of Investigational Medicinal Products (CTIMPs) study will need to have completed 'Good Clinical Practice' (GCP) training/update within the last 12 months. Other individuals may need to complete this training if they have not been involved with research for the last 12 months, so as to refresh their knowledge around current ways of working and policy/procedures.

6. Monitoring

6.1. The Research Manager is responsible for ensuring that compliance is achieved through adherence to Trust strategy, forecast objectives and on-going reports.

6.2. Any alterations/updates to this document will be agreed by the Senior Management Team

6.3. Any study identified as not adhering to this policy or other Trust policy/procedure will be reviewed as and when required by the Senior Research and Management Teams.

7. Audit and Review

7.1. The Research Manager is responsible for ensuring that this document is reviewed and changed as necessary in response to any legislative, guidance or organisational changes.

7.2. The document will be reviewed every three years, or sooner if new legislation, codes of practice or national standards are introduced.

7.3. All changes made to this procedure will go through the governance route for development and approval as set out in the Policy on Policies.

8. Associated Documentation

This policy links with the following documentation:

- Research Administration and Data Charging Policy
- Research Strategy
- Research and Development Sub-Group Terms of Reference
- Data Protection Policy
- Records Management Policy
- Patient Data and Health Records Management Procedure
- Patient Data and Health Records Policy
- Annual Plan Review

9. Equality and Analysis

9.1. The Trust believes in fairness and equality, and values diversity in its role as both a provider of services and as an employer. The Trust aims to provide accessible services that respect the needs of each individual and exclude no-one. It is committed to comply with the Human Rights Act and to meeting the Equality Act 2010, which identifies the following nine protected characteristics: Age, Disability, Race, Religion and Belief, Gender Reassignment, Sexual Orientation, Sex, Marriage and Civil Partnership and Pregnancy and Maternity.

9.2. Compliance with the Public Sector Equality Duty: If a contractor carries out functions of a public nature, then for the duration of the contract, the contractor or supplier would itself be considered a public authority and have the duty to comply with the equalities duties when carrying out those functions.

10. References

Data Protection Act. (2018) Department of Health. https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted

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