South East Coast Ambulance Service NHS
NHS Foundation Trust

Research Administration and Data Charging Policy

Contents

1 Statement of Aims and Objectives

Introduction

1.1. South East Coast Ambulance Service NHS Foundation Trust (the Trust) continues to develop a culture where research is valued and supported as an integral part of the organisation and evidence led change is at the forefront of all healthcare and employee developments. In order to achieve this the Research and Development Department (the RDD) recognises the need to expand its portfolio of studies and effectively collaborate with regulators, national research networks, professional bodies and academic institutions to facilitate strong cross organisational working.

1.2. All research studies undertaken within SECAmb require the RDD to undertake a local governance review and associated administrative processes in coordination with other departments, often without remuneration, which include activities such as application review, project impact assessment, feedback on protocol, capacity and capability confirmation, agreement provision, issuing letters of access/research passports, DPIA completion.

1.3. In 2021 the Health Research Authority (HRA) issued recommendations to help reduce the workload related to research within the NHS, stating that the number of academic research studies undertaken by students within the Healthcare setting should be reduced. To assist with this they advised that where possible alternate projects such as Service Evaluations or Systematic Reviews should be undertaken in order for students to meet the requirements of their academic programme of study.

1.4. In line with this transition the RDD has identified a series of changes to its practice that will allow us to support our employees and participate in quality collaborative research as identified by the National Institute for Health and Care Research (NIHR) more effectively.

Scope

1.5. This policy is applicable to all research led by individuals from outside of SECAmb, including that undertaken by students. It therefore sets out the scope of practice to which everyone must adhere. ***This policy does not affect any internal studies where employees members are undertaking research as part of their current workstream or academic programme.***

1.6. The policy makes use of recommendations as outlined by the HRA (2021) and the ongoing work undertaken by the NIHR and respective Clinical Research Networks (CRN).

1.7. All aspects of this policy support the expectations and practices assured by the UK Standing Committee for Quality Assessment and its respective collaborative documentation including the UK Quality Code for Higher Education (2023) and the Regulatory framework for higher education in England (2022).

Aims and Objectives

1.8. A move towards maximising quality research whilst reducing the financial impact of research upon NHS trusts has been recognised nationally by the NIHR and HRA, with joint working between representatives of HEIs. The RDD on behalf of the Trust supports this transition by implementing the following:

- No external research undertaken to satisfy the requirements of a master's level course will be supported within the Trust unless they are NIHR portfolio adopted or there is associated funding available to compensate the Trust for incurred costs.
- The Trust is under no obligation to support external research undertaken to satisfy the requirements of a PhD. Each study will be reviewed on an individual basis, considering the impact on internal processes, available funding, NIHR portfolio adoption and their alignment to the Trust's strategic goals.
- A set fee will be charged for each research study supported by the Trust, to cover all governance and related study activities.
- In addition to the above, external research studies requiring the provision of data sets must have appropriate funding in place to cover retrieval and processing.

The Trust reserves the right to potentially waive or reduce fees if the study is NIHR Portfolio adopted and accruals are to be allocated to SECAmb. Prospective accrual numbers must be at a level whereby they are considered a reasonable reimbursement alternative. This is fully at the discretion of the RDD.

2 Principles

Regulatory and Ethical Approvals

2.1. 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 governance and

ethical standards as outlined within the Trust's Research Governance Policy.

Use of data

2.2. All data and information accessed and collected for the purpose of a research study 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.

2.3. Where required a Data Protection Impact Assessment (DPIA) will be completed via the Information Governance Department. For external studies this will be undertaken by the RDD on behalf of the external research team.

Indemnity

2.4. Indemnity cover is only valid once the RDD has issued its final approval. The Trust will not be liable for any research study undertaken within the Trust that has not been approved by the RDD.

2.5. External research studies found to be running within the Trust without the required approvals in place will be halted immediately until a full review can be undertaken. The Research Manager on behalf of the RDD will contact the identified CI to discuss the project including the use of any collected data, governance issues and relevant fees.

3 Definitions

3.1. **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.

3.2. **Clinical Research Networks (CRN):** The CRNs support patients, the public and health and care organisations across England to participate in high-quality research, thereby advancing knowledge and improving care.

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

3.4. **Health Research Authority (HRA):** The HRA is the body that regulates 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/

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

3.6. **National Institute for Health and Care Research (NIHR):** THE NIHR is the British government's major funder of clinical, public health, social care and translational research. https://www.nihr.ac.uk/

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

3.8. **Internal research:** Research in which the Trust is the research sponsor or where an employee of the Trust is undertaking research within the Trust (e.g. academic study).

3.9. **External research:** Research in which the Trust is not the research sponsor or representation of the Trust is not present in the research steering committee.

4 Responsibilities

4.1. The **Chief Executive Officer** is accountable for the strategic direction and operational management of the Trust.

4.2. The **Medical Director** has responsibility for identifying, developing and implementing Governance Policies that support the Chief Executive in his responsibility.

4.3. The **Head of Research** has responsibility for ensuring the RDD collaborates with colleagues across the Trust to embed this policy in daily practice.

4.4. The **Research Manager** is responsible for the drafting, implementation and update of this policy.

4.5. **All employees** are responsible for adhering to this policy.

5 Procedures

5.1. All funded and/or portfolio adopted studies will be fully reviewed as outlined within the Trust's Research Governance Policy. This will be led by the Research Manager with support from the RDD and where required other departments.

5.2. Unfunded master's studies will be rejected upon receipt, unless they are NIHR portfolio adopted or there is associated funding made available to the Trust.

5.3. All research undertaken to satisfy the requirements of a PhD will be reviewed in line with 5.1.

5.4. Studies accepted by the RDD will follow the process outlined within the Trust's Research Governance Policy. Additional communications specific to the finances may be required as set out in section 6 of this policy.

5.5. Where studies are rejected by the RDD for not satisfying the funding criteria outlined within this policy, simple feedback will be provided by email as to why this has been done.

5.6. If requested the RDD will issue a formal letter to the applicant stating the reason(s) why the Trust is unable to support the study at this time. Where appropriate a representative of the RDD will be available to discuss the decision made.

6 Finance

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

6.2. 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.

6.3. Funding for studies is secured against a clear framework and 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.

6.4. The charges to be applied to external research studies are outlined in Table 1.

6.5. Fees outlined in Table 1 are based on a cost/time basis and will be agreed with the study CI before any agreement is put in place.

6.6. The RDD reserves the right to amend these fees should additional work be required, on top of that agreed by the CI at time of agreement, to meet the requirements of the study.

6.7. The fees listed in Table 1 detail activities undertaken by the RDD on behalf of the applicant.

6.8. Where required additional fees may be payable should studies require support from departments outside of the RDD and/or outside the Trust.

Table 1: Associated Funding

Task	**Fees**	
	Minimum	**Maximum**
Full Study Review: Local governance review. Confirmation of Capacity and Capability. Concise feedback if required. OID/mNCA completion. Complexity and resources required to determine costs.	£250	£2,000
Additional Tasks *(May be required in addition to the above)*	**Fees** *(in addition to above)*	
Study Set-Up: Depending on the nature of the study, liaison to secure process implementation may be required in various departments, including but not limited to Operations, Emergency Operations Control, Business Intelligence, Medicines Management, Estates and Fleet. The complexity and scope of liaison will determine costs (e.g. departmental observations, changes in process, set-up timeframe). Additional contracts or agreements (e.g. Internal DPIA or Standard Operating Procedure). Per Document:	£250 £500	£1,000 /
Recruitment: Recruitment of internal employees: Studies may vary from a single dissemination of invitations to participate, to those requiring the delivery of training and the processing of collected data prior to transferring to the CI. Disseminating the presence of studies outside of the Trust to inform public and/or professionals. Recruitment of external participants (e.g. patients): In addition to set up costs associated with identification/screening, costs may be incurred by the requirement for communications, the consent process and subsequent data collection and processing.	No Fee £250 £500	£2,000 £1,000 £2,000
Data Retrieval: Set-Up, processing, extraction and quality assurance Set-Up, processing, extraction and quality assurance: Provision of up to 1000 records with ≤5 variables.	£500	

Requests for datasets greater than 1000 records or with more than 5 variables will be costed accordingly with the appropriate department.	TBC	

7 Monitoring compliance

7.1. The Research Manager is responsible for ensuring external research studies comply with this policy and other policies such as the Research Governance Policy where relevant.

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

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

8 Audit and Review (evaluating effectiveness)

8.1. All policies and procedures have their effectiveness audited by the responsible Management Group at regular intervals, and initially six months after a new policy and procedure is approved and disseminated.

8.2. Effectiveness will be reviewed using the tools set out in the Trust's Policy and Procedure for the Development and Management of Trust Policies and Procedures (also known as the Policy on Policies).

8.3. This document will be reviewed in its entirety every three years or sooner if new legislation, codes of practice or national standards are introduced, or if feedback from employees indicates that the policy is not working effectively.

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

9 Associated Trust Documentation

9.1. Research Governance Policy

9.2. Information Governance Policy

9.3. Data Protection Policy

9.4. Patient Data and Health Records Policy

10 References

10.1. Data Protection Act. (2018). Department of Health.

10.2. EU General Data Protection Regulation (2018). European Commission.

10.3. National Health Service Act. (2006). Department of Health.

10.4. UK Policy Framework for Health and Social Care Research (2018). NHS Health Research Authority.

10.5. NHS Evaluation Toolkit (2020). Evaluation Works.

10.6. Higher Education Standards (2014). Office for Students.

10.7. UK Standing Committee for Quality Assessment

10.8. UK Quality Code for Higher Education (2023)

10.9. Regulatory framework for higher education in England

11 Financial Checkpoint

11.1. To ensure that any financial implications of changes in policy or procedure are considered in advance of document approval, document authors are required to seek approval from the Finance Team before submitting their document for final approval.

11.2. Finance has confirmed this document to have no unbudgeted financial implications.

12 Equality Analysis

12.1. 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.

12.2. 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.

Document Ends

Appendix

NHS
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Applicant Outline

This document provides a summary of the above policy providing information to those seeking to undertake research within South East Coast Ambulance Service NHS Foundation Trust (SECAmb).

In line with Health Research Authority (HRA) recommendations SECAmb has made a conscious move towards maximising quality research whilst reducing the financial impact of research upon the Trust. SECAmb's Research and Development Department (RDD) has therefore implemented the following:

- No external research undertaken to satisfy the requirements of a master's level course will be supported within the Trust unless they are NIHR portfolio adopted, or there is associated funding available to compensate the Trust for incurred costs.

- The Trust is under no obligation to support external research undertaken to satisfy the requirements of a PhD. Each study will be reviewed on an individual basis considering the impact on internal processes, available funding, NIHR portfolio adoption and their alignment to the Trust's strategic goals.

- A set fee will be charged for each research study supported by the Trust, to cover all governance and related study activities.

- In addition to the above, external research studies requiring the provision of data sets must have appropriate funding in place to cover retrieval and processing.

**The Trust reserves the right to potentially waive or reduce fees if the study is NIHR Portfolio adopted and accruals are to be allocated to SECAmb. Prospective accrual*

numbers must be at a level whereby they are considered a reasonable reimbursement alternative. This is fully at the discretion of the RDD.

If you have a research study that you feel could be undertaken within SECAmb and you are unsure as to whether it would be accepted please contact the RDD to discuss further. Research@secamb.nhs.uk

A breakdown of fees associated with this policy.

Task	**Fees**	
	Minimum	**Maximum**
Full Study Review: Local governance review. Confirmation of Capacity and Capability. Concise feedback if required. OID/mNCA completion. Complexity and resources required to determine costs.	£250	£2,000
Additional Tasks *(May be required in addition to the above)*	**Fees** *(in addition to above)*	
Study Set-Up: Depending on the nature of the study, liaison to secure process implementation may be required in various departments, including but not limited to Operations, Emergency Operations Control, Business Intelligence, Medicines Management, Estates and Fleet. The complexity and scope of liaison will determine costs (e.g. departmental observations, changes in process, set-up timeframe). Additional contracts or agreements (e.g. Internal DPIA or Standard Operating Procedure). Per Document:	£250 £500	£1,000 /
Recruitment: Recruitment of internal employees : Studies may vary from a single dissemination of invitations to participate, to those requiring the delivery of training and the processing of collected data prior to transferring to the CI. Disseminating the presence of studies outside of the Trust to inform public and/or professionals. Recruitment of external participants (e.g. patients): In addition to set up costs associated with identification/screening, costs may be incurred by the requirement for communications, the consent process and subsequent data collection and processing.	No Fee £250 £500	£2,000 £1,000 £2,000
Data Retrieval: Set-Up, processing, extraction and quality assurance Set-Up, processing, extraction and quality assurance: Provision of up to 1000 records with ≤5 variables. Requests for datasets greater than 1000 records or with more than 5 variables will be costed accordingly with the appropriate department.	£500 TBC	

*All researchers with fully funded research studies should contact SECAmb's RDD in the first instance to discuss participation (Research@secamb.nhs.uk).

No past or present collaborations will be impacted by the introduction of this new policy. All future collaborations will take the contents of this policy along with the Trust's Research Governance Policy into account.