Research & Development (R&D) Policy

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The East of England Ambulance Service NHS Trust has made every effort to ensure this policy does not have the effect of unlawful discrimination on the grounds of the protected characteristics of: age, disability, gender reassignment, race, religion/belief, gender, sexual orientation, marriage/civil partnership, pregnancy/maternity. The Trust will not tolerate unfair discrimination on the basis of spent criminal convictions, Trade Union membership or non-membership. In addition, the Trust will have due regard to advancing equality of opportunity between people from different groups and foster good relations between people from different groups. This policy applies to all individuals working at all levels and grades for the Trust, including senior managers, officers, directors, non-executive directors, employees (whether permanent, fixed-term or temporary), consultants, governors, contractors, trainees, seconded staff, homeworkers, casual workers and agency staff, volunteers, interns, agents, sponsors, or any other person associated with the Trust.

All Trust policies can be provided in alternative formats.

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1.0 Introduction

1.1 Definition of research

Research was defined by the Department of Health (DH) in 2005 as *".. designed to provide new knowledge. Findings should be potentially of value to those facing similar problems elsewhere i.e generalisable, and planned to be open to critical examination and accessible to all that could benefit from them – i.e publicly disseminated ".* This includes: clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; research undertaken by commercial organisations, charities, the research councils and universities within the health and social care systems that might have an impact on the quality of those services.

1.2 Background

The East of England Ambulance Service NHS Trust (EEAST and/or the Trust) recognises the importance of research to the successful promotion and protection of health and wellbeing. However, research can involve an element of risk, in terms of the safety and wellbeing of research participants, the Trust, and sometimes a return on investment. Therefore, proper governance of research is essential to ensure that the public can have confidence in, and benefit from, high quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.

The UK Policy Framework for Health and Social Care Research (2017) sets out principles of good practice in the management and conduct of research. These principles protect and promote the interests of patients, service users and the public in 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. The new guidelines replace separate Research Governance Frameworks in each UK country with a single, modern set of principles for the whole UK. It has been developed by the Health Research Authority (HRA) and the health departments in Northern Ireland, Scotland, and Wales, following public consultation. All individuals and organisations involved in research associated with health and social care must comply with the Framework when getting involved with any research.

1.3 Aim & Objectives

The aim of this policy is to advise the conduct of research within EEAST, which complies with good research practise as detailed in the UK Policy Framework for Health and Social Care Research. The objectives are as follows:

- To ensure compliance with regulatory requirements.
- Responsibilities for research are clearly defined.
- The financial aspects of research projects are well managed and appropriate.
- The Trust's medico-legal exposure is effectively managed.
- There is a system for the management of research misconduct.
- The interests of patients, researchers and the Trust inform research activity.
- The Trust gains recognition for the research conducted within it.
- Access to information on research activity is readily available.

1.4 Scope of the Policy

The Policy applies to all research activities that involve:

- Patients and users of the Trust and Trust staff.
- NHS patients treated under contracts with charity or private sector partners.
- Access to and use of data of past and present Trust patients and staff.
- The use of or access to Trust premises or facilities.

2.0 Managing the Research System

2.1 Responsibilities for Research

The Chief Executive (CE) is responsible for ensuring that there are effective systems in place to discharge requirements as laid down in the UK Policy Framework for Health and Social Care Research. The CE has delegated accountability for research to the Director of Nursing and Clinical Quality at Board level. The Consultant Paramedic gives approval for all research to commence, and the Research Manager (RM) is responsible for ensuring that research governance requirements are in place, as well as the management of clinical research activity.

The RM will prioritise and plan research activity to ensure that resources, including patients and staff, are available to deliver the study. The RM will also maintain a register of all research activity, will inform the Clinical Development and Effectiveness (CDE) Group about all research progress, will produce a Bi-annual Report for the Clinical Quality & Safety Group (CQSG), and will inform the Quality & Risk Assurance Committee (QRAC) of any misconduct or incidences related to research activity.

Governance of all research will be monitored internally by the QRAC and externally by the National Institute for Health Research. See Appendix 1 for a full explanation of research project roles and responsibilities.

2.2 General Principles

- Research must be conducted in accordance with the UK Policy Framework for Health and Social Care Research, other relevant legislation and Trust policy.
- All research must have a Research Sponsor.
- All researchers should ensure that they are able to meet their responsibilities.
- All researchers must demonstrate an appropriate level of research competence.
- Research should be to the benefit of the Trust, its patients or the wider NHS.

2.3 Sponsorship

All studies must have an identified sponsor who takes overall responsibility for the proper initiation, management and monitoring, and financing of the study. The decision for the Trust to sponsor a project should be based upon Trust capability and need, clinical and organisational improvements, staff development, risk, costs, and impact on organisational service delivery.

2.4 Research Ethics

Where appropriate, in accordance with current guidance, research projects must have approval of a Research Ethics Committee (REC) before they can commence.

All significant changes or developments to research proposals such as change in protocol, change in research staff, and risk events must be communicated to the REC approving the original research proposal.

2.5 Process for Research to Commence

Managers and staff of the Trust can initiate discussions with potential researchers but must refer all research proposals to Research Support Services (RSS) for advice and support through the approval to commence process. RSS will ensure that Health Research Authority (HRA) approval has been given, and will support proposals through the capacity and capability process, recording the outcome with regard feasible to deliver or not.

It is the responsibility of the Chief Investigator (CI) to ensure that the Trust is informed of the study, that the project approval process is followed, and that the study is not initiated until approval has been given. Studies will not be covered by NHS indemnity until they have been approved by the Trust.

2.5.1 Steps to be taken:

- CI completes HRA application
- Approval from REC in accordance with current guidance
- Capacity and capability confirmed (or not) by RSS
- Project outcome logged on research register by RM

2.5.2 Research not likely to be feasible

The Trust is unlikely to be able to confirm capacity and capability for a research project to commence if:

- The allocation of responsibilities (including financial) are not acceptable.
- The allocation of indemnity is not acceptable.
- The conduct of the research will have an unacceptable impact on service delivery.
- The risks to the Trust or individuals are considered insufficiently controlled.

2.6 Amendments to Research Protocols

It is the responsibility of the CI to notify the HRA, RM and any REC of research protocol amendments. All proposed changes will be reviewed by the RM, and major amendments will need further CDE review to inform whether the changes can be implemented. The CI will be notified by the RM whether the changes affect feasibility or not.

2.7 Research Passports or Letters of Access

In accordance with current legislation, it is the responsibility of the CI to ensure that Letters of Access or Research Passports are obtained for all researchers employed to conduct the work. The RM will facilitate this function in conjunction with Human Resources.

2.8 Agreements with Research Partners, Sponsors and Funders

In accordance with the UK Policy Framework for Health and Social Care Research, agreements clearly setting out responsibilities are to be obtained, where relevant, for research partners, sponsors and funders.

All research grants and contracts have contractual arrangements or regulations whether express or implied. All approaches should be discussed with the RM, appropriate head of department(s) and Trust Finance Department. All contractual arrangements and grant applications must be signed by a Trust Director.

2.9 Document Management

The CI should maintain a Master File with all relevant documents and approvals. This must, on reasonable notice, be available for inspection. The RM will hold electronic or hard copy files of key documents to include: the research protocol, Trust approval, REC approval notice, agreement documents, and final report. The length of time documents should be retained will be guided by the document Records Management: NHS Code of Practice. The minimum period for all research documents to be retained should be three years.

2.10 Research supervision

The sponsors of research undertaken by students have a responsibility to supervise the student throughout the project. When the Trust gives permission to act as a host organisation for such work, RSS will facilitate site engagement regarding delivery.

2.11 Access and Publication

Information on research being conducted within the Trust should be accessible to staff, the public, and all those that could benefit. It is intended therefore that, wherever possible, research findings will be published in peer review journals or other relevant publications. All papers should be approved by a Trust Director before submission.

All researchers should be aware of the current Data Protection Act, the document Information Security: NHS Code of Practice, and other guidance related to handling information.

3.0 Consent and Confidentiality

The CI has responsibility to ensure that, when required, informed consent is obtained (including all relevant signatures) according to study protocol. Copies of participant information sheets and consent forms will be kept in the research file. Consent documents should be retained by the CI for a minimum period of three years, and this period should be lengthened as best practice dictates for higher risk projects.

All researchers should be aware of and apply the document Confidentiality: NHS Code of Practice.

4.0 Risk

Most risk associated with research activity will be controlled by the following measures:

- Projects will have a sponsor.
- Projects will require HRA, Trust and appropriate REC approval to proceed.
- Researchers are obliged to act within the UK Policy Framework for Health and Social Care Research.
- Researchers must be sufficiently competent for the level of risk of the project.

4.1 Adverse Event Reporting

All adverse incidents to subjects or others should be reported to the study sponsor and REC according to the research proposal and Trust Risk Management Policy. In addition, incidences should be reported to the RM as soon as possible after the event.

The Research Sponsor is required to report unexpected serious adverse reactions to the Medicines and Healthcare Products Regulatory Agency (MHRA) within its deadlines, and Researchers should follow the conditions of ethical approval.

If, while undertaking a research project, any unexpected actual or potential harm is apparent the project should cease until the Trust gives approval for recommencement. Such events include, but are not limited to, any Health and Safety Incident, Adverse Drug Reaction, Adverse Event, Serious Adverse Event, Serious Adverse Reaction, or Suspected Unexpected Serious Adverse Reaction (SUSAR).

4.2 Health and Safety

The CI is responsible for taking appropriate measures to ensure that issues associated with health and safety are managed in accordance with the Health and Safety at Work Act and other relevant legislation.

5.0 Service Users, Patients and the Public

The involvement of service users, patients and the public is to be encouraged in the development of research protocols, undertaking research, and the review and dissemination of outcomes as appropriate.

6.0 Research Governance

The governance of all research is overseen by the QRAC, the minutes of which go to the Trust Board.

The QRAC and the Trust Board should be made aware of any fraud, misconduct or adverse incident occurring from research activity.

7.0 Staff Training and Development

The specific objectives are to:

- Increase general awareness of the research process, Trust systems, guidance and support available.
- Ensure adequate skills and awareness in accordance with professional regulatory body requirements.
- Develop the expertise and skills required to undertake research.
- Increase capacity of research knowledge and skills.
- Promote a culture in which research can flourish.

All staff undertaking research should have attended an appropriate level of training in research. Researchers should have received guidance on the UK Policy Framework for Health and Social

Care Research, which is intended to provide clear obligations of the researcher and will allow them to implement best research practices. The Trust will make available training in research methods and Good Clinical Practice for Trust staff, appropriate to their need, and subject to available funding.

8.0 Research Finance

Research proposals should contain clear financial arrangements, and be in line with current national costing templates. Externally sponsored research should be fully funded so as to be cost-neutral to the Trust. This may be waived if the Trust feels the research is in the best interest of the Trust, its patients or staff.

The RM will provide information and support to Trust researchers to assist them in the process of applying for external funding for research. Researchers need to involve the RM and Trust Finance Department at an early stage of discussions. All applications for external funding should be approved by a Trust Director.

Trust funding may be available for projects, in particular pilot studies which will provide data on which to base an application for external funding. Internal funding will require the authorisation of the relevant Trust budget holder.

8.1 Research Account Management

All research income will be managed in separate research accounts within specific Trust department cost centres. Trust budget holders are required to authorise all expenditure from the research accounts and all credits to budget accounts. The Trust Management Accounts Department will monitor and report on accounts for research purposes in accordance with Trust Standing Financial Instructions. The Consultant Paramedic may monitor or review any account used for a research project.

All payment relating to commercial research should be made via invoices issued by the Trust Finance Department. All requests to raise an invoice are to be made by the Trust department managing the research.

8.2 Payment to Research Participants

Any payments to participants must not be used to induce them to risk harm beyond that which they would risk without payment in their normal lifestyle. Payment to participants shall, therefore, only cover reasonable expenses and compensation for time.

8.3 Indemnity

Organisations sponsoring research must be in a position to compensate anyone harmed as a result of their negligence. Any organisation offering participant's compensation in the event of non-negligent harm must be in a position to do so.

The Trust will only offer indemnity for research activities when these activities have been registered and approved by the Trust. Researchers should not assume that their research is automatically covered by insurance provided by external bodies. Written clarification of

responsibility for indemnity arrangements should be included in any agreements made with Research Sponsors.

9.0 Research Fraud

All cases of suspected fraud or corruption are to be reported in accordance with the Trust's procedures. The general principles are that:

- An allegation of fraud or misconduct may be made by any person.
- Allegations should be written and should be as detailed as possible.
- Allegations should be recorded by the RM and reported to the Director of Nursing and Clinical Quality.
- Allegations will be investigated and outcomes recorded by the RM.
- Allegations and investigation outcomes should be reported to the CQSG and QRAC. The CQSG will monitor allegation investigations.
- In the event of serious allegation or continuing non-compliance with REC requirements the Trust will notify the approving REC.

10.0 Research Misconduct

Research misconduct includes, but is not limited to, the following, whether deliberate, reckless or negligent:

- *Misconduct in relation to grant applications and fund utilisation*
  - failure to obtain appropriate approvals to conduct research
  - deception in relation to research proposals
  - fraud or other misuse of research funds or research equipment
- *Misconduct in relation to treatment of/dealing with experimental subjects*
  - unethical behaviour in the conduct of research, for example in relation to research subjects
  - unauthorised use of information which was acquired confidentially
  - deviation from good research practice, where this results in unreasonable risk of harm to humans, animals or the environment
- *Misconduct in relation to analysis and reporting of findings*
  - fabrication, falsification or corruption of research data
  - distortion of research outcomes by distortion or omission of data
  - dishonest misinterpretation of results
  - publication of data known or believed to be false or misleading
  - plagiarism, or dishonest use of unacknowledged sources
  - misquotation or misrepresentation of other authors
  - inappropriate attribution of authorship
- *Misconduct in relation to misconduct of others*
  - attempting, planning or conspiring to be involved in research misconduct
  - inciting others to be involved in research misconduct
  - collusion in or concealment of research misconduct by others

Researcher misconduct, if not connected with fraud or corruption, will be investigated in accordance with the Trust's Disciplinary Procedure. Where a healthcare professional (clinical or

social work) is involved in research misconduct the matter will be reported to the appropriate professional body.

Allegations should be made to the relevant line manager or the RM, in which case the RM will liaise with the appropriate line manager. Allegations that refer to the RM should be made to the Director of Nursing and Clinical Quality.

Complaints relating to research activity should be referred to the Trust Complaints Team. The complaint should be dealt with within NHS Complaints Policy. The RM and relevant Trust head of department should be informed by the Complaints Team.

11.0 Research Support & Guidance

RSS will provide support and guidance to Trust researchers at all stages of the research process. This could include:

- Advice about literature searching and appraisal of the evidence.
- Access to reference books and journals.
- Study design, including advice on statistics, health economics and measurement of outcomes.
- Support preparing the research protocol, grant application and REC submission.
- Project management.
- Support with analysis and interpretation of research results.
- Dissemination of research findings, including publications, conference presentations, report writing and internet communications.

12.0 Monitoring and Inspection

The CI is responsible for the submission of progress reports for ongoing projects, and a final report when the project ends. The RM will keep a copy of such documents in the study file.

Research within the Trust may be subject to monitoring through audit, risk management or spot checks and supervision. Accordingly, all researchers must allow RSS to examine any aspect of their research activity.

The RM should use monitoring reports and the quality of completed projects to consider the suitability of current policy, procedures, and guidance to identify training needs, and should take appropriate action in light of these findings.

13.0 References

UK. Department of Health (Nov 2004) *Confidentiality: NHS Code of Practice*. http://www.dh.gov.uk/PolicyAndGuidance/InformationPolicy/PatientConfidentialityAndCaldicottGuardians/fs/en

Health Research Authority (Nov 2017) UK Policy Framework for Health and Social Care Research.

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

UK. Department of Health (April 2006) *Records Management: NHS Code of Practice*. http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4131747&chk=tMmN39

Appendix 1

Definitions & Responsibilities

For the avoidance of doubt, key definitions are given below. The meaning of other words in this Policy can be found in English Law, DH Policy, Trust Policy and Professional Codes of Practice, and precedence shall be given in the above order.

Care Organisation - The organisation(s) responsible for providing care to patients and/or users and carers participating in the study. The care organisation retains responsibility for research participants' care. It should ensure that research meets the standard set out in the UK Policy Framework for Health and Social Care Resarch, and that there is appropriate ethical approval for all research for which they have a duty of care.

Chief Investigator - The CI is the person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site. If the research is at more than one site, the CI takes overall responsibility for the study and for co-ordinating the Principal Investigators (PI) or Local Leads at each site.

The CI is accountable to their employer and the sponsor of the research. They are also directly accountable to the care organisation(s) within which the research takes place (or through which the research team has access to participants, their organs, tissue or data). It is the responsibility of the CI to ensure that:

- The research team give priority at all times to the dignity, rights, safety and wellbeing of participants.
- The study complies with all legal and ethical requirements.
- The research is carried out in accordance with the UK Policy Framework for Health and Social Care Research.

The **Principal Investigator** is the person responsible, individually or as the leader of the researchers, for the conduct of the study at a particular site.

Employing Organisation(s) - an organisation(s) employing the PI and/or other researchers. The organisation employing the CI will normally hold the contract(s) with the funder(s) of the study. Organisations holding contracts with funders are responsible for the management of the funds provided.

Funder(s) - organisation(s) providing funds for the study through contracts, grants or donations to an authorised member of either the employing and/or care organisation. The main funder is responsible for assessing the scientific quality of the proposed research, the quality of the research environment, and the experience and expertise of the CI, PI, and other key researchers involved.

Participants - patients, users, relatives of the deceased, professional carers, employees or members of the public agreeing to take part in the study.

Partner Organisation – any organisation that employs staff involved in collaborative research with the Trust.

Research - the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.

Research Ethics Committee – convened to provide independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for the study comply with recognised ethical standards.

Researchers - Researchers are those conducting the study. They are responsible for:

- Ensuring that any research they undertake follows the agreed protocol.
- Ensuring that participants receive appropriate care while involved in research.
- Protecting the integrity and confidentiality of clinical and other records and data generated by the research.
- Reporting any failures in these aspects, any adverse drug reactions and other events or suspected misconduct through the appropriate systems.

Note that researchers not employed by the Trust may require a Letter of Access or Research Passport.

Responsible Care Professional - the doctor, paramedic, nurse or social worker formally responsible for the care of the participant while they are taking part in the study.

Research Misconduct – this encompasses but is not limited to the following: Piracy (the deliberate exploitation of ideas and work of others without acknowledgement), fabrication, falsification (including the invention of data), wilful destruction of research materials, plagiarism (the copying of ideas, data or text, or any combinations of the three without permission or acknowledgement), deception in proposing, carrying out or reporting the results of research; deliberate or negligent deviations from accepted practice in carrying out research. It includes failure to follow any protocols contained in any ethical consent that has been given for the research and/or any protocols set out in the guidelines of appropriate recognised professional, academic, scientific and governmental bodies and/or procedures that avoid unreasonable risk or harm to humans, other living organisms or the environment. It also includes facilitating misconduct in research by collusion in, or concealment of, such actions by others, and any plan or conspiracy or attempt to do any of these things. Misconduct in research does not include honest and reasonable error, or honest and reasonable differences in interpretation or in judgment in evaluating research methods or results, or misconduct (including gross misconduct) unrelated to research activity.

Research Sponsor - The Sponsor takes overall responsibility for the proper initiation, management and monitoring, and arrangements for the financing of the study. It must satisfy itself that the research protocol, research team and research environment have passed appropriate scientific quality assurance. In addition, it should satisfy itself the study has appropriate ethical approval before it begins and that the research complies with the law.

Serious Adverse Event (SAE) Any serious adverse reaction or unexpected serious adverse reaction respectively that: results in death or is life threatening or requires hospitalisation or prolongation of existing hospitalization or results in persistent or significant disability or incapacity or consists of a congenital anomaly or birth defect

Student Researcher – a person undertaking research as part of an undergraduate or postgraduate educational or professional qualification. Student research is subject to the same procedures as all other research in the Trust.

Student Supervisor – a student researcher must have an identified Student Supervisor, who must be willing and appropriately qualified to assume the role of CI for the research.

Suspected Unexpected Serious Adverse Reaction (SUSAR) An adverse reaction the nature and severity of which is not consistent with the information (i.e. contained within the product characteristics or researchers brochure) about the medicinal product in question set out.