

## Research Policy v1.05



# Policy Summary

**Document title:** Research Policy  
**Author:** Stephen Mortley  
**Department:** Clinical Audit Department, Norwich  
**Directorate:** Clinical Directorate  
**Responsible Manager:** Clinical Audit Manager  
**Accountable Director:** Medical Director

**Purpose of document:** This Policy is written to assist with implementing the Trust Research Strategy and to help ensure that all research activity within the Trust is undertaken within the Law and to standards acceptable to the Trust and wider NHS

**For use by:** All Trust managers and staff involved with research.

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**External assessment references:** Healthcare Commission: C12, C23

## Key points of policy:

- All research will require approval by the Trust before it can commence.
- Those wishing to seek approval for their research must provide sufficient information to permit the Trust to assess compliance with the law and relevant guidance.
- Once approved the research must be properly conducted in accordance with Legislation, NHS Research Governance, Trust policy and any other conditions of approval.
- The Trust will monitor the progress of all research.
- Paramedics and Nurses should receive system and RGF awareness training
- Public and patients will have access to information about current and past research projects

## Key related Trust documents:

- Procedure for Staff when Expressing Concerns about Standards of Care and Trust Activity
- Risk Management Strategy
- Disciplinary Procedure
- Intellectual Property Rights Policy
- Research Guidance Manual
- Standing Financial Instructions

## Related external standards and legislation:

- Health and Safety at Work etc Act 1974
- Data Protection Act 1998; including the Caldicott principles
- Health and Social Care Act 2001
- Health and Social Care (Community Health and Standards) Act 2003
- The Medicines for Human Use (Clinical Trials) Regulations 2004
- The Human Tissue Act 2004
- Department of Health: NHS Research Governance Framework for Health and Social Care, Second Edition April 2005
- The Mental Capacity Act 2005
- Best Research for Best Health: A new national health research strategy. Department of Health, Jan 2006
- Confidentiality: NHS code of Practice, 2003
- Records Management: NHS Code of Practice, 2006
- The Freedom of Information Act, 2000
- The Human Rights Act, 1998
- The Medicines Act, 1968

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# **1. Introduction**

## **1.1 Background**

Research is essential to the successful promotion and protection of health and well-being and to modern and effective health and social care services. The proper governance of research is required 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.

*“For us, science and research constitutes a front-line service, as they too, reduce distress and pain and save lives”* Dr John Reid, Secretary of State for Health, 22<sup>nd</sup> March 2004

This Policy is written to assist with implementing the Trust Research Strategy and to help ensure that all research activity within the Trust is undertaken within the Law and to standards acceptable to the Trust and wider NHS.

## **1.2 Definition of research**

Research is defined within the NHS Research Governance Framework as

*“The attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods”.*

“This includes clinical and non-clinical research, research undertaken by NHS staff using NHS resources, and research undertaken by industry, the charities, the research councils and universities within the health and social care systems.”

## **1.3 Aim**

To facilitate a safe system of quality research that enables improvements in patient care and greater organisational efficiency and effectiveness.

## **1.4 Objectives**

- The interests of patients, researchers and the Trust are safeguarded.
- There is a documented policy to demonstrate compliance with legal, Department of Health and regulatory requirements.
- Responsibilities 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 Trust gains appropriate recognition for the research conducted on its premises or involving its employees or staff or patients or patients’ data.
- Public and patients have access to information on research activity

## 1.5 Scope of the Policy

The Policy applies to all research activities that involve:

- Patients and users of the East of England Ambulance Service NHS Trust (EEAST).
- NHS patients treated under contracts with private sector institutions
- Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the EEAST
- Access to and use of data of past and present EEAST patients, service users and staff
- The use of or access to EEAST premises or facilities
- EEAST staff recruited as research participants by virtue of their employment.
- The EEAST as a research sponsor
- Those undertaking the research while being employed by the EEAST
- Student research where courses are sponsored by the EEAST

The following projects fall outside the scope of this Policy:

- Clinical Audit projects: are a systematic analysis of the quality of care, including the procedures for the diagnosis, treatment and care, the associated use of resources and the resulting outcome and quality of life for the patient.
- Patient, service users and staff surveys and feedback gathering, conducted to monitor performance and promote involvement.
- Literature reviews and research critique
- Operational change in practice projects which involve the assessment of performance.

### Note

*The term 'Chief Investigator' is used throughout this document to mean the individual with the overall responsibility for the research project as referred to in the NHS Research Governance Framework'.*

## **2. Managing the Research System**

### **2.1 General principles**

Research must be conducted in accordance with the NHS Research Governance Framework and Trust policy.

All research must have a Research Sponsor.

All researchers should ensure that they understand and are able to meet their responsibilities.

All researchers must be able to demonstrate an appropriate level of competence to fulfil their research role.

### **2.2 Planning**

The Clinical Audit and Research Group (CARG) should work with Trust department's plans and if necessary, prioritise research activity in order to ensure that resources, including patients are available to support research.

An annual research programme, should be submitted by the CARG, and approved by Senior Management Team (SMT) and the Trust Board.

### **2.3 Sponsorship**

All studies must have an identified sponsor(s) who takes overall responsibility for the proper initiation, management and monitoring, and financing of the study.

Due to the high level research competence and risk involved, the EEAST will currently not sponsor clinical trials but may act as 'Care Organisation' for a sponsor of a clinical trial.

#### **2.3.1 EEAST sponsored projects**

The decision for the EEAST to sponsor a project should be based upon Trust need, clinical and organisational improvements, staff development, risk, costs, and impact of organisational service delivery.

### **2.4 Process for Trust Approval**

Research projects shall only be permitted to commence when a letter of approval signed by the Trust's Medical Director has been issued.

No studies should be initiated within the Trust until formal, written Trust approval has been issued. Studies will not be covered by NHS indemnity until they have been approved by the Trust. It is the responsibility of the Chief Investigator 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.

The EEAST may approve projects before being reviewed by a REC but should only then approve such projects as 'subject to REC approval'.

Managers and staff of the EEAST can take part in preliminary discussions with potential researchers and research sponsors and funders but must refer all research proposals to the Trust Clinical Audit & Research Department (CARD).

Each proposed research project will be subject to an internal review process. The Clinical Audit & Research Department will advice on proposals and will take proposals through the Trust approval process.

Researchers should agree to comply with all conditions of approval.

#### **2.4.1 Steps to be taken:**

1. Preliminary discussions with Clinical Audit & Research Department (CARD) and any appropriate Trust department
2. Submit research proposal to CARD
3. Review by CARD
4. If proposal is inadequate, CARD to feedback to researcher or sponsor
5. If proposal is adequate, CARD to pass proposal through review and approval process
6. Approval by appropriate Trust department manager
7. Review by EEAST Ethics Group
8. Approval from peer review
9. Authorisation by Trust Medical Director
10. Approval from Research Ethics Committee (REC)
11. Project registered with the CARD and can commence

#### **2.4.2 Disapproval**

The Trust should normally withhold permission for a research project if, amongst other things:

- The agreements for allocation of responsibilities are not acceptable
- The agreement for allocation of indemnity is not acceptable
- If conducting the research will have an unacceptable impact on service delivery
- Risk to the Trust or individuals is considered to be insufficiently controlled
- Failure to satisfy the approval procedure

### **2.5 Amendments to Proposals / Protocol**

It is the responsibility of the Chief Investigator (CI) to notify the Trust CARD and the approving REC of any protocol amendments.

Copies of proposal amendments, including changes in research team personnel, should be submitted to the CARD. The CI will be notified by the CARD whether the changes are approved or not. Changes to the research practice should only be made after the approval of the CARD. All proposed changes will be reviewed by the Medical Director who must approve the changes before any changes should be implemented. The CARD may refer the proposed changes through the whole Trust approval process if proposed changes are considered to be of significant importance or are fundamental to the project.

### **2.6 Peer review**

All studies will be subject to peer review with a satisfactory outcome before Trust approval is given.

For Trust sponsored projects the Peer Review would normally be conducted by the Trust Clinical Audit & Research Group (CARG) or a local NHS consortium. The CARG may decide that the research proposal requires peer review by an external group, if the CARG feel that they have insufficient research experience for the complexity of the project or have insufficient experience for the subject matter.

Externally sponsored research projects would normally have undergone peer review; in such cases the Trust would normally accept the review in preference of conducting a further review.

### **2.7 Honorary Contracts**

It is the responsibility of the Chief Investigator to ensure that Honorary Contracts are obtained, where required, for all researchers that are not employed by the NHS. Researchers working for

the NHS but not the EEAST need either an EEAST Honorary Contract or an agreement between the employing organisation and the EEAST.

Researchers not employed by the NHS should agree to an Honorary Contract or must be subject to a written agreement between the Trust and the Research Sponsor.

## **2.8 Agreements with Research Partners, Sponsors and Funders**

In accordance with the Research Governance Framework, 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 at an early stage with the CARD, appropriate head of department and the Trust Finance Department. All contractual arrangements and grant applications must be signed by the Medical director. All grant applications must be signed by the Medical Director or the Finance Director.

## **2.9 Access and publication**

Information on the research being conducted research should be accessible to staff and the public. Such information should be made available for all projects that have been given Trust approval.

On completion, research findings should be made available to staff and the public. Findings should also be available to research participants. Research participants should be informed of how findings can be obtained.

Research findings should be made available to all those to whom the findings may benefit. This should include relevant publications.

All researchers should be aware of the Data Protection Act and other guidance related to handling information.

## **2.10 Document Management**

For each research project, the Chief Investigator should maintain a Master File with all the relevant research documents and approvals. This must, on reasonable notice, be available for inspection.

The CARD will hold on file copies of key documents. These will include: the proposal, Trust authorisation, REC approval notice, agreement documents, and final report. The length of time documents should be retained will depend upon the type document and type of research, with low risk projects requiring a shorter retention period. The Trust 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.

## **2.11 Research supervision**

The research sponsors of research undertaken by students have a responsibility to supervise the student throughout the project.

When the Trust sponsors research that will be undertaken by a student, the Trust will appoint an appropriate Research Supervisor.

When the Trust acts as a host organisation for research undertaken by students sponsored by another organisation, the Trust will appoint a Trust Site Research Supervisor. This appointment will be over and above any supervision given by the Research Sponsor. Students may seek guidance from other Trust staff but should have only one appointed Trust Site Research Supervisor.

Trust staff undertaking a research project for the first time will be appointed a Research Supervisor.

Research Supervisors should have sufficient research competence and awareness of Research Governance and the Trust Research Policy. They may have a particular competence for research or for the subject area of the particular research project.

Research Supervisors must be approved by the Clinical Audit & Research Group (CARG). The Clinical Audit & Research Department (CARD) will hold copies of Curriculum Vita's (CV) for all Trust Research Supervisors.

## **2.12 Responsibilities**

See Appendix 1.

The Chief Executive is ultimately responsible for ensuring that there are effective systems in place to discharge responsibilities as laid down in the RGF. The Chief Executive has delegated accountability to the Trust Medical Director.

The Medical Director is the Executive Director with accountability for research and representation on the Trust Board.

The Clinical Audit & Research Manager is the manager responsible for the day to day management of research activity.

Governance of research will be monitored by the Trust Integrated Governance Group (IGG).

Trust guidance on research will come from the Clinical Audit and Research Department.

## **3. Ethical**

### **3.1 Research Ethics Committee**

For research to be undertaken in the NHS, an independent review of the research proposal must be obtained from a Research Ethics Committee (REC) recognised for that purpose by the Department of Health. Research Ethics Committees are not accountable in any way to NHS Trusts, and in particular are separate from Trust Research Departments in respect of the accountability for their operational processes and decision-making.

All research projects must have approval of a REC before the research can commence. The EEAST may approve projects before being reviewed by an REC but can only then approve such projects as 'subject to REC approval'.

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.

### **3.2 Trust Ethics Group**

The Trust Ethics Group will review all research proposals and advise the Trust on ethical matters. Comments from the Trust Ethics Group will be available to the Trust Medical Director prior to any research approval decision being made.

### **3.3 Consent**

The Chief Investigator has responsibility to ensure that, when required, prior informed consent is obtained (including all relevant signatures) for all research. Exceptions to this requirement could include, for example, projects exempted under Section 60 of the Health and Social Care Act 2001.

The Chief Investigator must ensure that consent must be taken in accordance with the Research Protocol. One copy is to be given to the participant, one to be kept in the research file. Such signed consent documents should be retained by the Trust for a minimum period of three years, this period should be lengthened as best practice dictates for higher risk projects.

### **3.4 Confidentiality**

All researchers should be aware, and apply, the NHS policy on confidentiality, as laid down in the document: Confidentiality: NHS Code of Practice

## **Risk**

Most risk will be controlled by the research systems and other systems in place.

Control measures include:

- Projects will have a sponsor
- Projects will be peer reviewed
- Projects will be approved by the Trust and by a REC
- Research proposals must be taken through a staged approach to approval before the research can commence
- Sponsors and Researchers are obliged to act within the NHS Research Governance Framework.
- Researchers must be of sufficient competence for the level of risk of the project
- Staff awareness training
- Having a research department responsible for monitoring projects.
- Audit of the research system

The EEAST will not currently sponsor higher risk research such as clinical trials. The Trust may decide to act as 'Care Organisation' for a sponsor of a clinical trial, when doing so the Trust will obtain a peer review from an independent competent source.

### **4.1 Risk Assessment**

Risk assessment should be used during protocol development to eliminate rather than manage risk.

All proposals will be assessed for risk by the Clinical Audit & Research Group. Risk will be assessed and reported as documented in the Trust Risk Management Strategy. The level of risk will be taken into consideration when deciding to approve a project or not.

Risk to the patient safety is considered as the increased risk arising from the research activity as opposed to the baseline level of risk arising from normal clinical practice.

## **4.2 Adverse event reporting**

In the event that a risk event occurring during a research project then it must be reported in accordance with Trust policy and procedures, and should also be reported to the CARD.

All adverse incidents should be reported as documented in the Trust Risk Management Strategy. In addition, incidences should be reported to the CARD as soon as possible after the event.

Researchers should immediately notify the CARD, the study sponsor and the main REC that originally approved the study of any unanticipated problems involving risks to subjects or others.

In addition 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 not limited to, any Health and Safety Incident, Adverse Drug Reaction, Adverse Event, Serious Adverse Event, Serious Adverse Reaction, Suspected Unexpected Serious Adverse Reaction (SUSAR)

Serious adverse events or serious adverse reactions are defined as any untoward occurrence or affect that:

- results in death
- is life threatening
- requires hospitalisation or prolongation of existing inpatient hospitalisation
- results in persistent or significant disability or incapacity
- is a congenital anomaly or birth defect

## **4.3 Health and Safety**

The Chief Investigator 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 etc Act.

## **5. Service Users, Patients and the Public**

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

The Trusts' Patient Forum will receive the Trusts' annual research programme and reports of the outcomes of research projects.

## **5.1 Making Research Accessible**

Research information will be made available to the public and patients. Patients and public should be able to find out what research is being conducted and what research has been completed.

The primary form of incoming contact from patients and public is through front-line staff and the Trust Patient Advice and Liaison service (PALS) office. Front –line staff and PALS personnel should be able to answer public / patient queries or be able to signpost the enquiry to where an answer would be found.

Frontline staff and the PALS office should be kept informed of research activity and where further information can be found.

## **5.2 Providing Research Participants with results of research**

When research involves human participants a system should be in place which enables participants to obtain the results of projects of which they have been involved with as a participant.

## **6. Governance**

The governance of research is overseen by the Trusts Integrated Governance Group (IGG). IGG minutes go to the Trust Operational Governance Committee (OGC) (a sub committee of the Trust Board).

The Trust Clinical Audit Group will become the Trust Clinical Audit & Research Group (CARG) and will ensure that the systems of research are reviewed and developed, and will peer review research proposals. The CARG will report the Trust Integrated Governance Group.

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

The Clinical Audit and Research Department should develop its capacity and competence to support the implementation of Research Governance and the management of research.

## **7. Staff Training and Development**

The specific objectives are to

- Develop the expertise and skills required to undertake research
- Increase awareness of the systems and guidance, and advice and support available
- Ensure adequate skills and awareness, in particular Health Care Providers as required by their professional regulatory body.

All staff undertaking research should have attended training in research.

Researchers should have received guidance on the NHS Research Governance Framework, 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 Research Governance for Trust staff, appropriate to their need, subject to available funding.

The Trust should support research elements of staff educational development. Where courses include training in research and the creation of a Research Proposal, but do not allow for the proposal to be undertaken, where ever possible the Trust should support the student undertake the research project.

The training programme for Paramedics and Emergency Care Practitioners (ECPs) should include awareness of the NHS Research Governance Framework and local research procedures.

The Clinical Audit and Research Department should develop its capacity and competence in order to effectively: support the implementation of Research Governance, facilitate research projects and be able to offer appropriate research guidance.

## **8. Financial**

Research proposals should contain financial arrangements.

Where ever applicable financial arrangements should be in accordance with the Trust Standing Financial Instructions (SFI).

### **8.1 Sources of funding**

Preliminary discussions with prospective sponsors or funders, should not commit the Trust to a project or its funding.

#### **8.11 External funding for Trust sponsored research funding**

The CARD should be able to provide information and support to researchers, to assist them in the process of applying for external funding for research.

Researchers need to involve the CARD and Trust Finance Department at an early stage of discussions with industry about commercial research agreements.

All applications for external funding should be approved by the Director of Finance or delegated authority.

#### **8.12 Internal funding for Trust sponsored research**

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.

When research projects are not budgeted for the application for Trust funding should follow the current standard Trust pathway for application for new funds.

#### **8.13 Funding for non-Trust sponsored research**

Projects not sponsored by the EEAST should be fully funded at no cost to the EEAST. The Trust should recover all costs incurred by hosting the project. This may be waived by the Trust if it feels that the research is in the best interest of the Trust its patients or staff.

## **8.2 Costing Research Projects**

All research should be realistically costed. Costing exercises should involve all Trust departments involved, the Finance Department and the CARD. There should be an agreement of how any budget is to be split between relevant internal and external parties.

The research costs of all projects funded via external grant applications, commercial agreements or the internal funding system will be calculated to ensure that operational service budgets do not subsidise research activity.

Where research is primarily for commercial purposes the Trusts will recover, from the commercial company on whose behalf it is carried out, the full costs relating to use of resources that are additional to normal patient care (Health Service Guidance (97) 32) and this will be subject to a research administration charge of 25 % applied to all costings (though this maybe varied with approval from an Executive Director). Commercial companies also support non-commercial work jointly with NHS bodies or non-NHS research funders. If the work is primarily for the public benefit, rather than the direct commercial benefit of the company concerned, it may be considered non-commercial.

## **8.3 Research Account Management**

All research income will be managed in separate research accounts within specific Trust department cost centres or within the CARD. This will include research activity using charitable donations.

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 Clinical Audit & Research Manager 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.

## **8.4 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.

## **8.5 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. Fraud and misconduct**

### **9.1 General principles**

An allegation of fraud or misconduct may be made by any person.

Allegations should be in a written format and should be as detailed as possible.

Allegations should be recorded by the CARD and reported to the Medical Director

Allegations will be investigated and outcomes recorded by the CARD.

Allegations and investigation outcomes should be reported to the CARG and IGG. The CARG will monitor allegation investigations.

In the event of serious allegation or continuing non-compliance with REC requirements the Trust will notify the approving REC.

### **9.2 Fraud and Corruption**

All cases of suspected fraud or corruption are to be reported in accordance with the Trust's Procedure for Staff when Expressing Concerns about Standards of Care and Trust Activity.

### **9.3 Research Misconduct**

The Principal Researcher is responsible to ensure that all researchers involved in a given project have read and understand relevant Trust's Policies in particular: Research Policy, Procedure for Staff when Expressing Concerns about Standards of Care and Trust Activity, Risk Management Strategy.

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.

#### **9.3.1 Definition of 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 permission 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 that do

not fit expected results

- 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

### **9.3.2 Allegations by EEAST staff about EEAST sponsored research**

Allegations should be made to the relevant line manager or the Trust CARD in which case the Trust CARD will liaise with appropriate line manager. Allegations that refer to the CARD should be made to the Medical Director. When allegations are about a Trust employee, managers will use the Trusts Disciplinary Policy to guide them on how to deal with the allegation.

### **9.3.3 Complaints from Non-EEAST personnel**

All complaints from outside the Trust, about the Trust, should be referred to the Trust Complaints Team. The complaint should be dealt with within NHS Complaints Procedure. The CARD and the relevant Trust head of department should be informed by the Complaints Team.

## **10. Intellectual Property Rights**

Intellectual Property Rights should be dealt with in accordance with the EEAST Intellectual Property Rights Policy.

## **11. Facilitation**

### **11.1 Research Support**

The CARD should provide, when requested, support to Trust researchers and management at all stages of the research process. This can include:

- Literature searching and appraisal of the evidence
- Study design, including advice on statistics, health economics and measurement of outcomes
- Preparing the research protocol, grant application and Research Ethics Committee submission
- Project management
  - analysis and interpretation of research results
- Dissemination of research findings, including publications, conference presentations, report writing and communicating results to patients, their doctors and health authorities

#### **11.1.1 Resources for Researchers**

Appropriate resources and facilities should be available to researchers. Resources should include:

Access to advice

Research Guidance Manual

A research library  
Stationary and printing  
Use of computer with access to the internet

## **11.2 Guidance**

The CARD should provide guidance to researchers and Trust managers on all aspects of research. To assist with this a Trust research Guidance manual should be available. The Manual should be regularly reviewed and updated.

## **12. Monitoring and Inspection**

Audit, risk management, staff appraisal, spot checks and supervision will be used to assist in the monitoring of research governance. Accordingly, all researchers must allow the CARD, or nominee, to examine any aspect of their research activity.

Research will be included in the Trusts' annual Internal Audit, the results of which will be reported to the Trust Board.

The Chief Investigator is responsible for the submission of annual reports for ongoing projects, and a report when the project ends. Annual reports would normally be a copy of the annual report sent to the approving REC.

In addition to this Chief Investigators should supply the CARD with update reports on their request.

The progress report will also link to the risk assessment process; information in the report may lead to a re-assessment of risk. Factors to consider include high turnover of staff, unexpected serious adverse events or a large number of protocol amendments.

The Trust would not normally duplicate the monitoring and audit conducted by external sponsor, but instead may request copies of reports. The CARD should be informed of any significant findings that either did or could potentially affect patient safety and/or the scientific / medical integrity of the study.

The CARD 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 any other appropriate action in the light of these findings.

## **16. References**

### **16.0.1 Government documents**

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

Health and Safety at Work etc Act 1974. <http://www.opsi.gov.uk/si/si1999/19993242.htm>

Health and Social Care Act 2001. <http://www.opsi.gov.uk/ACTS/acts2001/20010015.htm>

NHS Reform and Health care professional Act 2002  
<http://www.opsi.gov.uk/acts/acts2002/20020017.htm>

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[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4108962&chk=Wde1Tv](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4108962&chk=Wde1Tv)

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](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4131747&chk=tMmN39)

### **16.0.2 Trust documents**

Disciplinary Procedure (August 2004)

Health and Safety Policy Arrangements (July 2005)

Procedure for Staff when Expressing Concerns about Standards of Care and Trust Activity April 2006)

Risk Management Strategy (January 2006)

All Trust documents are available from the trusts intranet: *insite*

## **16.1 Abbreviations**

CARD	Clinical Audit and Research Department
CARG	Clinical Audit and Research Group
CARM	Clinical Audit & Research Manager
CI	Chief Investigator
ECP	Emergency Care Practitioners
EEAST	East of England Ambulance NHS Trust
IGG	Integrated Governance Group
MHRA	Medicines and Healthcare Products Regulatory Agency
NHS	National Health Service
OGC	Operational Governance Committee
REC	Research Ethics Committee
SFI	Standing Financial Instructions
SMT	Senior management Team
SUSAR	Suspected Unexpected Serious Adverse Reaction

## **Appendix**

**Appendix 1. Responsibilities**

**Appendix 2. Definitions**

**Appendix 3. General Research Process**

## Appendix 1. Responsibilities

The Research Governance Framework sets out the responsibilities of people and organisations involved in health and social care research. The key responsibilities for the proper conduct of a study are summarised below.

All those involved in research also have a duty to ensure that they and those they manage are appropriately qualified, both by education and experience, for the role they play in relation to any research.

The responsibility of the Trust or an employee will depend upon the role they are to take in the research project.

### Chief Investigator

The Chief Investigator 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 Chief Investigator takes overall responsibility for the study and for co-ordinating the Researchers who take the lead at each site. The **Principal Researcher** is the person responsible, individually or as the leader of the researchers, for the conduct of the study at a particular site.

The Chief Investigator is accountable to their employer, and, through them, to 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 Researcher to ensure that:

- The research team give priority at all times to the dignity, rights, safety and well being of participants
- The study complies with all legal and ethical requirements
- The research is carried out in accordance with the NHS Research Governance Framework

### Researchers

Researchers are those conducting the study and bear day to day responsibility for the conduct of the research. They are responsible for:

- ensuring that any research they undertake follows the agreed protocol
- helping care professionals to ensure 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

### Care Professionals

Care professionals retain responsibility for the care of their patients or service users, when they are participating in research.

Before agreeing to their patients or service users and carers being approached, care professionals must satisfy themselves that the Researcher has the permission of the appropriate authorities within their organisation or agency, and that any research relating directly to the care they provide complies with this framework.

### Care Organisation

The care organisation retains responsibility for research participants' care. It should ensure that research meets the standard set out in the research governance framework and that there is ethical approval for all research for which they have a duty of care.

### Organisations Employing Researchers

Organisations that employ Researchers and Researchers are responsible for promoting a quality research culture and ensuring researchers understand and discharge their responsibilities. It should also ensure that the research is properly designed, and that it is well managed, monitored and reported, and take action if misconduct or fraud is suspected.

### **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 ethical approval before it begins and that the research complies with the law.

The Medicines for Human Use [Clinical Trials] Regulations 2004 allow for more than one person or organisation to take on the role of sponsor. The partners can choose to take joint responsibility. In that case, all of them would accept joint liability for all of the sponsor's responsibilities. The regulations also allow for a group of partners to each take on a set of sponsorship responsibilities, grouped by function. As a group, they would collaborate to cover all of the sponsor's functions.

### **Funders**

The main funder is responsible for assessing the scientific quality of the proposed research, the quality of the research environment, in which the research will be undertaken, and the experience and expertise of the Chief Investigator, Principal Researcher(s) and other key researchers involved.

## Appendix 2. Definitions

For the avoidance of doubt, key definitions are given below. The meaning of other words in this Policy can be found in English Law, Department of Health Policy, Trust Policy and Professional Codes of Practice. In the event that there are multiple definitions then the 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.

**Chief Investigator** - the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of the study. There can only be one Chief Investigator per project.

**Clinical Research Organisation** - an organisation which may have some devolved responsibility for some of the duties of the Sponsor / Funder or other party.

**Development** - the experimental introduction into practice of alternative clinical procedures or methods of care, together with the simultaneous evaluation of their effectiveness, efficiency or both.

**Employing Organisation(s)** - an organisation(s) employing the Principal Researcher and/or other researchers. The organisation employing the Chief Investigator 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 funding for the study through contracts, grants or donations to an authorised member of either the employing and/or care organisation.

**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 EEAST.

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

**Research Ethics Committee** – the 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** - those conducting the study. Note that researchers not employed by the EEAST and may require an Honorary Contract.

**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 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

**Site Management Organisation** - an organisation which may have some devolved responsibility for some of the duties of the Sponsor / Funder /or other party.

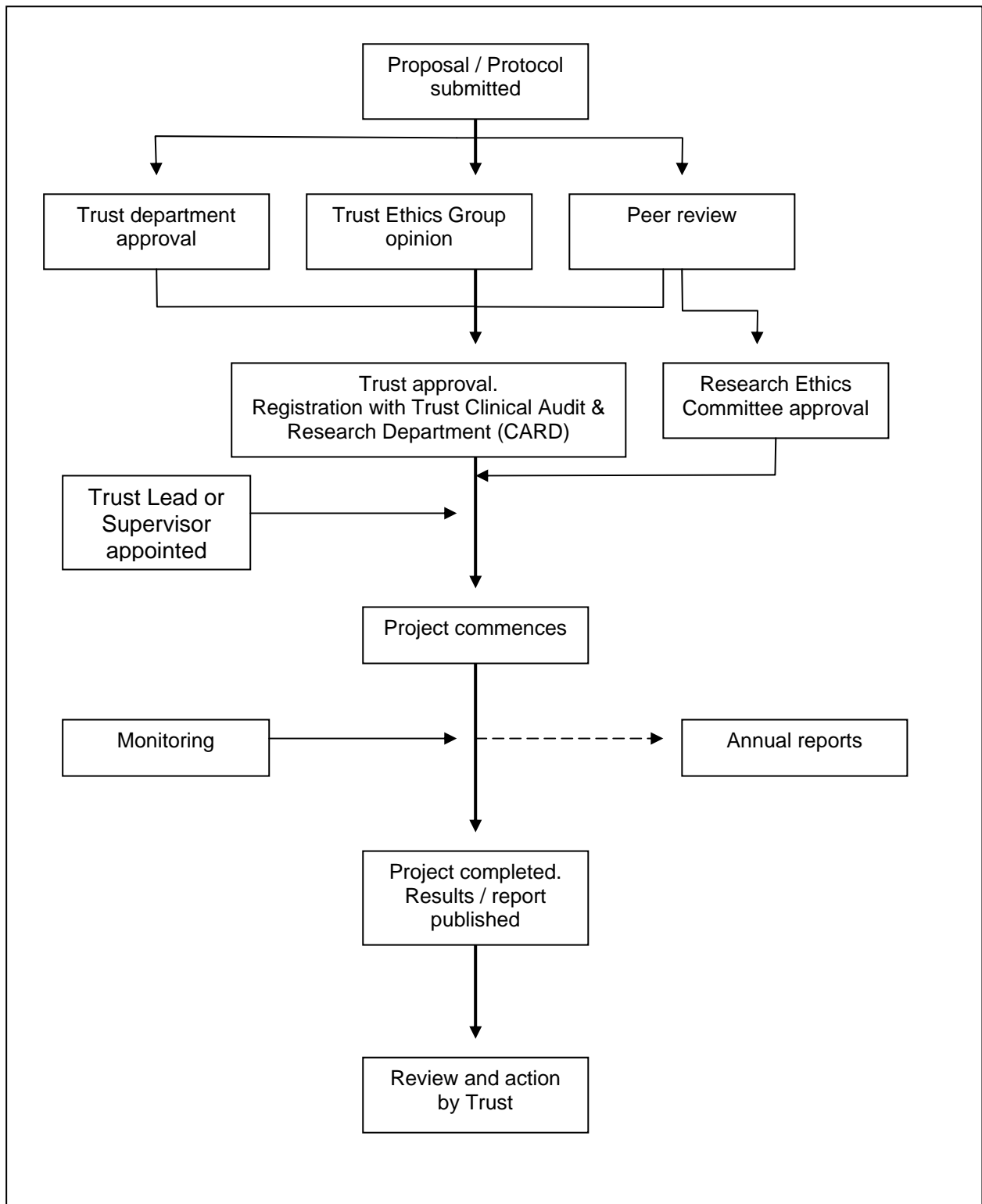
**Sponsor** - the organisation taking primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting; the sponsor is usually, but does not have to be, the main funder. It is acceptable to have two or more organizations acting as Co-Sponsors providing that there is documented evidence of the allocation of responsibilities.

**Student Researcher** – a person undertaking research as part of an undergraduate or postgraduate educational or professional qualification. This includes, but is not limited to, BSc, BA, MSc, MA, MD, PhD and other professional qualifications. Student research is subject to the same procedures as all other research in the NHS organisation.

**Student Supervisor** – a student researcher must have an identified Student Supervisor, who must be willing and appropriately qualified to assume the role of Chief Investigator and will be responsible for the ethical and scientific conduct of 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.

### Appendix 3. The EEAST Research System Process



The diagram shows the general process that a research project with travel through. There may be variations to the process