East London NHS Foundation Trust

Research Governance Policy

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Executive Director Lead	Medical Director
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Services	**Applicable to**
Trustwide	√
Mental Health and LD	
Community Health Services	

Version Control Summary

Version	Date	Author	Status	Comment
1.0	2001		Replaced/ Archived	
2.0	11 May 2011	Karin Albani, Research Manager	Replaced/ Archived	Replaces previous version of policy entitled 'R&D Management Policy Framework (R&D001)' Revised to comply with the National Institute of Health Research (NIHR)'s Research Support Services (RSS) initiative and collaboration with the Joint Research Office of the Barts and the London NHS Trust and Barts and the London School of Medicine and Dentistry
3.0	March 2015	Karin Albani, Research Manager	Final/ Approved	Revised to reflect evolution in Trust structures and process as well as relevant changes in the NIHR, the Health Research Authority (HRA) and the Trust's collaboration partner. The new document focuses on policy and excludes detailed operating procedures.
3.1	December 2018	Karin Albani, Ass Dir of Research	Draft	Updated with references to current regulations

Contents

Executive Summary

Sets out the Trust's policy for the conduct and governance of research activity in the organisation. The policy is applicable to all Trust employees and to non-employees who conduct research involving Trust patients, premises, or staff. This policy is intended to ensure that for all research hosted by the East London NHS Foundation Trust:

- the work complies with the relevant standards, guidance, safeguards and laws;
- all parties know their responsibilities and rights;
- the rights and safety of participants are protected;
- the results contribute to modern and effective health services and are widely disseminated.

1. Introduction

1.1. Research is essential to the successful promotion and protection of health and well-being and also to the development of modern and effective healthcare services. Research studies enable clinicians and investigators to develop new treatments and resolve uncertainty about existing treatments. Many of the key advances, large and small, in the last century have depended on research, and healthcare professionals and the public they serve are increasingly looking to research for further improvements.

1.2. Health research is core business for the NHS. It plays a vital role in improving health outcomes and the quality of care. It is therefore a core element of the NHS Operating Framework. NHS organisations have to demonstrate their contribution to research in Quality Accounts.

1.3. The East London NHS Foundation Trust (the Trust) has developed a clear plan for research that sets out the benefits of research to the delivery of services, the wider organisation, and our external relationships.

1.4. Health research is highly regulated. Clinical trials, medical device studies, use of patient data, professional qualifications, access to and treatment of NHS patients, and other aspects of research studies are regulated by EU directives, UK legislation, and professional standards of good practice. The UK Policy Framework for Health and Social Care Research describes the overarching framework within with research studies are delivered in the NHS.

1.5. Research can involve an element of risk, both in terms of return on investment (i.e. the new knowledge gained through the study might not warrant the monies, time and effort invested) and sometimes for the safety and well-being of the research participants. NHS organisations are legally responsible for their research activity including the safety of their staff and patients. Proper governance of research is essential to ensure that patients and the public can have confidence in, and benefit from, quality research in health care. Patients have a right to expect high standards (scientific, ethical and financial), transparent decision-making processes, clear allocation of responsibilities, and robust monitoring arrangements.

2. Purpose

2.1. This document sets out the policy for the conduct and governance of research activity in the East London NHS Foundation Trust. These principles and guidelines have been developed to ensure that all staff and investigators, and the Trust itself, conform to the requirements of Research Governance and Good Clinical Practice.

2.2. There are many documents that govern the conduct of research (see section 21 References). The purpose of this policy is not to replicate the contents of those documents but to outline the roles and responsibilities of both individuals and the Trust which are associated with participating in research and to describe the principles of the governance framework necessary for the management and conduct of research within the Trust.

2.3. The Trust aims to be a leader in governance process and practice and as such has developed this policy in order to ensure that it meets best practice in the sector and adheres to the relevant international and national regulations, standards, guidance, safeguards, and laws at all times. This will help ensure that research conducted in the Trust:

- achieves the highest scientific and ethical standards;
- respects patient dignity, rights, safety and well-being;
- is undertaken with scientific integrity, honesty, accountability, and openness; and
- values the diversity within society.

3. Scope of this policy

3.1. The Department of Health defines research as "the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods."[1] Broadly speaking, a piece of research has the following characteristics:

- It generates evidence to refute, support, or develop a hypothesis;
- It aims to find out what happens if we add or change (manipulate) clinical or service practice in some way, or aims to find out in a systematic way the views / opinions / experiences / understandings of stakeholders;
- It is designed to elicit information that will be applicable to and of interest to people outside the immediate research context/organisation.

3.2. There are a number of activities that, although similar to research in some aspects and sometimes referred to as 'research', nevertheless are not classed as research by the Department of Health and therefore are not subject to the provisions of this policy. The most common of these activities are Audit, Service Development and Evaluation, Case Studies, etc.[2]

3.3. This policy applies to all research being sponsored by and/or hosted by the Trust however funded and to all Trust staff. This includes research by any person employed by the Trust or their students and those external to the Trust wanting to undertake research within the Trust.

3.4. The policy applies to all research employing any methodologies (both qualitative and quantitative), regardless of the funding mechanisms, including:

- *externally funded non-commercial research* – activity funded by non-commercial bodies independent from the Trust (e.g., Medical Research Council and NIHR);
- *externally funded commercial research* – work being funded by any commercial body;

[1] UK Policy Framework for Health and Social Care Research (Department of Health 2017).

[2] Detailed information is provided in the leaflet Defining Research, published by the Health Research Authority, which gives guidance on distinguishing between research, audit, service evaluation, and public health surveillance.

- *research which does not involve external funding* – this involves work for which Trust facilities, staff time, and/or Trust patients/clients, are used although no specific, allocated funding is provided.

3.5. This policy applies to research and for which:

- the chief investigator on the project is a staff member of the Trust (the Trust is the *'Investigator Site'*), or
- the chief investigator for the project as a whole is based in another organisation such as another NHS Trust, GP practice or university (the Trust is the *'Collaborator Site'*).

3.6. This policy also applies to research being undertaken for undergraduate and postgraduate qualifications. It will be the responsibility of the appropriate University to ensure sufficient scientific quality and research governance.

4. Duties

4.1. It is a requirement to establish a governance facility which will take responsibility for the implementation and monitoring of the Trust's Research Governance Policy.

4.2. Research Committee

4.2.1. Oversight of research at the East London NHS Foundation Trust is provided by the Research Committee (RC) which reports annually to the Trust Board's Quality Assurance Committee. The Research Committee develops the overall plan via which research activities support the Trust's Strategy, including the development of partnerships, investment of resources, and commissioning of work.

4.3. Research Management & Governance (RM&G) group

4.3.1. The Trust Board has delegated responsibility to monitor and support the implementation of research management and governance processes both within the Trust and/or as outsourced to any external provider to the Research Committee. To keep its focus on strategic issues, the Research Committee has delegated operational oversight to a Research Management & Governance (RM&G) group.

4.3.2. The RM&G group is charged with promoting and supporting involvement in high quality healthcare research, promoting evidence-based healthcare, building research capacity, and fostering a research culture within ELFT. The RM&G group aims to promote high quality research and innovation, and oversee its organisation in the Trust. The RM&G group will also assure the Board, via the Research Committee, that it is discharging its functions and meeting its responsibilities with regards to the quality and safety of research activity carried out within the organisation.

4.3.3. The RM&G group will monitor the interface with any internal or external research offices involved in the governance of research studies in the Trust.

4.4. Research Department

4.4.1. The Trust has established a Research Department whose head reports indirectly via the Medical Director to the Chief Executive. This principal purpose of the Research Department is to:

- develop and implement a research plan in support of the Trust strategy,[3] and
- link the research expertise within the Trust to the organisation's performance management and business development.

4.4.2. Coordination and administration of the Research Governance Policy will take place through the Research Department, working with other internal and external departments and personnel to achieve the objectives set out in this policy.

4.4.3. The Research Department will ensure research undertaken in the Trust meets accepted standards of quality.

4.5. Trust Staff

4.5.1. It is the responsibility of all staff undertaking or facilitating research to ensure that the quality of research carried out in the Trust is to an acceptable standard.

5. General Principles

5.1. The East London NHS Foundation Trust supports and promotes high quality research as part of a service culture receptive to the development and implementation of best practice in the delivery of care.

5.2. Research in the NHS is subject to a large and complex regulatory framework, composed of laws, regulations and other statutory requirements, and directives and guidelines issued by a number of government and non-governmental bodies, including the Department of Health and the Medical Research Council.

5.3. These requirements have been brought together within the UK Policy Framework for Health and Social Care Research (2017) which sets out Principles for research taking place in the NHS. It also sets out the specific responsibilities of the different parties that might be involved in NHS research. Investigators each have an individual responsibility to comply with the UK Policy Framework for Health and Social Care Research in their own research practice. Investigators should refer in particular to the sections 'Research Teams' and 'Chief Investigator'.

5.4. To ensure that research is conducted within a 'Quality Research Culture', all research hosted by the East London NHS Foundation Trust must comply with all relevant international and national regulations, standards, guidance, and safeguards, and laws.

5.5. There are several national bodies[4] that have developed standard operating procedures (SOPs)[5] which NHS organisations, including the Trust, must adhere to in assessing whether a given research proposal is compliant. Where the Trust is a partner to a centralised research governance office it also engages to adhere to that office's governance SOPs.

[3] The Research Department develops the research plan, which is then presented to the Research Committee for discussion and comment prior to its submission to the Quality Commitee for ultimate ratification.

[4] For example the Health Research Authority (HRA), the National Institute for Health Research (NIHR), the Clinical Research Network (CRN), and the Medicines and Healthcare Products Regulatory Agency (MHRA).

[5] Such as the Research Support Services (RSS).

5.6. Research within the East London NHS Foundation Trust must fit with the current research plan. This is developed to fit with the Trust's overall strategic direction.

6. Safety (Principle 1)

6.1. The dignity, rights, safety and wellbeing of participants must be the primary consideration in any research study. The Department of Health requires that, generally speaking, research involving patients, service users, or their organs, tissue or data, is reviewed independently to ensure it meets ethical standards.

6.2. It is the responsibility of the investigator to ensure that the study is ethical and meets all the requirements specified by the Health Research Authority (HRA) for assessment, including an ethical review and compliance with requirements for informed consent.

6.3. Failure to obtain HRA Approval constitutes research misconduct and may result in formal disciplinary action being taken.

Adverse events and Incidents

6.4. Investigators must report to the study Sponsor any adverse events and safety incidents arising in research, as defined and required by the study protocol.

6.5. In addition, in line with the Trust's own incident reporting policy, investigators must report to the Trust both any events and incidents that cause injury to a participant (i.e. Clinical Incident reporting) and any 'near misses', this being any incident that had the potential to cause harm but was avoided.

6.6. Protocol violations in clinical studies should be reported as incidents or near misses, as appropriate.

6.7. Furthermore, investigators should report all adverse events relating to research being conducted within Trust to the Research Department, and the MHRA if appropriate, as well as the routine procedures for reporting such events (DATIX). This includes both clinical adverse events and non-clinical adverse events such as issues concerned with gaining consent and record keeping.

6.8. In the event of any issues (including serious adverse events) coming to light during the course of a research project or during the Trust Research Governance monitoring, the Research Department will work closely with investigators, the organisation sponsoring the study, and the appropriate Trust Departments in order to resolve issues as soon as possible.

7. Employment Contracts (Principle 2)

7.1. Persons not substantively employed by the Trust who wish to engage in research at the East London NHS Foundation Trust must hold either a placement, honorary research contract, or formal Letter of Access.

7.2. It is the responsibility of the Lead Investigator to ensure that these contracts are in place and that all members of the research team are suitably qualified (including training in GCP).

8. Scientific Quality (Principle 3)

8.1. All research, no matter how funded, should be appropriately independently scientifically reviewed. A project of good scientific quality is one that uses an appropriate and rigorous method to answer a valid and specific question. Investigators have an obligation to design and conduct work to the highest possible

standard, to ensure that the study is of sufficient quality to contribute something useful to existing knowledge. Research which is poorly designed is regarded as being unethical, and is also not the best use of staff/clients' time.

8.2. Research of a limited scope is acceptable within the boundaries of research being carried out in part fulfilment of an educational qualification. Such research should still be of a sufficient quality to contribute to the local knowledge base.

9. Patient, Service User and Public Involvement (Principle 4)

9.1. The Trust strongly supports the principle that NHS service users should be involved in decision-making regarding research strategy, policy and activity.

9.2. Wherever possible, investigators should aim to involve service users, carers, and/or representatives of the communities involved, throughout the design, conduct, data collection, analysis, and dissemination of the research. Where this is not possible expert organisations, e.g. the Alzheimer's Society, may be consulted. Research that does not seek to involve service users, carers, or expert organisations in its design, conduct, analysis, and/or reporting is less likely be supported.

9.3. All service users and carers involved in the design, conduct, analysis and reporting of individual funded projects must be offered payment in line with Trust Policy on the Service User and Carer Reward and Recognition Policy. Service users and carers that wish to volunteer will still be able to do so. Wherever possible, expenses for service user and carer involvement will be paid on the day.

9.4. The Trust has a duty to ensure that patients or users and carers are provided with information on research that may affect their care. This should be made available in an accessible and appropriate format which may include non-English language, audio etc. If a patient's care will be affected by a piece of research, then staff have a responsibility to make the patient aware of that fact – assuming that they are not actually a participant in a study that requires individual consent. An example might be a health services research project that pilots a new type of service delivery, e.g. a minor injuries triage unit.

10. Financial Management (Principle 5)

10.1. The Trust and individual investigators collectively have a responsibility to ensure the good financial management of research projects. Good financial management is essential to the successful conduct and completion of research studies, and good collective financial management is essential to the Trust's standing as a secure a competent host organisation.

10.2. All research funding must be managed in full compliance with the Trust's Standing Financial Instructions and other relevant policies.

10.3. Any funding for research purposes should be transparent. There should be no Incentive to prescribe more of any particular treatment or product other than in accordance with the peer-reviewed and mutually agreed protocol for the specific research intended.

10.4. Research income generated does not belong to individual Trust staff. Under no circumstances may a Trust employee retain any research monies as a payment outside the employee's NHS salary, e.g. as a personal gift from the company, nor may any monies be paid into an external account, e.g. a building society account.

After the full costs of the research are covered, the general principle is that Investigator should have access to the remaining funds for spending on Trust-related activities for example to provide training, conference attendance, equipment. Expenditure will be authorised by the local Project Lead in line with the Trust's Standing Financial instructions.

10.5. When a commercial company contracts with a investigator to undertake a clinical trial on its behalf, the contract, which is made between the investigator and the drug company, invariably makes it clear that the results are owned by the drug company. Therefore, even if in due course the results are made available to the public, it is the drug company that receives the results first in order to see if they are capable of being exploited commercially. This is therefore a business service undertaken by the NHS trust and not a charitable activity. Any income should be accounted for within the Trust's exchequer funds as income generation and should not pass through NHS charitable funds – even as a matter of convenience. It is therefore not appropriate to place income from commercial work into charitable accounts that enjoy charitable status.

Costs

10.6. A guiding principle in UK Policy Framework for Health and Social Care Research is that through accountability and transparency all research undertaken in NHS organisations will be seen to offer the taxpayer value for money. Therefore, all research whether externally funded or not (see section 3.4 [Scope]) will be fully costed.

10.7. One objective of the policy is cost recovery for full costs (including overheads and VAT where appropriate) in the conduct of commercially sponsored research. This includes charges for staff time, consumables, support services, treatment costs, extra treatment costs and service support costs. Where research is primarily for commercial purposes, the Trust needs to ensure that the full cost (including overhead) are recovered from the commercial company on whose behalf it is carried out.

10.8. The principles for meeting patient care costs associated with externally funded non-commercial research are set out in the Health Service Guidelines HSG (97) 32 and AcoRD guidelines. In all cases where there are associated treatment costs, excess treatment costs and/or service support costs, the Trust should be notified with the appropriate information about the proposed research as early as possible.

10.9. When considering a research proposal, the Trust will wish to consider how the continuing costs of any pharmaceutical or other treatment initiated during the research will be managed once the study has ended and should the research show the intervention to be effective.

11. Protocol (Principle 6)

11.1. Any deviation from the approved protocol should be agreed with the HRA, the Trust, and external Funder (if externally funded) and notified to the Research Department.

12. Legality (Principle 7)

12.1. The Lead Investigator and all staff working on a research project or programme of research have both individual and collective duties to ensure that studies are conducted in accordance with GCP, national regulations, and the Trust's standing orders and corporate policies. Service Managers and the Research Department are charged with a duty to ensure that staff adheres to this regulatory framework.

12.2. Investigators are required, when undertaking clinical activities as part of their research, to adhere to the appropriate Trust policies. Particular attention should be paid to the following core policies:

- Risk Management Strategy
- Health and Safety Policy
- Incident Policy
- Legal Claims Policy
- PALS and Complaints Policy

Sponsorship

12.3. For any research that takes place in the context of the NHS or social care services in England there must be a sponsor. The sponsor is the individual, or organisation (or group of individuals or organisations) that takes on responsibility for confirming there are proper arrangements to initiate, manage and monitor, and finance a study. Normally, the sponsor will be one of the organisations taking the lead for particular aspects of the arrangements for the study, typically the Chief Investigator's employing organisation.

12.4. For research in which the Chief Investigator is a substantive employee of the East London NHS Foundation Trust, he or she can request that the Trust acts as Sponsor. Sponsorship is awarded at the discretion of the Trust following a risk assessment of the proposed study and the study management arrangements.

12.5. Research undertaken in part or whole fulfilment of a qualification from a higher education institute should ordinarily be sponsored by that institute.

13. Benefits and Risk (Principle 8)

13.1. All research activities carry a definable level of risk and must be adequately managed to ensure that these risks are minimised. Staff undertaking research in the Trust will minimise the associated risks by adhering to national and local regulatory frameworks.

14. Approval (Principle 9)

14.1. The UK Policy Framework for Health and Social Care Research requires that investigators obtain confirmation of capability and capacity from each NHS organisation whose patients, staff, premises, data or resources will be involved in the research before any work, including the identification and recruitment of participants, begins.

14.2. It is the responsibility of the investigator to gain written confirmation from the Research Department that the East London NHS Foundation Trust has the capability and capacity for this study in place. The investigator must comply with all conditions of approval throughout the lifetime of the project for the approval to remain valid.

14.3. The carrying out of research without Trust confirmation constitutes professional misconduct and is grounds for disciplinary action and/or reporting to the appropriate professional bodies (see section 19 [Compliance]). Investigators should note that NHS indemnity cover for clinical negligence might not be in place if the incident has occurred in unauthorised research (see section 17.6 [Indemnity]).

15. Accessible Findings (Principle 11)

15.1. The UK Policy Framework for Health and Social Care Research requires public sector organisations to actively disseminate the findings of their work to appropriate public sector, academic and public audiences. In addition, effective dissemination is an important means of raising the profile of an organisation, enhancing the recruiting and retention of staff and improving clinical practice.

15.2. All investigators are encouraged to publish their work and to make the work open to critical review through the accepted scientific and professional channels. Investigators are encouraged to draw up a plan for disseminating their findings during the design phase of the project.

15.3. Where the research funding / sponsorship contract includes restrictions for dissemination, such as prior notification of the funding body, it is the responsibility of the author to ensure compliance.

Record Keeping

15.4. All research project information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification. All data shall be stored according to Ethics Committee and/or recognised good practice guidelines (e.g. Medical Research Council).

15.5. Records of all participants' informed consent and carers'/relatives' assent, and all appropriate research records should be stored and made available when requested by the Trust and other authorised agents (such as the MHRA).

15.6. Commercial companies may have additional stipulations with regard to retention of records from research studies that will need to be adhered to.

15.7. Any praise or complaints or Health and Safety issues relating to research should be handled through the normal Trust mechanisms (see sections 19 [Compliance] and 6 [Adverse Events]).

16. Choice (Principle 12)

16.1. Informed consent is at the heart of ethical research. Investigators are required to ensure that the study has appropriate arrangements for obtaining consent that have been approved by the HRA.

16.2. In the case of research that affects a patient's clinical care, the investigator must ensure that the patient's participation in the study is noted in the patient's health record, preferably by including a copy of the patient's consent form in the record.

17. Insurance and Indemnity (Principle 13)

17.1. In commercial research, the Sponsor must indemnify and hold harmless the Trust and its employees against all claims and proceedings made or brought (successfully or otherwise) by or on behalf of research subjects against the Trust for personal injury arising out of any procedure required by the protocol to which the subjects would not have been exposed but for their participation in the study. Investigators must ensure a Form of Indemnity, properly agreed by a Trust authorised signatory, is in place for any commercial research study.

Typically this indemnity does not apply to any claim to the extent that such personal injury is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Trust or the individuals conducting the study, including the failure of the researchers to conduct the study in accordance with the protocol.

Existing arrangements for NHS Indemnity cover harm caused to patients or healthy volunteers by clinical negligence in research, when that research has been approved by the Trust and follows the approved protocol.

17.2. Where a trial is sponsored by a non-commercial organisation, that sponsor shall remain responsible for the design of the study and any materials, drugs or equipment they supply. In most circumstances, formal Trust approval of non-commercial research will secure indemnity for negligent harm via the Clinical Negligence Scheme for Trusts (CNST) scheme.

17.3. NHS indemnity does not extend to cover for independent contractors or their employees, who instead must ensure they are covered by satisfactory professional indemnity policies.

17.4. Historically, there has been a distinction between indemnity/compensation arrangements available to patients and healthy volunteers. Further, the level of protection afforded to trial subjects and advance definition of compensation arrangements available has depended on source of sponsorship. The Trust has adopted a position which minimises these anomalies as far as is possible whilst retaining compliance with current guidelines which may impose a financial limit on the amount of compensation payable. This policy applies to injury caused to patients in Phase II, Phase III and Phase IV trials and where appropriate to healthy volunteers in Phase I studies. Compensation will also be considered for injury caused by licensed or non-licensed products administered to the patient or healthy volunteer for the purpose of comparison with the test substance. Details of coverage, limitations and claims are included in Appendix B [Clinical Trials Compensation].

17.5. NHS bodies may not offer advance indemnities for non-negligent harm. In exceptional circumstances, the researcher's employing organisation may consider whether an ex-gratia payment could be offered.

17.6. Should a claim for compensation arise from unauthorised research – i.e. research that has not had formal approval from the Trust – then the researcher may be personally liable for (a) meeting the legal and administrative costs of defending any claim for negligent or non-negligent harm or of reaching a settlement, (b) the plaintiff's costs, and (c) any damages awarded.

18. Respect for Privacy (Principle 14)

18.1. The Data Protection Act,[6] Caldicott Report,[7] UK Policy Framework for Health and Social Care Research,[8] the EU,[9] funding and professional bodies[10] have all issued guidance on how patient information for the purposes of research should be

[6] Data Protection Act, 2018

[7] Caldecott Committee (1997) Report on the Review of Patient - Identifiable Information.

[8] Department of Health (2017) UK Policy Framework for Health and Social Care Research and The Department of Health (2003) Code of Confidentiality.

[9] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996.

[10] MRC Guidelines for Good Clinical Practice in Clinical Trials, 1998.

Safeguarding Good Scientific Practice (1998) Joint Statement by the Director General of the Research Councils and the Chief Executives of the UK Research Councils.

General Medical Council (2000) Confidentiality: Protecting and Providing Information.

General Medical Council (2002) Research: The Roles and Responsibilities of Doctors.

ABPI (1998) Guidelines of Good Clinical Research Practice.

gathered, handled, stored and disclosed. Investigators are responsible for ensuring that research data are handled in compliance with these regulations.

18.2. Lead Investigators are responsible for ensuring that all other research staff under their supervision understand fully the standards expected, and the importance of confidentiality.

Confidentiality

18.3. The confidentiality of information provided by patients or collected from or on patients as part of their healthcare is central to the public's trust in the NHS and healthcare professionals. The appropriate use and protection of personal information is paramount. All those involved in research must be aware of their legal and ethical duties in this respect; it is a legal requirement that personal information remains confidential, including information associated with tissue and biological samples.

Use of Existing Personal Information

18.4. The Data Protection Act 2018 requires that when people give information they should be told what it will be used for and to whom it will be passed. As a public authority, our lawful basis for processing data to conduct research is the public interest.

18.5. However, the DPA also requires the Trust to be fair and transparent in how we hold and use personal data. In other words, we must be open and honest with research participants about how we intend to use personal data nd the types of data we will be using, etc. The consent process aids transparency and fairness for research participants. Consent can also help manage expectations in terms of who has access to confidential information. Our preference, therefore, is for investigators to obtain consent from each individual patient whose data they wish to access or process. This consent must be obtained on a study-by-study basis, i.e. for each individual study.

18.6. There are two exceptions to the expectation of obtaining informed consent:

a. A person from within the patient's clinical care team may legitimately access identifiable information without consent in order to prepare a fully anonymised data set. This means undertaking the minimum necessary data processing required to extract and immediately anonymise the information. This person must be a member of the patient's clinical care team – i.e. a person directly involved in the diagnosis, care and treatment of an individual: people external to this team are not permitted to process data, regardless of their contractual status with the NHS organisation and regardless of the data protection registration status of the organisation or database involved. If it is not clear whether or not an investigator is a member of the patient's clinical care team, advice should be sought from the Trust's Caldicott Guardian.

   Notwithstanding the above, however, investigators directly employed by the Trust within the Research Department (i.e. Research Nurses, Clinical Studies Officers or Research Assistants, not those with Research Passports or honorary contracts) carrying out research activity such as screening notes or randomising patient lists on behalf of clinical teams can be viewed as part of the clinical team and allowed access to this information. The clinical team would still make the first approach to eligible participants to invite them to take part in specific studies.

b. Sometimes referred to as 'Section 251 support, approval or waiver', the Health Service (Control of Patient Information) Regulations 2002 enables the common law duty of confidentiality to be overridden to permit disclosure of confidential patient information for medical purposes, where it was not possible to use anonymised information and where seeking consent was not practical, having regard to the cost and technology available. Confidentiality Advisory Groups (CAGs) review applications and advise whether there is sufficient justification to access the requested confidential patient information. Using CAG advice as a basis for their consideration, the HRA or Secretary of State will take the final approval decision.

19. Compliance (Principle 15)

19.1. The validity of research and other academic endeavour is based on the implicit assumption of honesty and objectivity by the investigator and on the explicit premise that research data can be verified. Both the Trust and organisations working in partnership with the Trust must uphold this principle and endeavour to maintain public trust in the research process. As stated by the UK Policy Framework for Health and Social Care Research: 'Employers are expected to encourage a high-quality research culture, including ensuring employees are supported in and held to account for conducting research in a professional manner, including research integrity, and … take proportionate, effective action in the event of errors and breaches or if misconduct or fraud are suspected.'

19.2. Research misconduct includes research fraud, non-disclosure of research fraud, violations of Trust policies including this Research Governance Policy, violations of ethical approval, financial probity, and local procedures for approval of research and indemnity arrangements. Research fraud includes: the intentional fabrication or falsification of research data; the omission in publications of conflicting and/or non-conforming observations or data; the theft of research methods or data from others; the plagiarising of research ideas, results or publication(s); or other failure to follow established protocols, deviations from accepted practices in carrying out or reporting results from research.

19.3. Any significant breach by an investigator of the principles and standards set down in the UK Policy Framework for Health and Social Care Research and associated regulations and guidelines shall be considered research misconduct. Research fraud or misconduct constitutes professional misconduct and is grounds for disciplinary action and/or reporting to the appropriate professional bodies.

19.4. These guidelines augment the Trust's standard policies and guidelines to address issues relating to misconduct in research and should be read in conjunction with the Trust Disciplinary Policy and Procedure, Raising Concerns (Whistleblowing) Policy and where appropriate the Standards of Business Conduct Policy, PALS and Complaints Policy, Counter Fraud and Bribery Policy, Grievance Policy and Procedures, and Dignity at Work Policy and Procedure.

19.5. These policies apply to investigators who are employees of the East London NHS Foundation Trust as well as employees of other organisations holding placements, honorary research contracts, or letters of access to the Trust and engaged in clinical research activities within the Trust.

19.6. All persons not employed by ELFT who carry out research using Trust patients, patient samples, patient records, premises, facilities, staff and/or services must be bound by Trust policies and hold a current placement, honorary research contract, or letter of access with clear lines of accountability. The Trust will inform the human resources department of other organisations immediately upon notification

that an allegation of misconduct has been reported. Suitable arrangements between the organisations will then be made to address the allegations.

19.7. Should an incident of research fraud of misconduct be substantiated, the Trust will issue a retraction at the earliest opportunity relating to any publications made by its staff based on that research, and work with the substantive employers of staff holding honorary contracts or letters of access to retract their publications

20. Implementation, Monitoring, and Review

20.1. As per the Trust's Policy for the Development and Management of Procedural Documents, this policy will be submitted to the Risk and Datix Manager on receipt of which he/she will enter this revised version into the Trust library and move the previous version to the archive.

20.2. A master copy will be published on the Trust website and intranet. All current staff made aware of it via standard communications channels (printed newsletters, internal email circulars); new staff joining the Trust staff will be informed of the policy via corporate induction.

20.3. Research Governance will be periodically audited through the Trust's mandatory audit programme, and through participation in national audit projects.

20.4. This policy will be reviewed by the Research Committee every three years unless there is a need to review it more frequently.

21. References

UK Framework for Health and Social Care Research (Department of Health, 2017)

Sets requirements and recommended guidelines for hosting, conducting and managing research; it defines the roles and responsibilities of individuals and organisations and sets good practice standards.

Best Research for Best Health: A new national health research strategy (Department of Health, 2006)

Outlines an overhaul of NHS research and development intended to ensure a world-class environment for conducting and using NHS health research; it established the National Institute for Health Research (NIHR).

Research Support Services Framework (NIHR May 2011)

A set of tools and guidelines intended to support a consistent and streamlined approach to managing health research studies in the NHS.

Medicines for Human Use (Clinical Trials) Regulations (2004) / European Union Clinical Trials Directive

These regulations apply to studies that investigate the efficacy and safety of a medicinal product. Before starting a clinical trial involving medicines, regulatory approval in the form of a Clinical Trial Authorisation must be received from the Medicines and Healthcare products Regulatory Agency (MHRA). An algorithm to help people identify whether their research falls under the EU Clinical Trials Directive is available in Appendix A of that Directive.

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice ('ICH GCP') 10/06/96

The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities. The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

GCP Directive 2005/28/EC

Lays down principles and detailed guidelines for good clinical practice with regard to investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products ('GCP directive') 08/04/05

International Committee on Harmonisation Good Clinical Practice Guidelines

Comprehensive set of guidelines regarding quality, safety, and efficacy on clinical trials.

Medical Research Council Guidelines for Good Clinical Practice in Clinical Trials (MRC, 1998)

Provides guidelines for Good Clinical Practice in MRC-funded trials.

Mental Capacity Act (2005)

Designed to empower and protect vulnerable people who cannot make their own decisions. Research involving incapacitated or potentially incapacitated subjects must comply with the Act.

Data Protection Act (2018)

Introduced to protect individual's rights regarding the access to and use of their personal information. The Act is designed to ensure that the inappropriate use of data does not lead to any unnecessary harm or distress in individuals. The Data Protection Act 2018 is the UK's implementation of the General Data Protection Regulation (GDPR).

NHS Confidentiality Code of Practice

Attributing the costs of health and social care Research & Development (AcoRD)

AcoRD establishes a mechanism for the Department to meet some of the costs of charity-funded research in the NHS, for charities that are members of the Association of Medical Research Charities (AMRC). The AcoRD guidance clarifies the distinction between the three categories of costs associated with non-commercial research studies: Research Costs, NHS Support Costs, and Treatment Costs.

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Appendix A: Acronyms

ABPI	Association of the British Pharmaceutical Industry
AcoRD	Attributing the costs of health and social care Research & Development
CRN	Clinical Research Network
ELFT	East London NHS Foundation Trust
GCP	Good Clinical Practice
HRA	Health Research Authority
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute for Health Research
RM&G	Research Management & Governance
SOP	Standard Operating Procedure

Appendix B: Clinical Trials Compensation

1.1. Historically, there has been a distinction between indemnity/compensation arrangements available to patients and healthy volunteers. Further, the level of protection afforded to trial subjects and advance definition of compensation arrangements available has depended on source of sponsorship. The Trust has adopted a position which minimises these anomalies as far as is possible whilst retaining compliance with current guidelines which may impose a financial limit on the amount of compensation payable. This policy applies to injury caused to patients in Phase II, Phase III and Phase IV trials and where appropriate to healthy volunteers in Phase I studies. Compensation will also be considered for injury caused by licensed or non-licensed products administered to the patient or healthy volunteer for the purpose of comparison with the test substance.

1.2. For the purpose of this policy, Trial Subject means:

1.2.1. A patient, *i.e.* an individual, whose participation in a piece of research derives from either:

- Having sought or accepted medical care within the Trust primarily for treatment of a condition the investigation of which is the subject of the clinical trial; or
- Having been selected from the general population because of known or suspected abnormality;

1.2.2. A healthy volunteer, *i.e.* an individual, who is generally healthy and does not suffer from the condition expected to be modified by the trial intervention; or

1.2.3. A child *in utero* - a child subsequently born alive whose mother was a trial subject while the child was *in utero*. While this policy at a minimum also would apply to non-patient volunteers (i.e. "healthy volunteers"), arrangements for this category of Trial Subjects are receiving further considerations.

1.3. <u>Coverage</u>

1.3.1. Compensation will be available for all subjects injured by their participation in clinical trials once, on the balance of probabilities, causation is established.

1.3.2. Compensation will be paid when, on balance of probabilities, the injury was attributable to the administration of a medicinal product or device under trial or any clinical trial intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the subject in the trial.

1.3.3. Compensation will be paid regardless of whether the trial subject is able to prove that the investigators, clinical staff or manufacturers have been negligent.

1.3.4. Where injury is caused by a commercially sponsored trial, the sponsor will provide compensation on terms at least as generous as those recommended by the ABPI for patients and for healthy volunteers.

1.3.5. Where injury is caused by a non-industry sponsored trial and the non-industry sponsor does not provide an acceptable indemnity arrangement, the Trust shall be liable to pay such compensation.

1.3.6. Where a trial design includes pregnant women, the principles of compensation under this Policy will apply to injuries caused to a mother or to

her child *in utero*. However, since strict criteria are laid down by the Research Ethics Committee for the exclusion of pregnant women from clinical trials in general, compensation will be paid in the event of injury to a child *in utero* only where the mother's participation in such an excluding trial has been non-negligent on her part.

1.3.7. Where there is an adverse reaction to a medicinal product or device under trial and injury is caused by a procedure adopted to deal with the adverse reaction, compensation will be paid for such injury as if it was caused directly by the medicinal product or device under trial.

1.3.8. Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the trial subject has freely consented (whether in writing or otherwise) to participate in the trial, should exclude a trial subject from consideration for compensation under this policy although compensation may be abated or excluded in the light of the factors described in paragraph 1.6.

1.3.9. Compensation will also be paid for injury caused by licensed or non-licensed products administered to the trial subject for the purpose of comparison with the product under trial.

1.4. Limitations

1.4.1. Compensation will not be paid:

- for temporary minor pain or discomfort;
- for the failure of a medicinal product, device, technique or procedure to benefit a patient;
- to patient receiving placebo in consideration of its failure to provide a therapeutic benefit; or
- through contributory negligence by the trial subject.

1.4.2. The maximum amount of compensation payable under this policy will be the maximum *ex gratia* payment permitted by the Department of Health national insurance provisions.

1.4.3. The undertaking given by the Trust extends to injury arising (at whatever time) from all administrations, clinical interventions or procedures occurring during the course of the trial but not to treatment extended beyond the end of the trial at the instigation of the investigator. The use of unlicensed products beyond the trial period or on a named patient basis is wholly the responsibility of the treating doctor. Doctors should notify their protection society of their use of unlicensed products.

1.5. Investigators' Liability

1.5.1. Where the cause of an adverse reaction or injury is attributed wholly or partly to a significant departure from the protocol as approved by the Research Ethics Committee and the Trust, the Trust, in respect of its liability to compensate the trial subject, shall be entitled to claim indemnity to the appropriate extent from the investigator(s) responsible. For this reason investigators are required to maintain appropriate professional indemnity insurance.

1.6. Assessment of Compensation

1.6.1. Subject always to any overriding financial limit imposed on the Trust, the amount of compensation should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by an English court in cases where legal liability is admitted.

1.6.2. Compensation may be abated, or in certain circumstances excluded, in the light of the following factors:

a) the seriousness of the disease or condition being treated;

b) the risks and benefits of established treatments relative to those of the trial intervention;

c) the known or suspected risks and benefits of the trial medicine or device;

d) the information and warning given to the patient as to (a) to (c) above, in the knowledge of which he or she has given consent; or

e) to the extent that the injury has arisen through the wrongful act or default of a third party for whom the Trust is not responsible (e.g. the patient's own doctor).

1.6.3. Where Trust has agreed in principle to compensation being paid but the amount offered under clause 1.4.2 is not acceptable to the trial subject, the question may, if the trial subject agrees, be submitted for the decision of an independent arbitrator accepted by both parties, and failing such appointment, to be appointed by the President of the Law Society.

1.7. Procedure and claims

1.7.1. All research studies must receive NHS Permission from the East London NHS Foundation Trust via the appropriate procedure. Failure to obtain such permission, or disregard of any conditions for permission, would be a breach of the investigator's terms of employment with the Trust. Further, the investigator could bear personal responsibility for any harm resulting to a patient.

1.7.2. An investigator undertaking a non-commercially sponsored trial should make it clear to participating trial subjects as a part of the informed consent process that the trial is being conducted in accordance with this Clinical Trial Compensation Policy.

1.7.3. The management of claims will be decided by the Trust, on a case by case basis, with due regard to the employment status of the Investigator, any contractual arrangements with external funders, honorary contract considerations and insurance coverage. Once agreement has been reached, and where it is possible, one organisation will conduct the procedures involved in examining and settling claims.

1.7.4. Claims pursuant to this policy should be made by the trial subject to the Trust setting out details of the nature and background of the claim and are conditional upon the trial subject providing, on request, an authority for the Trust to review any medical records relevant to the claim.

1.7.5. Trial subjects should be required to accept that any payment made under the policy is in full settlement of their claims.

1.7.6. The fact that the Trust has agreed to abide by this policy does not affect the right of a trial subject to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nevertheless, it is hoped that by adopting this policy the organisation will be seen to deal fairly with trial subjects and will avoid litigation with its attendant expense, publicity and uncertain outcome.

1.7.7. Where relevant, the basic principles and procedures described in the Trust's Legal Claims Policy will apply to this clinical trials compensation policy except where the procedures are in conflict, in which case the wording of this clinical trials compensation policy will take precedence.

1.7.8. In providing financial compensation in accordance with this policy the Trust accepts the need for an expeditious settlement and will make every effort to complete the necessary investigations as a matter of urgency.