

RESEARCH & DEVELOPMENT (R&D) POLICY

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POLICY SUMMARY	
<p>This policy and associated guidance sets out the Trust policy for the development, conduct and management of research within the organisation in accordance with the key legal, quality, ethical and safety frameworks underpinning research in the NHS in order to ensure the rights, privacy and dignity of all who are recruited as participants in a research study. Detailed processes for conduct and management of research are set out in R&D Standard Operating Procedures (SOPs).</p>	
<p>The Trust monitors the implementation of and compliance with this policy in the following ways;</p>	
<p>Monitoring of implementation and compliance with this policy and associated procedures will be undertaken by the Executive Medical Director, Research manager, Research lead, and R&D group.</p>	
Services	Applicable Comments
Trust-wide	✓

The Director responsible for monitoring and reviewing this policy is the Executive Medical Director

ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

RESEARCH & DEVELOPMENT (R&D) POLICY

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RESEARCH & DEVELOPMENT (R&D) POLICY

1.0 INTRODUCTION

- 1.1 The purpose of this policy is to put in place a framework to communicate the principles, legal requirements and standards for all research conducted in the Trust.
- 1.2 This policy also puts in place the delivery mechanisms to ensure that these standards are met and arrangements to monitor quality and adherence to these standards, ensuring compliance with the UK Policy Framework for Health and Social Research (2017) and compliance with other regulatory and statutory requirements.

2.0 DEFINITIONS

- 2.1 **Research** has been defined as “research is defined as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods” (UK Policy Framework for Health and Social Care Research, DH, 2017). The Health Research Authority (HRA) provides a decision tool to help understand if a study would be considered research by the NHS: <http://www.hra-decisiontools.org.uk/research/>. One or more of the following criteria must be true for the study to be considered research:
- The study involves randomisation
 - The protocol demands changing treatment / patient care from accepted standards for any of the patients involved
 - The findings will be generalisable

Generalisable in this context means the extent to which the findings of a clinical study can be reliably extrapolated from the subjects who participated in the study to a broader patient population and a broader range of clinical settings.

If, having consulted the HRA decision tool, there is still doubt, then applicants are advised to consult the R&D office. A HRA email address has also been set up in case of ambiguity - hra.queries@nhs.net

Note that the following are not research and therefore not subject to the research governance process:

Clinical Audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.

Service Evaluation can be seen as a set of procedures to judge a pilot's merit by providing a systematic assessment of its aims, objectives, activities,

outputs, outcomes, and costs. Evaluation provides practical information to help decide whether a development or service should be continued or not. Evaluation also involves making judgements about the value of what is being evaluated.

- 2.2 Research activity may include observational or interventional designs (such as clinical trials) which may be externally funded or undertaken within existing resources. A range of methodologies and tools may be employed in the design of the projects, including quantitative or qualitative methods, randomization, blinding and cohort designs.

3.0 BACKGROUND

- 3.1 This policy and the related procedural guideline are based upon the UK Policy Framework for Health and Social Care Research 2017. All NHS studies need to be conducted according to this framework. Clinical Trials of Investigational Medicinal Products (CTIMPs) are subject to additional regulation and must be conducted according to International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) standards.
- 3.2 All research in the NHS must be conducted ethically. Research involving service users, or service user data that is not fully anonymised, requires formal approval from an independent Research Ethics Committee (REC). Formal REC approval is not required for studies involving staff only.
- 3.3 All research in the NHS requires centralised HRA approval to verify the proposed study is compliant from a legal and governance perspective. To meet legal requirements, additional approvals may be required depending on the study setting, use of data, investigational medicinal products, gene therapy or administration of radioactive substances. Applications for HRA, REC and a range of other research approvals are made via the online Integrated Research Application System (IRAS). Researchers are advised to contact the R&D office as early as possible for advice on setting up a new study. As a final step, new studies generally require “Confirmation of Capacity and Capability” from the Trust (detailed in a Trust Standard Operating Procedure). This involves R&D office led local assessment of feasibility, putting into place practical arrangements for study delivery and, if appropriate, issuing of a final email to confirm the study can go ahead at EPUT.
- 3.4 This policy aims to ensure sound research governance arrangements are in place for the conduct of research in the Trust in order to ensure the rights, privacy and dignity of all who are recruited as participants in a research Study, to ensure service users are informed of opportunities to take part in research relevant to them and to contribute to generation of new knowledge with potential to improve care.
- 3.5 This Trust promotes and encourages a culture of high quality research within the organisation working with its research partners including but not limited to other NHS organisations, academic institutes and commercial partners. The Trust aims to secure R&D capability to improve services and bring benefits to service users.

- 3.6 The National Institute for Health Research (NIHR) and its operational organisations, the Clinical Research Networks (CRNs) informs the research agenda in terms of research management and funding processes. EPUT is a member of the NIHR Clinical Research Network: North Thames (CRN: North Thames).
- 3.7 The NIHR Portfolio is made up of high quality clinical research studies across a range of specialities. Studies adopted to the NIHR portfolio are eligible for the NIHR Study Support Service. NIHR Portfolio studies may also be eligible for support from CRN funded R&D staff employed by EPUT who can assist with study set-up, co-ordination, conducting assessments and recruiting participants. Studies are automatically eligible for the Portfolio if funded by NIHR or NIHR non-commercial partners. Organisations are more likely to be accepted as a NIHR non-commercial partner, if funding is awarded via open competition across England. Commercially funded studies are a “high priority for NIHR portfolio adoption”. Other non-commercial studies may be eligible, based on potential value to the NHS. Researchers are advised to contact the R&D office to explore whether a proposed study may be eligible for NIHR adoption as CRN support is often invaluable to the success of a project. Further detail is available on the NIHR site: <https://www.nihr.ac.uk/funding-and-support/study-support-service/eligibility-for-nihr-support/>
- 3.8 Studies with both a Commercial Sponsor and Commercial Funder are not subsidised by the NHS and all activity must be paid for by the company involved. Cost attribution for non-commercial studies in the NHS is more complex and worked out through the “Attributing the costs of health and social care research (AcoRD) framework (DH, 2012-2015). In summary, AcoRD considers 3 costs of research:
- **Research Costs** - the costs of the R&D itself that end when the research ends. They relate to activities that are being undertaken to answer the research questions. (usually met by grant funders, though some specific research activities may be met by Department of Health – see Annex A and Annex B costs)
 - **NHS Treatment Costs** - the patient care costs, which would continue to be incurred if the patient care service in question continued to be provided after the R&D study had stopped (met by NHS)
 - **NHS support costs** - the additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided (met by CRN if on NIHR portfolio, otherwise by Sponsor or Funder)

Further details on AcoRD are available from the DH:

<https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research>

4.0 SCOPE

- 4.1 This policy applies to clinical and non-clinical research undertaken by all staff in all disciplines wanting to undertake a research study in the Trust. It also applies to all researchers from external organisations who may apply to the Trust to conduct research in this organisation.

5.0 DUTIES

5.1 **The Trust Board of Directors** is responsible for:

- ensuring that the principles of this policy, related standard operating procedures and other associated policies are implemented across the organisation;
- ensuring that necessary financial resources are available.

5.2 **The Executive Medical Director** will ensure:

- The delegated responsibilities to the R&D group are met, monitored and effective.
- This policy and related standard operating procedures are embedded within clinical and research practice.
- This policy and related standard operating procedures are reviewed and updated regularly in accordance with best practice and national guidance.
- Learning derived from quality monitoring and review of local and national best practice guidance is incorporated into clinical and research practice.

5.3 **The Trust R&D Lead** is responsible for:

- Providing advice to the Trust Board and Trust Management on all matters relating to R&D, and their implications for service delivery and development.
- Representing the Trust's research interest to external organisations, both locally and regionally, in both academic and healthcare sectors.
- Representing the Trust as a member of the Clinical Research Network: North Thames Partnership Group.
- Ensuring that research taking place in the Trust is actively promoted, both internally and externally.

5.4 **The Chief Pharmacist** will ensure:

- Pharmacy standard operating procedures are in place for the receipt, handling and issue of IMPs
- Capacity and capability to participate in individual CTIMPs is considered from a pharmaceutical perspective
- The safe and secure handling of IMPs

5.5 Responsibilities of the Research & Development Department:

- Developing and establishing systems for the management of research involving EPUT.
- Developing and maintaining the EPUT study feasibility process to meet the requirements of applicable laws and regulations.
- Conducting effective feasibility checks on new studies and ensuring that appropriate assessment and approvals are in place before commencement of research within EPUT.
- Maintaining a record of all research being conducted within EPUT.
- Assessing applications for EPUT to act as a sponsor for individual studies or to support grant applications
- Arranging for written agreements to be put in place where required for studies involving an external partner, funder and/or sponsor, including agreements with universities or other employers in relation to student supervision and arrangements for sub-contracting.
- Ensuring that adequate payment is obtained for participation in commercial clinical research, which is not subsidised by the NHS, and that such payment flows to departments supporting the study.
- In relation to commercial research, in partnership with the finance department: costing commercial research studies, negotiating contracts, developing and establishing systems to ensure financial probity.
- Permitting and assisting with any monitoring, auditing or inspection required by relevant authorities and conducting internal monitoring as appropriate.
- Contributing to development of the EPUT R&D Strategy with the R&D Lead in consultation with researchers and the R&D Group.
- Promoting dissemination of research findings.
- Promote awareness of the Trust Intellectual Property Policy and the identification, management and exploitation of intellectual property generated from research.
- Compiling and submitting R&D reports and returns as required by national and regional bodies and the Executive Medical Director.
- To develop research opportunities and experience with within the Trust by fostering a research culture.
- Ensure that research taking place in the Trust is actively promoted, both internally and externally.

- Meeting internal and external performance targets.
- Monitoring and reporting on implementation of this policy on an ongoing basis.
- Ensuring the R&D department and research within the Trust operates in line with national standards and Trust policies including data protection, health and safety requirements, monitoring of misconduct and fraud and financial probity.
- the identification, management and exploitation of intellectual property generated from research in the Trust through promotion and raising awareness of the Trust Intellectual Property Policy (CP45)
- the health, safety, dignity and well-being of those involved in research through monitoring of policy and procedural adherence including reporting requirements in accordance with SOPs and Trust policy and monitoring of ongoing studies.

6.0 STANDARD OPERATING PROCEDURES

- 6.1 Standard Operating Procedures (SOPs) are detailed written instructions to achieve uniformity and set out the way practice and procedures must (i.e. mandatory) or should (i.e. advisory) be performed. SOPs are written instructions and records of procedures agreed and adopted by the Researchers following consultation and discussion as appropriate.

In many cases, external Sponsors will provide study-specific SOPs. With agreement of the Trust PI, these will generally be preferred to the generic SOPs below, to ensure uniformity across the study.

Note that while some SOPs are specifically for CTIMPs, they may be used as a reference for best practice for other study types.

- 6.2 SOPs applicable to all studies:

- Amendments to Research Projects
- Confirming Capacity and Capability
- Generating and Submitting REC annual progress reports
- Performing and Documenting Training for Research Staff
- Preparation, Approval, Review and Implementation of Research SOPs
- The Process of Obtaining Informed Consent for a Research Study
- Identification of Potential Research Participants
- Staff Exiting Procedure
- Use of Centrifuges and Handling of Bodily Fluids for Centrifuging in Research

SOPs for CTIMPs only:

- Archiving and Destroying Documents
- Audit and Inspection
- Case Record Form Completion
- Definition of Responsibilities for Externally Sponsored Clinical Trials

- Externally Sponsored Study Close Down
- Initiation Visit
- Study Files and Filing for Externally Sponsored Clinical Trials
- Monitoring Visit
- Notification of Serious Breaches of GCP in Clinical Trials
- Safety Reporting in Externally Sponsored Clinical Trials

7.0 OTHER RELEVANT POLICIES AND GUIDANCE

- 7.1 Other relevant Trust policies and procedures include:
- Adverse Incident (Including Serious Incidents) policy and procedure CP3 and CPG3
 - Trust Standard Financial Instructions
 - Management of Trust Intellectual Property policy CP45
 - Mental Capacity Act 2005 policy and procedure MCP 1 and MCPG1
 - Information Governance and Security Policy CP50 and CPG50
 - Information Risk Policy & Procedure CP57 and CPG57
 - Information Sharing & Consent Policy and Procedure CP60 and CPG 60
 - Corporate Health & Safety Policy RM01
 - Disciplinary (Conduct) Policy HR27
 - Safe and Secure Handling of Medicine CLPG13
- 7.2 Other relevant national policies and guidance include:
- NIHR Research in the NHS: Human Resource (HR) Good Practice Resource Pack
 - ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) – GCP (Good Clinical Practice)
 - HRA guidance documentation
 - UK Policy Framework for Health and Social Care Research 2017
 - Caldicott principles
 - Attributing the costs of health and social care research (DH, 2012)

8.0 RESEARCH PRIORITIES

- 8.1 The Trust will contribute to research in national priority areas as set out by the Department of Health. The current priorities for the Trust are as follows:
- Mental Health
 - Older people
 - Reducing inequalities
 - Improving the patient experience
 - Building capacity to deliver health and social care
 - Progressive, degenerative mental conditions (e.g. dementias)
 - Community research

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- 8.2 The Trust will encourage contribution to research projects in national priority areas of other NHS Trusts and academic and clinical institutions.
- 8.3 The Trust will work with and foster strong collaborative links with academic institutions.
- 8.4 The Trust will work collaboratively with academic institutions to seek external research funding and will liaise closely on the appropriate management of research grants and contract arrangements.

END

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