Leicestershire Partnership NHS Trust

RESEARCH POLICY

(APPROVAL, GOVERNANCE, FINANCE, HOSTING, CONDUCTING & COLLABORATING)

This policy sets out to outline **expected** standards, defines **individual** roles and **responsibilities** and the **processes** involved in registering, adopting and gaining relevant **permissions** for research to begin in or involving LPT as Sponsor or Host. This follows the establishment of the Health Research Authority (HRA) as an independent provider of regulatory assurance, and the implementation of HRA Approval from April 1st, 2016. This policy sets out to ensure that the Trust is fully compliant with and gives due regard to the provisions of the Research Governance Framework for Health and Social Care and the wider UK Policy Framework for Health & Care Research.

Key Words:	Ethics, Governance, Health Research Authority, Research, Investigator, Management Permission, Research and Development, Innovation, Sponsor, Confirmation of Capacity, Time & Target, Performance Metrics, Reporting, Contracts, Service Support, Grant Income, Incentives.	
Version:	7.01	
Adopted By:	Quality Forum	
Date this version was adopted:	February 2024	
Name of Author(s):	Dr Dave Clarke & Dr Karishma Joshi	
Name of responsible Committee:	Research Committee	
Please state if there is a reason for not publishing on website:	Not applicable	
Date issued for publication:	February 2024	
Review date:	1st August 2027	
Expiry date:	31st March 2028	
Target audience:	All Staff	
Type of Policy:	Clinical	Non-Clinical
	Yes	Yes
Which Relevant CQC Fundamental Standards?	Good Governance	

CONTENTS

Version Control & Summary of Changes

Version Number	Date	Comments
V7.01	This Submission	Minor changes made after circulation
V7.0	Version of circulation	Re-Named – simplification to RESEARCH POLICY (Re-structure/ordering and updates through legislative changes): inclusion of role and reach of the research delivery team: expectation of research as core business.
V6.0	23/02/2021	Re-Name to (TRUST MANAGEMENT APPROVAL OF CLINICAL RESEARCH POLICY), Re-structure and simplification
V5.2	11/2020	Inclusion of "WeImproveQ" Pathway, updates to OID and Sponsorship Pathways. Typographical errors. Revisions to HRA Pathways.
V5.1	11/2017	Revisions recommended CEG and QAC Review and adjustments to performance metrics in line with national policy.
V5.0	09/2017	Policy renamed to "Trust Management Approval for Clinical Research Policy". Update to include reference to "confirmation of capacity" replacing NHS Management Permission and associated streamlined approval process updates through HRA, changes to performance metrics and reporting.
V4.0	06/2015	Revised and simplified policy incorporating initial Health Research Authority changes and R&D Performance requirements
V3.1	02/2012	Harmonised key elements – Leicestershire Partnership NHS Trust, Leicester City Community Health Service, Leicestershire County & Rutland Community Health Service.
V3.0	01/2012	Document reorganised and reclassified to map NHSLA requirements
V2.0	03/2011	Version 2 Developed in response to performance framework within NIHR "Research Support Services".
Previous versions from 2000 onwards not version-controlled		

For further information contact: Research and Development Team (lpt.research@nhs.net)

Equality Statement

Leicestershire Partnership NHS Trust (LPT) aims to design and implement policy documents that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

It takes into account the provisions of the Equality Act 2010 and promotes equal opportunities for all. This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity. In carrying out its functions, LPT must have due regard to the different needs of different protected equality groups in their area. This applies to all the activities for which LPT is responsible, including policy development and review. If you require this policy in another format please contact the Corporate Governance Team.

Due Regard

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In carrying out its functions, LPT must have due regard to the different needs of different protected equality groups in their area. This applies to all the activities for which LPT is responsible, including policy development, review and implementation. A Due Regard assessment for this policy is in Appendix 3.

Acronyms used within this Policy

AAC	Assess, Arrange, Confirm Process
ACoRD	Attributing Costs of Research & Development in the NHS
AHSN	NIHR Academic Health Sciences Network (now re-badged as “Health Innovation”)
ARC	NIHR Applied Research Collaborative
ARSAC	Administration of Radioactive Substances Advisory Group
BAF	Board Assurance Framework
BRC	NIHR Biomedical Research Centre
CDA	Confidential Disclosure Agreement
CI	Chief Investigator
CoCC	Confirmation of Capacity & Capability
CPMS	Central Portfolio Management System
CRF	Case Report Form
CRN	NIHR Clinical Research Network (transitioning to Regional Research Delivery Network (RRDN) in October 2024
CRO	Contract Research Organisation
CTA	Clinical Trial Agreement
DDO	Dedicated Delivery Officer
DHSC	Department of Health and Social Care
DSA/DPA	Data Sharing/Processing Agreement
EDGE	NIHR CRN Supplied Local Portfolio Management System (LPMS)
EoI	Expression of Interest
ETC	Excess Treatment Cost
FGP	First Global Patient/Participant
FPFV	First Patient First Visit
GCP	Good Clinical Practice
HRA	Health Research Authority
HTA	Human Tissue Act (also Health Technology Assessment)
IRAS	Integrated Research Application System
IRMER	Ionising Radiation (Medical Exposure) Regulations
KPI	Key Performance Indicators
LADP/LIP	Local Adoption & Delivery Plan/Local Implementation Plan
LIP	Local Information Pack
LPMS	Local Portfolio Management System
LPT	Leicestershire Partnership NHS Trust
mCTA	Model Clinical Trial Agreement
MDS	Minimum Document Set (defines an incomplete LIP)
MHRA	Medicines and Healthcare Products Regulatory Agency
mNCA	Model Non-Commercial Contract
NIHR	National Institute for Health and Care Research
MTA	Material Transfer Agreement
NCVR	National Contract Value Review
NSA	Non-Substantial Amendment
OID	Organisation Information Document
ORCA	Organisational Research Capacity Assessment
PI	Principal Investigator
PID	Performance in Initiating & Delivering Research
PIS	Participant Information Sheet
QAC	Quality Assurance Committee
R&D/R&I	Research & Development or Research & Innovation (aka Research Department)
REC	Research Ethics Committee
ResC	Research Costs (Part A or Part B)
SA	Substantial Amendment
SAE	Serious Adverse Event
SGL	Sponsor Green Light
SoE	Schedule of Events
SoECAT	Schedule of Events Cost Attribution Template
SOP	Standard Operating Procedure
SSC	Service Support Costs
SSI	Site Specific Information
TMA	Trust Management Approval

TTA	Tissue Transfer Agreement
VRA	Valid Research Application

DEFINITIONS

Term	Explanation
ACoRD	Attributing the costs of health and social care research: A framework for the NHS and its partners to correctly attribute, identify, and recover the costs of health and social care R&D
Chief Investigator	The individual who is responsible for the conduct of the whole trial/study, across all sites nationally and potentially internationally.
Clinical Academic	A position that facilitates the post holder to participate within both a clinical service and an academic role. Most commonly the primary employer is the academic institution, but the NHS can and should be the employer subject to agreement. An honorary contract is held with the non-employing party.
Confirmation of Capacity and Capability (CoCC) (once known as "NHS Permission")	This is an NHS Trust's written confirmation that following the "Assess, Arrange, Confirm" Process (triggered by the HRA Initial Approval Letter) that it can undertake the research, and in most cases, deliver to target. This confirmation may be made by any or all of: • A standard template e-mail provided by the HRA. • A formal contract between partners (such as a mNCA, CTA or OID). • A template letter from the R&D Office CoCC always precedes the final signature of any relevant contracts and the need for CoCC is specified on the final HRA Approval Letter.
East Midlands Clinical Research Network (EM CRN)	EM CRN is one of 15 local networks of the NIHR supporting the delivery of high-quality research in the NHS and social care across the East Midlands. This is transitioning to become one of 12 RRDNs (Regional Research Delivery Networks) from October 2024.
EDGE	A cloud-based data platform for the management of clinical research studies developed at Southampton and provided free-of-charge to NHS Partner Providers to fulfil the role of the "Local Portfolio Management System" to record, manage and report recruitment and other performance metrics.
Health Research Authority (HRA)	A special health authority of the Department of Health and Social Care (DHSC) that from April 2016 was charged with protecting and promoting the interest of the patients and public in health and social care research.
HRA and Health and Care Research Wales (HCRW) Approval (abbreviated to HRA Approval for the purposes of this policy)	All research in the NHS must have secured HRA Approval before it can begin. HRA approval is undertaken by independent, dedicated HRA staff (it may also include independent ethical review) to assess the governance and legal compliance of a research study that aims to take place in the NHS. HRA approval applies to all project-based research taking place in the NHS in England and Wales, it provides permission for any study, advises on the need for Confirmation of Capacity and Capability, and provides independent assurance to both the public and NHS Trusts as research sites. This enables NHS R&D or R&I (aka the "R&D Office") to focus their resource on whether capacity exists, or can be put in place, for the research to be successfully delivered, and to be proactively managed and monitored (usually for adherence to protocol). Where a research project is led from Northern Ireland or Scotland and involves NHS/Health and Social Care sites then applications should be made through the appropriate permission process for that lead nation.
Named Sponsor Representative	The person authorised to by the sponsor organisation to act on behalf of the sponsor. This list is recognised by the HRA and only those listed will be accepted on documents avowing LPT Sponsorship.
Non-Portfolio Research	Any research which for any reason is not adopted onto the NIHR Portfolio and therefore may make no call on resources provided by NIHR CRN.
"Own-Account" Research	Any research which is wholly or partially resourced from any retained income legitimately held by and individual, group or department, and where there is no conflict of interest.

Research Ethics Committee (REC)	RECs review research proposals to deem if the research is being ethically conducted, to protect the rights, safety, dignity, and well-being of research participants. REC approval is integrated into the process of applying for HRA approval.
R&D/R&I Office	The "Research Office" is formally identified within the Research Governance Framework for Health & Social Care (RGF) and the UK Policy Framework for Health & Social Care Research as a key element within the process of research approval. All research active Trusts are expected to have an adequately resourced research office. The Office is formally a part of the Trust Assurance Structure with delegated authority from the CEO for all aspects of research activity, giving due regard to all principles of the UK Policy Framework for Health and Social Care Research, with considerable freedom to operate. As such, it is mandatory that the office is informed of all research planned to take place in the Trust, and to consider acting as Research Sponsor on occasions. Research that takes place in the absence of HRA Approval and/or Confirmation of Capacity is not covered by NHS or Professional Indemnity.
Research Sponsor	As defined by the UK Policy Framework for Health and Social Care Research, a research sponsor is an individual, organisation or partnership that takes overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All research in the NHS must have a Sponsor. Most Sponsors have a "green light" process such that no work at a site can begin without SGL being in writing.
Student Research	Any research activity that is undertaken "primarily for an educational purpose". This must seek all appropriate approvals and if required, the default sponsor will be the host University.
Trust Management Approval (TMA)	TMA is a check and balance where service management provide confirmation that they agree that staff from all disciplines may engage in the research and that capacity exists in the service. This is considered as part of the "arrange" process under AAC and precedes full Confirmation of Capacity and Capability. This is also defined as the process of confirming that a study may proceed for single-site studies where the Trust is also the research SPONSOR. Governance decisions are undertaken via the Research Office in consultation with services and research delivery staff as appropriate, balancing time-critical metrics with proportionate levels of consultation.
Trust Research Delivery Team (RDT)	This refers to CRN[1]-funded R&D staff in LPT whose primary work stream is supporting and executing the delivery of studies on the NIHR portfolio and adopted for delivery in LPT. The team scope research relevant to patients and services in our Trust, liaise with services about running research, assess the feasibility of a study, support set-up and support the delivery of the study. This may include identifying service users and informing them of studies, obtaining participant consent, undertaking interventions and follow-up activity and liaising with research teams and clinical services to ensure smooth running of studies in LPT. Research Delivery staff are always considered part of the extended clinical team in respect of any Portfolio study they support. The Trust operates an "opt-out" system such that anyone under the care of LPT Services may be approached by the RDT if eligible to participate in research.

[1] Note that CRN funded staff will from October 2024 be funded through new Regional Research Delivery Networks (RRDNs)

1. Background

Leicestershire Partnership NHS Trust recognises that involvement in and conducting high quality research to produce the best evidence, is fundamental to the continual improvement of services locally, nationally, and internationally. The creation of a vibrant research culture and the opportunities that presents to attract and retain staff as embedded core business of the Trust will lead to positive innovations and developments; especially in partnership with national and regional networks and institutions a strong research culture will progress one of the objectives of LPT to become a University Trust. As a Trust and system partner, we are committed to enabling and promoting excellence in research at all levels and for all staff. We will play our part whenever it is possible to do so by actively participating in research, by leading research as sponsor, and by promoting opportunities for staff and supporting service-user/carer involvement in research. Wherever possible we will reflect the diverse nature of the population we serve, whether through Trust services or where we can influence research in the wider Integrated Care System and through engaging in partnerships of mutual benefit.

A high performing organisation recognises the importance of investing in research; enabling our staff to learn and grow and our community to participate in healthcare improvement. There is extensive evidence that patients and service users have better outcomes in NHS organisations which are research active or research-led and therefore we see research as a core part of the service we provide for our community. We are committed to encouraging all staff to have the opportunity to "Be Part of Research" within their clinical or non-clinical roles and in synchrony with the national campaign of the same name.

The Trust actively and enthusiastically collaborates in research alliances and clinical research networks and will always pay due regard to the fundamental principles of the UK Policy Framework for Health & Social Care Research protecting the rights of patients and the public. This policy also recognises that as a "Category A" holder of a NIHR Partner Contract, there is an overriding obligation on the organisation to strive wherever possible to support the delivery of research studies adopted within the NIHR Portfolio. As a result, the Trust hosts clinical research network-funded staff to support services across the organisation to meet this obligation and such studies will have first call on Trust resources.

We are committed to Continuous Improvement in Research Office functions including all research approvals, capacity and risk assessment, governance activity and research compliance monitoring. We will do this with a robust, but flexible approach aimed at rapid study set-up and delivery, whilst adhering to, and understanding fundamental underlying principles.

For the purposes of this policy research uses the HRA definition:

> *"The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies."*

Research became specific in CQC Well Led inspections for trusts in Oct 2018; such that research activity has been formally recognised as a key component of best patient care. The CQC now focuses on how well a Trust as a whole supports research activity across all disciplines and localities via strategic, divisional and local leadership, and providing patient and staff opportunity and access around research.

2. Purpose of the Policy

The purpose of this policy is to help staff understand the mandatory procedures involved in gaining approval for and conducting research within the NHS. Leicestershire Partnership NHS Trust (LPT) is a research-active organisation that aims to promote a sustained improvement in the leadership, scale, delivery and uptake of research. Employees and service users of LPT or a partner organisation should be aware of the expectations and requirements involved.

POLICY HIGHLIGHT: For all research activity, it is staff's individual responsibility to ensure that they have all of the relevant regulatory body approval(s) in place. These approvals are now all encapsulated within the HRA Approval process, and this applies to all research taking place in the NHS. All research in the NHS must have an agreed Research Sponsor who must ensure that all approvals are in place.

No research in the NHS can begin without final HRA Approval being in place (which may also include NHS Research Ethics Committee approval) and the completion of an "Assess, Arrange, Confirm" process within a host Trust to "Confirm Capacity and Capability" (aka management permission) for the proposed research to start. AAC may require confirmation of service management approval.

Individuals are also responsible for ensuring complete transparency with regard to the conduct and outcomes of all approved and hosted research.

This policy outlines the standards expected in respect of the conduct of research activity and defines roles and responsibilities, and the processes involved in registering research, and gaining relevant permissions. This policy is to ensure that the Trust is fully compliant with the provisions of the Research Governance Framework for Health and Social Care (which outlines individual and organisational responsibilities) and relevant legislation and pays due regard to the UK Policy Framework for Health & Social Care Research.

The UK Policy Framework for Health and Social Care Research (2017) sets out the principles of good practice in the management and conduct of health and social care research across the UK. The status of this document is statutory guidance to which local authorities and NHS Trusts in England must have regard. Its purpose is to ensure that the public will feel safe when they take part in research, whilst enabling the development of innovations which will help to improve the quality of health and care in the UK. The Framework helps bodies that commission care to fulfil their legal duty under the Health and Social Care Act 2012 to promote the conduct of research.

As an organisation we recognise that our staff are our greatest asset and we are committed to developing a culture whereby research is embedded as a core part of clinical services, enhancing our offer to those who access our services, but also making Leicestershire Partnership NHS Trust an excellent place for staff to work, learn and innovate.

2.1 Key Drivers

- The Health Research Authority (HRA) and the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments require that an organisation taking on the role of 'Sponsor' or Host must have proper arrangements in place to initiate, manage, monitor and finance a study.
- Where the organisation is providing care to research participants within studies with other Sponsors, the organisation must ensure that legislation related to research is followed.
- These requirements not only apply to the initial approval of a research protocol, but throughout the conduct of the research, including where the protocol is amended.
- This policy covers the proportionate process of both internal Trust Management Approval (TMA) as part of Assess, Arrange, Confirm (AAC) that leads to an agreement with the Sponsor that the Trust has the necessary capacity and capability to undertake the research.
- The Trust is contracted with the National Institute of Health and Care Research (NIHR) to report on and publish its performance against national benchmarks for both initial set-up of research studies; and recruitment to time and target over the life-course of a study. Failure to achieve these targets, could affect the provision of NIHR funding in the future.
- The National Health Service (Quality Accounts) Regulations 2010 require that NHS Trusts provide information on the clinical research undertaken, where a Research Ethics Committee (REC) has given a favourable opinion on an annual basis. This cannot happen unless all research is registered and monitored.
- Ensuring that our Research Delivery Team (RDT) is fully supported to make the maximum contribution possible to these national priorities through our obligations under the NIHR Partner Contract.

3. Policy Statement

In summary, it is Trust Policy to:

- Maximise the opportunities available for staff, service users and carers to take part in, and lead high quality clinical and health research.
- Prioritise support for NIHR Portfolio research as the first call on resources.
- Encourage clinical service management to consider research at all relevant meetings and consider staff requests for time and other resources transparently and in good faith considering research to be "core business" of the Trust.
- Protect the safety, dignity, rights and well-being of all patients and staff involved in clinical and non-clinical research.
- Abide by the HR Good Practice Guidance for Research (Research Passport scheme).
- Ensure that arrangements are in place for the management and monitoring of clinical trials and all other research studies where Leicestershire Partnership NHS Trust ('the Trust') has taken on the role of SPONSOR, as a HOST, or a COLLABORATOR institution, including compliance with all applicable laws and regulations.
- The Trust will still strive to meet the former NIHR benchmarks for "performance in initiation" (time in days to approve valid applications); for "first patient first visit" (FPFV); to strive towards "first global; first European; first UK" patient, and to recruit to "Time and Target" to remain an attractive site to conduct research.
- Encourage all research outside of the NIHR Portfolio to comply with and perform to similar performance metric levels and benchmarks.
- Conduct "Assess, Arrange, & Confirm" (AAC) procedures and other mandatory processes using a consistent yet flexible, risk-proportionate approach, delegated to be conducted by the Trust Research Office combined with robust feasibility to ensure timely approval and delivery of sponsored and hosted research with proportionate oversight and delegation of responsibility.
- Consider that conducting research outside of internal, national and international regulatory and approval frameworks is considered serious misconduct and would justify disciplinary action, up to and including dismissal in the worst cases.

4. Duties & Responsibilities

General Responsibilities

It is recommended good practice for staff in developing research, to ensure that in principle the target clinical service management and staff are aware of the expectation and demands likely to be imposed by conducting or hosting the research. This "local authorisation" is a key component in the eventual "confirmation of capacity and capability" and can speed final approval and in ensuring research becomes embedded "core business".

As in the Policy Statement (3) anyone undertaking research within the Trust without the relevant approval(s) in place, is substantially in breach of the UK Policy Framework for Health and Social Care Research and other relevant legislation e.g. ICH Guideline to Good Clinical Practice (GCP) and therefore disciplinary action can and will be taken against them.

"Local Authorisation" can be obtained directly from the Medical Director or Divisional Directors, Clinical Directors and Service Management. They can give approval for research studies to proceed in principle, within any service within the Trust. Obtaining this level of approval to proceed does not of itself enable a researcher to commence a research study without having obtained confirmation of approval and regulatory compliance from the Research Office (which has delegated responsibility for Sponsorship etc.).

4.1 Chief Executive

The CEO has overall responsibility for ensuring that the Trust can fulfil its role as a research sponsor, as defined by the UK Policy Framework for Health and Social Care Research, that it is able to fulfil its role as a research active site and that the Trust supports the NHS Constitution's aspiration to use research to improve the current and future health and care of the population. These responsibilities are further delegated as follows:

4.2 Director of Research (currently fulfilled by a Deputy Medical Director)

The Director is responsible for profiling the Research Priorities of the Trust as a critical system partner in relation to LLR and national drivers within the overall Trust strategy of "Step Up to Great". The role directs operational and delivery functions, and fosters alliances (including the clinical group) to ensure it fulfils its role

as research sponsor and optimises patient and staff participation in research in order that the Trust's research ambitions are achieved.

4.3 Head of Research Operations

The HRO leads the Research Office under delegated authority from the CEO and all operational functions of the research team, with Trust-wide responsibility for UK Policy Framework for Health and Social Care Research compliance, as well as supporting, helping define and enable strategic objectives. The development of research-specific SOPS and Guidance for all aspects of conduct and delivery also sits with the HRO and Research Office staff. These documents need to be frequently updated due to changes in legislation or regulatory processes. Policies related to research are considered Trust Procedural Documents and are approved through that process.

The "Research Office" (see 4.6) is a defined part of the compliance system within the UK Policy Framework for Health & Social Care Research and has specific functions and responsibilities within the HRA processes, and with other regulatory authorities.

4.4 Head of Nursing and AHP Research

Together with 4.2 & 4.3, this role forms the triumvirate operational leadership for research in LPT, with specific responsibility for the strategic direction of nursing and AHPs research and clinical academic career development. As indicated by the title, this role is primarily concerned with leading the development of research capacity and capability for nurses and AHPs and the implementation of the Nursing and AHP National strategies for Research in LPT.

4.5 Research Committee

The Research Committee seeks to ensure collective leadership for research across the Trust (and with Partners) in order that all research activity[2] is aligned to achieving the Trust's strategic objectives. The committee is also a means of escalating issues to higher committees as part of the Trust's governance structure.

This Committee will also be the accountable body in overseeing investigations into Research Misconduct (see also R&D/SOP/010 Identifying and Dealing with Research Misconduct, Bribery and Fraud (V2.51)

4.6 Research Office/Research Operations

The Research Office and staffing therein has a broad remit, including overseeing operational delivery, performance monitoring, contracts and governance, relationships with clinical networks and the Health Research Authority. The office can also advise and signpost staff and others on research design and identifying potential funding sources, often in liaison with the Research Design Service or the CRN Study Support Service. (see "Research Functions").

4.7 Research Functions

As a sponsor the Trust relies on functions within and outside of the Research Office itself to meet its obligations under UK Policy Framework for Health and Social Care Research. The Research Office, RDT and Trust staff will collectively (and in alliance with external agencies) deliver these functions including (not an exclusive list):

- Advise on grant funding applications and ensure studies are costed in line with ACoRD.
- Host and manage contracts, sub-contracts, non-disclosure, confidentiality and collaboration agreements relevant to research.
- Maintain records of all Trust research projects through the portfolio management system, EDGE.
- Consider requests for Trust sponsorship, and ongoing Sponsor oversight thereafter.
- Confirm all sponsored research has an appropriate level of independent peer review, that the literature supports the need for the research and the research has considered, and where practical accommodated, the needs of our diverse population.
- Ensure that researchers have appropriate contractual documentation and that studies have the necessary indemnity arrangements.

[2] It is recognised that NIHR "Portfolio" research may not always align with Trust Priorities, but the national imperative to support such work overrides local considerations.

- Ensure a risk proportionate approach to study design and monitoring.
- Record dissemination of completed research, inform relevant services and service users of research outcomes and work towards inclusion of papers and publications in an Evidence Repository (to be developed).
- Provide information relating to performance management of Research Functions in line with the requirements of the NIHR, HRA, the Research Committee and other relevant parties.
- Streamline research governance processes and remove unnecessary bureaucracy.
- Review information governance and data protection issues and refer to specialist advice where necessary (for example DPIAs for activity not otherwise contracted)
- Promote/develop schemes to give service users and staff the right to hear about and actively participate in research, including its initiation and design, where these schemes will consider diversity of our population.
- Ensure researchers cite the Trust in publications.

4.8 All Staff

The policy aims to provide guidance to researchers regarding the mandatory requirements for conducting research in the Trust as outlined in the UK Policy Framework for Health and Social Care Research. This policy will cover the responsibilities of all staff, as well as researchers to ensure that they:

- Are aware of the obligation to contact the Trust Research Office whenever any research involving the Trust is being proposed.
- Can correctly identify the type of study (i.e. research, quality improvement, service evaluation or audit) they are proposing to conduct and the routes towards confirmation that the study can proceed. (as discussed at the QI Design Huddle contacted at: WeImproveQ@nhs.net)
- Are aware of the distinction between research adopted within the NIHR Portfolio (and the performance metrics inherent to such studies) and “non-portfolio” research.
- Can identify the minimum document set to be included within a research proposal to constitute a valid research application.
- Put in place the relevant policies and procedures in all Trust support services, including Pharmacy and third-party suppliers of services.
- Are aware of the need to confirm the appropriate Research Sponsor for their research study.
- Are aware of the parallel processes for Trust Confirmation of Capacity and HRA Approval that must be completed before initiating any research.
- Are aware of their responsibility to ensure that sufficient resources (which may include external funding) have been identified to ensure successful completion of a study.
- Are aware that there are Standard Operating Procedures and other Guidance available from the HRA, Trust R&D etc. which are updated wherever possible.
- Are aware of the requirement to disseminate research findings via all necessary means, including the Trust Research Forum (this also ensures compliance with the HRA Transparency agenda).
- Are aware of the requirements of Good Clinical Practice as applied to research (ICH-GCP)
- Are familiar with the specific roles and responsibilities of individuals and organisations in respect of health research activity.

The Trust requires all Trust employees, full-time, part-time, salaried or honorary, students, and those who are not employees who plan or who are authorised to conduct research in the Trust or to use Trust facilities or resources in the conduct of research, to observe the highest standards in the conduct of their research. In pursuing such high standards, they shall:

- Seek to address gaps in evidence in the care we provide through research that considers the diverse population we serve across Leicester, Leicestershire & Rutland.
- Work with the Research Office, Finance and Partners in costing proposals that involve the Trust and ensure appropriate agreement is in place before submitting funding applications.
- Notify the Research Office at the earliest possible stage in the development of research proposals which involve the Trust. And provide copies of research proposals which involve Trust patients, staff, data or facilities.
- Apply for research sponsorship from the Trust Research Office (where the research is not part of an academic qualification where the academic institution will be obliged to fulfil this responsibility)
- Not start any research project prior to receiving Research Office approval (or confirmation of capacity).

- Ensure that they only undertake research activities for which they have relevant training, qualifications and experience.
- Ensure that they have appropriate contractual status and indemnity arrangements to undertake research at the Trust.
- Follow relevant legislation and guidance on the appropriate conduct of research including the UK Policy Framework for Health & Social Care Research (2017), the EU Directive for Clinical Trials, Mental Capacity Act, Human Tissue Act and other relevant legislation and guidance.
- Only conduct research that is in line with the approved protocol including the arrangements for identifying and obtaining the consent of participants.
- Ensure that research participants have information about whom to ask questions about the research and to how to raise any complaints.
- Adhere to all relevant Trust policies and procedures.
- Comply with relevant legislation and guidance on confidentiality including the General Data Protection Regulations, the Data Protection Act, NHS Code of Confidentiality and Caldicott Principles.
- Regularly submit recruitment and performance data to the Research Office function or take responsibility to maintain the EDGE record of their study in accordance with data cut-off deadlines, if using EDGE for study management.
- Support audit and monitoring exercises as required by the Research Office, regulatory bodies and the study sponsor.

4.9 Human Resources

This policy states that LPT will abide by the HR Good Practice Resource Pack for Research, including adoption of the Research Passport for researchers outside of the NHS. This will involve joint working with the Research Office and Trust HR to expedite the issuing of necessary contracts (Letter of Access, Honorary Research Contract, License to Operate) on receipt of valid documentation and the development of an agreed SOP to this end.

The Research Office already has delegated authority from Trust HR to issue a “letter of access” for research to researchers external to the Trust where this is allowed under the HR Good Practice Algorithm.

5. Scope of this Policy

a) This Policy applies to anyone conducting or taking part in research within the Trust, irrespective of whether such research is sponsored or hosted by the Trust.
b) This Policy applies to all areas of the Trust, and all employees of the Trust, including individuals employed by a third party (operating under a letter of access or honorary contract), by external contractors, as voluntary workers, as students, as locums or as agency staff.

6. Involvement of Service users and the Public in Research

Public and Patient Involvement (PPI) in research ensures that research within the NHS is both patient/service-user driven and focused. This may include the involvement of patients, service users, Carers and members of the public in consultation, collaboration, co-design and co-production of research studies. People with lived experiences contribute vital expertise and give valuable, novel insights to research teams throughout the life cycle of the research. This involvement will lead to improved study designs and the conduct research that is meaningful to and addresses the needs and priorities of people with lived experience.

The Trust is committed to offering service users, patients, Carers and members of the public the opportunity to get involved and sees PPI in research as a collective responsibility of all those involved in research delivery and management. We will strive to ensure the research we sponsor and the studies we support are considering the needs of our diverse population and seek to be inclusive of under-served groups in clinical research. Trust services will ensure they are able to meet the requirement of the NHS Constitution by enabling the promotion, conduct and use of research to improve the current and future health and care of the population.

The “Research Partners Collaborative” supported by the Trust Charity is one such initiative and is of immense value in supporting researchers across the Trust to embed meaningful PPI in their research.

6.1 Transparency & Dissemination

Confirmation of Capacity to conduct research is always conditional, and this policy reinforces the DHSC position that states that there is an obligation to disseminate the results for all approved research studies. "Research Transparency" enables all research results to be openly available such that the work can be replicated and understood by the target audiences. This should be more than solely publishing an academic paper or poster (all such papers must credit the Trust) and should involve direct feedback to the Clinical Services (and where relevant and achievable, service users), most affected by the findings and potentially directly to the Trust Board.

As a matter of principle, research should, wherever possible, add value to the organisation and the wider health economy and this is facilitated by timely dissemination of findings, with a countervailing obligation on the organisation to assess the potential value of evidence, and amend practice accordingly.

All research findings should be shared with participants wherever possible, and copies of publications logged with the Trust Research Office (subject to copyright obligations).

7. Research Sponsorship

The UK Policy Framework for Health and Social Care Research states that all research conducted in the NHS must have a research sponsor, with the Sponsor having defined responsibilities within the Framework. The application process and conditions for LPT Research Sponsorship is fully detailed in R&D/SOP/005/Applying for LPT Research Sponsorship. All applications should be directed to lpt.researchsponsor@nhs.net

As a prospective investigator, before submitting an application for HRA Approval, a study sponsor should be identified and agreed in writing. Sponsors can be organisations such as NHS Trusts, pharmaceutical or device companies, or universities. The role of the study Sponsor is to ensure and confirm that everything required for undertaking the research is in place and to ensure that the requirements for the study can be effectively delivered.

Please note that HRA maintains a list of eligible counter-signatories for confirmation of Sponsorship given the legal obligations of the Sponsor role. An application not counter-signed by one of these named individuals will be declined for HRA Approval including NHS Research Ethics Committee Approval.

Where research is designed, and conducted by Trust staff, the Sponsor will usually be the Trust itself (but this must be confirmed in writing).

For those conducting research as part of an academic programme, the University where the member of staff is studying will, by default be the Study Sponsor. If for any reason the Academic Institution is unable or unwilling to take on the role of study sponsor, this may be undertaken by LPT (subject to written confirmation). Please contact Trust Research Office at (lpt.researchsponsor@nhs.net) as soon as possible in all such instances.

For research on the NIHR portfolio, by the time the Trust is asked to participate, a study Sponsor will usually already have been identified. The necessary arrangements are then negotiated between R&D and the Sponsor.

Leicestershire Partnership NHS Trust, through the Trust Research Office is an HRA-registered Sponsor organisation and can (subject to Research Office Capacity) fulfil the requirements of a research sponsor for all research except clinical trials of investigational medicinal products (CTIMPS) and clinical trials of medical devices used outside their scope of intended use or are not CE marked. An appropriate risk assessment is undertaken for all studies where sponsorship is being requested from the Research Office.

To qualify for sponsorship by Leicestershire Partnership NHS Trust most or all of the following should apply:

- That the Chief Investigator is substantively employed by the Trust, or holds an honorary research contract with the Trust, or holds an honorary clinical contract with the Trust; and
- the research has demonstrable benefit to the patients and/or staff of the Trust or the wider care system; and
- the Trust will be the grant/funding holder; and
- the research is well designed, peer reviewed, can demonstrate a clear involvement of patients and/or the public in its development, has a robust literature review and is statistically sound; and
- poses no significant legal, financial and reputational risks.

The Trust does not support and will not indemnify research conducted under the sponsorship of any of its employees nor named individuals. The Trust will not normally sponsor research for academic qualifications, unless there are exceptional circumstances, or Sponsor research that happens outside the UK.

7.1 Sponsorship Costs

Whilst the cost of Sponsorship may in part be defrayed by Research Capacity Funding this can only be used in respect of NIHR Portfolio research. In the next iteration of the Research Finance Policy consideration will be given to charging modest fees for sponsorship to support the activities of the Research Office and other support departments involved.

7.2 Shared sponsorship

Co-sponsorship – where two or more organisations divide the responsibilities and liabilities between them such that each has a subset of overall responsibilities. Leicestershire Partnership NHS Trust may consider this in exceptional circumstances (primarily within the Clinical Group)

Joint sponsorship – where two or more organisations are jointly and severally responsible for all duties of the sponsor, such that all are responsible in the event of failure of any one of the joint sponsors to discharge their responsibilities. Leicestershire Partnership NHS Trust will not participate in arrangements of this kind.

As Research Sponsor, the Trust will require the use of EDGE to manage and monitor the progress of any research.

8. Management of Research Income

It must be understood that the default position for Research Funding in NHS Trusts is that there is no automatic provision of resource to or within Provider Trusts. All Research Funding from the DHSC is managed centrally through the NIHR with a system of competitive programmes and grants (see www.nihr.ac.uk etc.). Any funding that is received by the Trust to support NIHR Portfolio activity, and that incurs additional treatment costs to the Services involved will be released to the Service(s), following the principle established in “Best Research for Best Health” that funding follows eligible activity.

There is therefore no funding available to conduct investigator-led (own account) research unless this is approved directly by the Trust Board or within Clinical Services from within their existing budgets. This can and should include areas of clinical priority within the Trust permitting the release of staff from all disciplines to undertake such work. This is however, discretionary and does not remove the need for regulatory approvals.

There are streams of funding from a range of bodies that can provide support for research and related activity. Advice and guidance on funding sources can be sought from the R&D Office, University Partners and the Research Design Service

HIGHLIGHT: Ensure that any study is properly resourced.

It is a critical principle that no research should impose any additional costs on clinical service budgets that are not agreed prior to the research starting. This principle, first established under the Culyer process for identifying NHS Research Expenditure and reinforced in HSG 97(32) is to ensure that research does not impact negatively on clinical services.

Specific research activities must be attributed as either Research Costs (Part A and Part B), Treatment Costs, or Service Support Costs (ACoRD) and must be clearly identified prior to the research being approved.

All research activity has a cost, and ideally this is covered by income to cover such costs. The attribution of costs of research is detailed in the ACoRD guidance, and this is further fully described in R&D/POL/002

Research & Development Finance: Income Distribution & Management but the key principles are summarised here. Investigator-led research that has no external income can only be supported subject to discretionary decisions taken by Directorates.

Research Income may be derived from a number of different sources, but these are primarily categorised as:

- Infrastructure
    - Usually derived from various different elements of the NIHR but primarily the Clinical Research Network directly funding research delivery staff.
    - Additional funding such as RCF when linked to performance metrics.
    - Excess Treatment Costs
- Commercial
    - Pharmaceutical or medical device trials and studies
    - As of November 2023 LPT will use the NCVR (National Contract Value Review) process for commercial trials
- Non-Commercial
    - Grants from Charities or similar directly to the Trust or to Academic Institutions

The Research Office (with Trust Finance support) is responsible for managing all financial aspects of research including invoicing and distribution of income. Similarly, the Research Office will link with Trust finance to provide costs for grant submissions from LPT Staff, or NHS Costs for grant submissions from partners.

R&D/POL/002 Research & Development Finance: Income Distribution & Management also describes the operation of the Research Protected Income Cost Centre, to ensure that all research income is ring-fenced and cannot be used outside of research, and that grants are appropriately managed and facilitate ASTOX (Annual Statement of Expenditure) returns.

Whether the research is commercial or non-commercial, the Trust expects all to follow ACoRD and/or NCVR principles and to cover the actual cost incurred, and for commercial research (and RCF) to allow the development of additional capacity for future research (NCVR and the Interactive Costing Template). This policy recognises that early-stage research may not be fully resourced, and any such activity or subsequent larger work are subject to discretionary permission from Directorates and Clinical Teams within their resources.

For commercial studies and non-commercial studies, each trial will have an individual analysis code within the R&D Protected Income Cost Centre (allocated by the finance department). This ensures that services and staff engaged in such trials are correctly remunerated and to enable the sustainability of research projects, grants and programmes across financial year-end. Where studies are not to be included on the NIHR research portfolio the NIHR Industry costing template will be used as a guide to define the relevant costs.

In keeping with the advice from the NIHR, income generated from commercial research will be distributed as follows:

- Direct Staff Costs (NHS) – these will be paid directly to the relevant department of the staff member, unless the member of staff is CRN funded when it will be used to reimburse the CRN budget allowing the budget to reinvest to increase capacity to support the NIHR Portfolio.
- Direct Staff Costs (Academic) - An agreement must be in place before the study starts to clearly document expectations of how these will be distributed.
- Investigation costs. These will be paid directly to the appropriate service.
- Indirect costs. These will be shared between the investigator/research team and Research Office (with 50% to cover corporate costs and 50% to the investigator/research team) in a ring-fenced budget under the Protected Income Cost Centre (PICC) managed by the Research Office to be used to develop further research.
- Capacity Building. Retained by Research Office to allow capacity for research to be developed strategically across the Trust.
- Pharmacy costs. These will be paid directly to Pharmacy.
- Set up and other trial related costs. The Trial set up fee will be retained by the Research Office. The investigator set up fee will be paid to the appropriate cost centre which met the cost. All other fees will be paid according to the cost centre(s) meeting the cost(s).

9. Research Contracts

Research funded by non-commercial and commercial organisations will normally be subject to a written contract/agreement between the Trust and the funding organisation. Contracts will be signed by the Research Director or delegated to the Head of Research Operations and further, subject to Trust Standing Financial Instructions. Confidentiality and/or Non-disclosure agreements are signed by the HRO or delegate.

Multi-party collaboration agreements will be set up where research income and grants are to be shared by parties to the collaboration and signed by the Research Director or delegate.

10. Grant Applications

Grant applications requiring the use of Trust resources of any kind must not be submitted to funders without Trust authorisation and will be submitted to the Trust in good time (initial contact at least one month before deadline) with sufficient information for the costs of Trust involvement to be clearly and fully accounted for. Researchers preparing such applications must refer to Department for Health and Social Care guidance and ACoRD guidance to ensure they have clearly identified and attributed all costs. Where necessary, applicants should seek support to complete a SoECAT as part of the grant application process.

11. Differentiating between Research, Service Evaluation, Quality Improvement, Innovation and Clinical Audit

Although there may be many superficial similarities between research, service evaluation and audit, in terms of the language and terminology used, the regulatory requirements for each are substantially different. As NHS-based clinical research may involve the testing of new, innovative treatments and interventions not otherwise available or commissioned it is of vital importance that there is public confidence in the approval processes before this can begin. The HRA (see mission statement highlight below) has been established to provide this assurance both to the public, and to NHS organisations.

HRA Mission Statement

Our vision is for high-quality health and social care research that improves people's health and wellbeing, and our core purpose is to protect and promote the interests of patients and the public in health and social care research.
To achieve this we:

- make sure that research is ethically reviewed and approved
- promote transparency in research
- oversee a range of committees and services
- coordinate and standardise research regulatory practice and
- provide independent recommendations on the processing of identifiable patient information where it is not always practical to obtain consent, for research and non-research projects.

You can find out more about our work and what we do on this website, in our monthly newsletter HRA Latest and via social media. We are one of a number of organisations that work together in the UK to regulate different aspects of health and social care research. Most of our functions apply to research undertaken in England, but we also work closely with the other countries in the UK to provide a UK-wide system.

We are an arm's length body of the Department of Health and Social Care (DHSC), which means the Government has devolved some of its responsibilities to us. We have our own budget and Board, but are accountable to DHSC.

This policy and associated research-specific SOPS and processes apply only to HRA approved research, and do not apply to Quality Improvement, Innovation, Service Evaluation and Audit, but all are collectively elements in the improving healthcare ecosystem. The first step, therefore, is to appropriately categorise the planned activity:

Once an area of potential research has been identified and an initial design has been formulated (ideally including PPI and Service Management), the first important step is to determine the type of study being considered.

1. HRA decision tools can be used to determine if a study qualifies as research within the HRA Definition (https://www.hra-decisiontools.org.uk/research/) and if so, if the study requires NHS REC approval (https://www.hra-decisiontools.org.uk/ethics/)
2. Check with the Research Office to confirm this categorisation of research and/or necessity for NHS REC approval.
3. If the study does not require NHS REC approval, it should be checked if University Ethics approval is necessary if conducting research as part of a degree/postgraduate programme.
4. If the study is research, then HRA Approval is mandatorily required through IRAS (https://www.myresearchproject.org.uk) as part of assurance. NHS REC approval is additionally sought through IRAS.
5. Depending on the type of research, it should be explored in conjunction with the Research Office if any further type of approval should be sought i.e., Medicines and Healthcare products Regulatory Agency (MHRA), Confidentiality Advisory Group (CAG) etc.,
6. If considered research, the process for confirmation of Trust Sponsorship should be followed if this is required, or an alternative Sponsor should be identified.
7. Contact the Research Office and arrange to submit the initial document set and receive a R&D Reference Number and/or EDGE ID.
    a. This may include a CPMS ID if the study is eligible for inclusion on the NIHR Portfolio
8. For all studies confirmation of capacity and capability obtained from LPT Research Office is required prior to the study starting. This final confirmation is only provided after HRA Approval is in place, although the process of securing this can begin in advance of application for HRA Approval.
9. A key milestone in securing confirmation, is provision of an assurance to Research Office from the host clinical service that the proposed work can be supported.

If a particular area of study is deemed not to be research, but is instead considered to be Audit, Service Evaluation or Quality Improvement, then review and approval should be sought via the WeImproveQ pathway (lpt.weimproveq@nhs.net).

11.1 Activity not considered "research".

Please consult the LPT Research Office (lpt.research@nhs.net) if you are in any way unsure of the categorisation of any planned work. All potential projects should engage with the Trust WeImproveQ Team (lpt.weimproveq@nhs.net) by submitting a 'Conversation Starter'. The Research Office reviews 'Conversation Starters' which are submitted and will identify any projects which meet the definition of research to ensure they apply for the necessary approvals prior to the work commencing within the Trust.

In general, the following types of projects are not considered research and fall outside the remit of this policy: case studies/case reports, clinical investigations, consensus methods, data management/analysis/business intelligence, literature review, clinical audit, clinical innovation, quality improvement and service evaluation.

Similarly, where it becomes clear that a programme of investigation has "become" research, for example, a service evaluation has clear intent to modify practice or health interventions or to generalise outside of the immediate context, then it too must seek appropriate retrospective regulatory review and approval.

It is however strongly advised that investigators check with the Research Office regarding this interpretation, as the Office is the final arbiter of such a distinction and can at need refer to the Research Comm.

11.2 Research-specific Standard Operating Procedures & Other Documentation

The Research Office has delegated authority to maintain and develop a range of SOPs (including laboratory SOPs), templates and guidance documents to underpin the key elements of this policy. Where a SOP or document does not yet exist, all staff should follow the advice of the Research Office. These documents will be made available on the Research section of the Trust Intranet website as they are developed and approved.

This includes the adoption of SOPS from external Sponsors as they relate to the conduct of a study hosted in LPT, for the duration of that study.

SOP Templates and SOP Naming and Numbering conventions are detailed in:

- R&DSOP/001 - WRITING & REVIEWING RESEARCH SPECIFIC STANDARD OPERATING PROCEDURES (SOP), WORKING INSTRUCTIONS (WKI), ADVICE (ADV) AND GUIDANCE (GUI) or TEMPLATE (TMP) DOCUMENTS AND POLICIES
- R&D/TMP/001 – Procedural Document Template for Research

All SOPs etc. are considered uncontrolled documents if printed, requests can be made to lpt.research@nhs.net for the latest versions of any SOP or obtained by visiting the R&D Section of the Trust intranet.

12 Defining portfolio and non-portfolio research

The aim of the National Institute of Health and Care Research (NIHR) is to foster and support large, high quality research studies to provide the best evidence to transform care and services. Any study that is funded, either wholly or in part by the NIHR itself or by an eligible partner funding organisation through open competition can apply to be included in the NIHR Portfolio, which provides access to the support funding and infrastructure (staff embedded in Trusts or networks) to ensure and promote study delivery.

To apply for research to be considered for adoption on to the NIHR portfolio, the box under Section 5b in the main IRAS form must be checked.

There are significant advantages to seeking Portfolio Adoption, and this process can be supported by the Trust Research Office, and by the CRN Study Support Service. All NHS organisations (if they are signatories to the NIHR Partner Contract) are required wherever possible, to support recruitment to NIHR portfolio studies and to provide opportunities for their staff and service users to participate in such studies.

Any costs or impacts on the NHS organisation should be reimbursed (otherwise known as “Service Support Costs”) either from the Grant (Research Costs Part A) or more usually directly delivered by NIHR-CRN funded staff embedded within the Trust in lieu of service support costs. Where a treatment as part of a non-commercial trial includes Excess Treatment Costs these will be reimbursed retrospectively from NHS England via the Network.

LPT is a partner organisation of East Midlands Clinical Research Network (EM CRN). Within the LPT R&D department as a whole, co-located with the Research Office, research delivery staff are funded by the EM CRN to support Services in the delivery of NIHR portfolio studies.

Priority for resources will always be given to NIHR portfolio research should the need arise in line with National Policy. An example of this would be to address the need for evidence during pandemics.

A “non-portfolio” study is therefore any research that either does not qualify to be on the NIHR portfolio or chooses not to apply for inclusion. These are primarily relatively small-scale, local studies and are also usually unfunded. Whilst these studies may also be of high quality and produce important results, there is currently no funding within NIHR/DHSC to support this work unless directly linked to related Portfolio activity. They may be undertaken subject to discretionary permissions and support within Directorates.

The duty placed on new ICS/ICB systems to ensure research is promoted and embedded across the system may in time lead to more local funding for local non-portfolio research.

As a result, support for such studies can only come from local services and resources and are therefore entirely at the discretion of the Host Trust. “Non-portfolio” research is still subject to the same regulatory strictures that apply to NHS-hosted research as detailed elsewhere (e.g., HRA Approval, UK Policy Framework for Health and Social Care Research Compliance).

Development funding awards for testing local innovation, new services, or practice, such as those provided by local Integrated Care System/Integrated Care Board, do not usually qualify for the NIHR Portfolio, but are nonetheless important. These projects may lead on to an application for larger competitive grant awards in the future, which would subsequently qualify for Portfolio status.

Research projects carried out as part of post-graduate qualifications tend to be classed as “non-portfolio” but nonetheless are also important in the development of research-experienced clinicians.

13 Organisational Research Capacity Assessment (ORCA)

The LPT interpretation of the requirement for an “Assess, Arrange, Confirm” process towards capacity confirmation is encapsulated in the ORCA SOP, and is proportionate to the risk of the study. This is both a Research Office and RDT process and may include the following activity:

- Prior to submission of any study for consideration, the Principal/Chief Investigator must ensure that all of the relevant Service Support Departments have been approached and have undertaken to accommodate the study; that the relevant service/directorate manager is aware of the study; and that the study team are, themselves ready to recruit, once permission has been granted.
- The capacity assessment process can begin as soon as documents have been finalised, and once other applications (REC, HRA, and MHRA, where applicable) have been submitted. The process can continue in parallel to these applications and evidence of those approvals can be provided when available. However, permission will not be granted until such approvals are in place.
- When a valid application is received, along with all other required localised documents, the study will be validated and a project registration ID (this will usually be the EDGE ID or a local study code) allocated.
- Where a contract is required for any study, it is strongly recommended that a standard agreement (usually those devised by the HRA) is used. Any non-standard contracts and agreements must be fully executed (negotiated and signed) before the study can be validated and may require extensive checks from Trust legal advisors.
- A member of the Research Office (working with Delivery Staff where appropriate) will collate all relevant documents; assess feasibility with the PI; ascertain capacity and capability; and conduct the required level of governance review to assess the level of risk and impact on the Trust. Further information may be requested, where anything is unclear. In the case of Portfolio Studies, all activities related to assessing study feasibility will be conducted by Research Delivery staff, proportionate to risk, to advise the Research Office accordingly.
- The process of review and confirmation of capacity and capability is designed to be proportionate to the risk of the study and external performance metrics. Any form of delay from Sponsor or site may require the process to be suspended to allow for resolution of issues.
- The PI will usually be asked to sign a form of agreement accepting the responsibilities of being a PI.
- A study may not begin until all the relevant approvals are in place and, if applicable, a contract, signed by all the relevant parties, and Sponsor Green Light has been received by the Trust Research Office where LPT is a host site.
- It is expected, but not mandatory, that all studies will make use of the EDGE project management system to ensure that all recruitment is logged in a timely fashion. The Research Office will ensure that all relevant personnel will have the appropriate level of access for those studies they are delivering.

13.1 Ongoing Capacity

- Once granted, retention of capacity approval is conditional on regular updates being provided by the investigator team.
- The investigator is required to inform R&D of the date of the first patient recruited to the study as soon as that occurs. Studies failing to recruit within the NIHR benchmarks, without a valid reason for this failure, may lead to capacity being withdrawn. This caveat also remains for non-portfolio studies.
- The investigator on Portfolio Studies is also required to provide data for reports to the NIHR on a quarterly basis regarding progress of study recruitment to time and target, and to provide reasons where recruitment is not achieving agreed targets. This requirement will automatically be fulfilled where recruitment data is uploaded to EDGE.
- In addition, the investigator team will also be required to provide further information on an annual basis for the Trust Quality Accounts
- Other updates can generally be derived from progress reports, during monitoring visits (where relevant) and from end of study reports.
- The investigator team is required to copy the Research Office into any correspondence with the relevant ethics committee, HRA and MHRA: annual progress reports; Development safety update reports; end of study notifications.

- Any proposed change in the status of the PI (e.g. departure from the Trust, maternity leave) must be communicated to the Research Office, prior to that change taking place as this can affect ongoing capacity.

13.2 Protocol Amendments

It is recognised that it is very rare that a study protocol and accompanying documents remain unaltered through the life course of a project. Any necessary changes to ensure a successful outcome for the study are classed as “Amendments”.

Trust Sponsored Studies

- If a study is sponsored by the Trust, then the local Chief Investigator must prepare the HRA Amendment Tool and update all relevant documents. The R&D Office needs to approve the amendment before it is submitted to regulatory bodies, or shared with other sites.
- The Local Chief Investigator is responsible for submitting the amendment for regulatory approval.
- The local Chief Investigator must forward all received correspondence to the Trust Research Office regarding the amendment.

Trust Hosted Studies

- Amendments for studies hosted but not sponsored by the Trust will be received frequently, with the process for dealing with these outlined in R&D/SOP/004 Dealing with Study Amendments by Classification.
- Depending on the amendment categorisation, amendments are considered to be implemented immediately at site, or there is a 35-day period following receipt to consider raising an objection to the amendment using a streamlined ORCA process.
- HRA Approval of an amendment triggers the need to make the necessary arrangements to implement amendments or very occasionally, and in discussion with the sponsor, withdraw from participation in the study if the amendment adversely affects the capacity and capability of the organisation to deliver the research to the new requirements.
- The Research Office will acknowledge, confirm or deny continued capacity for the study to continue at LPT based on the amendment received.

13.3 The Valid Research Application (aka Local Information Pack)

The DHSC wishes to reduce the bureaucracy and delays that have been experienced in setting up and approving research in the NHS, whilst ensuring sufficient scrutiny to assure patients and the public of the quality and safety of approved studies. This has seen the introduction of performance criteria against which NHS organisations are measured, including a quarterly reporting framework (applicable to Portfolio and Non-Portfolio studies)[3]. To this end, the concept of the Local Information Pack (LIP) has been developed which is the essential minimum information that should be provided to an NHS organisation (such as LPT) to trigger the formal process (and associated performance metrics) for the Research department to issue NHS Management Permission or Confirmation of Capacity and Capability following the ORCA processes. This permission should be provided within 30 days of receipt of a LIP. The First Participant recruited into any study, should be recruited within 70 days of receipt of LIP.

Official receipt of the Local Information Pack can only occur if the materials are sent to lpt.research@nhs.net and formally receipted by the Research Office.

The “Assess, Arrange, Confirm” Process, including contract negotiations and so forth is set in motion formally, by receipt of the LIP. LIP information is normally provided by a Research Sponsor, or by an investigator/investigator team with the permission of the Sponsor. Within the HRA Process, this should occur at the point at which the HRA Initial Assessment Letter is issued to the Sponsor by the HRA. It is good practice for a Sponsor to communicate at the earliest opportunity with a planned NHS Site, in order to minimise delay, and to avoid triggering the first metric point unnecessarily. The process should be a dialogue between research sponsor and site, to enable both to fully understand what is being required, and how it might be implemented at the site.

[3] Suspended during the pandemic and under review, but still a requirement

The delivery of the LIP is a key trigger within the performance management of research initiation and delivery. Ideally, the Sponsor should contact a potential site in advance of sending the LIP to avoid undue delays. The precise content of information to be supplied to a site is determined both through the HRA Process and Sponsor discretion, but will commonly include:

Document:	LIP Trigger Invalid if Absent, Draft or Incomplete
Copy of Completed IRAS Form	Yes
Research Protocol (including any amendments to date)	Yes
Participant Information & Consent Documentation	Yes (Non-localised acceptable)
Template Statement of Activity (non-commercial studies only)	Yes
Relevant Template Contract/Model Agreement/OID (as applicable)	Yes
Costing Template (Commercial Studies Only) (sourced online)	Yes
Schedule of Events/SOECAT (Non-Commercial Sponsors Only)	Yes
Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study	No (but lack of information regarding certain documents may delay processing – therefore, access through site Sponsor negotiation)
Copy of HRA 'initial assessment' letter and (when issued) HRA Approval letter and final document versions	Yes

14 Supporting NIHR Portfolio Research in LPT

The NIHR through the Clinical Research Networks enable NHS organisations to support the recruitment of that Trusts' service users and carers to NIHR portfolio studies. As indicated elsewhere, the primary claim on Trust resources for research will be Portfolio Research.

14.1 Opportunities for LPT involvement

There are many routes through which LPT becomes involved in the delivery of a study on the NIHR portfolio, including:

- When researchers, either within the Trust or in external organisations, are preparing a grant application;
- When researchers directly contact staff in services regarding a study;
- When East Midlands CRN (RRDN) are aware of research relevant to Trust service users and share with the Trust;
- A Research Team searching through relevant registers of studies e.g., EDGE;
- Successful completion of an expression of interest in studies open to new sites via the EM CRN Portal

Regardless of the route, it is imperative that the LPT Research Office are contacted and made aware of potential research at the earliest opportunity. This policy strongly encourages staff to consider becoming a Principal Investigator for such studies, as a means of developing research expertise and increasing capacity in the Trust. This may include the NIHR Associate PI Scheme for mentoring in these responsibilities.

14.2 Enabling NIHR Portfolio research to be conducted in LPT

The HRA will take the primary role in assuring that all regulatory requirements (governance, ethics, MHRA etc.) for a study, project or programme have been met. However, enabling portfolio research to be conducted in LPT requires a dialogue regarding the practicalities of the study between the Research Office, study sponsor, Clinical Network staff (embedded in the Trust) and clinical services, including the identification of local Principal Investigators or Collaborators. This process follows the same ORCA dimensions outlined earlier, with members of the RDT completing study feasibility:

HIGHLIGHT

Assessment of Trust Capacity for NIHR Portfolio Studies:

1. The feasibility of running the study locally e.g., population group, services.
2. Establishing interest from clinical services staff
3. Assessing resource requirements, availability, and capacity in the Trust.
4. Co-ordinating resources with CRN, investigator teams/Sponsor and R&D Department
5. Identifying a member of LPT staff to be PI (Principal Investigator) and if required, Co-Investigators/support staff (e.g., from Pharmacy).
6. Coordinating with external investigator teams on approval processes
7. Measures to ensure and support the completion and submission of regulatory forms for approval.
8. Localisation of study documentation (e.g., ensuring study materials are relevant for LPT)
9. Ensuring Clinical Trial Agreements (CTAs) and other contracts (e.g., Material Transfer Agreements, Intellectual Property Agreements etc.) are in place and valid.
10. Obtaining documentation necessary for HR (Honorary Research Contracts and Letters of Access)
11. Identifying any necessary training requirements
12. Adoption of study-specific SOPs
13. Establishing a recruitment/study promotion strategy
14. Coordinating Site Initiation Visits (SIVs)
15. Strategies for efficient achievement of Trust Capacity Approval
16. Identification of possible obstacles to study delivery
17. Ongoing monitoring of study progress after initiation
18. Processes to archive the study on completion.

15 Practical Implications within the Organisation

15.1 The Trust Board has a legal responsibility for Trust policies and procedures and that they are carried out effectively. Therefore, ensuring that research is managed and supported appropriately is part of the "well-led" dimension within CQC inspections.

15.2 Divisional Directors and Heads of Service are responsible for:

- Supporting approved research activity and engaging with the process of agreeing the approval of research.
- Ensuring blocks and obstacles to delivery of approved research (especially Portfolio research) are minimised or removed (this will primarily be release of staff time).
- Establishing a process to consider the research priorities of the service, to better understand the applicability of any proposed research within that service.
- To identify, report and assist in the investigation of research misconduct and fraud.

15.3 Managers and Team leaders are responsible for:

- Supporting and releasing staff engaged in research activity where not critically compromising clinical services.
- Supporting compliance and monitoring activities.
- To identify and report instances of misconduct and fraud.

15.4 Responsibility of Staff

- To understand all delegated roles within research.
- To act in accord with all applicable regulations and legislation.

16 Building Research Capacity

This policy recognises that the research base of the organisation in terms of active research staff is limited, and that collaboration with NIHR Portfolio research alone will not bring change to the research culture. The latter will expose more staff to the rigours of high-quality research, and through the Associate PI scheme will increase leadership capacity over time.

In parallel to Portfolio activity, this policy reinforces the work of the Clinical Academic Careers pathway, and other schemes (Research Envoys; Clinical Research Associates etc.) designed to take people from all disciplines through to leading their own research in the future.

This policy references that there is discretionary scope within services to release staff to undertake early phase research, and that study leave should be utilised for this purpose. Across all clinical and non-clinical disciplines this policy encourages managers and workforce planning to build research into everyday job descriptions as a means of changing the culture person by person. This is a cultural shift to become a questioning organisation, that challenges the status quo at every turn, innovating, researching and improving every day.

"Investigator-led" or own account research can only be resourced from within existing Trust resources but supporting this can lead to leveraging major funding streams into the Trust, either independently or in collaboration.

Building capacity is also an element of working closely with University, Commercial and other partner organisations. This relates to "Step Up to Great" in that we will know we have succeeded when all staff know how they can either use, support, or lead in research.

17 Monitoring Metrics

There are a number of key performance indicators (KPI) embedded within this policy, primarily derived from the "PID" (Performance in Initiating & Delivering Research) criteria established by the DHSC and the High-Level Objectives of the NIHR Clinical Research Network (but no longer enforced). These KPIs are monitored by the Research Office and the East Midlands Clinical Research Network. Although no longer externally reported, these indicators are of value in ensuring rapid study set-up and delivery.

Target/Standards	Key Performance Indicator
Efficiency in providing NHS Confirmation (CoCC) within 30 days of Valid Research Application	100% of studies within 30 days
Effectiveness in initiating research.	80% of studies to have "First Patient First Visit" within 70 days of receipt of Valid Research Application
Effectiveness in delivering research	80% of approved studies to meet Time & Target recruitment trajectory

18 References and Bibliography

This policy was drafted with reference to the following:

- Department for Business and Innovation Skills (2011). Strategy for UK Life Sciences: London: Office for Life Sciences
- Department of Health (2012). Governance Arrangements for Health Research Ethics Committees: A harmonised edition. London: Home Office
- Department of Health (2013).The NHS Constitution. London: Home Office
- Department for Innovation and Business Skills (2011). Plan for Growth. London: HM Treasury
- Performance in Initiating and Delivering Clinical Research Information Submission Guidelines; NIHR Central Commissioning Facility
- ICH Harmonised Tripartite Guideline for Good Clinical Practice
- The National Health Service (Quality Accounts) Regulations 2010
- The NHS Long Term Plan (Jan 2019)
- UK Policy Framework for Health and Social Care Research (2017)
- NHS England Research Plan (Apr 2017)
- Health and Social Care Act (2012)

19 Policy Review

- This policy will be reviewed in 3 years, as set out in the Policy for the Development and Implementation of Procedural Documents.
- The Trust Management Executive has delegated authority to the Head of Research Operations, Research Office and RDT under the guidance of the Research Committee for the approval of any further research-specific supporting or associated documents.
- Changes in legislation relating to R&D may require interim modifications to this policy and supporting documentation.

Appendix 1: Principal Categories of Research Project

Clinical Trial of an Investigational Medicinal Product (CTIMP)

Any investigation in human subjects, other than a non-interventional trial*, intended to:

a. discover or verify the clinical, pharmacological or other pharmaco-dynamic effects of one or more medicinal products,
b. identify any adverse reactions to one or more medicinal products or
c. study the absorption, distribution, metabolism and excretion of one or more such products
d. ascertain the safety or efficacy of those products.
e. Such trials will be governed by the Medicines for Human Use (Clinical Trials) Regulations 2004 and updates.
f. Such trials would require the approval of the Health Research Authority and an NHS Research Ethics Committee

** The Medicines and Healthcare products Regulatory Agency (MHRA) view a trial as interventional where a drug is being given as an intervention and assessments are being undertaken to assess the effects. This is not dependent on the prescription of that drug being undertaken as part of the protocol.*

Device Trials

A clinical investigation designed to establish the performance of a medical device (these include software, e.g., Apps) to reveal adverse events under normal conditions of use, and permit assessment of the acceptable risks having regard to the intended performance of the medical device. Such trials are regulated by the UK Policy Framework for Health and Social Care Research and would require the approval of the Health Research Authority and an NHS Research Ethics Committee. Trials using non-CE marked devices are also regulated by the Medical Devices Regulations (2002)

Interventional Trial/Study

Any investigation in human subjects which involves some form of clinical intervention: surgical, medical, social, or psychological, but which is not classified as a CTIMP. Such studies are regulated by the UK Policy Framework for Health and Social Care Research and would require the approval of the HRA and an NHS Research Ethics Committee.

> For purposes of classification, the term “interventional” should not be confused with “invasive”. Interventional studies involve changing the course of clinical care. Invasive studies would involve invasion of the body, for example venepuncture.

Non-interventional Study

Any investigation in human subjects, who are patients, which is observational and does not involve any intervention in addition to their normal clinical care. Such studies are regulated by the UK Policy Framework for Health and Social Care Research and would require the approval of the HRA and an NHS Research Ethics Committee. Some non-interventional studies may include the participation of NHS staff who are recruited by virtue of their professional role in the NHS i.e., questionnaire studies, such studies would require HRA approval alone.

Research Tissue Bank (Biobank)

A collection of human tissue or other biological material, as defined by the Human Tissue Act 2004, which is stored for research use beyond the life of a specific project with ethical approval or for which ethical approval is pending.

> Under the UK Policy Framework for Health and Social Care Research, HRA/REC approval for tissue banks is voluntary and neither sponsorship nor Trust Management Approval is mandatory. However, it is a requirement under the Human Tissue Act (HTA) 2004 that NHS organisations via Clinical Directorates have procedures in place to ensure appropriate governance of research tissue banks.

Research Databank (termed ‘Research Database’ on the Integrated Research Application System (IRAS))

This is defined as a collection of data, which is stored for potential research, beyond the life of a specific project, with ethical approval, or for which ethical approval is pending. All studies using data supplied by a

databank need separate approval from the Steering Committee, whether or not the Databank has ethics approval.

> It is a requirement that NHS organisations have procedures in place to ensure appropriate governance of research databanks, The Trust therefore requires that Research Office and Data Privacy are notified of all research databanks being set up (as an "information asset") in order to meet the requirement. This will usually involve the Research Office being represented on a Database Steering Committee.

Categorisation of Studies in IRAS[4]	
1	Clinical trial of an investigational medicinal product (CTIMP)
2	Clinical investigation or other study of a medical device
3	Combined trial of an investigational medicinal product and an investigational medical device
4	Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
5	Basic science study involving procedures with human participants
6	Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
7	Study involving qualitative methods only
8	Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
9	Study limited to working with data (specific project only)
10	Research tissue bank
11	Research database

Please consult the Research Office for specific guidance on the regulatory approvals needed in each category, and/or consult IRAS Help.

[4] Studies that are categorised as 1 through 4 in IRAS are subject to quarterly performance reporting in terms of initiation and delivery through the Clinical Trials Platform

Appendix 2: HRA definitions of Research, Clinical Audit and Service Evaluation

	Research	Clinical Audit	Service Evaluation
Definition	The attempt to derive generalisable new knowledge, including studies that aim to generate hypotheses as well as those that aim to test them	Designed and conducted to produce information to inform delivery of the best care.	Designed and conducted solely to define or make a judgement on current care
Purpose	Quantitative research – designed to test a hypothesis. Qualitative – identifies and explores themes and concepts within defined methodological approaches.	Designed to answer the question: "Does this service reach a pre-determined standard?"	Designed to answer the question: "What standard does this service achieve?"
Measures	Addresses clearly defined questions, aims and objectives within a protocol	Measures against a standard (e.g. 100%)	Measures current service without reference to a standard
Interventions	Quantitative: may involve evaluating or comparing interventions, particularly new ones vs. "treatment as usual". Qualitative: can involve studying how interventions, services or relationships are experienced.	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference)	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference)
Data Source	Usually involves collecting data that are additional to those for routine care but may include data derived from normal clinical practice. May involve treatments, samples or investigations additional to routine care	Usually involves analysis of existing data but may include administration of interviews, questionnaires and surveys.	Usually involves analysis of existing data but may include administration of interviews, questionnaires and surveys.
Groups	Quantitative: study design may involve allocating participants to intervention and non-intervention groups. Qualitative: uses a clearly defined sampling framework underpinned by theoretical or conceptual justifications	No allocation to intervention groups: the health care professional and participant have chosen intervention prior to clinical audit.	No allocation to intervention groups: the health care professional and participant have chosen intervention prior to clinical audit.
Randomisation	May involve randomisation	No randomisation	No randomisation
HRA Approval	Mandatory	Not required	Not required
NHS Research Ethics	Yes, in most cases	Not required	Not required
Permissions	YES (Service, Sponsor and Research Office)	YES (Clinical Governance)	YES (Clinical Governance)

Appendix 3: Organizational Research Capacity Assessment (ORCA) - Sample

Process 1: The Initial Feasibility Assessment (IFA)

The IFA is designed as a proportionate response tool, aimed at providing to investigators and Sponsors a rapid evaluation of the acceptability of a proposal within the organization. If the IFA results in a "NO" then this is conveyed to the Sponsor or third party.

Table 1: Initial Feasibility Assessment Form

R&D Office	
CRN Research Delivery Team	

Who?		STUDY INITIAL FEASIBILITY/EXPRESSION OF INTEREST		DATE LAST UPDATED: 29/02/2024
		EOI Deadline:		
		Facilitator(s) completing initial feasibility R&D Office: CRN Delivery Team: LPT Clinical Service:		
		Study short title:		
		Study Summary: **Local research activities:**		
		LPT Directorate:	**CRN Division:**	
		IRAS Number:	**Ethics Reference:**	
		CPMS Number:	**EDGE ID:**	
		Sponsor (incl. contact):	**Funder:**	
		Portfolio: Yes/No	**Commercial / Non-commercial** (Delete as applicable)	
		Study Type:	**Site Type:**	
		Initial Assessment:		**Evidence**
		1 Is the target service provided by the Trust?	**YES/NO**	
		2 Are we likely to have the target participant population? What is the target?	**YES/NO**	
		3 Do we have competing studies in the target timeframe?[5]	**YES/NO**	
		4 Are there potentially critical issues that would cause the study to fail?[6]	**YES/NO**	
		5 If a local PI is required, is there anyone with capacity and interest?	**YES/NO**	
		6 Will external staff require LoA or HRC?	**YES/NO**	
		7 Is the study affected by force majeure (e.g., pandemic response)?	**YES/NO**	

If Q1, Q2, Q3 & Q5 are all "NO", and Q4 is "YES", then the study is considered not feasible for the local Trust. The assigned reviewer should evidence this decision. If answers are indeterminate, then proceed to AAC table for in depth consideration

Appendix 4: The NHS Constitution

Principle	Policy Compliance
The NHS will provide a universal service for all based on clinical need, not ability to pay. The NHS will provide a comprehensive range of services Shape its services around the needs and preferences of individual patients, their families and their carers	☑
Respond to different needs of different sectors of the population	☑
Work continuously to improve quality services and to minimise errors	☑
Support and value its staff	☑
Work together with others to ensure a seamless service for patients	☑
Help keep people healthy and work to reduce health inequalities	☑
Respect the confidentiality of individual patients and provide open access to information about services, treatment and performance	☑

Appendix 5: Stakeholders and Consultation

Key individuals involved in developing the document.

Name	Designation
Dr Dave Clarke	Head of Research Operations
Dr Karishma Joshi	Research Support Officer
Ms Jenn Harrison	Change Lead (HRA)
Manjit Dharam	Trust Finance
Michele Eve	EM:CRN Senior Link & Workforce Lead

Circulated for comment to:

Name	Designation
Dr Bhanu Chadalavada	Medical Director
Professor Sudip Ghosh	Deputy Medical Director
Professor Hari Subramaniam	Deputy Medical Director (Co-Chair – Research Committee)
Dr Lizelle Bernhardt	Research Lead: Nursing & AHPs (Co-Chair Research Committee)
Trust Policy Experts	
Mark Howells	Peer Review: Head of Research & Evidence (Notts HC)

Appendix 6: Due Regard Template

Due Regard Screening Template (Section 1)	
Name of activity/proposal	**Trust Research Policy**
Date Screening commenced	31/07/2023
Directorate / Service carrying out the assessment	Medical Directorate/ Enabling
Name and role of person undertaking this Due Regard (Equality Analysis)	Dr Dave Clarke
Give an overview of the aims, objectives and purpose of the proposal:	
AIMS: The aim of this policy is to help staff understand the mandatory procedures involved in categorising and conducting research.	
OBJECTIVES: This policy outlines the standards expected in respect of research activity and defines roles and responsibilities and the processes involved in supporting and leading research activity and gaining relevant permissions.	
Section 2	
Protected Characteristic	If the proposal/s have a positive or negative impact please give brief details.
Age	N/A
Disability	N/A
Gender reassignment	N/A
Marriage & Civil Partnership	N/A
Pregnancy & Maternity	N/A
Race	N/A
Religion and Belief	N/A
Sex	N/A
Sexual Orientation	N/A
Other equality groups?	N/A

Section 3			
Does this activity propose major changes in terms of scale or significance for LPT? For example, is there a clear indication that, although the proposal is minor it is likely to have a major affect for people from an equality group/s? Please tick appropriate box below.			
YES		NO	
☐	High risk: Complete a full EIA starting click here to proceed to Part B	☑	Low risk: Go to Section 4

Section 4			
If this proposal is low risk please give evidence or justification for how you reached this decision:			
The policy does not contain activities that would discriminate against any groups, nor put groups at risk of harm (or not harm unbalanced by potential benefits of approved research). Instead, it provides details of external and internal assurance processes to maximise the safety and well-being of all staff, service users and carers involved in research conducted in the Trust. This Policy is therefore NEUTRAL in respect of Due Regard.			
Signed by reviewer/assessor		Date:	5th February 2024
Sign-off that this process does not require a full Equality Analysis as it is Low Risk.			
Head of Service Signed		Date:	