Leicestershire Partnership NHS Trust

Trust Management Approval of Clinical Research Policy
(Hosting, Conducting & Collaborating in Research)

The Trust desires to see a significant improvement in the leadership, scale, uptake and delivery of research. 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 following the implementation of Health Research Authority (HRA) Approval from April 1st, 2016. This is to ensure that the Trust is both fully compliant with the provisions of the Research Governance Framework for Health and Social Care and the wider UK Policy Framework, whilst increasing the engagement and opportunities for staff, service-users, carers and partner organisations.

The policy and process referred to herewith are considered "proportionate and pragmatic" as required for the role of the "NHS R&D Office" following implementation of HRA processes and approval.

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Version Control and Summary of Changes

Version number	Date	Comments (description change and amendments)
Version 5.1	November 2017	Revisions following CEG and QAC Review and adjustments to performance metrics in line with national policy.
Version 5	September 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.
Version 4	June 2015	Revised and simplified policy incorporating initial Health Research Authority changes and R&D Performance requirements
Version 3 (Draft 2)	February 2012	Harmonised –Leicestershire Partnership NHS Trust, Leicester City Community Health Service, Leicestershire County & Rutland Community Health Service.
Version 3 (Draft 1)	January 2012	Document reorganised and reclassified to map NHSLA requirements
Version 2.6	March 2011	Version 2 Developed in response to performance framework within NIHR “Research Support Services”

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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.

Due Regard

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 advances 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, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

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 can be found in Appendix 3.

Acronyms used within this Policy –

AAC	Assess, Arrange, Confirm Process
ACORD	Attributing Costs of Research & Development
AHSN	Academic Health Science Network
ARSAC	Administration of Radioactive Substances Advisory Group
BAF	Board Assurance Framework
CDA	Confidential Disclosure Agreement
CI	Chief Investigator
CLAHRC	Collaboration for Leadership in Applied Health Research & Care
CoCC	Confirmation of Capacity and Capability
CPMS	Central Portfolio Management System
CRN	Clinical Research Network
CRO	Contract Research Organisation
CSP	Coordinated System for NHS Permission
CTA	Clinical Trial Agreement
DDO	Delegated Delivery Officer
EDGE	The Trust Local Portfolio Management System
EoI	Expression of Interest
ETC	Excess Treatment Costs
FGP	First Global Patient/Participant
FPFV	First Patient First Visit
GCP	Good Clinical Practice
HRA	Health Research Authority
IRAS	Integrated Research Application System
IRMER	Ionising Radiation (Medical Exposure) Regulations
KPI	Key Performance Indicators
LAP	Local Adoption Process
LIP	Local Implementation Plan
LPMS	Local Portfolio Management System
LPT	Leicestershire Partnership NHS Trust
mCTA	Model Clinical Trial Agreement
MDS	Minimum Document Set
MHRA	Medicines and Healthcare Products Regulatory Agency
NIHR	National Institute for Health Research
MTA	Material Transfer Agreement
ORCA	Organisational Research Capacity Assessment
PI	Principal Investigator
PID	Performance in Initiating & Delivering Research
QAC	Quality Assurance Committee
R&D	Research and Development
REC	Research Ethics Committee
ResC	Research Costs
SoA	Statement of Activities
SoE	Schedule of Events
SOP	Standard Operating Procedures
SSC	Service Support Costs
SSI	Site Specific Information
TMA	Trust Management Approval
TTA	Tissue Transfer Agreement
VRA	Valid Research Application

Definitions:

Term	Explanation
HRA Approval	National permission for assuring the conduct of a research study within all NHS Trusts. (This new process began a staged introduction in May 2015). All research in the NHS must have secured HRA Approval before it can begin. HRA approval is undertaken **independently** of the Trust and provides an **assurance** that a proposed piece of research is compliant with all applicable laws and regulations. This enables NHS R&D (aka the "R&D Office") to focus resource on whether capacity exists, or can be put in place, for the research to occur "successfully".
Trust Management Approval (TMA)	Agreement on behalf of the Trust with the Principal Investigator that they may conduct the research. This is also defined as the process of confirming that a study may proceed for single-site studies where the Trust is the research SPONSOR.
NHS Management Permission or "Confirmation of Capacity & Capability (CCC)"	An NHS Trust's formal written confirmation that assessment has been undertaken that it has the capability and capacity to undertake the research. This will take the form of either a formal contract or a Statement of Activities. The LPT R&D Office **must** be informed of all research occurring in the Trust, and, subject to HRA Approval being in place will issue a management permission (where there is no requirement for CCC) or confirmation of capacity communication as appropriate. This is required for all types of research. Trust Management Approval (TMA) is given in lieu of CCC where a study is single-site (within LPT), and sponsored by the Trust.
Study Sponsor	The organisation, company or individual with ultimate responsibility for a piece of research. For student's research work this is now their University by default.
Trust Delivery Staff	This refers to CRN-funded R&D staff in LPT whose work stream is supporting and executing the delivery of studies on the NIHR portfolio. 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 to ensure smooth running of studies in LPT.

1.0. Purpose of the Policy

The aim 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. In addition, employees and service users of LPT or a partner organisation should be aware of the expectations and requirements involved.

For all research activity, it is your individual responsibility to ensure that you have the relevant regulatory body approval(s). These approvals are now encapsulated within the HRA Approval process and this applies to all research taking place in the NHS. No research in the NHS can begin without HRA Approval being confirmed (which may also include NHS Research Ethics) and the completion of an "Assess, Arrange, Confirm" process within a host Trust to "Confirm Capacity" (aka management permission) for the proposed research.

This policy outlines the standards expected in respect 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 and relevant legislation.

Key Drivers

A. The Health Research Authority and the Medicines for Human Use (Clinical Trials) Regulations 2004 and amendments require that an organisation taking on the role of 'Sponsor' must have proper arrangements in place to initiate, manage, monitor and finance a study.

B. 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.

C. 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.

D. This policy covers the process of both Trust Management Approval (TMA) and agreement with the Sponsor that the Trust has the necessary capacity and capability to undertake the research.

E. The Trust is contracted with the National Institute of Health 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.

F. The National Health Service (Quality Accounts) Regulations 2010 require that NHS Trusts provide information on the clinical research undertaken, where a Research Ethics Committee has given a favourable opinion on an annual basis.

2.0 Policy Statement

It is Trust Policy to:

- Protect the safety, dignity, rights and well-being of all patients and staff involved in clinical and non-clinical research.
- 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.

- To meet the required 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" (TnT) as contracted to do.
- To encourage all research outside of the NIHR Portfolio to perform to similar levels and benchmarks.
- Conduct "Assess, Arrange, Confirm (AAC)" procedures (formerly known as research management & governance) using a consistent, risk-proportionate approach, combined with robust feasibility to ensure timely approval and delivery of sponsored and hosted research with proportionate oversight and delegation of responsibility.
- 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.

3.0. Summary and Key Points

The creation of a vibrant research and innovation culture as embedded core business of the Trust, in partnership with national and regional networks is one of the objectives of LPT. The Trust is also passionate about delivering safe, effective patient centred care. As stated in the NHS Constitution (2013) the organisation has a 'commitment to innovation and to the promotion, conduct and use of research to improve the current and future health and care of the population' (p.3). Research has a key role to ensure these aims happen and therefore needs to be considered as a core part of the Trust's work.

Directly or indirectly, all research in the Trust should be of relevance to and help improve the delivery of health care and well-being in Leicester, Leicestershire & Rutland. It should wherever possible also strengthen the Trust's profile and contribute to business development.

This policy also recognises that as holder of a NIHR Partner Contract, there is an obligation on the organisation to strive wherever possible to support the delivery of research studies within the NIHR Portfolio. As a result, the Trust hosts network-funded staff to support services across the organisation to meet this obligation.

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

- Are aware of the obligation to contact Trust R&D whenever any research in 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.
- Are aware of the distinction between research adopted within the NIHR Portfolio (and the performance metrics inherent to such studies) and "non-portfolio" research.
- Are able to identify the minimum document set to be included within a research

proposal to constitute a valid research application.

- 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 in order to successfully prosecute 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.
- 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 main aim of research in healthcare settings is to improve understanding, and to provide robust analyses that contribute to the world-wide evidence base and, directly or indirectly – lead to improvements in health care in the short, medium and long-term. To achieve this aim, research has to be of highest scale and quality possible and receive recognition up to and including at an international level.

- All research in the NHS must be properly funded or resourced, such that it does not impose additional costs on clinical services, and that all costs to the NHS have been evaluated and agreed prior to the research beginning. This also ensures that the completion rates of research are significantly improved.
- All research in the NHS must be registered and notified to the relevant Host NHS organisations as a core principle of the Research Governance Framework for Health & Social Care.
- No research project can begin in the NHS in the absence of appropriate ethical approval[1] obtained through an authorised ethics committee (where necessary) and without written NHS Confirmation of Capacity (aka Trust Management Approval) from the LPT R&D Office. This NHS Confirmation of Capacity is achieved after an internal proportionate review known as "Assess, Arrange, Confirm" (AAC), incorporating dialogue with the researchers, Trust services and the R&D Department about the feasibility of undertaking the research and procedures required to ensure high quality research is undertaken. The AAC process occurs in parallel with the HRA Approval process, which provides assurance to an NHS Trust as to the regulatory compliance of a proposal.
    - Assess: whether or not the Trust has the capacity and capability to participate in the study.
    - Arrange: putting any practical arrangements in place to provide the capacity and capability to deliver the study.
    - Confirm: that the Trust has the capacity and capability in place to deliver the study and will deliver the study.
- Research, service evaluation, quality improvement and clinical audit share many methodological characteristics and similarities, but are differentiated by the aims, scale and scope of the activity (see appendix). Only research

[1] Please note, not all research in the NHS now requires ethical approval, for example, research involving NHS Staff only requires HRA Approval, but not NHS Research Ethics. Such studies may be required to seek an alternative ethical review (e.g. via a University).

projects fall within the remit and permission processes of NHS R&D and are within the scope of this policy.

3.1 Scope of this Policy

a) This Policy applies to anyone conducting research within the Trust, 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, by external contractors, as voluntary workers, as students, as locums or as agency staff.

3.2 Aim of this Policy

a) This policy sets out a consistent procedure for the review and authorising of TMA for studies for which the Trust has been asked to take on the role of 'Sponsor' or host institution.
b) This procedure aims to ensure that the Trust takes responsibility for the ongoing quality of research studies.
c) This policy aims to ensure that the Trust achieves national benchmarks related to initiation of research and recruitment to time and target

4.0 Principal Categories of Research Project

4.1 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.

* 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

4.2 Device Trials

A clinical investigation designed to establish the performance of a medical device 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 Research Governance Framework (RGF) and would require the approval of the Health Research Authority (and an ethics committee). Trials using non-CE marked devices are also regulated by the Medical Devices Regulations (2002)

4.3 Interventional Trial / Study

Any investigation in human subjects which involves some form of clinical intervention: surgical, medical, or psychological, but which is not classified as a CTIMP as defined in

paragraph 4.2. Such studies are regulated by the RGF and would require the approval of the HRA (and an ethics committee).

> **4.31.** 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.

4.4. 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 RGF and would require the approval of the HRA (and an ethics committee).

4.5 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

> **4.51**. Under the RGF, HRA/REC approval for tissue banks is voluntary and neither sponsorship nor TMA is required. However, it is a requirement under the Human Tissue Act (HTA) 2004 that NHS organisations have procedures in place to ensure appropriate governance of research tissue banks, The Trust therefore requires that R&D are notified of all research databanks being set up in order to meet the requirement.

4.6. 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 Trust Management Approval, whether or not the Databank has ethics approval.

> **4.61** It is a requirement that NHS organisations have procedures in place to ensure appropriate governance of research databanks, The Trust therefore requires that R&D are notified of all research databanks being set up in order to meet the requirement.

Categorisation of Studies in IRAS[2]	
1	Clinical trial of an investigational medicinal product
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

[2] 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 Trial Platform.

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

Table 1: Options for Study Type Categorisation in IRAS

5.0: Outline of Process

5.1 Differentiating between Research, Service Evaluation/Quality Improvement 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. In particular, as NHS-based clinical research may involve new, innovative and potentially risky treatments it is of vital importance that there is public confidence in the approval processes before this can begin. The HRA has been established to provide this assurance both to the public, and to NHS organisations. It is important to recognise that a programme of work within the NHS may include research, and non-research elements, as well as a mixture of both quantitative and qualitative approaches.

The first step therefore, is to accurately categorise activity appropriately (please see Appendix 1 for a full description)

Step 1

Once an area of potential research has been identified and an initial design has been formulated, the first important step is to determine the type of study being considered. There is plentiful advice available in this area, and a useful first point of call is the Health Research Authority online "Decision Tools" http://www.hra-decisiontools.org.uk/research/ to help determine:

1. If a study qualifies as research within the Dept. Of Health definition (see Appendix 1)
2. Please check with the R&D Office as to the categorisation of a study.
3. If it is research, whether review by an approved research ethics committee is required (this will either be via the REC, by completing the IRAS form, https://www.myresearchproject.org.uk and/or by a University if conducting research as part of a degree/postgraduate programme).
4. If it is research then HRA Approval is mandatorily required through IRAS.
5. Contact the R&D Office and arrange to submit the initial document set and receive a R&D Reference Number or EDGE ID.
    a. This may include a CPMS ID if the study is Trust-sponsored and eligible for inclusion on the NIHR Portfolio.
6. For all studies, Trust Management Approval or Confirmation of Capacity & Capability obtained from LPT R&D 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
7. A key milestone in securing TMA or CCC is provision of an assurance to R&D 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 CASER-R groups within each Service (AMD/LD; CHS; FYPC)

5.2: Dimensions of Qualitative and Quantitative Research

Research will typically employ quantitative or qualitative methods, or a mixed-methods approach incorporating both. The table below is a broad (not exhaustive) summary of some of the typical dimensions that characterise each approach. Irrespective of the specific approach, if the study is categorised as research, then it must have HRA Approval (but not necessarily NHS Research Ethics) in order to proceed.

	Quantitative	Qualitative
Why the research is needed		
To test a new practice, intervention, therapy or drug	√	(√)
A study rationale based on theoretical frameworks and building on the methodology of past research	√	√
To test hypotheses or predictions of what is likely to be found based on the findings of past research	√	(√)
To explore a new topic not previously researched	√	√
Participants		
Direct contact with service users, carers or staff	√	√
A well-defined selection (inclusion/exclusion) criteria with a strong rational (or justification) for the participant sample selected	√	√
A sample size usually defined by statistical methods (power analysis) and usually large in number	√	
A small sample size based on experience of the topic under investigation	**(√)**	√
Types of data		
May involve contact with tissue samples or bodily fluids	√	
May involve collecting data from medical records	√	(√)
May use interviews or questionnaires	√	√
May use observational methods	√	√
Data analysis and findings		
An in depth exploration of the thoughts and opinions of individuals or small groups small groups		√
Data analysis involves interpretations of what the participants have said or written		√
The analysis of the data involves statistical analysis to explore differences, predictive capabilities or associations between groups of participants	√	
Findings that can be generalised to the wider population	√	(√)
The results may change practice if new interventions, tests, etc. are shown to be effective.	√	

Table 2: Characteristics of Qualitative & Quantitative Research

5.3 Activity not considered "research".

Please consult the LPT R&D Office (research@leicspart.nhs.uk) if you are in any way unsure of the categorisation of planned work, but in general case studies/case reports; clinical investigations; consensus methods; data management/analysis; literature review; clinical audit, quality improvement and service evaluation are not considered research and fall outside the remit of this policy. It is however possible that within a programme of work, some elements would be considered research, and these elements are then subject to the same regulatory framework.

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, then it too must seek appropriate regulatory review and approval.

It is however strongly advised that investigators check with the R&D Office regarding this interpretation, as the Office is the final arbiter of such a distinction.

"Approval" or notification of such activity is outside the scope of this Policy, but will typically involve the provision of information to service-based CASE-R (Clinical Audit, Standards, Effectiveness and Research) Groups.

5.4 Defining portfolio and non-portfolio research

Step 2
Once you have identified that your study is research you then need to consider whether or not it is eligible for inclusion in the NIHR Portfolio.

What is the difference between the two types of studies?

The aim of the National Institute of Health 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 (and that funding has been achieved following 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 your research to be considered to be included on the NIHR portfolio, check the box under Section 5b in the main IRAS form. This triggers the creation of the Portfolio Adoption Form and starts the process with the National Co-ordinating Centre and Lead Research Network of ensuring this support. The process of adoption can be supported by the Trust R&D Office, and the CRN Study Support Service.

There are significant advantages to seeking Portfolio Adoption, and this process can be supported by the Trust R&D 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") through the NIHR Clinical Research Networks or directly delivered by NIHR-funded staff embedded within the Trust. 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 R&D Office, research delivery staff are funded by the EM:CRN to support Services in the delivery of NIHR portfolio studies.

All Portfolio studies, and especially clinical trials (IRAS Categories 1-4), are subject to stringent performance metrics which include:

- Performance in Initiation
    - Time (in days) from receipt of valid application to confirmation of capacity/management permission (aka time to study opening)
    - First Patient First Visit (time in days to first participant recruited)
- Performance in Delivery
    - "Time and Target" (over the life course of a study, is the projected target being met)

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 (with some notable exceptions) primarily relatively small-scale, local studies and are also usually unfunded (perhaps generated from local priorities or as part of an educational qualification). Whilst these studies may also be of high quality and produce important results, there is currently no funding within NIHR/DH to support this work unless directly linked to related Portfolio activity. As a result, support for such studies has to come from within local services and resources.

"Non-portfolio" research is still subject to the same regulatory strictures that apply to NHS-hosted research as detailed elsewhere (e.g. HRA Approval, RGF Compliance).

5.5 Trust Management Approval Process

5.51 Prior to submission of any study for NHS Management Approval, the Principal 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.

5.52 The TMA process can begin as soon as documents have been finalised, and once other applications (Research Ethics Committee (REC), HRA, and MHRA, where applicable) have been submitted. The TMA 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.

5.53 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 EDGEID or a local study code) allocated.

5.54 Where a contract is required for any study, it is recommended that a standard agreement is used. Any non-standard contracts and agreements must be fully executed (negotiated and signed) before the study can be validated.

5.55 A member of the R&D Office 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, some of this activity will be delegated to senior Research Delivery staff to advise the R&D Office accordingly.

5.56 Where the process of review and granting of TMA is delayed for a significant period of time, it may become necessary for the application to be rejected, with a view to review and update the contents, once any obstacle has been resolved.

5.57 Once the final approval letters relating to the study have been provided, a letter to the PI, confirming TMA will be prepared and signed by the authorised signatory as appropriate.

5.58 A study may not begin until all the relevant approvals are in place and, if applicable, a contract, signed by all the relevant parties, has been received by the Trust R&D Office.

5.59 It is expected that all studies will make use of the EDGE project management system to ensure that all recruitment is logged in a timely fashion. R&D will ensure that all relevant personnel will have the appropriate level of access for those studies they are delivering.

5.6 Ongoing Approval

5.61 Once granted, TMA is conditional on regular updates being provided by the investigator team.

5.62 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 have TMA withdrawn.

5.63 The investigator is also required to provide data for reports to the NIHR on a quarterly basis to inform of 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.

5.64 In addition, the investigator team will also be required to provide further information on an annual basis for the Trust Quality Accounts

5.65 Other updates can generally be derived from progress reports, during monitoring visits (where relevant) and from end of study reports.

5.66 The investigator team is required to copy the R&D Office into any correspondence with the relevant ethics committee, HRA and MHRA: annual progress reports; Development safety update reports; end of study notifications.

5.67 Any proposed change in the status of the PI (e.g. departure from the Trust, maternity leave) must be communicated to the R&D Office, prior to that change taking place as this can affect ongoing TMA or CCC.

5.7 Protocol Amendments

5.71 All protocol amendments should be submitted for review by the R&D Office (see SOP for Research Protocol Amendments *(in development)*). If a study is sponsored by the Trust then the R&D Office needs to approve the amendment before it is submitted to regulatory bodies.

5.72 Following an updated HRA Approval 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 information.

5.8 The Valid Research Application (aka Minimum Document Set)

The Department of Health 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 of approved studies. There are therefore, performance criteria against which NHS organisations are measured, including a quarterly reporting framework (applicable to Portfolio and Non-Portfolio studies).

To this end, the concept of the Valid Research Application (VRA), Local Information Pack (LIP) or Minimum Document Set (MDS) has been developed which is the essential (minimum) information that should be provided to an NHS organisation (such as LPT) in order to trigger the formal process (and associated performance metrics) for the R&D department to issue NHS Management Permission or Confirmation of Capacity. This permission should be provided within 30 days of receipt of a VRA/MDS/LIP. The First Participant recruited into any study, should be recruited within 70 days of receipt of VRA/MDS/LIP.

The Assess, Arrange, Confirm Process, including contract negotiations and so forth is set in motion formally, by receipt of the MDS.

VRA/MDS 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.

The delivery of the Valid Minimum Document Set is a key trigger within the performance management of research initiation and delivery. The Sponsor does not need to obtain detailed information from the local research team at a site before sending the pack by email to the local research team (if identified), the R&D office (who may help to identify the local delivery team) and Local Clinical Research Network (where relevant). The locally applicable details are then completed jointly between all relevant parties and then confirmed in writing. The precise content of information to be supplied to a site is determined through the HRA Process, but will commonly include:

Document:	MDS 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 (as applicable)	Yes
Costing Template (Commercial Studies Only)	Yes
Schedule of Events (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[3]	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

Table 3: Characteristics of the Minimum Document Set

5.9 Securing Research Sponsorship

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.

Please see R&D/SOP/Number TBC Identifying Studies Eligible for Trust Sponsorship

Step 3

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

For those conducting research as part of a degree 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 R&D (research@leicspart.nhs.uk 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 and the necessary arrangements negotiated between R&D and the Sponsor.

[3] In particular, commercial studies and CTIMPS may supply extensive documentation, including product brochures etc.

5.10 Supporting NIHR Portfolio Research in LPT

The aim of the NIHR is to foster, support and fund high quality research studies to provide the best evidence to transform care and services. The NIHR has a significant number of studies adopted onto its Portfolio at any time. 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.

5.10.1 Opportunity for LPT involvement

There are many routes through which a portfolio study becomes a one with which LPT is involved in delivering, including:

- When researchers are preparing a grant application;
- Through personal contact with staff in services;
- When East Midlands CRN are aware of research relevant to Trust service users;
- A member of the R&D Office searching through relevant registers of studies;
- Successful completion of an expression of interest in studies open to new sites.

Regardless of the route, it is imperative that the LPT R&D Office are contacted and made aware of potential research at the earliest opportunity.

5.10.2 Enabling NIHR Portfolio research to be conducted in LPT

The Health Research Authority will take the primary role in assuring that all regulatory requirements (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 R&D Office, study sponsor, Clinical Network staff (embedded in the Trust) and clinical services.

It is this dialogue, collectively under the title "Organisational Research Capacity Assessment" (ORCA) that determines, through the "Assess, Arrange, Confirm" Process, that any study (including those not on the Portfolio) can be delivered in the Trust to applicable performance metrics.

Step 4: Assessment of Capacity through ORCA dialogue includes:

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. How to localise study documentation (e.g. ensuring study materials are relevant for LPT)
9. How to Ensure Clinical Trial Agreements (CTAs) and other contracts (e.g. Material Transfer Agreements, Intellectual Property Agreements etc.) are in place and valid.
10. Identifying any necessary training requirements
11. How to promote the study
12. Coordinating Site Initiation Visits
13. Strategies for efficient achievement of Trust Management Approval
14. Identification of possible obstacles to study delivery
15. Ongoing monitoring of study progress after initiation
16. Promotion and dissemination of findings

5.11 Supporting non-portfolio research in LPT

In the case of non-portfolio studies, a similar management/delivery plan should be established with clear responsibilities identified amongst the investigating team. This is especially important for those studies where LPT is the Sponsor.

5.12 Supporting research for an educational award

As outlined, all regulatory requirements apply equally to all activity deemed within the scope of the HRA.

5.13 Supporting other non-portfolio studies

A similar dialogue to that outlined in Step 4 should be held regarding the practicalities of the study between the R&D Office, study sponsor and student.

5.14 Research Finance

It must be understood that the default position for R&D Funding to NHS Trusts is that there is no automatic provision of resource to Provider Trusts. All R&D Funding from the Department of Health is managed centrally through the NIHR with a system of competitive programmes and grants (see www.nihr.ac.uk). Any funding that is received by the Trust to support CRN Portfolio activity, and that incurs 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 research unless this is approved directly by the Trust Board or within Clinical Services from within their budgets.

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 and the Research Design Service (www.rds-eastmidlands.nihr.ac.uk)

Please see also R&D/POL/002 "Establishing and Implementing an Income Distribution Model for Commercial and Non-Commercial Research".

Step 5: 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, established under the Culyer process and reinforced in HSG 97(32) is to ensure that research does not impact negatively on clinical services.

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

For commercial studies, the Trust has adopted the standard trial costing template (developed by the NIHR), with each trial having an individual analysis code within the R&D Cost Centre (allocated by the finance department). This ensures that services and staff engaged in such trials are correctly remunerated. The model costing template incorporates a pre-negotiated Trust market forces factor figure to ensure the correct attribution of cost, and provides a breakdown of eligible activity. In addition, an "R&D set-up Fee" and a "capacity building element" within the template may provide additional central income for re-

investment in developing further research.

Full details of the financial model are detailed in R&D/POL/002 Adoption & Implementation of an Income Distribution Model.

Each non-commercial grant study will also be given an individual cost-centre and managed appropriately to ensure research engagement by services. This will be arranged by R&D with the Finance department. This will once again be (unless otherwise specified) held within the "protected income" R&D Cost Centre to enable the sustainability of research projects and programmes across financial year-end.

The principles of ACORD (Attributing Costs of Research & Development in terms of research costs, service support costs, treatment costs and excess treatment costs are followed as part of the establishment of the management delivery plan and the requirement of the Research Governance Framework to ensure that services are not burdened with unforeseen costs.

5.15 Standard Operating Procedures & Other Documentation

The R&D Office maintains and develops a range of 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 R&D Office. These documents will be made available on the R&D section of the Trust website as they are developed and approved.

4.16 Dissemination & Implementation

One of the main aims of clinical and healthcare-related research is to improve the health and well-being of the population, by providing the best possible evidence for transforming and delivering services.

Step 6 Dissemination

Trust Management Approval is conditional, and this policy indicates that for all approved research studies states that there is an obligation to disseminate the results. 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, 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 staff should be aware that within the NIHR, the "Collaboration for Leadership in Applied Health Research & Care" (CLAHRCs) was established to link academic research to clinical services, to improve the pipeline of communication between the two and to build capacity in healthcare staff to implement research findings. In addition the AHSN (Academic Health Sciences Network) as another part of the NIHR works to speed the path of innovation into

clinical services. Both may be helpful in helping researchers implement their findings.

6.0 Responsibilities

General Responsibilities

Anyone undertaking research within the Trust without the relevant approval(s) e.g. NHS REC, Health Research Authority, Clinical Services and Trust Management Approval, is substantially in breach of the RGF and other relevant legislation e.g. ICH Guideline to Good Clinical Practice (GCP) and therefore disciplinary action can, and will be taken against them.

It is imperative that all intended research within the Trust has had an appropriate level of approval before the research can commence. “Local Authorisation” can be obtained directly from the Medical Director or Divisional Directors, Clinical Directors and Service Management. They can give approval for 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.).

The Trust Board

Is responsible for driving quality assurance through checks on compliance to governance standards, and has an obligation to promote and support research activity (primarily Portfolio research) through ensuring resources and policies are in line with this objective.

Quality Assurance Committee (QAC)

The QAC is authorised by the Trust Board to monitor the Trust’s quality strategies and to provide the Trust Board with assurance on quality, Key Performance Indicators (KPIs) and deliverables which includes research, clinical audit and effectiveness.

Medical Director

The Medical Director is the Executive Lead for Research and is responsible for providing leadership for the delivery of the research programme. Where appropriate the Medical Director informs the Trust Board of research activities that provide assurance on clinical effectiveness and for the mitigation of risks recorded on the Board Assurance Framework (BAF).

Research & Development Strategy Group

This group is responsible for overseeing and developing research capacity, the implementation of the R&D Strategy and partnership working with respect to research. The group also reviews R&D Key Performance Indicators and reports to the Trust Board via Clinical Effectiveness Group and Quality Assurance Committee.

This group meets quarterly and is Chaired by the Head of R&D.

Clinical Directors/Service Governance Leads

Each Service has a Governance Lead who supports the proper governance of Service-

based research, evaluation and audit programmes, with clinical leadership from the Clinical Directors. Priority should be given to Portfolio studies or internal research addressing key Trust or Service priorities in determining whether a study can be hosted.

This may potentially include:

- Establishing a Service Research Group (or similar focus) as a sub group of the Service Clinical Governance group (see below).
- Establishing a communication mechanism through which clinical staff are potentially released to support CRN Portfolio studies (with or without funding to support this activity), and to prioritise non-portfolio work in line with Service strategy.
- Supporting development of systems to ensure the discussion, dissemination and implementation of research recommendations.

Providing dedicated time for regular multidisciplinary and professional meetings to discuss indicators of clinical quality and research projects, with records of attendance, topics considered, actions agreed with responsibility for actions.

Principal Investigators

A principal investigator (PI) has primary responsibility for ensuring any research study is conducted according to the protocol, recording protocol deviations, progress reporting, consent and so forth as defined in the Research Governance Framework. The PI is also responsible for establishing a delegation log to ensure that all staff and duties involved are properly accounted for.

Research & Development Office

The R&D Office is responsible for overseeing operational delivery, performance monitoring, contracts and governance, including 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.

CRN-Funded Research Delivery Team

The Trust hosts a number of staff wholly or partly funded by the Clinical Research Network in order to fulfil the obligation as a Partner Organisation of the national CRN, to support the delivery of Portfolio studies wherever possible as these apply to services provided by the Trust. This team is directly managed through the R&D Office (and R&D Operational Lead) and plays a key role in supporting TMA processes, including CCC but is primarily dedicated exclusively to supporting the delivery (i.e. participant recruitment) to approved studies. As a multi-skilled team, they may deployed in any area of the Trust, and are considered to be part of the clinical team with which they are working on the delivery of a particular study.

The requirement for CRN Delivery Team support is determined through the Assess, Arrange, Confirm process and the implementation plan arising from this. This support is available only to NIHR Portfolio studies, although the team may support staff wishing to see their study adopted onto the Portfolio.

Patient & Public Involvement

The Trust entirely supports the premise that early and continuing involvement of patients and

the public in all aspects of the research process, including leading and designing research, both strengthens and improves the relevance and applicability of research.

6.1 Specific Responsibilities

1. The Chief Executive has overall responsibility for this policy.
2. The Head of R&D develops the strategic direction, strategic partnerships, research career pathways and priorities for research in the Trust.
3. The Operational Lead (R&D) has delegated authority on behalf of the Trust to:
    - Authorise TMA Letters to Principal Investigators as required.
    - Provide confirmation that the Trust will act in the role of Sponsor.
    - Provide "confirmation of capacity" to Sponsors as required
    - Provide a mechanism for escalation for R&D and/or investigators when required, to ensure NIHR timelines are met.
    - Sign-off collaborative agreements, contracts and non-disclosure arrangements.
    - Ensure (with the support of Trust Finance) that all aspects of any research are appropriately costed, and to operate full cost recovery.
    - Ensure good HR practice in relation to research is followed.
    - To give leadership, support and advice relating to research governance and oversight.
4. Service management are required to:
    - Provide timely confirmation to R&D on service capacity when required to do so.
    - Support all approved research, subject only to critical clinical priorities.
5. The R&D Office has the responsibility:
    - To provide advice and information to investigators/staff on the process covered by this policy for the various study types**.**
    - To conduct proportionate reviews of the study including arranging assessments of capability and feasibility assessments according to the type of study, size of study and level of risk, liaising with investigators and sponsors as required, to ensure NIHR timelines are met.
    - To conduct Safety Reporting Risk Assessments for all hosted CTIMPS – commercial and non-commercial.
6. Chief Investigator (CI) (or delegate[4]) has the responsibility to:
    - Be the individual, as identified in the ethics application, who takes overall responsibility for the conduct of a clinical study.
    - Ensure that confirmation of support has been obtained from the relevant service support departments, prior to approaching R&D (e.g. pharmacy, radiology, labs, pathology) and that the relevant service manager is aware of the study.
    - Ensure that recruitment targets are realistic, feasible and achieved wherever possible.
    - Ensure that the study team is in full readiness to begin study recruitment promptly, following agreement with the Sponsor and TMA/Confirmation of Capacity being granted. This is to ensure that FPFV (First Patient First Visit) timelines are achieved.
    - Provide all necessary information and documentation in a timely manner.
    - Provide information on research activity, as required for the quarterly

[4] In many case "delegate", will be the CRN-funded Research Delivery Team

reports to the NIHR, CTP and annually for the Quality Accounts Regulations in a timely manner.
- Ensure that the local study team are appropriately qualified by experience and training to undertake the study including information governance training and appropriate GCP training for conducting clinical trials.
- Ensure that the conduct of the study is in compliance with the protocol, the terms of the Research Ethics approval, all relevant legislation, and any relevant contracts.
- Ensure that R&D is informed of any change in the status of the Principal Investigator (e.g. leaving the Trust; maternity leave), prior to that change taking place.

7. Principal Investigator (PI) (or delegate[5]) has the responsibility to:
    - Be the individual who takes on responsibility for conduct of the study at a particular site.
    - Act in accord with the requirements of the CI in terms of the local site.

7.0 Duties within the Organisation

7.1 The Trust Board has a legal responsibility for Trust policies and for ensuring that they are carried out effectively.

7.2 Trust Board Sub-committees have the responsibility for ratifying policies and protocols.

7.3 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
- 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.

7.4 Managers and Team leaders are responsible for:

- Supporting 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

7.5 Responsibility of Staff

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

[5] In many case “delegate”, will be the CRN-funded Research Delivery Team

8.0 Training Needs

There is no training requirement identified within this policy

9.0 Monitoring Compliance & Effectiveness

There is a number of key performance indicators (KPI) embedded within this policy, primarily around the "PID" (Performance in Initiating & Delivering Research) criteria established by the Department of Health. These KPIs are monitored by the R&D Office and the East Midlands Clinical Research Network. These indicators are reported quarterly by R&D to DoH, with data made available on the Trust website.

TARGET/STANDARDS	KEY PERFORMANCE INDICATOR
Efficiency in providing NHS Management Permission (TMA/CCC) within 30 days of Valid Research Application	100% of studies within 30 days
Effectiveness in delivering research.	80% of studies to have "First Patient First Visit" within 70 days of receipt of Valid Research Application/Minimum Document Set (effectively 40 days from TMA)
Effectiveness in delivering research	80% of approved studies to meet Time & Target recruitment according to the agreed management delivery plan

Consideration is being given to the implementation of other internal performance indicators, including:

Aspect of compliance or effectiveness being monitored	Monitoring method	Responsibility for monitoring (job title)	Frequency of monitoring	Group or Committee that will review the findings and monitor completion of any action plan
Issue of Trust Management Approval letters	Report numbers approved	Operational Lead (R&D)	Annual	**R&D Strategy Group**
Issue of Confirmation of Capacity and Capability	Report numbers approved	Operational Lead (R&D)	Annual	**R&D Strategy Group**
GCP Training	Report numbers trained	Operational Lead (R&D)	Annual	**R&D Strategy Group**
Provision of information for Quality Accounts	Report volume of non-responders	Head of R&D	Annual	**R&D Strategy Group**

10.0 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 of Health (2005). Research Governance Framework for Health & Social Care (2nd Edition). London: Home Office (this document is under revision following the establishment of the Health Research Authority)
- 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

11.0 Policy Review

11.1 This policy will be reviewed in 3 years, as set out in the Policy for the Development and Implementation of Procedural Documents.

11.2 The Trust Management Executive has delegated authority to the Research & Development Lead for the approval of any further supporting or associated documents.

11.3 Changes in legislation relating to R&D may require interim modifications to this policy and supporting documentation.

Appendix 1

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.*	*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 evaluation.*
Randomisation	*May involve randomisation*	*No randomisation*	*No randomisation*
HRA Approval	*Mandatory*	*Not required*[6]	*No usually required*
NHS Research Ethics	*Yes, REC Review required*[7]	*Not required.*	*Not required*
Management Permission	*YES (via Service, Sponsor and R&D)*	*YES (via Service CASE-R and Audit Dept.)*	*YES (via Service CASE-R)*

[6] Unless evaluation becomes "research" during the course of the activity

7 Research Studies that involve NHS staff only do not require NHS REC review. Please seek Research Office advice in all cases.

Appendix 2

The NHS Constitution

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 3

Stakeholders and Consultation

Key individuals involved in developing the document

Name	Designation
David Clarke	Operational Lead for R&D
Lisa Hopkins	Research Support Officer
Will Navaie	Health Research Authority
Jo Edgar	Research Business Manager

Circulated to the following individuals for comment

Name	Designation
Members of Clinical Effectiveness Group	Misc

Appendix 4

Due Regard Template

Section 1	
Name of activity/proposal	**Trust Management Approval of Clinical Research Policy**
Date Screening commenced	20/09/2017
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 conducting research.	
OBJECTIVES: This policy outlines the standards expected in respect of research activity and defines roles and responsibilities and the processes involved in registering research, and gaining relevant permissions. The policy is	

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. Rather it states a number of mandatory steps to ensure the safety and wellbeing of all staff, service users and carers involved in research conducted in the Trust. The policy is therefore Due Regard NEUTRAL.			
Signed by reviewer/assessor		**Date**	
Sign off that this proposal is low risk and does not require a full Equality Analysis			
Head of Service Signed		**Date**	

Appendix 5

Organizational Research Capacity Assessment (ORCA)

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

STUDY IFA(1)					
Assigned Reviewer:					
Short study title				**Site:**	
IRAS number:		**Ethics Reference:**		**PI/Local Collaborator Identified:**	Yes/No (Name)
Sponsor:		**Sponsor contact:**			
Portfolio Yes/No		**Commercial Yes/No**		**Non-commercial interventional Yes/No**	**Other (type)**
Initial Assessment:					Evidence
Q1	Is the target service provided by the Trust?			**YES/NO**	
Q2	Are we likely to have the target participant population?			**YES/NO**	
Q3	Do we have competing studies in the target timeframe?[8]			**YES/NO**	
Q4	Are there potentially critical issues that would cause the study to fail?[9]			**YES/NO**	
Q5	If a local PI is required, are there any with capacity and interest?			**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. This decision is then conveyed to the Sponsor and/or Enquiry Contact.

If answers are indeterminate, then proceed to second tier feasibility.

[8] If "YES", but the Sponsor is flexible as to dates, consider moving forward.
[9] Service transformation, service pressures, unattributed excess treatment costs etc.