Leicestershire Partnership NHS Trust

R&D/POL/002
Research & Development Finance: Income Distribution & Management

The purpose of this document is to describe the accountability, management of and distribution of research income, irrespective of source (commercial or non-commercial grants, core infrastructure funding, Trust support etc). This policy and embedded model within it, addresses the mechanisms through which research income is ring-fenced, compliant with Standing Financial Instructions, but also made available appropriately through utilisation of the Standard Industry Costing Template (NIHR CRN 2008; HRA 2017) and cost attributions derived from the SOECAT (Schedule of Events Cost Attribution Template) for non-commercial grants according to ACORD (HSG 97/32) principles. The process and rules for incentivising individuals, service and teams to increase participation in research are also outlined.

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Contents

Version Control and Summary of Changes

Version number	Date	Comments (description change and amendments)
1.0	29/12/2015	Original Document
1.01	01/04/2016	Minor typographical revisions and template format
2.0	01/01/2022	Addition of duties and accountability framework, detailed operation of the PICC, the online commercial costing tool, grant management, excess treatment costs
3.0	26/05/2022	Addition of statement with regard to “conflict of Interest”
3.01	27/07/2022	Reference to single National Contract Review Process

For further information contact: Document Controller (R&D)

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.

Due Regard

LPT will ensure that Due regard for equality is taken and as such will undertake an analysis of equality (assessment of impact) on existing and new policies in line with the Equality Act 2010. This process will help to ensure that:

- Strategies, policies and procedures and services are free from discrimination.
- LPT complies with current equality legislation.
- Due regard is given to equality in decision making and subsequent processes.
- Opportunities for promoting equality are identified.

Definitions that apply to this Policy (Universal across Research & Development)

AAC	Assess, Arrange, Confirm Process
ABPI	Association of the British Pharmaceutical Industry
ACORD	Attributing Costs of Research & Development
AHSN	Academic Health Science Network
ARC	NIHR Applied Research Collaborative
ARSAC	Administration of Radioactive Substances Advisory Group
CDA	Confidential Disclosure Agreement
CI	Chief Investigator
CoCC	Confirmation of Capacity and Capability
CPMS	Central Portfolio Management System
CRN	Clinical Research Network
CRO	Contract Research Organisation
CTA	Clinical Trial Agreement
DDO	Delegated Delivery Officer
EDGE	The Trust Local Portfolio Management System (Cloud Database)
EoI	Expression of Interest
ETC	Excess Treatment Costs
EudraCT	(European Union Drug Regulating Authorities Clinical Trials) is the European Clinical Trials Database of all clinical trials commencing in the European Union after 1 May 2004
FGP	First Global Patient/Participant
FPFV	First Patient First Visit
GCP	Good Clinical Practice
HRA	Health Research Authority
iCT	Interactive Costing Tool
IRAS	Integrated Research Application System
IRMER	Ionising Radiation (Medical Exposure) Regulations
KPI	Key Performance Indicators
LAP	Local Adoption Process
LIP	Local Information Pack
LPMS	Local Portfolio Management System
LPT	Leicestershire Partnership NHS Trust
mCTA	Model Clinical Trial Agreement
MDS	Minimum Document Set
MFF	Market Forces Factor
MHRA	Medicines and Healthcare Products Regulatory Agency
mNCA	Model Non-Commercial Agreement
NIHR	National Institute for Health Research
NIHR CRN	National Institute for Health Research Clinical Research Network
NIHR CRN SSS	National Institute for Health Research Clinical Research Network Study Support Service
MTA	Material Transfer Agreement
NCVR	National Contract Value Review
NDA	Non-Disclosure Agreement
OID	Organisation Information Document
ORCA	Organisational Research Capacity Assessment
PI	Principal Investigator
PICC	Protected Income Cost Centre
PID	Performance in Initiating & Delivering Research

R&D	Research and Development (aka Trust R&D Office)
RDS S1	Research Delivery Service Systm1 Unit
REC	Research Ethics Committee
ResC	Research Costs
SoA	Statement of Activities
SoECAT	Schedule of Events Cost Attribution Template
SOP	Standard Operating Procedures
SSC	Service Support Costs
SSI	Site Specific Information
TMA	Trust Management Approval
TTA	Tissue Transfer Agreement
VRA	Valid Research Application
USM	Urgent Safety Measure

1. Background

Research is core business for the NHS and is integral to improving the quality and productivity of services. As research activity develops at LPT and we make progress against the Trust's research strategy, it is anticipated expected that research income and expenditure may increase substantially.

Therefore, it is imperative that we have systems and processes in place to ensure robust management and governance of all financial activities relating to research in the Trust. This includes all stages of the research process, from initial accurate costing of grant applications and financial review for approval of prospective projects to reporting of accounts for completed studies.

The Department of Health and Social Care considers the support and delivery of commercial industry-funded and sponsored research to be a key priority (Plan for Growth, March 2011), within the overall framework of NIHR Portfolio research. Additionally, the money generated from this research is a potentially valuable source of additional income for NHS Organisations. Therefore, it is crucial that all parties consider that there are sufficient incentives in place to promote participation in commercial/industry-sponsored research, as well as academic research. It is also a key principle that this income not only covers costs, but is also available to be used to develop capacity for new research within NHS Organisations and to support future income generation. Whilst it is important that investigators are incentivised to carry out commercial research, this must be balanced with protecting the interests of potential participants, the requirements and capacity of the NHS Organisation and other stakeholders (including NIHR CRN and University Partners) to recover their costs wherever appropriate.

2. Purpose and Underlying Principles of the Policy (Summary & Scope)

The purpose of this document is to advise all stakeholders within Leicestershire Partnership NHS Trust (the Trust), and partner organisations (commercial and non-commercial) of the principles underlying the management of research income into the Trust. The sources of this income (not exhaustive) include:

- NIHR Clinical Research Network (under the Partnership Agreement) "Infrastructure" Budget
- Commercially-sponsored IMP and Device Trials
- Non-Commercial IMP and Device Trials
- Non-commercial/Academic Research Grants

This policy covers all research projects whether internally or externally funded, including student projects.

The purpose of this policy is to provide information on the processes and systems in place for the appropriate costing and financial management of research at LPT, and the co-dependencies thereof. This policy also covers guidance that the levels of incentives for participation are fair and appropriate. The applicability of these core principles to non-commercial research is also described.

2.1. All research at LPT must comply with the relevant Department of Health, Funding organisation and LPT regulations, policies and guidance for financial management, monitoring and reporting of research

2.2. All research projects must be registered with the Trust R&D Department.

2.3. All proposed research involving the Trust will need to show evidence of adequate funding and resources before approval.

2.4. The R&D Finance Lead and R&D Office must be engaged at an early stage to take an active part in costing and approving research projects and reviewing agreements and contracts.

2.5. To ensure financial probity and transparency, all research related funding is to be managed within the three R&D Cost Centres.

2.5.1. (8790) NIHR CRN Core Infrastructure Funding & Supplementary Payments

2.5.1.1. 8790 is also known as the Research Delivery Infrastructure Budget, and it's use subject to a monthly review by CRN, and a periodic audit of operation and supporting policies and process known as the "financial health check".

2.5.2. (8791) Protected Income Cost Centre (Grants, ETC Receipts, Service Support Receipts) with one sub-centre per project.

2.5.2.1. 8791 is also known as the Project-specific Transition Ledger and must be ring-fenced to allow reporting to FSTOX for grants etc.

2.5.2.2. Income held in the PICC will supplement and reimburse relevant service budgets as agreed during set-up and implementation.

2.5.3. (8794) Core R&D Office activity (Sponsorship, RCF etc.)

2.5.3.1. 8794 is the only budget potentially subject to CIP, as this is provided from Trust resources.

2.6. All R&D staff, as with all Trust staff, must adhere to the Trusts' Standing Financial Instructions. Any query regarding these should be addressed to the appointed Research and Development Finance Lead in the first instance.

2.7. This document focuses primarily on the model and processes for commercial income only, although this model can be usefully applied to all funded studies.

2.8. The money generated from industry-sponsored studies is potentially a valuable source of income for the Trust. It should, wherever possible, be used to encourage key stakeholders to develop capacity for new research within the Trust.

2.9. The income generated from industry-sponsored studies is a relatively small proportion of R&D Income at present but has the potential to grow significantly, especially as services move out of acute care. A policy to recognise the Trust, departments and individuals for their contribution to commercial research is now a necessity.

3. Principles of Income Distribution & Management

The principles of commercial and non-commercial income distribution are:

3.1. Individuals and departments are incentivised for their contribution to research where possible, with recognition and encouragement from service management. These are not personal awards unless otherwise specified.
3.2. All costs incurred by the Trust are fully recovered, and any instances of "double-funding" are identified and appropriately reimbursed.
3.3. Investigators and the Trust can utilise commercial research income to fund additional, research-related activity.
3.4. Commercial research income can, with some limited exceptions, be distributed and carried over financial year end, in line with Trust financial control policies.
3.5. Commercial research income must be used according to the details listed in the costing template specific to that study (i.e. reimbursed for staff costs, support services etc.); this includes retention of "set-up fees" within the R&D Core Budget.
3.6. Where there are "Capacity-building" funding elements within the costing template/Study budget, the Service hosting the Investigator Team should have initial priority in using this funding. This funding should be retained in the "protected income centre" budget and should be authorised by the Investigator Team if used for any other purpose.

The principles of Non-Commercial Grant income distribution are:

3.7. Non-Commercial Income is either:

3.7.1. DIRECT (where an individual or team are the LPT grant holders, or are named and reimbursed co-investigators on the grant)

OR

3.7.2. INDIRECT (where local services have been asked to contribute to the delivery of a study, and may therefore be due funding either from the research grant, or through service support cost mechanisms, treatment or excess treatment costs)

3.8. Individuals, Teams and Services are correctly and fairly recognised for their contribution to non-commercial research.
3.9. Service Management, in association with R&D, is supportive of staff in receipt of Direct or Indirect Grant income, on the assurance that legitimate costs are covered.
3.10. All costs incurred by the Trust are fully recovered or agreed through Service.
3.11. Investigators and Services may use this income only for the purposes outlined in the study site agreement/contract, with the exception of residual funds following expiry of the study/grant (wherein first call is with the grant holder/investigator, and any subsequent usage agreed with the latter).

4 Duties and Accountabilities within the Organisation

4.1 Finance Director

The Finance Director (or delegated representative) is responsible for ensuring that research in the Trust complies with all latest applicable national guidance and with the Trust's policies and procedures for the financial monitoring and reporting of research activities. This includes responsibility to:

- Ensure that proposed research is reviewed and assessed for financial risks and implications to the Trust appropriately and in a timely fashion, as required.
- Check and confirm that all studies are costed and resourced appropriately as guided by the NIHR financial costing templates.
- Advise on research contracts with funding organisations, including NIHR and commercial companies.

- Provide specialist, and timely, financial support and advice to staff applying for research grant applications, including completion of finance forms.
- Support the R&D Lead, R&D Finance Lead and Business Manager in monitoring and reporting on funding for research received by the Trust (incl. FSTOX returns).
- Provide information and advice to support the R&D Lead and Business Manager in business planning and budget setting.

4.2 Medical Director

The Medical Director (or delegated authority) has responsibility for ensuring a high quality of research management and governance, including the financial management and reporting of all research in the Trust. This includes ensuring R&D policies, procedures and processes in the Trust meet all statutory requirements

The Medical Director (or delegated authority to the R&D Lead) will, after financial review by the Finance Director or delegated representative and if appropriate, provide sign-off for:

- grant applications,
- Trust Sponsorship
- R&D authorisation for relevant studies e.g. CTIMPs ,
- Commercial contracts and non-disclosure agreements, and for
- financial contracts with research funding organisations.

The Medical Director has responsibility for ensuring that Research Capacity Funding (RCF) allocation is linked to the strategic agenda of the Trust.

4.3 Research Lead

The Research Lead will support the Medical Director to ensure that all research in the Trust meets national and local finance regulations and guidance for research.

The Research Lead has delegated responsibility from the Medical Director for authorisation of research contracts, R&D Authorisation (Confirmation of capacity and capability) etc. research expenses, excluding salaries (as detailed under 4.2).

The Research Lead will lead in the provision of expert advice & guidance to researchers (often in association with the NIHR RDS) and other colleagues in relation to costing research grant applications, reviewing contracts, and seeking appropriate support costs.

4.4 Researchers

It is the responsibility of researchers to ensure that research funding for which they are responsible is spent appropriately and is accounted for. This research funding, by default, will be held in a designated PICC Code unless specifically requested to be directly within a service budget.

Researchers must be familiar with and follow the guidance set out in this document and comply with national and local regulations, policies and procedures regulating the management of research funding.

Researchers are requested to notify the Medical Director (delegated to Research Lead) about planned studies, and grant applications, and especially studies that involve **Excess Treatment Costs (ETC)** at the earliest opportunity.

This should be before submission of grant applications and proposals to enable the Trust and their commissioners to build these costs into their financial and commissioning plans where it is possible to do so. Please see the health service guidelines to patient costs, Excess Treatment Costs, and Trust guidance to research costs at the end of this document.

R&D Finance staff should also be consulted to accurately cost and assist in the development of the application/project proposal.

The researcher is expected to notify the Research Lead about the grant funder's funding decision as soon as this is known so that the Trust can amend its financial plans accordingly. Reference to the R&D Finance manager should be made to update them on the outcome of any grant applications.

(Please see NHS publication for definition and guidance on Research Costs)

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

4.5 All research staff

Any member of staff, including individuals holding honorary research contracts, participating or considering participating in research must:

- Make themselves aware of this guidance and related procedures
- Raise issues of concern with the Medical Director or Research Lead

4.9 All staff

Any member of staff, including individuals holding honorary contracts, that becomes aware of incidents or practices causing concern or not in accordance with this guidance must inform their line manager or the Medical Director or Research Lead.

5 Procedures

5.1 Costing & approval of research costs for grant applications

The R&D Finance Manager will provide advice and support to the R&D Office in preparing accurate costings for research studies.

All projects led by LPT staff or service users will require financial review and approval by the Finance Manager and the Research Lead prior to submission of grant applications.

Please note: In the case of collaborative NIHR grant applications where LPT is the lead organisation, a contract of responsibilities between the partner organisations (that includes finance management and delegated responsibilities of the finance manager), will need to be negotiated and approved by the R&D Office prior to submission of application. These applications are often further supported by the NIHR RDS.

All research applications involving external collaboration where an employee is either a named applicant or full collaborator are required to involve the R&D Office and the R&D Finance Manager at the earliest opportunity to ensure that research projects are appropriately costed, and the Trust derives the maximum benefit from the collaboration.

Collaborative research is an iterative process including many partners, and so where the Trust is involved in such grant applications it is to be remembered that final costs will not be finalised until close to the submission deadline for the grant.

However, Trust costs etc should be identified as early as possible to allow research collaborators to accurately conduct financial modelling for their projects. This may involve development of arrangements for financial management across several collaborating organisations.

All financial aspects of grant applications should be presented to the R&D Finance Manager and sign off received from the Director of Finance, or delegated person, prior to grant application submission.

Important: all researchers wishing to submit for any specific grant, should ensure that there is sufficient time in anticipation of the deadline for submission that costs are as accurate as possible, to both improve competitiveness but also to ensure that there is no need to ask for supplementary income. It is recommended that costs are requested at least 15 working days before deadline. Submissions closer to the deadline pose a risk of inaccurate costing, and a potential cost burden.

5.2 Financial review for sponsorship

5.2.1 Sponsorship for research projects is not the same as FUNDING for research projects. Sponsorship refers to the process by which an organisation takes responsibility for ensuring the funding, accountability and delivery of that research project.

5.2.2 All projects for which sponsorship by the Trust is sought must be fully costed and provide evidence of appropriate funding. Costing and funding arrangements will be reviewed by the R&D Finance Manager and agreement that the Trust will act as sponsor given by the Research Lead.

Please see R&D/SOP/005 Applying for Trust Sponsorship V2.01 for further details on sponsorship by the Trust.

5.3 Financial review for R&D Authorisation

All projects will require financial review and approval prior to Trust R&D approval.

All projects involving the Trust will require registration with the R&D Office as part of the Trust's R&D Authorisation process.

Researchers are recommended to contact the Trust's R&D Office for advice before registering a project.

5.3.1 Own Account Research

'Own Account Research' i.e. single centre studies which have no external funding and are supported by internal Trust resources or funds, internal charities etc. will need to be approved by the Trust prior to the start of research. All such projects will be required to:

- Meet quality standards and be peer reviewed
- Obtain approval by the researchers' department within the organisation before seeking Trust approval

- Be self-supporting. It will be expected that the relevant department will support any additional costs that the project incurs.

5.3.2 Student projects

Student projects e.g. Masters and PhD projects may be supported in terms of overhead costs by the Trust. Agreement for this must be sought from the relevant host department prior to application for Trust R&D Approval. There are no R&D Funds available to support this level of work.

5.3.3 Non-commercial studies

The majority of non-commercial studies will be adopted onto the National Institute for Health Research (NIHR) Portfolio and will be supported by the research networks through the Clinical Research Network – East Midlands (CRN EM).

As part of the study feasibility process, proposed portfolio studies will be assessed and reviewed by the assigned delivery officer, R&D Finance Manager (if required) and Head of Research to identify any support funding that can be accessed from the CRN or other research network. It is important to recognise that Service Support Costs (SSCs) are now deemed to be within the Core Infrastructure budget provided to the Trust as a partner organisation.

Assessments by the R&D Office, supported by delivery staff project manager staff will determine the requirement for Excess Treatment Costs (ETCs), and should follow the relevant guidance for assessment of, and application for ETCs following consultation with the R&D Finance Manager. Up to the threshold level (see 5.3.4) services participating in approved Portfolio research are expected to absorb these costs as part of their commissioned envelope.

Other non-commercial projects may be supported by direct grant awards from charities and universities. Again, it is important that the R&D Office and the R&D Finance Manager are involved in negotiations when considering participation with external organisations to ensure that costs in participation are assessed and are fully recovered.

This will include the application for Excess Treatment Costs from the relevant source, as described in the guidance.

5.3.4 Excess Treatment Cost THRESHOLD

All research active NHS Organisations are expected to absorb any excess treatment costs up to the assigned threshold in any financial year. Any ETCs calculated once the threshold is exceeded are reimbursed to the relevant service incurring the cost.

ETC thresholds are constantly reviewed, and in 2021/22 were reduced to 10% of their previous level. Research engagement will therefore significantly reduce the burden on services, and may bring additional income.

5.3.5 Commercially funded studies

These are commercially contracted studies that are initiated and sponsored by a commercial or industrial company. Please note that research is not automatically considered “commercial” simply because there is industrial funding. Commercial companies also

support non-commercial research jointly with NHS bodies or non-NHS research funders. If the work is primarily for the public benefit, rather than the direct commercial benefit of the company concerned, it may be considered non-commercial. In general, research is regarded as “commercial” when the Intellectual Property will be owned by a commercial sponsor and “non-commercial” when the Intellectual Property remains with the Trust.

Where research is primarily for commercial purposes (e.g. studies of a new drug or medical device prior to licensing), the Trust needs to be able to recover the full cost from the commercial company on whose behalf it is carried out. This includes all patient-related costs such as nursing time, blood tests etc.

In addition to full direct costs, a standard overhead will be levied to cover infrastructure costs. This is to ensure that all the support services which are required to support the Trust, including the costs of providing accommodation are covered. As this overhead is in addition to the direct costs, care groups and services will need to have sufficient funds to still carry out research.

Details of these costs will be presented in the CRN Standard Industry Costing Template, and this will accompany all commercial projects as part of the feasibility process, and authorisation will not be grated until it has been approved by the R&D Office.

The Costing template is now hosted online, with a single, centralised financial review process using a baseline costing framework marginally higher than the MFF level.

There will also be a research governance set up fee of (Approximately £750) upon application for R&D Authorisation (Also known as Confirmation of Capacity and Capability) of the project, as indicated on the CRN Standard Industry Costing Template.

Apart from exceptional circumstances, the online CRN Standard Industry Costing Template will be utilised as this includes standard tariffs, capacity and R&D Governance costs.[1]

Researchers considering involvement in any commercially funded studies should consult the R&D Office as early as possible in order to determine the appropriate costs for the project.

Researchers should ensure that preliminary discussions with prospective sponsors/funders do not commit the Trust to a project or its funding. Involvement of the R&D Office at an early stage is important to ensure the progress of commercial projects meets the appropriate regulation.

6. Guiding Principles (Commercial Research)

- Departments and individuals are recognised for their contribution to the commercial studies run within NHS Organisations (either Portfolio or Non-portfolio) and are provided with fair incentives, transparently and flexibly as per the individual study requirements

[1] https://www.nihr.ac.uk/funding-and-support/study-support-service/early-contact-and-engagement/commercial-study-costing-templates.htm

- All relevant costs incurred by the NHS Organisation, and where applicable Universities or other Partner Organisations, are recovered from the Commercial Sponsor as per the Industry Costing Template e.g. study costs associated with non-routine patient care. Where the standard template is not used, these costs must be properly attributed and agreed with Trust finance and recovered.
- Commercial research affords investigators and NHS Organisations with opportunities to fund additional research related activities; funding arrangements between stakeholders should be cognisant and pragmatic in managing this important benefit of commercial research
- Income from commercial research can be distributed and carried over financial year-end, in line with the standard financial control procedures of individual NHS Organisations and in accordance with the research priorities agreed between research departments, service support departments, individual investigators and NHS Organisation management.
- Where NHS Organisations utilise CRN-funded resources they should consult with local CRN when:
    - Ensuring appropriate deployment of current Network-supported research resources
    - Assessing local research needs across the whole spectrum of activities and departments which may require Network support
    - Setting research priorities across the NHS Organisation
    - Planning for the future of research locally and how this can be supported by the Network
    - Growing research capacity in the long-term to meet national research ambitions
    - Giving due regard to time versus value considerations in procedures for itemising, invoicing and recovering costs.

7. The role of "Commercial Flight" from the UK

7.1. Commercial research is defined as research that is sponsored and funded by commercial companies, usually pharmaceutical or device manufacturers, and is directed towards safety, profiling, efficacy, effectiveness, product licensing and commercial development (post-market surveillance).

7.2. The benefits of commercial research include:

7.2.1.1. Wealth generation for the UK Economy

7.2.1.2. Income generation for the Trust

7.2.1.3. Access to novel compounds, new devices, new practices and procedures.

7.2.1.4. Access to large scale clinical trials producing potentially significant results.

7.2.2. Access to well-managed, well-resourced and strictly monitored clinical trials for both investigators and patients.

7.3. In the context of a globally competitive clinical research market, the UK has tended to be more expensive than other countries in Europe and Asia for conducting industry sponsored studies (The Economic Environment for Clinical Research & Development in the UK, Novartis, 2012) *"Trials in the UK are, on average, 70% more expensive than trials conducted in Poland and 30% more expensive than trials conducted in Germany.*" In addition, there has been a widely varying cost of conducting a study throughout the UK and inconsistent and non-transparent methods used by NHS Trusts to calculate commercial prices. This is now being mitigated by a number of world-first initiatives to strengthen the UK's competitive position to provide quality, over and above simple numbers.

7.4. These initiatives include the central role played by well-resourced R&D Office infrastructure within the HRA Processes, aligned with CRNs, to minimise delays in delivering against clinical trials. This performance is monitored by the Clinical Trials Platform to which participating Trusts must provide a quarterly data submission.

7.5. The price variability, especially for multi-centre studies, linked with unreliable delivery of patients and their data (time, target and accuracy), has been identified by industry as a significant factor in explaining why the UK has, in recent years, not been seen as a cost effective place to conduct later phase clinical trials.

7.6. As a remedy to these issues, the NIHR CRN released the Standard Industry Costing Template in May 2008 (revised April 2014) (https://www.crn.nihr.ac.uk/wp-content/uploads/Industry/GUIDE%20to%20Industry%20Costing%20Template-APRIL2014.pdf). This research pricing tool has been adopted as the industry standard (including recommendation for its use by the Association of British Pharmaceutical Industries) and has provided companies and NHS Trusts with a clear and transparent method in negotiating and establishing a price for commercial research within the NHS. Along with the Model Commercial Trial Agreement (mCTA) http://www.abpi.org.uk/our-work/library/guidelines/Pages/mcta-england.aspx these provide a solid, competitive set of tools for facilitating new trials.

7.7. The standard industry template is now hosted via CPMS, and was modified in 2019 and will be continuously updated using this new technology. NHS and other partners can access the CPMS data relating to a trial via an organisation login (usually the R&D Office) provided by the NIHR.

8. Using the Standard Industry Costing Template

The Standard Industry Costing Template forms the basis of the costing process that has been developed on behalf of the NIHR, and addresses a specific recommendation made in the Cooksey Report, which highlighted the need for a transparent and consistent national costing system. Although developed primarily for the facilitation of studies managed via the NIHR Clinical Research Networks, the methodology is also freely available to companies and NHS Trusts intending to run trials (commercial or non-commercial) outside of the Networks.

Although designed primarily for commercial/industry research, the methodology adopted for this costing template is readily applicable to non-commercial studies. In establishing the true cost of either a bid for funding, or the local cost of a non-commercial grant, the approach taken of breaking down the schedule of activities into direct, in direct or treatment costs etc. will ensure full transparency for later income distribution.

Advantages of the NIHR CRN Industry Costing process:

- Provided free via the online CPMS platform and with a single, national central review of proposed costs.
- Provides a clear methodology, and is the preferred method to calculate consistent and transparent prices associated with industry-sponsored studies to support the Life Sciences industry, the NHS and the NIHR Networks.
- Ensures all NHS Trusts are fully reimbursed for any activities associated with industry studies, in accordance with the requirements of the NHS Finance Manual
- Identifies standard rates for staff time, overheads, capacity building, investigations and costs for departments supporting research, which are acceptable to all parties

- Speeds up the negotiation process for costing and is one of several tools being introduced to speed up trial initiation and ensure the Networks provide a value for money environment for trials
- Provides clear guidance for Industry and the public sector.

The NIHR Standard Industry Costing Template provides a standard tool to calculate the prices associated with individual industry-sponsored studies. The activities documented in the protocol are entered by the company into the template. The template automatically calculates the full costs of the study unique to the study site (i.e., the cost to the NHS inclusive of direct costs and overheads). Additionally, the template generates the total price to be charged to the company (comprising the full cost plus a capacity building element and a local cost adjustment for each Trust, subject to the single national costing level). The individual costing elements of the Industry Costing Template are described in full in its support and guidance document, Costing Industry Sponsored Research through the NIHR Networks.

The template provided by the sponsor is intended as a starting point for limited negotiation (as the national process provides a baseline framework) and is subject to local review prior to finalisation by the NHS Host. The local review is conventionally undertaken by the Trust R&D Office or Department with support from Trust Finance to ensure that all eligible costs are detailed and appropriately recovered, and also should there be the need for sub-contracting elements of provision with other organisations (typically Pathology services etc.). This internal review builds upon work with Study Sponsors that may take place within the CRN Study Support Service. The elements that make up the template are detailed below:

Direct Costs

NHS Staff Time: {The fee paid by the Sponsor to cover the cost of the research teams' involvement}

Investigation Costs: {NHS Direct Costs for investigations}

Indirect Costs (previously Overheads)

An automatic 70% indirect cost is added to the staff costs only. These indirect costs include physical aspects such as heating, lighting, building maintenance and security, as well as the support functions required to deliver a clinical trial such as finance, general administration, human resources, information systems and corporate management.

Capacity Building:

A capacity building rate of 20%, is added to both direct staff time costs and investigations. This should be considered as 'system optimisation' which is designed to build sustainable research and innovation capacity to the benefit of all research partners.

Market Forces Factor (MFF):

NHS England, commissioned by the Department of Health, annually publishes a Market Forces Factor tariff via the group 'Monitor' as part the National Tariff. This factor provides an adjustment value to accommodate the unavoidable cost differences of providing healthcare across the country; this is incorporated into the costing template.

Pharmacy Costs:

Pharmacy costs are calculated separately and not included in the per-patient budget. These costs reflect the work involved in the set-up, maintenance and close-down of the study for the pharmacy department, which is not directly dependent on the number of patients.

Set-up and Other Trial-related Costs:

The pre-trial and ongoing related study costs are managed through the use of set-up fees and separate costs which are assigned to the relevant department. The Industry Costing Template uses

recommended fees based on national averages to provide a list of potentially applicable fees depending on the study requirements.

Once the costing template has been applied to a study, a per-patient budget is generated which has all these various costs built in, along with the one-off fees. At this stage an NHS organisation is aware of all the potential income, and can be assured that all costs are met, and can then consider how this will be distributed.

The National Contract Value Review Process (NCVR)

Work on the NCVR process began in 2018/19 with the aim of bringing together two key elements to improve commercial contract research study set up:

1. The use of an unmodified model site agreement and standard costing methodology, including the use of the interactive costing tool (iCT) has been mandated since October 2018.
2. The introduction of a national coordinator role (now referred to as contract value review coordinator) responsible for completing the NCVR for the study, ensuring that NHS providers achieve full cost recovery associated with delivering a commercial research study.

The NCVR is underpinned by the National standard contract and the National directive on commercial research studies. After a period of review the National Directive has been updated to reflect the revised process and incorporates the following additions:

1. A single national price list to facilitate study costing, with NHS organisations required to confirm either that they adhere in full to the costing tool price, or to provide up-front information on price variations and details of what this variation means for commercial sponsors. This price list will be based upon the data collected for the National Institute for Health and Care Research (NIHR) Clinical Research network (CRN) interactive costing tool (iCT): getting started. This information will be available to commercial companies to inform their selection of NHS organisations to take participate in the study.
2. On a study by study basis, a single negotiation of the resources required to deliver that study in the NHS will be undertaken by a contract value review coordinator on behalf of all participating organisations. The outcome of this negotiation being the application of the costing tool price calculations, with any site-specific variations, and the local execution of the contract, with no subsequent price negotiation by participating organisations.
3. From 1 October 2022 all new commercial research proposals submitted for a study resource review will undergo a review by the lead site. Following this review eligible studies will enter into the NCVR process.
4. Eligible studies are all those commercial studies which will be conducted in acute, specialist and mental health trusts in England and counterparts in the devolved administrations, with the exception of phase I – IIa and advanced therapy medicinal product (ATMP) studies.

This policy indicates that LPT will adhere to the NCVR process and outputs.

9. Contracting and Income Collection

It is critical that an NHS Organisation establishes clear processes and accountability for effective contract negotiation and subsequent trial management, together with timely and effective income collection from commercial sponsors. The key steps and responsibilities are:

Step	Lead Responsibility	Supported by/Delegated to:	Accountability
Submitting Expression of Interest/Site Feasibility	R&D Office	Potential PI; R&D Delivery Team Lead; R&D Finance; Service R&D Lead; CRN:SSS[2]	CEO via R&D Head
Identifying Possible Conflicts of Interest	R&D Office	Potential PI; Sponsor:	CEO via R&D Head
Liaising with Sponsor regarding any new trial proposal & subsequent negotiations	R&D Office	Potential PI; R&D Delivery Team Lead; R&D Finance; Service R&D Lead; CRN:SSS	CEO via R&D Head
Quantification & agreement of the detailed work required to complete a commercial or non-commercial trial, including staff time, interventions and tests required	R&D Office	Potential PI; R&D Delivery Team Lead; Service R&D Lead; Support Departments; CRN:SSS	CEO via R&D Head
Obtaining agreement from relevant support departments such as R&D, pharmacy and pathology	Potential PI; Delivery Team Lead	R&D Operational Lead; R&D Delivery Team Lead; Service R&D Lead; R&D Business Manager	CEO via R&D Head
Ensuring Principal Investigator oversight throughout the process	Sponsor; R&D Office	R&D Delivery Team Lead; Service Management	CEO via R&D Head
Obtaining R&D confirmation / ready to start (Post HRA Approval)	Sponsor / Study Support Service	R&D Office; R&D Delivery Team; R&D Admin	CEO via R&D Head
Obtaining financial approval prior to contract signature	Sponsor / Study Support Service	R&D Office; R&D Delivery Team; R&D Admin	CEO via R&D Head
Contract signature and record keeping	Sponsor / R&D Operational Lead[3]	R&D Office; R&D Delivery Team; R&D Admin	CEO via R&D Head
Invoicing and Credit Control	Sponsor / R&D Business Manager	R&D Delivery Team Lead; Investigator	CEO via R&D Head
Monitoring and reporting activity	Sponsor / R&D Operational Lead	R&D Business Manager(s)/EDGE Local Data Administrator(s)	CEO via R&D Head
Income distribution in accordance with Trust policy	R&D Finance Lead	R&D Office / R&D Business Manager	CEO via R&D Head
Contract Amendments	Sponsor	R&D Office / R&D Business Manager	CEO via R&D Head

9.1 Income distribution model approach

[2] CRN:SSS is the Clinical Research Network Study Support Service designed to provide a consistent and transparent experience for investigators in setting up studies in the NHS. "Approval" remains the province of the host NHS organisation subject to capacity review, but the CRN:SSS may play a facilitative role.

[3] Unless Contract value would breach Trust Standard Financial Instructions

A consistent and transparent income distribution model is the most effective means of ensuring robust oversight with appropriate incentivisation to services and individuals. This will both ensure that all costs are met, together with an understanding of the actual profit that may be available for re-distribution back to individual departments.

Transparency is achieved by good local accounting allocations, the consistent application of distribution rules, and oversight through a central enabling function (such as the R&D Office). The usage of re-distributed income should be managed and monitored through spending plans reviewed and approved centrally by the NHS Organisation (in LPT This would be the R&D Committee) to ensure both an integrated approach and as part of the strategic development of R&D Capacity.

Due consideration must be given to special circumstances with regard to NIHR CRN Portfolio studies, to ensure that network resources are properly reimbursed, and to avoid double-funding. The essential elements of the income distribution model are identical for Portfolio and Non-Portfolio studies where income is generated. Therefore, once received, the income distribution model is outline below:

Type	Model
Direct Costs (NHS Staff Time)	These should be reimbursed directly to the staff member's department. Where studies involve University staff, an agreement should be in place between the NHS organisation and the University to agree suitable distribution of the NHS Staff Time costs or the mechanism to be employed to compensate for the work involved. • Reimbursement to CRN of time committed by the CRN East Midlands RST (flexible Research Support Team) is expected where these are deployed, subject to a separate mechanism agreed before study initiation. • Where a study team member is already funded by CRN, this activity cannot also be funded by commercial study income, as double funding is not legal. This funding may be retained by the CRN Partner Organisation, but usage will be subject to review meetings with CRN with the expectation that it is reflected in revisions to infrastructure plans and reinvested appropriately.
Investigation Costs	The funding for the investigations (e.g. scans, pathology tests etc.) should go directly to the appropriate support department to cover the actual costs. In some cases these costs may go to a non-NHS provider, if this has been expressly agreed and contracted for the provision of their services.
Indirect Costs (aka Overheads)	The distribution of the indirect cost element should be subject to Trust Standard Financial Instructions. It is recommended that the model for LPT is that 50% is retained corporately by the Trust, sub-divided on a 60/40 split between Corporate (Service) and R&D Costs. Therefore, 50% of indirect costs are due to the Investigator(s) Account, which may be held within the host Service, or centrally ring-fenced within the R&D Cost Centre and used for developing further research. The principles behind the use of residual funding are outlined in Appendix 2.
Capacity Building	The intended use of the Capacity Building element within the NHS organisation should be clearly documented to support and evidence its' reinvestment in research, and to monitor the outcomes of such investment via the approving authority. Where commercial income accrues as a result of utilisation of CRN infrastructure (for portfolio studies), the further usage of this income would be discussed and agreed in Budget Review meetings with CRN.
Pharmacy Costs	The funding attributed to Pharmacy (or other support departments) will be reimbursed, in full to cover their actual costs.
Set-up & Other Trial related Costs	An element of the set-up work for NIHR Portfolio studies (commercial and non-commercial) may be undertaken by the CRN:East Midlands, which is funded by NIHR to provide this infrastructure. Therefore, the R&D management fee will flow to the host R&D department with other

	costs being allocated to the appropriate cost centre where the activity occurs; typically, the Site initiation fee allocated to the research team and the support department set-up fee to the relevant support department.
University Staff:	The NHS Organisation and the University should establish arrangements within their local Memorandum of Understanding or service level agreements to recover costs incurred through the involvement in commercial contract studies, which may also include honorary employment contracts where appropriate. The University cost recovered should not exceed those agreed by the NHS Organisation with the Sponsor for the University staff or facilities.

9.2 Industry Costing Template (Details) aka interactive costing tool (ICT)

There are several elements of the Industry Costing Template: Per Patient Budget, Pharmacy costs, R&D and Other trial related costs.

Additional information can be found at
http://www.crncc.nihr.ac.uk/index/industry/costing.html.

Per Patient Budget

The per patient budget is calculated by adding the following elements together:

Staff costs: NHS direct costs + 70% overhead + 20% capacity building.
Investigation costs: NHS direct costs for investigations + 20% capacity building

Overheads (Indirect Costs)

In the Industry Costing Template a standard overhead rate of 70% is added to the staff costs only of the study. This includes the overheads payable to the Trust for indirect costs (e.g., heating, lighting, building maintenance, security, finance, general admin, human resources, corporate management and all other resources which allow the organisation to function).

The 70% overhead rate used within the Industry Costing Template broadly captures the immediate management costs incurred by organisations in delivering a service and also provides for a high-level, corporate overhead associated with the efficient management of an organisation or clinical site (e.g., corporate oversight offered by the CEO, the finance director, the Head of R&D, R&D Office costs) and others to ensure efficiency and cost savings within the organisation/unit). This includes the corporate responsibility to drive research and find efficiencies to incentivise individuals and services involved in research and delivering initiatives that find savings and efficiencies that deliver commercial research at the margins of planned services. The application of a 70% overhead is an attempt to both standardise terminology and to ensure that there was a mechanism within the Standard Industry Costing Template to capture indirect costs with other utility and efficiency margins for the Trusts. Where a particular study is undertaken by an NHS and an Academic organisation in partnership, all NHS direct and indirect costs must be covered, with a fair proportion of overheads split between organisations.

Capacity Building

A capacity building rate of 20% is added to both staff costs and investigations. It is intended that this element should be ring-fenced for building research capacity in the local research community, to ensure a greater volume of research can be delivered in the future.

Pharmacy costs

Pharmacy costs are calculated separately and not included in the per-patient budget. These costs reflect the work involved in the set-up, maintenance and close-down of the study for the pharmacy department, which is not wholly dependent on the number of patients or study design.

R&D and Other trial related costs

The pre-trial and ongoing R&D related study costs are managed through the mixed use of set-up fees and separate costs, documented and paid upon completion or delivery. The Industry Costing Template uses a recommended R&D set-up fee based on the national average of fees charged. This R&D set-up fee covers pre-trial work; especially the costs incurred negotiating the study costs, finalising the contract and issuing Confirmation of Capacity & Capability (through the HRA assess, arrange, confirm process: see R&D/SOP/014 Organisational Research Capacity Assessment (ORCA)), as the emphasis for NHS Organisations moves towards the practical delivery of studies (i.e. Do we have capacity? Are all the costs covered? etc.) through the implementation of the Health Research Authority (HRA) Single Assessment Process removing much of the former research governance processes. The costs of meeting other trial related costs can be documented as needed and should be listed separately from the per patient budget amount within this section.

10. Income Distribution Model

Staff costs, investigation/procedure costs and pharmacy charges will be paid directly to the relevant departments that have incurred the costs, via the designated R&D PICC Code.

Services will be fully engaged in the decision to host industry-sponsored research, with the expectation that nominated researchers (when acting as Principal Investigator) must be given time to carry out the research. Income to the department can therefore be used to allow for "backfill" of the researchers post.

If backfill is not provided the researchers cost will be allocated to the Investigators[4] nominated research fund to facilitate future research.

Indirect costs will be divided between the Investigator and the Trust – 60:40 split

- Investigator to reinvest income in research.
- NHS organisation R&D to cover indirect costs of NIHR research activity

Capacity Building attributed to investigations will be reinvested by R&D, guided by the R&D Committee.

The key to the distribution model is fairness if the department aids in the facilitation of the research it will be reimbursed, however, if the department plays a passive or disinterested role in the research then it is appropriate that the researcher is allowed to invest the income into further research.

11. Accounting Treatment & the Protected Income Cost Centre (PICC)

Research activity is usually time limited, and does not easily fit within the financial year, and may span several financial years. In order to meet the requirements of the "financial health check" audit undertaken by CRN, and the grant reporting stipulations (such as annual FSTOX), it is also critical that individual project budgets are separate, ring-fenced and to some degree carried over financial year end (subject to Finance Lead agreement).

[4] The "Investigator" as referenced, is always the local individual within the Trust.

Staff costs, investigation costs and pharmacy charges will be coded directly to the relevant study cost centre. The income will be distributed to the departmental, investigator, R&D and Trust cost centres via Departmental Transfer. In this way the PICC Study cost centre becomes the “Income & Expenditure” account for the study providing transparency to both the Sponsor and the Trust.

The 70% overhead/indirect cost charge will be split 60:40 and coded to Trust overheads and an R&D account held for the investigator on the invoice to the commercial company.

The 20% capacity building element will be credited to the central R&D Cost Centre (including study-specific cost centre) on the invoice to the commercial company.

Funds held in the R&D accounts for either the Investigator or R&D can only be accessed with the agreement of the R&D Committee Lead (or delegated authority, usually R&D Lead).

The two capacity building accounts (70% investigator overhead and 20% capacity building cost centres) will be held under the R&D PICC (including sub-codes attributable to individual studies).

Individuals and teams holding R&D accounts should submit annual spending plans to the Trust R&D Finance Lead between Jan – Feb each Financial Year. Annual spending plans will be agreed with the R&D Board Lead (or delegated authority) to guarantee that funds are utilised to discharge the fundamental principle of encouraging key stakeholders to develop capacity for new research within the Trust.

The PICC (as detailed earlier) is subject to Trust standing financial instructions, with the use of the resources therein subject to audit. Any movement of funds into and out of these centres is therefore closely monitored.

It is recognised that in any one financial year, the overall accrued resources nominally available within all accounts within the PICC could not be spent in year, as the PICC is often used to balance overspend elsewhere in the Trust. These balances are restored at the baseline of the subsequent financial year.

12. Conflicts of Interest

Conflicts of interest are pervasive in medical and clinical research and must be managed effectively to maintain the integrity and transparency of research and public trust. Although most of the focus on conflicts and their management has been on financial conflicts, it is likely that non-financial and intrinsic conflicts have similar potential for creating bias and exerting undue influence on the judgment and actions of the investigator. This policy notes the need to effectively identify conflicts of interest, whether in respect of:

- Regulation of the individual
- Design and regulation of the research process
- Critical assessment of the research product

This policy therefore references the R&D SOP “Research Misconduct & Fraud”, as a means of mitigating negative aspects of research incentivisation, whilst also balancing the management of such issues with the overriding need to promote high

quality research, protection for research subjects, and public trust in medical research.

This policy also pays due regard to the "Research Transparency" agenda promoted by the HRA. Research transparency is central to ethical research practice. Research studies should be registered, and the results made public, so that participants are protected from unnecessary studies and research funding maximised. When research is carried out openly and transparently, everyone will be able to see what research is happening and the outcomes from finished studies.

13. Standards and Performance Indicators

The model and process within this policy relates to CQC Regulation 17 "Good governance", by establishing a robust and transparent system, with clear lines of accountability for disparate sources of, and utilisation of, research income.

TARGET/STANDARDS	KEY PERFORMANCE INDICATOR
Good Governance	Annual audit of Research Cost Centres and transactions.

14. Conclusions

A. The money generated from industry-sponsored studies is a valuable source of income for NHS Trusts. This income can be used to encourage key stakeholders to develop capacity for new research within the Trust and increase the volume and therefore future income generation.
B. It is important that investigators are incentivised to carry out commercial research, but this should not be to the detriment of the NHS Trust and NIHR Local Research Networks, who must be able to recover their costs.
C. The NIHR CRN wants to ensure that systems to manage and distribute commercial income work towards and achieve the strategic research priorities outlined by the local research community and the Department of Health. A critical part of achieving these objectives will be making sure that investigators and service support departments in the research system are sufficiently incentivised and reimbursed.

15. References

This policy was drafted with reference to the following:

The Economic Environment for Clinical Research & Development in the UK, Novartis, 2012

The Plan for Growth. HM Treasury (Department for Business, Innovation & Skills), March 2011

Commercial Clinical Trials: How does the UK really compare with Europe? Insight, December 2014

Model Clinical Trial Agreement (mCTA). UKCRC (United Kingdom Clinical Research Collaboration) 2011

Model Clinical Trial Agreement (mCTA) and Clinical Research Organisation mCTA (CRO-mCTA) (March 2020) https://research.hscni.net/model-clinical-trial-agreement-mcta-and-clinical-research-organisation-mcta-cro-mcta

Model Non-Commercial Agreement (mNCA); UKCRC 2008

Attributing the costs of health and social care Research &Development (AcoRD); DH Research and Development Directorate (April 2012)

Guide to the NIHR CRN Industry Costing Template: Costing Industry Sponsored Studies; NIHR CRN April 2014

NIHR The interactive Costing Tool (iCT): Getting started (2019) https://www.nihr.ac.uk/documents/interactive-costing-tool-ict-getting-started/12170

NIHR Model site agreements (model contracts, standard research agreements) (2019) https://www.nihr.ac.uk/documents/model-site-agreements-model-contracts-standard-research-agreements/11612

16. CASE STUDIES: Recommended Income Distribution Model[5]

All figures within Case Study models (Per Patient Budget divided into Procedures & Investigations) are drawn from a completed Standard Industry Costing Template, agreed between Commercial Sponsor and Site.

Study Summary 1
A complex, industry-funded interventional study in secondary care (in-patient setting), requiring the input of a CRN-funded staff member over the full course of the study.

TOTAL STUDY BUDGET (Inclusive of Indirect Costs, Capacity Building & Market Forces Factor)

Per patient Budget	**x**	**Number of Patients:**	**=**	**Total Patient Budget:**	**+**	**Pharmacy Costs:**	**=**	**Total Study Budget:**
£7950		**10**		**£79500**		**£5625**		**£86650**
						Set-up Costs: £1525		

All values inclusive of Market Forces Factor (in this example 1.048 (4.8% uplift)

Total Patient Budget: (£79500)	**PROCEDURES: (£56,250)**			
	Staff Time	£29623	Retained by Employing Department	£21,503
			Direct Costs of NIHR CRN-funded staff (potential double funding)[6]	£8,120
	70% Indirect Cost	£20710	60% of Indirect Costs (£12426)	Allocated to Trust for indirect cost coverage
			40% of Indirect Costs (£8284)	Allocated to a research account for the PI & Team
	20% Capacity Building:	£5917	*(retained by Trust for re-investment in research)*	
	INVESTIGATIONS: (£23,250)			
	Value	£18955	*(retained by Trust to reimburse provider support departments)*	
	20% Capacity Building:	£4295	*(retained for re-investment in research)*	

[5] Assume full details with standard costing template.
[6] CRN Infrastructure staff can be used to support commercial research, but the role(s) cannot be double-funded – therefore the use of such funding must be agreed with CRN

PHARMACY COST: (£5625)		
Staff Time:	£2959	*Direct staff costs retained by Pharmacy*
70% Indirect Cost	£2071	*Indirect Costs retained by Pharmacy or Trust*
20% Capacity Building:	£592	*To Pharmacy for re-investment in research*

Set-up COST: (£1525)		
R&D Management Fee:	£733.60	*Full fee distributed to the Trust R&D Department where set-up task(s) performed/costs incurred.*
Support Department Fee:	£372.20	*Full fee distributed to the Trust Support Department where set-up task(s) performed/costs incurred*
20% Capacity Building:	£419.20	*Full fee distributed to the Trust Clinical Department where set-up task(s) performed/costs incurred*

Total Non-Allocated Funding		
Use subject to Trust rules on re-investment:	£10,212	*This assumes that **all** legitimate NHS costs have been covered (including expenses etc.)*
R&D Management Fee	£733.60	*Retained for R&D Office.*

Study Summary 2

A complex, industry-funded interventional study in secondary care (in-patient setting), run through a partnership between the NHS Organisation, an Academic (University) partner and also requiring the input of a CRN-funded staff member over the full course of the study.

TOTAL STUDY BUDGET (Inclusive of Indirect Costs, Capacity Building & Market Forces Factor)

Per patient Budget	**x**	**Number of Patients:**	**=**	**Total Patient Budget:**	**+**	**Pharmacy Costs:**	**=**	**Total Study Budget:**
£7950		**10**		**£79500**		**£5625**		**£86650**
						Set-up Costs: £1525		

All values inclusive of Market Forces Factor (in this example 1.048 (4.8% uplift)

Total Patient Budget: (£79500)	**PROCEDURES: (£56,250)**			
	Staff Time	£29623	Retained by Employing Department (NHS)	£11,483
			Retained by Employing Department (University – assume not already CRN-Funded[7])	£12,020
			Direct Costs of NIHR CRN-funded staff (potential double funding)	£6,120
	70% Indirect Cost	£20710	30% of Indirect Costs (£6213)	Allocated to Trust for indirect costs
			30% of Indirect Costs (£6213)	Allocated to cover University indirect costs (<u>only</u> where NHS Costs are already recovered).
			40% of Indirect Costs (£8284)	Allocated to a research account for the PI & Team
	20% Capacity Building:	£5917	*(retained by Trust for re-investment in research)*	
	INVESTIGATIONS: (£23,250)			
	Value (NHS)	£16455	*(retained by Trust to reimburse provider support departments)*	
	Value (University)	£2500	*(transferred to University for specific investigation activity)*	

[7] Double-funding is not permissible except with the expressed permission of CRN.

	20% Capacity Building:	£4295	*(retained for re-investment in research)*

PHARMACY COST: (£5625)		
Staff Time:	£2959	*Direct staff costs retained by Pharmacy*
70% Indirect Cost	£2071	*Indirect Costs retained by Pharmacy or Trust*
20% Capacity Building:	£592	*To Pharmacy for re-investment in research*

Set-up COST: (£1525)		
R&D Management Fee:	£733.60	*Full fee distributed to the Trust R&D Department where set-up task(s) performed/costs incurred.*
Support Department Fee (NHS):	£166.10	*Full fee distributed to the Trust Support Department where set-up task(s) performed/costs incurred*
Support Department Fee (University):	£166.10	*Full fee distributed to University department for specific non-NHS activity required*
20% Capacity Building:	£419.20	*Full fee distributed to the Trust Clinical Department where set-up task(s) performed/costs incurred*

Total Non-Allocated Funding		
Use subject to Trust rules on re-investment[8]:	£10,212	*This assumes that **all** legitimate NHS costs have been covered (including expenses etc.)*
R&D Management Fee	£733.60	*Retained for R&D Office.*
Total Fee to University Partner:	£18,399.10	*This is the <u>maximum</u> proportion of costs legitimately available to the University partner, as the first priority is to ensure all NHS costs are met.*

[8] Re-investment in respect of research capacity development.

Study Summary 3

The following case study is a fictional example of a non-commercial study, where the primary costs have been determined using AcoRD (Attributing Costs of Health & Social Care R&D) Guidelines for determining Research Costs, Service Support Costs, Treatment Costs and Excess Treatment Costs. AcoRD is more fully explained in Appendix 4.

An observational, charity-funded study across the organisational boundaries of a community mental health Trust and a voluntary sector provider, run through a partnership between the NHS Organisation, an Academic (University) partner and also requiring the input of a CRN-funded staff member over the full course of the study.

Superficially, this is very different to the instances above where the funding is from a commercial source. However, the same principles of ensuring full cost recovery and balanced incentives to individuals and organisations are retained. The major difference is that such studies do not conventionally adopt the "per patient budget" approach, although there are significant benefits to doing so.

Research Grant Breakdown			
Direct NHS Staff Costs	*(inclusive of 70% overhead if applicable)*	*Cost Attribution*	*Annual Value*
	Consultant Paediatrician (0.5 wte)	*Any of Research Cost/Treatment Cost/Support Cost*	*£36,298*
	Health Visitors (Band 6) 1.0 wte * 2	*Research Cost*	*£81,394*
	Clinical Administration (Band 3) 0.2 wte	*Research Cost*	*£6,391*
Direct Non-NHS Costs:	*(inclusive of relevant institutional overhead, if applicable)*		
	Senior Lecturer 0.2 wte	*Research Cost*	*£18,118*
	Research Associate (1.5 wte)	*Research Cost*	*£76,384*
	Charity Co-ordinator (0.2 wte)	*Research Cost*	*£10,006*
Other Direct Costs:			
	Volunteer Expenses/Payments	*Research Cost*	*£7500*
Investigations & Procedures			
	Screening Participants	*Research Cost (met by CRN Infrastructure)*	*N/A*
	Investigations/Psychometric Tests	*Research Cost (partially through CRN infrastructure)*	*N/A*
	Informed Consent	*NHS Support Cost (via CRN SSC Procedure)*	*N/A*
	Novel Therapy/Patient Pathway	*Treatment Cost or Excess Treatment Cost*	*To be agreed by Host and/or CCG*

In all cases, the Research Costs (Part A or Part B; AcoRD) must be met through the research grant, except where offset by the commitment of CRN Infrastructure if applicable. All NHS Staff costs are inclusive of the agreed overhead, which is retained by the host Service/Department. The level of overhead for third party institutions is set out in the Research Contract and paid directly to that institution where the costs are incurred. Where there are NHS Costs of any kind, it must be clear through which mechanism these are being met, as NHS subsidy for research activity is not permissible without expressed Service agreement.

The key difference between commercial and non-commercial research is that there is no capacity building element available for re-investment, as at best, such studies are cost-neutral to the NHS.

17.0 Training needs

There is no training requirement identified within this policy. This model for income distribution is intended as a management tool, and to provide transparency and assurance to individuals and teams that their contribution to research delivery (commercial or non-commercial) is appropriately recompensed.

18.0 Monitoring Compliance and Effectiveness

Ref	Minimum Requirements	Evidence for Self-assessment	Process for Monitoring	Responsible Individual / Group	Frequency of monitoring
15	Maintenance of Income Distribution Log/Ledger	Model devised within R&D negotiations with Sponsor	R&D Finance	R&D Committee	Annually

Appendix 1

Training Requirements

Training Needs Analysis

Training topic:	None Required
Type of training: (see study leave policy)	☐ Mandatory (must be on mandatory training register) ☐ Role specific ☐ Personal development
Division(s) to which the training is applicable:	☐ Adult Mental Health & Learning Disability Services ☐ Community Health Services ☐ Enabling Services ☐ Families Young People Children ☐ Hosted Services
Staff groups who require the training:	*Please specify…* N/A
Regularity of Update requirement:	N/A
Who is responsible for delivery of this training?	N/A
Have resources been identified?	N/A
Has a training plan been agreed?	N/A
Where will completion of this training be recorded?	☐ ULearn ☐ Other (please specify)
How is this training going to be monitored?	N/A

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

Name	Designation
Dr Dave Clarke (Author)	Interim Lead (R&D)
Dan Kumar	Deputy Chief Operating Officer (EM:CRN)
Francesca Desai	Industry Liaison (East Midland CRN)
Beth Moss	EM:CRN Chief Operating Officer
Jo Edgar	Research Business Manager
Dr Karishma Joshi	Research Support Officer (RPC Link)
Trudi Simmonds	Senior Civil Servant (NHS R&D Finance)
Manjit Dharam	R&D Finance Lead

Circulated to the following individuals for comment

Name	**Designation**
Members of R&D Committee	
Professor Sudip Ghosh	Deputy Medical Director
Sharon Murphy	Director of Finance

Appendix 4

Due Regard Screening Template

Section 1	
Name of activity/proposal	Research Income Management
Date Screening commenced	
Directorate / Service carrying out the assessment	
Name and role of person undertaking this Due Regard (Equality Analysis)	
Give an overview of the aims, objectives and purpose of the proposal:	
AIMS:	
OBJECTIVES:	

Section 2	
Protected Characteristic	**If the proposal/s have a positive or negative impact please give brief details**
Age	Neutral
Disability	Neutral
Gender reassignment	Neutral
Marriage & Civil Partnership	Neutral
Pregnancy & Maternity	Neutral
Race	Neutral
Religion and Belief	Neutral
Sex	Neutral
Sexual Orientation	Neutral
Other equality groups?	Neutral

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:			
Policy and process designed for compliance with national guidance, already assessed for impact.			
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

DATA PRIVACY IMPACT ASSESSMENT SCREENING

Data Privacy impact assessment (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet Individual's expectations of privacy.
The following screening questions will help the Trust determine if there are any privacy issues associated with the implementation of the Policy. Answering 'yes' to any of these questions is an indication that a DPIA may be a useful exercise. An explanation for the answers will assist with the determination as to whether a full DPIA is required which will require senior management support, at this stage the Head of Data Privacy must be involved.

Name of Document:	Research Finance Policy	
Completed by:		
Job title		**Date**

Screening Questions	**Yes / No**	**Explanatory Note**
1. Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document.	No	
2. Will the process described in the document compel individuals to provide information about them? This is information in excess of what is required to carry out the process described within the document.	No	
3. Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information as part of the process described in this document?	No	
4. Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?	No	
5. Does the process outlined in this document involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics.	No	
6. Will the process outlined in this document result in decisions being made or action taken against individuals in ways which can have a significant impact on them?	No	
7. As part of the process outlined in this document, is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or other information that people would consider to be particularly private.	No	
8. Will the process require you to contact individuals in ways which they may find intrusive?	No	

If the answer to any of these questions is 'Yes' please contact the Data Privacy Team via Lpt-dataprivacy@leicspart.secure.nhs.uk
In this case, ratification of a procedural document will not take place until review by the Head of Data Privacy.

Data Privacy approval name:	
Date of approval	

Appendix 6:

Management of Non-Commercial Grant Income

1. There are many strong similarities between the principles underlying commercial studies and those that are designated as non-commercial (even though on occasions some funding may come from commercial sources and still be non-commercial).
2. The principles within the industry costing template can be adopted in terms of itemising relevant activity, which should then follow AcORD guidance (see Appendix 4) in ensuring that these are correctly attributed and recovered where possible.
3. The introduction of the SOECAT (Schedule of Events Cost Attribution Template) reviewed and signed off by an approved reviewer (usually based in a CRN) ensures that activity within a study is correctly attributed. The SOECAT does not however, provide any sort of costing of such activity. Thus, during study negotiation, it is critical that so far as is possible any costs due to the Trust are recovered.
4. In contrast to commercial income, non-commercial grants may have differing treatments for indirect costs, and in many cases, funding bodies will not meet the FEC (Full Economic Cost) of University commitments.
5. Non-commercial grants will have direct and indirect costs specified within the award itself, and will vary according to the funding body.
6. All such grants will be assigned a specific Finance Sub-Code, through which all expenditure on staff or other costs is logged.
7. Non-commercial grants and income will include overheads, depending upon the particular characteristics and rules of the Funding Body. They do not as a rule include capacity building elements for re-investment.

Appendix 7:

Utilising Income Transparently within the PICC

1. The core principle of transparency is central to ensuring trust in the usage and distribution of R&D Income (Commercial or Non-commercial).
2. All income is held for the use of the income-generating individual and/or team, until it is explicitly no longer required; such as when a study is closed, which can in certain circumstances require residual funding to be returned to the sponsor.
3. All income is held within a holding account within the overall R&D Cost Centre (PICC), with specific sub-codes allocated to each individual project. This funding will be held therein until an appropriate call upon this resource is made.
4. Deposits and withdrawals for all studies, portfolio and non-portfolio are monitored both by Trust Finance and by the Research & Innovation Business Manager to ensure a robust process with checks and balances. A high proportion of these sub-codes will see extensive activity as studies are processed on a per participant basis.
5. Only nominated individuals and teams listed for each project specific sub-code within the overall holding account may make a call on this resource. Funding may not be vired between these sub-codes without the expressed permission of the local lead.
6. It is inappropriate (and subject to review by auditors) that funding may therefore lie "unused" within such accounts, therefore provision should be made for utilising this resource at an appropriate time, therefore:
    a. All sub-codes are linked to the planned study duration.
    b. In the first year after study close-down, funding within the sub-code remains for the sole use of the income generating team/individual. At three months before the expiry of this period, the key contact is forewarned of the expiry of this primary date, when a case may be made for further retention of the whole sub-code.
    c. In months 13-24, 50% of the residual, unallocated income will be transferred to the R&D Core Income Budget, to be used under the direction of the Head of R&D through the R&D Strategy group. This latter clause does not take effect if the named individual/team associated with the budget code is not warned (see Clause B), and should as a courtesy, be consulted before this funding is used.
    d. After two years post study close, the remainder of any unused income is also made available via the same provisions as above.

Appendix 8:

Source Guidance & Acknowledgements

1. Long-standing NHS Guidelines (HSG (97)32), indicate that NHS Trusts are obliged to recover all the additional costs of commercial research and development from the company or organisation concerned.

2. Extensive guidance initially through ARCO (2005) and ACoRD "Attributing the Costs of Health and Social Care Research & Development) (2012) provides a framework for the NHS and its partners to identify, attribute and recover any costs associated with the NHS in a robust, transparent manner. (see Appendix 4)

3. The NHS is specifically encouraged (under the "Plan for Growth") to support commercially sponsored research wherever possible as it offers opportunities to:
    3.1. Participate in drug and device development
    3.2. Evaluate new equipment
    3.3. Generate additional income for re-investment into further research, facilities and patient care.
    3.4. Become involved in the development of improved treatment for current and future NHS patients and the wider community.
    3.5. Make available potentially life-changing treatments otherwise unavailable.
    3.6. Ensure the UK remains a key player in the world life sciences industry.

4. The NHS Constitution confirms:
    4.1. The commitment of the NHS to "the promotion and conduct of research."

5. The Handbook to the NHS Constitution states:
    5.1. "the NHS will do all it can to ensure that patients, from every part of England, are made aware of research that is of particular relevance to them".

6. The NHS Operating Framework states:
    6.1. "the NHS must play it's full part in supporting health research."
    6.2. "all providers of NHS care will need to increase their participation in research."

7. Many industry-sponsored studies are also now included within the NIHR Portfolio and can access the staff and infrastructure provided through the 15 Clinical Research Networks. This priority is at least partly prompted by the flight of commercial trials from the UK. It is therefore essential that participation is encouraged, and transparent incentives are exist within the relevant regulatory frameworks. This document sets out principles and good practice for achieving this.

Appendix 9: AcoRD Attributing Costs of Health & Social Care Research & Development

AcorD provides a list of common research activities associated with research, with advice on their attribution to Research Costs, NHS Treatment Costs (Including Excess Treatment Costs) and NHS Support Costs

One of the key concepts here is to examine the primary purpose of the activity in question as a means of determining the correct attribution, and thereby, where responsibility for meeting costs lies.

Activities that are attributed to Research Costs include:

The costs of activities listed in Part A should be funded in full by all grant funders. The costs of activities listed in Part B will also need to be funded in full by grant funders except where the funder is a medical research charity that is a member of the Association of Medical Research Charities (AMRC) and the activity is undertaken by existing staff employed by the NHS, NIHR Clinical Research Network or other organisations funded by the NHS to provide patient care services. Under these circumstances, the cost of the activities in Part B will be met by the Department of Health.

Part A

1. Any screening tests/assessments, to determine whether a patient is eligible to participate in a study, performed after the patient has been approached to ask if they wish to participate in the study, but before they are accepted onto the study.
2. Study specific central trial co-ordination and management.
3. Patient randomization.
4. Investigations, assessments and tests relating to if, how, why and when an intervention/procedure works - in other words, activity which is intended to answer the research question.
5. Investigations, assessments and tests where the results are anonymous and unlinked to a patient identifier, or where the individual results will not be reported back to study participants or their clinicians, since such information is collected primarily for the purpose of answering the research question. However, exceptional circumstances may arise where there is an overwhelming clinical need to convey results to the clinician providing care. The possibility of such exceptional circumstances does not change the primary purpose.
6. Patient follow-up where the follow-up is not a part of individual patient clinical management.
7. Cash reimbursements or payments to volunteers to participate in the study.
8. All costs associated with placebos including but not limited to producing, formulating, disguising, shipping, storing and dispensing placebos, including administering sham treatments, since these costs do not form part of the patient's care and would not continue to be incurred once the study is finished.
9. Registration of trials, including MHRA clinical trial authorisation fees.
10. Data storage archiving of clinical research records.

11. Costs associated with making the results accessible.
12. Training where new skills are required to carry out the R&D activity, but not training in obtaining informed consent, or training to deliver the treatment under investigation.
13. Data analysis needed to answer the questions that the research study is addressing.

Part B

1. Local study trial co-ordination and management.
2. Data collection needed to answer the questions that the research study is addressing (including collecting data for and completing the report).
3. Regulatory preparation and compliance including obtaining ethical approval and complying with the Medicine for Human Use (Clinical Trials) Regulations 2004.
4. The time taken by Chief and Principal Investigators (CI and PI) to explain the study to professional colleagues, and to understand, the research elements of a study. (e.g. the time taken to explain the criteria for patient eligibility or to explain the randomisation protocol.

Activities that are attributed to NHS Treatment Costs include:

1. Supplying and administering the medicine/device/therapy being studied.
2. Supplying and administering any active comparators - including medicines, devices or therapies, but not placebo or sham treatments.
3. Training of clinicians to deliver the treatment.
4. Investigations and tests which would continue to be incurred if the patient care service in question continued to be provided after the R&D study has stopped.
5. Patient follow-up where this is required as part of the clinical management of a patient. If the primary purpose of the follow up is to inform the long-term evaluation of an experimental treatment, the activity should be attributed as a Research Cost. If the primary purpose of the follow-up is to monitor patient safety rather than efficacy, the activity should be attributed as an NHS Support cost.

Activities that are attributed to NHS Support Costs include:

1. The processing of the patient record to identify NHS patients who may be suitable to approach to ask if they wish to participate in a research project.
2. Obtaining informed consent from patients where the study is a health research study, taking place within the NHS.
3. Additional investigations, assessments and tests where the results are required by the patient's care team to ensure patient safety and where arrangements are in place to feed the results back to the clinician.

Appendix 10: PPI for Finance Policy (Karishma Joshi)

Referring to this: https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392

Within LPT, a historical group Enhancing Patient and Public Involvement Collaboration (EPPIC) had been running for many years and in July 2020, the decision was made to close the group and re-launch it as a new forum as a collaboration between the R&D Team, the Patient Experience and Involvement Team and Public Contributors. The new group launched in August 2020 and, from February 2021, has chosen to be known, though co-production as the Research Partners Collaborative (RPC), with funding held in the PICC.

The vision of the Research Partners Collaborative (RPC) Steering Group is to embed and support service users, carers, and the public in co-production of research within Leicestershire Partnership NHS Trust (LPT). This group will work in partnership with research active members of LPT staff to embed patient and public involvement in research. The group is in possession of fund which is designated to support patient and public involvement in research.

Historically in LPT, patient and public research partners have been remunerated at a rate of £10 per hour; however, consultation with other Trusts has shown that most comparable organisations offer payment in line with NIHR rates (2009).

It was the view of the RPC to ensure that research partners are appropriate remunerated as per the NIHR guidance rates, to showcase the groups commitment to service user involvement and meaningful collaboration. This was approved by the Trust R&D Committee in June 2021.

As such, remuneration rates for research partners reflect that of the NIHR guidance, as in the table below:

For involvement in a task or activity such as reading and commenting on an abstract which equates to less than half an hour.	£12.50
For involvement in a task or activity requiring little or no preparation and which equates to approximately one hour of activity or less. For example, participating in a focus group to provide feedback on a proposal.	£25
For involvement in a task or activity likely to require some preparation and which equates to approximately two hours of activity. For example, a teleconference with related papers to read or review a few short documents.	£50
For involvement in a task or activity where preparation is required and which equates to approximately half a day's activity. For example, participating in a meeting to interview a small number of candidates who have applied to join a committee or panel, participating in a focus group, or delivering training.	£75
For involvement in all-day meetings. For example, attending a committee or panel meeting as an observer prior to becoming an active public member of a committee/panel.	£150
For involvement in all-day meetings that require substantial preparation. For example, when chairing or co-chairing a meeting or when carrying out other discretionary work, which requires additional responsibilities.	£300

For participation in meetings remotely from home, a standing allowance per meeting to cover the cost of telephone calls, paper, printing ink and paper, internet connection and other home sundries.	£5
Please see the following link for further guidance: https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392	

Research Partners involved in PPI activities within LPT are offered to receive remuneration for their time either by BACS or by receiving vouchers of their choice following completion of an Expenses Claim Form. The Expenses Claim Form is submitted to lpt.research@nhs.net for approval from the Budget Holder (80002 SUCRAN Fund: Dave Clarke and Claire Armitage, 80003 Research Fund (EPPIC commitment 12586): Sarah Baillon), and subsequent processing.

Research Partners are made aware that it is their responsibility to complete their Expenses Claim Form accurately. They are also made aware that if they are in receipt of state benefits and claiming reimbursement from the Trust, it is the individual's responsibility to inform the benefit agency of any payments and/or vouchers, which may affect their benefits. In any cases of payment, it is also the individual's responsibility to ensure that payments are declared to HMRC, and if necessary, tax and NI is paid. Individuals can be paid less or turn down the payment, depending on their circumstances.