Leicestershire Partnership NHS Trust

R&D/POL/002
Adoption and Implementation of an Income Management and Distribution Model for Commercial (Industry) Research Trials & Non-Commercial Research Grants

The purpose of this document is to describe the structure and attribution of costs in research, and how this is manifested through ACORD guidance. Further, this describes the management of study-related income through the "protected income" cost centre, with especial attention to model income distribution arising from Commercial (Trials) Research through utilisation of the Interactive Industry Costing Template (NIHR CRN 2019). This model outlines the justification and process for incentivising individuals, services and teams to increase participation in commercial and/or funded research. The model can be usefully applied to income derived from non-commercial research (grants etc.)

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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	01/10/2019	Revision to include acknowledgement of detailing of the research “protected income” centre, HRA Changes, development of the interactive costing tool (June 2019), Excess Treatment Cost management etc.

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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

LPT must have **due regard** to the aims of eliminating discrimination and promoting equality when policies are being developed. Information about due regard can be found on the Equality page on e-source and/or by contacting the LPT Equalities Team.

The Due regard assessment is Appendix 8 of this document

Section A: Table of Definitions (Universal across R&D Activity)

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 Implementation Plan
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
NDA	Non-Disclosure Agreement
OID	Organisation Information Document
ORCA	Organisational Research Capacity Assessment
PI	Principal Investigator
PID	Performance in Initiating & Delivering Research
R&D	Research and Development (aka Trust R&D Office)
REC	Research Ethics Committee
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. Purpose of the Policy

The purpose of this document is to advise all stakeholders within the Leicestershire Partnership NHS Trust (the Trust), and partner organisations of the principles underlying the costing and management of clinical research income in the NHS, derived from commercial and non-commercial sources. This is to ensure that the availability and distribution of income from industry/commercially-sponsored trials, and from non-commercial grants is transparent, appropriately reimbursed, and to ensure that the levels of incentives for participation are fair and appropriate.

2. Summary and Key Points

2.1. This document focuses initially on processes for commercial income, as this model provides an exemplar for defining and reimbursing the costs of research in the NHS. Non-commercial income is not dissimilar in principle, with a growing convergence in terms of cost attribution through the Schedule of Events Cost Attribution Template (SoECAT), but this requires expert interpretation in order to ensure that all NHS Costs are properly covered (or agreed to be absorbed).

2.2. Interpretation of the SoECAT and the OID (Organisation Information Document) provided as part of the local information package form the Study Sponsor, is a key element of the ORCA Process (the LPT interpretation of "Assess, Arrange Confirm").

2.3. Whilst there is little or no "Profit" in commercial research in monetary terms, there is an implicit guarantee that all applicable NHS Costs will be paid for. The advent of the forthcoming Single Contract Value negotiation may mean that depending on local costs, the ability to support a commercial study may be affected. In both instances, the intangible value of access to new knowledge and new treatments must be considered

2.4. 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 once the costs for conducting the research are covered.

2.5. 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.

2.6. The key principles of commercial income distribution are:

2.6.1. Individuals and departments are fairly incentivised for their contribution to commercial research, and are appropriately recognised and encouraged by service management. These are not personal awards unless otherwise specified.

2.6.2. Any incentives to individuals would be reported through the normal process of self-declaration, to avoid any perception of conflict of interest.

2.6.3. All costs incurred by the Trust are fully recovered, and any instances of "double-funding" are identified and appropriately reimbursed.

2.6.3.1. Critically, where NIHR CRN-Funded members of staff are deployed to support commercial research, this income is retained in R&D to offset the cost of this support, as it is not permissible to subsidise commercial research through this infrastructure. This is operationalised through the monthly return to CRN on the use of the budget as a reduction in salary cost for the individuals concerned.

2.6.4. Investigators and potentially, the Trust can utilise commercial research income to fund additional, research-related activity.

2.6.5. Commercial research income can, with some limited exceptions, be distributed and carried over financial year end, in line with Trust financial control policies.

2.6.6. Commercial 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 Office Governance Budget to support the ORCA capability and assessment activity, and for staff development.

2.6.7. Where there are "Capacity-building" funding elements within the costing template/Study budget, the Service hosting the Investigator Team should have priority in using this funding. This funding should be retained in the named "protected study income" budget and should be authorised in writing by the Investigator Team if used for any other purpose.

2.6.8. Utilisation of funds held within a "protected income" budget is at the discretion of the Investigator Team, where it is expected that this is discussed and authorised with both R&D and Service Management.

2.6.9. Where funds held in a "protected income" budget have not been used, and there is no indication or plan to use, then this funding is recycled using the principles outlined in Appendix 4

2.7. Managing income distribution using this model will enable the Trust to:

2.7.1. Identify research active areas.

2.7.2. Potentially Identify research priorities for investment across the Trust.

2.7.3. Develop research capacity and culture for long-term sustainability.

2.8. The key principles of Non-Commercial Grant Income involve:

2.8.1. An understanding that Non-Commercial Income is either:

2.8.1.1. DIRECT (where an individual or team are the grant holders within the Trust) OR

2.8.1.2. 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, treatment or excess treatment costs where applicable and where properly attributed)

2.9. Individuals, Teams and Services are correctly and fairly recognised for their contribution to non-commercial research.

2.10. 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 and/or recovered.
2.11. All costs incurred by the Trust are fully recovered or agreed through Service.
2.12. 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).
2.12.1. Use of funding outside of the terms of the contract would be considered as potentially fraudulent, and as misconduct.
2.13. It is recommended that **all** research income is managed through the "8791" Research Protected Income Cost Centre, unless specifically requested otherwise by the individual grant holder and/or Service, who are then responsible for ensuring these monies are appropriately used.

3.0. Introduction

The Department of Health considers the support and delivery of commercial industry-funded and sponsored research to be a key priority (Plan for Growth, March 2011). Additionally, the money generated from this research is a potentially valuable source of additional income for NHS Organisations. It is therefore, crucial that all parties consider that there are sufficient incentives in place to promote participation in commercial/industry-sponsored research. It is also a key principle that this income is 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.

Commercial research is only one part of the wider NIHR Portfolio, but provides a strong, structured model that can be readily applied to non-commercial grant income as a means of ensuring a consistency of approach.

The purpose of this document is to describe the structure of income that can be made available through utilisation of the Standard Industry Costing Template (NIHR CRN 2008) and outlines a process for incentivising individuals, services and teams to increase participation in commercial research. The template is applicable as a model for commercial research whether on the "Portfolio" or considered "Non-Portfolio".

Though the NIHR and its' funding partners, there has been a significant growth in non-commercial grant opportunities since 2006. These funding streams are highly competitive, but require action from both the grant-holder (which is often an NHS Provider in alliance with an academic partner), and from sites agreeing to "host" activities related to the study, either as a recruiting site, or some alternative arrangement (such as a participant identification centre). In all cases, due regard must be given to the potentially disruptive effects of research activity and income on normal clinical activity, to ensure that, so far as is possible, this is not compromised.

4. Core 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
- 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 in support of commercial research they should abide by guidance and/or 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.
    - Ensuring that remuneration for CRN resources deployed for commercial research is retained and set against the appropriate elements of the CRN Budget provided to the Trust.

5. Key Drivers & Definitions

5.1. 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).

5.2. A significant proportion of commercial research is undertaken by CROs, specialising in study delivery, and in turn, the CRO will seek to contract with research delivery functionality within the NHS.

5.3. The benefits of commercial research include:
   5.3.1. Wealth generation for the UK Economy
   5.3.2. Access to novel compounds, new devices, new practices and procedures.
   5.3.3. Access to large scale clinical trials producing potentially significant results.
   5.3.4. Access to well-managed, well-resourced and strictly monitored clinical trials for both investigators and patients.
   5.3.5. Income generation for the Trust

5.4. In the context of a globally competitive clinical research market, the UK has previously 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 an emphasis on quality and robust data, over and above simple numbers.

5.5. 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.

5.6. 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.

5.7. As of June 2019, the updated Industry Costing template is also available as an interactive module within CPMS, thus providing a centralised single point for sponsors and sites to agree the core costing. This reduces the amount of local variation and the need for extensive correspondence between Sponsor and Site. The template is also available in secondary and primary care versions as Excel spreadsheets. https://www.dev.nihr.ac.uk/documents/the-excel-industry-costing-template-getting-started/12177

5.8. The development of the interactive Industry Costing Template coincides with a drive towards further efficiencies in the system by reducing the degree to which local negotiation of costs can be arranged. This will be through the "Single Contract Value" negotiation via the NIHR, and is aimed at reducing variations in costs between centres delivering a trial. Depending on the level at which the single contract value is set, may mean the potential of revenue being above or below local cost profiles.

6. 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:

A. 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.
B. Ensures all NHS Trusts are fully reimbursed for any activities associated with industry studies, in accordance with the requirements of the NHS Finance Manual
C. Identifies standard rates for staff time, overheads, capacity building, investigations and costs for departments supporting research, which are acceptable to all parties
D. 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
E. 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). 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.

As of June 2019 the NIHR have introduced an interactive costing module (iCT) within CPMS such that:

- The new iCT will be a fundamental tool underpinning the transition to a new single review process for all commercial studies - minimising the time required to negotiate the cost for delivering research at an individual site.

- Will ultimately make it quicker and easier to set up commercial studies in the NHS through increased accuracy and visibility of commercial costing.
- The iCT is primarily a tool used by the SPONSOR, and through coordination with NIHR CRN reduce the level of negotiation between sites.
- Were LPT to be a Sponsor of such a multi-site trial, it could conceivably use the iCT to relay information to potential sites.

Key Features:

- The new web-based iCT will work on any computer - overcoming software compatibility issues with the existing Excel-based version of the tool
- With a simple layout, the new iCT will be a fully automated costing solution - accessible from the NIHR Central Portfolio Management System (CPMS) and no longer involving any manual steps from users
- Updates or changes to the new system will be a seamless process, improving system reliability
- The new app will contain a central log of all adjustments made as part of the contract negotiation process - enabling NIHR to further streamline processes by identifying any issues or delays
- The new iCT will enable resource requirements determined at a site level to be shared with others involved in the study within the system, avoiding duplication of effort.
- The iCT will draw upon data from:
    - *Review of the site Market Forces Factor by NHSE annually*
    - *Annual Salaries from NHS Employers including prospective uplifts*
    - *Apprenticeship Levy from NHS Employers 0.5%PA for all NHS gross pay costs*
    - *Investigation cost baselining via Specialist Working Groups at senior Institute Level (e.g. Royal College of Pathology, Royal Institute of Ophthalmology) via the NIHR Costing Models Working Group*
    - *NHS Inflator value from NHSE used to inflate investigation costs on an annual basis.*

With the introduction of the iCT, it is expected that over time the view of the costing template as a "starting point for negotiation" between site and sponsor will be reduced. There remains the need for a local review prior to finalisation by the NHS Host, undertaken by the Trust R&D Office with support from Trust Finance, to ensure that all eligible costs are detailed and appropriately recovered, and 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. In addition, as part of the Assess, Arrange, Confirm process within ORCA the specification within the study implementation plan locally will determine the proportion of income to be set aside centrally, offset against CRN Delivery, and to defray Service Costs to ensure transparency.

The elements that make up the template are detailed below:

Direct Costs

NHS Staff Time: {The fee(s) 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 fee 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 (including iCT) 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.

7. Non-Commercial Research (Cost Attribution)

A significant proportion of research in the NHS is non-commercial, and this may be funded or unfunded. Irrespective of whether a particular study is funded, all activity within that study should be evaluated to ascertain the potential financial impact, even if considered nominal. This is embedded within the concept of "cost attribution".

7.1 The Process of Cost Attribution

All activity within the NHS comes at a cost. This is exemplified through the contracting process through which Commissioners (NHS England, CCGs, Specialised Commissioning etc.) award resources to Provider Organisations through a variety of means, such as a "payment by results" tariff and so forth. Research in the NHS is not however generally part of the commissioning of Provider services, but will almost certainly create costs or cost pressures within Provider services.

It is an important principle that research should not take place in the NHS, unless all the cost of doing so is either met from external sources, or there is an explicit agreement or acknowledgement within the service(s) affected that any costs are deemed acceptable and can be "absorbed". It is an embedded part of the Trust Research Policy that a review takes place for all research, as part of the "Assess, Arrange, Confirm" process before Confirmation of Capacity and Capability can be given, following HRA Approval. It is central to the concept of "capacity and capability" that the review examines resource cost and availability before the research can be initiated. This process does not distinguish between complex, multi-centre "portfolio" research or smaller-scale student research, as all have "costs" even if in the latter these are relatively limited.

7.1 The Development of the SOECAT

June 2019 saw the introduction of the SOECAT, as a replacement for the Schedule of Events, enabling the sign-off of study cost attribution by accredited SOECAT advisors. The SOECAT is now an expected component of all applications for research funding (primarily through the NIHR and Partner Agencies) and is aimed at:

a) Ensuring correct cost attribution at an early stage.

b) Reducing variance in interpretation of cost attribution by different sites to reduce set-up time

c) Identifying excess treatment costs at an early stage in the process to allow for scoping of Provider Thresholds and Network obligations.

It should also be noted that the SOECAT, whilst a very useful instrument for attributing activity within a research protocol appropriately, currently is not able to provide any sort of accurate costing for any study, merely a confirmation of correct attribution.

In submitting a bid for funding therefore, the grant submission should be properly costed and signed off by nominated leads in Trust Finance, with the active participation of Research Office staff.

7.3 The Details of Cost Attribution

Research Activity involves costs to the NHS, and these are set out and defined in the AcoRD (Attributing Costs of Research & Development in the NHS) Guidance (May, 2012), following on from HSG 97(32) and partitions research activity according to the "primary purpose" (see table below) of the activity in the research protocol:

Activity[1]	Definition	Responsibility[2]
Research Costs (Part A)	The costs of the R&D itself that end when the research ends. They relate to activities that are being undertaken to answer the research questions (but see Part B below).	Should be funded **in full** by the grant awarding body
Research Costs (Part B)	As above, the costs of the R&D itself. Part B Includes: • Local Trial Management • Data Collection needed to answer research question • Regulatory Preparation & Compliance • Time of Investigators to explain the study to colleagues	Should be funded **in full** by the grant awarding body, **except** where the funder is a member of AMRC when these **may** be met from the Clinical Research Network (if portfolio eligible and adopted)
Service Support Costs	Additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided. Includes: • Processing patient records to identify potential participants to approach • Obtaining informed consent • Tests to ascertain patient safety	Met by the NHS R&D Budget via NIHR Clinical Research Networks (Portfolio **only**) or through RCF (Research Capability Funding)
Treatment Costs	The patient care costs, which would continue to be incurred if the patient care service in question continued to be provided after the R&D study had stopped	Met through the normal commissioning process
Excess Treatment Costs	ETCs occur when treatment costs (the patient care costs) in a research study are greater than in routine care. For example, a patient taking part in research may be given a new drug to see how it performs in comparison with the standard drug given to the non-research patients. If the cost of the new drug being tested in the study is more than the one usually prescribed, then it is an 'excess treatment cost', as it would not occur in standard care.	The NHS: mediated by LCRNs on behalf of commissioners as of October 2018

The above attribution primarily applies to **non-commercial** research, whereas for **commercial** research (portfolio or non-portfolio) the activity within the protocol may be similarly attributed but this must be fully-funded by the commercial sponsor. In line with NIHR Guidance, research support infrastructure (i.e. clinical research nurses/practitioners) funded by the NIHR **can** be utilised in support of such research, but **only** on a full cost recovery basis. Although NIHR Research infrastructure can be used to support commercial portfolio research, the NIHR CRN is not allowed to

[1] Note; the "research infrastructure" budget allocated to Partner Organisations from CRN is in effect a form of "service support cost", although in actuality the contribution made by such staff will often fall into the Research or Treatment Cost category

[2] Where there is no grant award the costs continue to exist, and it is usual in the case of student research for the key costs to be met by the academic sponsor, except where staff are released to undertake such training as part of personal development agreed through the learning and development process

subsidise commercial research, such that any income from commercial research deriving from infrastructure support must be retained centrally by the host NHS Partner organisation to offset the costs of hosting CRN Infrastructure, rather than as income to the service.

NHS Treatment Costs are the patient care costs that would continue to be incurred if the treatment being researched continued to be provided after the research study has stopped. Excess Treatment Costs (ETCs) occur when the costs of a drug or treatment are higher (or different from) in a research study than in routine care. For non-commercial research studies ETCs are the responsibility of the NHS.

7.4 Dealing with Excess Treatment Costs

As of October 2018, the process for dealing with Excess Treatment Costs has been revised, such that this is now mediated by the Clinical Research Network in each geographical footprint (15 across England). This is a significant advance on the previous process wherein the Study Sponsor would make an application in their "home" centre, and even if awarded, there was no guarantee that should the study wish to take place in other centres, the process of agreeing ETCs with the relevant Commissioning Body, in each area, had wide variation, and often led to no award being granted and the study failing.

This was further compounded by a widespread lack of knowledge that within a Provider budget, this was commissioned to include an element that treatment and excess treatment costs were, to a degree, already within Provider budgets.

7.4.1 The Excess Treatment Cost "Threshold"

The new system builds upon this by all Commissioners (with the exception of Specialised Commissioning) called upon to provide from their budget a contribution to a regional and national fund moderated by the NIHR CRN. In addition, each Provider Trust is asked to make arrangements to ensure that they are able to provide resources to fund ETCs up to an individual "threshold" level, set at 0.01% of operating budget. As an example, for Leicestershire Partnership NHS Trust this equates to £27,766.40.

Therefore, within any one financial year a Provider Trust has an obligation (if a signatory to the NIHR CRN Partner Organisation Contract) to meets ETCs up to the value of the threshold. Thereafter, costed ETC activity attracts funding from the CRN to the Trust, to reimburse the costs of supporting this research within the service.

This policy will be further updated once the process within LPT for handling ETCs is agreed. The initial proposal (see Appendix 5) will form the basis of this approach having been discussed with the Deputy Director of Finance.

8. Accountabilities, 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 Operational Lead	Potential PI; R&D Delivery Team Lead; R&D Finance; Service R&D Lead; CRN:SSS[3]	CEO via R&D Head
Liaising with Sponsor regarding any new trial proposal & subsequent negotiations	R&D Operational Lead	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 Operational Lead	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 Operational Lead	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 Operational Lead; 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 Operational Lead; R&D Delivery Team; R&D Admin	CEO via R&D Head
Contract signature and record keeping	Sponsor / R&D Operational Lead[4]	R&D Operational Lead; 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 Operational Lead / R&D Business Manager	CEO via R&D Head
Contract Amendments	Sponsor	R&D Operational Lead / R&D Business Manager	CEO via R&D Head

[3] 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.

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

8.1 Income distribution approach

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 Strategy Group) 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.

8.2 Industry Costing Template (Details)

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 NHS permission (or confirmation of capacity and capability), as the emphasis for NHS Organisations is 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 providing an assurance that any study has met all the necessary regulatory requirements, other than the site being able to host the research within its resources, thus removing elements of duplication in research governance. 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.

8.3 Income Distribution Model

Staff costs, investigation/procedure costs and pharmacy charges will be paid directly to the relevant departments that have incurred the costs.

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[5] 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.

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.

9. Accounting Treatment

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 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 Board Lead (or delegated authority, usually Head of R&D).

The two capacity building accounts (70% investigator overhead and 20% capacity building cost centres) will be held under the R&D Accounts Cost Centre 8791 (including sub-codes attributable to individual studies).

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

Individuals and teams holding R&D accounts must 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.

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.
D. Achievement of transparency and the management of non-commercial grant income flexibly, and with regard to Standing Financial Instructions is achieved, thus enabling individual investigators and teams to have confidence that the resource they have been successful in securing is available for the delivery of the research. Service management will therefore be able to manage clinical services in the knowledge that so far as is feasible approved research activity is cost neutral.

10. References

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 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

CASE STUDIES: Recommended Income Distribution Model[6]

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)[7]	£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)*	

[6] Assume full details with standard costing template.

[7] 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[8])	£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)*	

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

	INVESTIGATIONS: (£23,250)		
	Value (NHS)	£16455	*(retained by Trust to reimburse provider support departments)*
	Value (University)	£2500	*(transferred to University for specific investigation activity)*
	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[9]:	£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 maximum proportion of costs legitimately available to the University partner, as the first priority is to ensure all NHS costs are met.*

[9] 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.

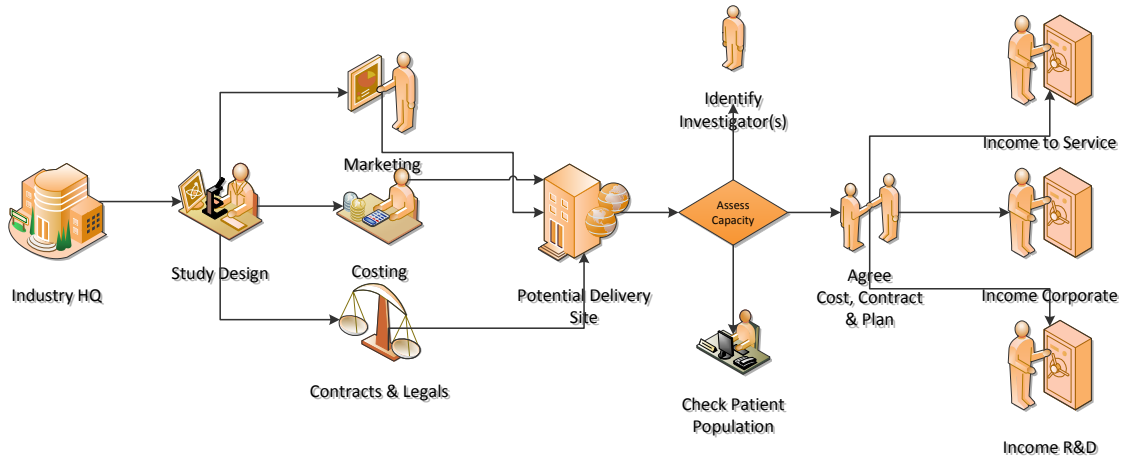
Research Grant Breakdown			
Direct NHS Staff Costs	*(inclusive of 70% overhead if applicable)*	*Cost Attribution*	*Annual Value*
	Consultant Paediatrician (0.5 wte)	*Any of Research Cost/Treatment Cost/Support Cost*	*£36,298*
	Health Visitors (Band 6) 1.0 wte * 2	*Research Cost*	*£81,394*
	Clinical Administration (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.

11.0. Outline Flowchart (Industry Study)



12. Duties within the Organisation

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

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

12.3 Divisional Directors and Heads of Service are responsible for:

- Providing a receptive environment for clinical trials and studies.
- Ensuring appropriate staff training.
- Monitoring service involvement
- Oversight of capacity investment.
- Informing staff of potential studies.

12.4 Managers and Team leaders are responsible for:

- Informing staff and patients of potential studies.
- Assisting in the identification of potential investigators
- Managing clinical and other workloads to accommodate approved studies.
- Proactively troubleshooting issues in study delivery.
- Identifying potential areas of cost in liaison with R&D.
- Access to appropriate training.

12.5 Responsibility of Staff

- Engage with study recruitment teams.
- Undertake appropriate training.
- Inform patients of potential trials for which they are eligible.

13.0. Training needs

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

14.0 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	Model devised within R&D negotiations with Sponsor	R&D Finance	R&D Strategy Group	Bi-annually
Subject to regular "financial health check" external monitoring via NIHR Clinical Research Network in terms of compliance with the Partner Organisation Contract					

Appendix 1: Management of Non-Commercial Grant Income

1. There are strong similarities between the principles underlying commercial studies within the non-commercial sphere, especially with regard to cost attribution.
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. 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.
4. Non-commercial grants will have direct and indirect costs specified within the award itself, and will vary according to the funding body.
5. All submissions for non-commercial grants must be appropriate costed through the R&D Office with the support of Trust Finance (see separate SOP for this process and timelines)
6. All such grants will be assigned a specific Finance Sub-Code, through which all expenditure and transactions 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.
8. Non-commercial grant income will by default, be managed through R&D Cost Centre 8791 (Research Protected Income), where the responsible officer is the Operational Lead (R&D), and accountable officer the Head of R&D supported by the R&D Finance Lead.
9. Non-commercial grant income may, at the discretion of the individual/team securing the grant, be managed through any applicable Cost Centre.

Appendix 1a: R&D Cost Centres (Purpose)

There are three main Cost Centres in R&D, these are:

Cost Centre	Description	Responsible Officer	Accountable Officer
8790[10]	Ring-fenced CRN Research Delivery Infrastructure Budget as required under Partner Contract	Operational Lead (R&D)	Head of R&D
8791[11]	Research "Protected" Income (holding account for study-specific transactions with leeway to carry-over financial year-end)	Operational Lead (R&D) – supported by Business Manager	Head of R&D
8794[12]	R&D "Corporate" Costs *(primarily staff funded by Trust as R&D Office and Support Functions)*	Head of R&D	Executive Director (R&D) (Medical Director)

[10] It is a fundamental requirement of the NIHR Partner Organisation Contract that the Research Delivery Infrastructure budget is ring-fenced, and not used for purposes outside of the contract

[11] Each study-specific, or study amalgam code has a designated budget holder, with the latter required to demonstrate expenditure against this code (for example on training capacity)

[12] Note – the costs of the "Head of R&D" role are not within 8794, but are instead reported under the Medical Director Budget

Appendix 2: Utilising Income Transparently (Inc. Budget Transfers)

1. It is a fundamental principle of this policy, and of the NIHR that "resource follows activity", and that there is an elimination of cross-subsidy between research activity and clinical/support services without agreement.
2. The core principle of transparency is central to ensuring trust in the usage and distribution of R&D Income (Commercial or Non-commercial).
3. All income is held for the use of the income-generating individual and/or team, until it is **no longer required**; such as when a study is closed, which can in certain circumstances require residual funding to be returned to the sponsor.
    a. Any income net of costs, is held in a specific 8791 Cost Code until required.
    b. Relevant attributed service support costs may pass through 8790, to 8791 and then on to service budgets as needed.
    c. Per-participant fees (and SSCs) are similarly passed through 8791 to service budgets, unless these fees are primarily accrued via CRN Research Delivery activity, in which case they may be used to:
        i. Provide opportunities for training and development of research delivery and R&D Corporate staff to ensure continued skills improvement.
        ii. Set against the cost of Research Delivery Infrastructure so as to ease budget pressures.
        iii. Establish an offset against the need to meet the Trust ETC Threshold
    d. Retention of funding beyond reasonable period is strongly discouraged, but with due regard to the "resource follows activity" principle.
4. The use of attributed research cost income must be used in accordance with the terms of the relevant contract, and/or Sponsor instructions unless a specific variation is agreed with the Sponsor. Misuse, or unlawful retention of funding can be seen as gross misconduct and subject to disciplinary action. Examples follow:
    a. Purchase of equipment in addition to that required to deliver the procedures in the study, at additional cost.
    b. Receiving income to release time from normal workload should be reimbursed to the host service (and the relevant budget), and not retained further by the individual or team unless specifically allowed by the Sponsor in writing (excludes residual income).
5. All income is held within a holding account within the overall R&D Cost Centre, with specifically allocated sub-codes for each individual project. This funding will be held therein until an appropriate call upon this resource is made.
6. 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.

7. 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.
    a. Where several sub-codes are held by the same individual, these may be merged for efficiency.
    b. The key contact must demonstrate that their plans for expenditure against these assets are agreed by relevant service management
8. It is inappropriate 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 **final** 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. If the key contact at this time expresses a "reasonable intent" or a considered plan to utilise the funding, then the "clock" is reset to zero and the funding is retained for the use of the key contact.
    d. Unless otherwise specified, in line with the key principle that "resource follows activity", the default recipient of any unused protected funding is the service within which the costs were incurred – otherwise, see below:
    e. In months 13-24, 25% of the residual, unallocated income will be considered for transfer to the R&D Core Income Budget (8794), to be used under the direction of the Head of R&D but only after presenting a recommendation to the R&D Strategy group and approved by the Executive Director using the prioritisation below. This latter clause does not take effect if either the named individual/team associated with the budget code is not warned (see Clause B), or, the clock on the budget has been reset. As a courtesy, any budget holder **must** be consulted before this funding is used.
    f. After two years post study close, the 50% of the remainder of any unused income is also made available via the same provisions as above, until after Year three, the budget is cycled through the Trust according to the prioritisation below.
    g. The Prioritisation of funding accrued in this way is as follows:
        i. To establish a year-on-year contribution towards the Trust overall threshold for meeting Excess Treatment Costs of further studies.
        ii. This will be prioritised and apportioned according to the areas where ETCs were previously incurred, so as to offset costs before ETC income is triggered.
        iii. To establish a fund to incentivise participation in research through an internal "service support cost" mechanism.

iv. To offset the invisible costs of supporting research within services where this is otherwise not reimbursed (i.e. to support service budgets)

v. To meet the reasonable training needs of research active staff – this may include postgraduate fees where there is a clear and unequivocal link to future research activity.

Appendix 3: 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 4: 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 5: Further details and draft option for dealing with Excess treatment Costs.

All research activity involves costs to the NHS, and these are set out and defined in the AcoRD (Attributing Costs of Research & Development in the NHS) Guidance (May, 2012), following on from HSG 97(32) and partitions research activity according to the "primary purpose" of the activity defined in the research protocol. Wherever possible, research activity should be cost neutral, or minimal impact on clinical service delivery in the absence of formal Trust agreement to absorb costs. This cost attribution structure applies to all research, but only qualifying "portfolio" research activity (which we are obliged to support where feasible) can access the additional resources available through the Clinical Research Network:

These cost attributions are, as of April 2019 for all new studies, verified by specialists within the funding system (AcORD specialists in the LCRN) as part of the Schedule of Events Cost Attribution Template (SOECAT) and is enforceable across the UK. Staff within a Trust R&D Office may also be AcORD-trained, but may not be empowered to sign-off a SOECAT.

The Excess Treatment Cost, is therefore, usually the only element of any research study's cost profile that requires additional resource, and there is the expectation that such costs must be considered, as to whether they can be absorbed. Even for student research it is assumed that all other costs are met, even if this is through the agreed utilisation of study leave for example.

The Excess Treatment Cost Threshold

As of October 2018 a new system for providing excess treatment costs has been trialled, and now adopted as of April 2019. This has involved Commissioner's budgets being in effect, top-sliced, to provide a regional pot based on the geographic footprint of the 15 Local Clinical Research Networks. As part of this revision, 0.01% of a Provider Organisation operating budget, is now considered to be the threshold, below which is it expected that the Provider will meet the costs of ETCs for qualifying research. Once qualifying costs exceed the threshold, then on a quarterly, retrospective basis, the Clinical Research Network will reimburse the Trust on the basis of the agreed ETCs within the SOECAT for that study on per-participant basis.

For 2019/20, the ETC threshold for Leicestershire Partnership is **£27,766.40**

As a "Category A" research-active Trust, there is an expectation that the Trust will agree to meet eligible excess treatment costs up to this threshold.

How ETCs can be dealt with (An outline proposal)

One unfortunate side-effect of the "first-come, first-served" approach provided by the threshold is that there is the real possibility that a particular service may host ETC-incurring research during the first two quarters of a financial year, and take the Trust globally over the threshold for the whole year. This would mean that this service would "suffer" all of the cost impact but would see the financial reimbursement potentially go to services elsewhere, that later in the same financial year host ETC-incurring research. The pressures and benefits must be fairly, and equitably shared across the organisation. This is perhaps best achieved by:

- Allowing R&D access to a central funding stream[13] to the value of the threshold, so as to provide assurance to services wishing to take part in qualifying research that these costs will be covered.

[13] More than one East Midlands Trust has taken a similar approach, by providing "R&I" with a budget equivalent to the threshold so as to manage the cost pressure.

- R&D will, as now, identify ETCs as early as possible in the "Assess, Arrange, Confirm" process and liaise with Finance to manage the process.
- Once the threshold is reached within a financial year, income will continue to flow through R&D to relevant services through the per-participant trigger process mediated by the LCRN.
- If the threshold is projected not to be reached by the end of the financial year, any residual figures are carried over to the following year to set against the following year threshold.
- This transparency allows services to back-fill or cover for resource deployed to meet the needs of the research and plan accordingly.
- Wherever possible, capacity building elements of commercial research, and or other R&D residual income may be used to top-up the ETC Threshold budget.

This process has the advantage that the Trust would then be meeting the obligation under the NHS Constitution to support research, whilst providing full transparency.

Case-Study: The ReTAKE Trial

The Trust was approached to take part in this trial of Early Supported Vocational Rehabilitation in Stroke led from the University of Nottingham. The study involves identifying eligible participants with a new stroke, and randomising them to receive either ESSVR (the new intervention) or effectively "treatment as usual". The study was enthusiastically embraced by the Trust CINNS Service, but identified that the deployment of therapy staff into the intervention arm was an excess treatment cost. An application was made under the pre-October 2018 system, but not resolved or approved by the CCGs. Nonetheless, the training and development opportunities for staff, as well as the prospect of improved patient outcomes led to the study going ahead. The study also attracted service support costs, and on a per-participant basis these have been fed through to the service.

Subsequently, in 2018/19 the recruitment to ReTAKE was so good, that on the basis of this trial alone, the Trust ETC Threshold was exceeded. This has led at the end of Q1 2019/20 to a payment of nearly £9000 being made to the Trust and this will be passed on to the services concerned by the end of Q2, 2019/20 for qualifying studies (Including ReTAKE, ORBIT, and TRIANGLE).

Currently, recruitment to these studies is pushing towards again exceeding the ETC Threshold in 2019/20.

Appendix 6: 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 7: Stakeholders and Consultation

Key individuals involved in developing the document

Name	Designation
Dr Dave Clarke (Author)	Operational Lead (R&D)
Dan Kumar	Industry Liaison (East Midland CRN-SSS)

Circulated to the following individuals for comment

Name	**Designation**
Professor Susan Corr	Head of R&D
Joanne Edgar	Research Business Manager
Amjad Kadri	R&D Finance Lead
Sharon Murphy	Deputy Director of Finance
Members of R&D Strategy Group	

Appendix 8: Due Regard Screening Template

Section 1	
Name of activity/proposal	
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:			
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**	