Local CRN Guidance Suite

Income Distribution from NIHR CRN Industry Portfolio Studies

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Document Control

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Readers should ensure that the latest version is being viewed.

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1. Executive summary

This document provides good practice guidance for the distribution of income generated through the conduct of NIHR CRN Portfolio commercial-contract clinical research within NHS Organisations in England to incentivise research teams and grow research capacity.

The NIHR CRN supports the healthcare research system which yields real benefits for the NHS, its patients, the Life Sciences Industry and investigators. Ensuring its success is dependent on consistent, fair and balanced funding flow arrangements.

The principles which underpin this model, and could also apply to non-NIHR CRN Portfolio studies, are:

a) Departments and individuals are recognised and incentivised for their contribution
b) All relevant costs incurred are recovered from the Commercial Sponsor
c) Commercial research affords opportunities to fund additional research or research related activities
d) Income from commercial research can be distributed and carried over in line with the finance control procedures of individual NHS Organisations.
e) Involvement of the Local CRN in NHS Organisations research planning
f) Overly onerous itemisation and invoicing of study costs are avoided where possible.

The model proposed has been developed and refined from the observed good practice and feedback on the initial NIHR CRN Income Distribution Model released in April 2011.

This guidance is intended to prompt local discussions and consideration of an income management structure to support investigators, NHS service support departments and NIHR CRN research infrastructure.

2. Introduction

The NIHR CRN supports the fair and balanced distribution of income from NIHR CRN Portfolio commercial research alongside the provision of incentives where possible.

The Department of Health considers the support and delivery of industry-funded and sponsored research to be a priority. Therefore, it is crucial that all stakeholders are incentivised to participate in industry-sponsored research as reflected in this guidance.

Income from industry-sponsored research on the NIHR CRN Portfolio has historically been managed in a wide variety of ways. While this document does not provide prescriptive guidance on how income should be distributed, it is expected that appropriate local systems are in place to allow funding flows from NIHR CRN Portfolio commercial research to support investigator incentives and the local infrastructure provided by Local CRNs.
This guidance applies to NHS Organisations providing acute, mental health and tertiary services. Good practice guidance for NHS Primary Care or Independent Sector Healthcare Providers (ISHPs) will be developed available separately.

3. Background

The NIHR CRN has specific objectives to support commercial research within the NHS, reflecting the importance and benefits of commercial research which include:

- Access to novel compounds, new practices and procedures
- Access to well-managed and monitored clinical trials for investigators and patients
- Access to large-scale international clinical trials
- Income generation for NHS Organisations
- Wealth generation for the UK economy.

Addressing a specific recommendation made in the Cooksey Report (December 2006), which highlighted the need for a transparent and consistent national costing system, the NIHR CRN released the first Industry Costing Template in May 2008, which later expanded to Primary Care and Medical Device versions. This costing tool has provided companies and NHS Organisations with a single consistent approach to calculating commercial trial costs which is both clear and transparent for negotiating and establishing a price for research within the NHS.

The Income Distribution model described in this guidance is based on the NIHR CRN Industry Costing Template cost methodology to support the redistribution of commercial contract income for NIHR CRN Portfolio studies.

4. The Industry Costing Template

The NIHR Industry Costing Templates provides a clear methodology to calculate consistent and transparent prices associated with commercial contract studies to support the Life-Sciences Industry and the NHS. It is the preferred method for cost calculation for NIHR CRN Portfolio Industry studies and it supports the full reimbursement of the NHS for activities associated with industry studies (in accordance with the requirements of the NHS Finance Manual and the Health Service Guidelines [HSG] 97-32 detailing the ‘Responsibilities for meeting patient care costs associated with research and development in the NHS’) while provides clear expectations for Industry. As such, the templates are incorporated into many CRN processes to help minimise set-up time related to cost agreement.

The template format identifies standard rates for specific bands of NHS staff time representing the direct costs. Any indirect costs (including overheads) are covered by the indirect cost and capacity building elements. Prices for investigations and costs for departments supporting research are also included. These values are all localised with the National Tariff Market Force’s Factor (MFF) for the NHS Organisation in which the research takes place. This document outlines good practice for appropriate funding flow of these elements to participating departments and supports the establishment of suitable local arrangements.
Further information and support regarding the Industry Costing Template and the development of its cost structure and values are available on the CRN Industry website at www.supportmystudy.nihr.ac.uk

Direct Costs – NHS Staff Time

National hourly rates are calculated for the agreed NHS staff bands using the highest salary in the relevant Agenda for Change band which are adjusted to incorporate the NHS employer contributions for National Insurance and Pension. This is a standardised representation of the direct cost to an employing NHS organisation and is used to calculate the template values for all procedures or tasks that are related to staff time.

Ideally these direct costs should be reimbursed to the department where the staff member is employed to compensate for the work performed.

For commercial studies involving University staff, agreement should be in place between the relevant NHS Organisation and University to agree suitable distribution of the NHS Staff Time costs or the mechanism to be applied to accommodate alternative cost approaches, eg Application of Full Economic Costing (FEC), based on the NIHR CRN Industry Costing Template (further information regarding the involvement of Universities in commercial research is available in Section 6, Practicalities of implementation).

Indirect Costs (Overheads)

A standard rate of 70%, added only to the NHS staff time direct costs, provides a representative value for the indirect costs when conducting a commercial trial which are not already covered by the direct costs (ie the real cost of carrying out a research activity). 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 (eg, corporate oversight offered by the CEO, the finance director, R&D director 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 the individuals and services involved in delivering research. This element has a direct impact on the sustainability of the individual research activity and the research environment as a whole.

The distribution of the indirect cost element varies between NHS Organisations: some retain the full amount to cover their indirect costs, while others divide it between the NHS Organisation, the Investigator/Research team and the R&D Department in varying proportions. Being open, realistic and accountable about indirect costs and their distribution builds a trusting and mutually beneficial relationship between research partners and requires strong managerial and financial systems to deliver. Not all indirect costs are incurred within Directorates: some central charges may need to be made and the distribution model in place should recognise this.

Capacity Building

A capacity building rate of 20%, which is added to both direct staff time costs and investigations, should be considered as a ‘system optimisation’ which is designed to build sustainable research
and innovation capacity to the benefit of all research partners. The successful utilisation of this element requires significant commitment and resources from all research partners.

This element is separate from the 70% indirect costs to enable it to be easily ring-fenced for maintaining, strengthening, adapting and growing sustainable research capacity over the long-term. It is supported by the Health Service Guidelines (HSG) 97-32 ‘Responsibilities for meeting patient care costs associated with research and development in the NHS’ which acknowledges that NHS income derived from commercial contract studies is raised through NHS Income Generation powers for ‘improving the health service’.

**Market Forces Factor**

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 which consists of four component indices: Staff, Medical & Dental (London only), Land and Buildings. In the Industry Costing Templates it is applied to localise the national rates for the location in which the research is being conducted.

For funding flow, this factor should be applied to each element of the cost methodology to provide a true reflection of the cost for that location (eg NHS staff time including MFF; indirect costs including MFF; and Capacity Building including MFF). Ideally, this should not be treated as a separate element but an integral part of each cost complement. This approach is reflected in the invoice generation functionality of the Secondary Care Industry Costing Template.

**Per Patient costs (including additional itemised costs)**

The ‘per patient budget’ and the ‘additional itemised cost’ sections (the latter being where trial related costs that may not directly correlate with patient numbers or visits are included) applies all these aspects to two different cost calculations:

\[
\text{Procedures costs} = \text{NHS staff time (direct) costs} + 70\% \text{ indirect costs} + 20\% \text{ capacity building} + \text{MFF}
\]

\[
\text{Investigation costs} = \text{NHS direct costs for investigations}^1 + 20\% \text{ capacity building} + \text{MFF}
\]

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^1 Already inclusive of the NHS Organisation’s indirect costs and operating overhead.
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.

5. Income distribution principles of good practice

Key principles which exemplify good practice and work to reassure and incentivise all stakeholders in the local research community (and could also apply to non-CRN portfolio studies) are:

- Departments and individuals are recognised for their contribution to the commercial NIHR CRN portfolio studies run within NHS Organisations and are incentivised fairly and flexibility as per the individual study requirements
- All relevant costs incurred by the NHS Organisation, and where relevant Universities, are recovered from the Commercial Sponsor as per the Industry Costing Template eg study costs associated with non-routine patient care
- 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 in line with the finance 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.
- NHS Organisations include the Local CRN in their consultations when:
  - Managing 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 Networks
  - Growing research capacity in the long-term to meet national research ambitions
- Overly onerous itemisation and invoicing of study costs are avoided where possible (time versus value is considered).

These key principles represent good practice supported by the NIHR CRN and local application is strongly encouraged to support the long-term stability of clinical research infrastructure.
6. Recommended model for income distribution from NIHR CRN Portfolio commercial studies

The recommended model was initially developed from good practice and has since been refined using implementation feedback. It is offered for consideration and to inform local funding flow decisions for NIHR CRN Portfolio commercial studies, with particular relevance when Local CRN funded research staff are actively involved in the delivery of commercial research.

The implementation of an income distribution model may take several forms:

- A Local CRN wide model adopted by the host and all participating NHS Organisations
- NHS Organisation specific models adapted as required to enable implementation within the host and participating NHS Organisations
- A combination of a Local CRN wide model with specific NHS Organisations adapting the Local CRN model as required to enable implementation within that NHS Organisation.

Prior to any recommendations, an initial review of income distribution arrangements within the Local CRN Host organisation and participating organisations should be conducted to understand the current position. This review may identify a common approach which is already in place which can be expanded as required. If successful income distribution processes and operational arrangements already exist locally, these should be reviewed to ensure all relevant NIHR CRN recommended model principles of good practice are or can be appropriately accommodated through adaptation.

Recovery of NIHR CRN staff costs:

Where deemed appropriate, the Local CRN should aim to recover staff costs for research staff it funds when the staff are directly involved in the delivery of NIHR CRN Portfolio commercial study and it is practical to quantify the staff’s contribution.

This should be considered on a study-by-study, site-by-site basis through agreement of ‘CRN cost recovery plan’ between the Local CRN and the NHS Organisation as relevant which is monitored and revised through-out the study as required. Where applicable, invoices for network staff costs should only be raised once relevant monies have been recovered from the commercial Sponsor. Any invoices should reflect the involvement of NIHR CRN staff, study recruitment and the agreed financial arrangements for staff costs within the relevant model Clinical Agreement. Ideally, the Local CRNs should aim to recover true NIHR CRN staff costs to offset against costs in the current financial year.

For example, if an NIHR CRN funded research nurse was extensively involved in NIHR CRN Portfolio commercial study activities; the NHS Organisation has recovered the related staff costs from the Sponsor; and these funds are documented within the NHS Organisation finance system, then the NIHR CRN should look to recover costs.

Local knowledge and judgement are key components in the decisions to apply the NIHR CRN staff cost recovery aspect of this model.
Distribution of the 70% indirect cost element added to direct costs in the Industry Costing Template

The wide reach of tasks covered by the 70% indirect costs component supports the splitting of this value to enable representative but practical distribution to the relevant parties involved in delivering the commercial research and may vary for each NHS organisation.

The NIHR CRN Income Distribution model recommended approach is:

a) **Half of the indirect cost element stays with the NHS Organisation to cover the indirect costs which enable the NHS Organisation to carry out the underlying operations of conducting research and contribute to any variability between the negotiated prices where required.** Additionally, this percentage may be used to supplement or incentivise individual NHS Organisation departments, as per local agreements.

b) **Half of the indirect cost element is designated for the Principal Investigator and provides a method to incentivise participation in commercial research.** This amount should be allocated to a commercial research cost centre or similar supervised research account within the NHS Organisation finance system, through which the Principal Investigator has a decision making capacity in the use of the funds in line with the NHS Organisation practices and finance control procedures.

The “equal split” approach is the recommended approach, however local arrangements may support different splits to be used and agreed locally to suit each NHS Organisation’s needs. These percentages should be developed and agreed based on the NHS Organisation’s methods for recovering indirect costs and the degree of efficiencies and savings that are realised to make available as incentives. The alternative split should be evidenced with supporting data from NIHR CRN Portfolio commercial studies to demonstrate the involvement or requirement for the proposed proportion of income. The implication of agreeing alternative approaches to the equal split recommended in this model should be considered for each NHS Organisation individually, eg the impact of reducing the percentage available to the Investigator and team. The following table shows examples of some alternative splits in use at NHS Organisations.
Examples of income distribution splits in use across the NHS

<table>
<thead>
<tr>
<th>Split #1</th>
<th>Split #2</th>
<th>Split #3</th>
<th>Split #4</th>
<th>Split #5</th>
<th>Split #6</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% to PI</td>
<td>65% to PI</td>
<td>70% to PI</td>
<td>75% to PI</td>
<td>36% to PI</td>
<td>80% to the department</td>
</tr>
<tr>
<td>25% to Clinical Division</td>
<td>20% to add to staff costs</td>
<td>30% to NHS Organisation</td>
<td>25% to NHS Organisation</td>
<td>32% to Clinical Division</td>
<td>20% to R&amp;D</td>
</tr>
<tr>
<td>25% to R&amp;D</td>
<td>15% to R&amp;D</td>
<td></td>
<td></td>
<td>32% to R&amp;D to fund commercial trial support roles</td>
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NOTE: The distribution split of the indirect cost element assumes that all direct staff costs and the cost of investigations are paid direct to the NHS Organisation as per the arrangements of the relevant model Clinical Agreement and where these costs are incurred by support departments or external providers, the costs are paid or passed through as per local agreement.

Distribution of the 20% capacity building element within the Industry Costing Template

The previous version of this model recommended that the Capacity Building element was pooled from all Local CRN Partner Organisations and held under the control and management of the Local Network Board (removing instances where this element has been used as a surrogate for Network staff costs). In practice, this was not found to be applied and was instead retained by the NHS Organisation where the money was generated which is reflected in this revised model.

The intended use of the Capacity Building element within the NHS organisation should be clearly documented to support and evidence its reinvestment in research in line with the overarching intention to ‘improve the health service’. It is recommended for the NHS Organisation to involve the Local CRN in defining the application of this element and ensure consideration and inclusion of the wider research community needs and national research ambitions.

Regardless of Local CRN involvement, it is best practice for NHS Organisations to have some form of expenditure plan for the capacity building element with supporting accounting processes to manage and evidence the distribution. This could be incorporated into existing reports or plans to minimise duplication. For example, the expenditure plan may include:

- an aggregate expenditure for large-scale, long-term resource and infrastructure projects (eg funding additional staff posts, building resource in research constrained departments or services)
- small-scale department or unit specific plans as part of an open local competition/application process (eg development of training programmes, part funding of department specific research posts, “buying-out” or reserving “blocks” of research time in departments and units)
- a mixture of both.
In the event that consensus cannot be reached locally on the best use of Capacity Building income, the funds should be distributed back to the NHS Organisation service support departments and clinical units in the exact amounts that they each generated through their involvement in commercial contract studies.

**Considerations for implementing the recommended model**

Where no Network resource has been used to carry out the NIHR CRN Portfolio commercial study at a specific site, the Local CRN should not expect to recover NIHR CRN staff costs.

Case studies within section 7 demonstrate how under different study situations, the distribution and recovery of staff costs can be managed locally.

**Control of the funds**

Feedback to date has shown an income distribution model is most effective when all income values are transparent to all departments involved through good local accounting allocations, clear distribution rule application and central NHS Organisation oversight (eg by the R&D Department). While income is distributed back to individual departments to support engagement in commercial research, the use of this income should be managed and monitored through spending plans which are reviewed and approved centrally by the NHS Organisation. This approach ensures an integrated approach to research development across the NHS Organisation. Consideration may be needed to distinguish NIHR CRN Portfolio studies from non-portfolio studies if using different approaches for income distribution.

**Carryover of funds**

Local agreements should be used to manage the carryover of funds generated from commercial contract research which may be key to raising the profile of research within the NHS Organisation.

For example, if an NHS Organisation has a strict policy on what can be deferred across financial years, the capacity building element will need to be deemed to meet the NHS Organisation’s criteria for deferred income. It can then be separately identified for all trials using the individual NIHR CRN Industry Costing template, enabling the application of the allocation principles by using a research capacity building subjective code on the finance system. This allows the income to be deferred within the Directorates to be used to help build the research capacity with the NHS Organisation.

While the above example provides a mechanism to carry forward unspent monies, Financial Auditors also need to be satisfied that appropriate accounting principles are being followed.

The ‘matching’ principle ensures that income and the associated direct costs shows in the same accounting period. As commercial contract study sponsors pay at intervals as described in the financial arrangements appendix of the model Clinical Agreement upon approval of tasks completed, the onus is for the NHS Organisation to accrue for monies owing based on activity so both income and expenditure should match. Based on the definition of the indirect costs in the NIHR CRN Industry Costing Templates and the recommended distribution model, it could be concluded that half the indirect costs cover costs already incurred, thus the NHS Organisation may also be able to accrue for this income at the year end as well as the direct costs, the other half being allocated to the Principal Investigator.
For the remaining capacity building element, which by definition is allocated to support future research, Financial Auditors would likely require a spending plan to support funds being carried forward which would help avoid large balances being continually carried forward and never spent. Larger NHS Organisations who are very research active may be earning and spending almost simultaneously, however smaller NHS Organisations with less research activity may wish to build up the capacity element to a certain size (eg based on patient recruitment) before it can be appointed accordingly, which carries its own risk.

To support this example, it may be beneficial for the Research Department to present a local interpretation of the guidance to the NHS Organisation Management and Finance Department. This would support the understanding of the context of deferring income to a future period as part of the research agenda and highlighting that this is separate to clinical Income and Expenditure (I&E).

The indirect costs relating to the Principal Investigator, as recommended in this model, should be managed in accordance with the NHS Organisation’s financial management arrangements with the Principal Investigator retaining authority to use the funds in line with NHS Organisation’s practices and control procedures. Again, this could be supported with local agreement between the R&D Department and the NHS Organisation by presenting a spending plan similar to that for the capacity building element.

An alternative example is allocating the capacity building element and half the indirect cost element to the directorate that has generated it within the boundary of the Research Directorate and subsequently requests a spending plan. If no plan is forthcoming the R&D Department recovers the values and allocates it centrally, which means the actual spend is monitored and managed against the plans.

Another approach is allocating all the indirect cost element to the NHS Organisation against a spending plan to cover the cost of the R&D department development until such time as it is deemed to be complete and fully paid for.
NIHR CRN recommended income distribution model summary

*All values inclusive of the relevant Market Forced Factor uplift for the NHS Organisation

### PROCEDURE COSTS

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Staff Time*</th>
<th>Indirect Costs*</th>
<th>Capacity Building*</th>
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<tbody>
<tr>
<td>70%</td>
<td>Half (or other agreed value) collected and collated for allocation to the NHS Organisation for indirect cost coverage ie the real costs of conducting research</td>
<td>Half (or other agreed value) collected and collated for allocation to the Principal Investigator managed account as financial incentive to reinvest in further research</td>
<td>Collected, collated and reinvested by the NHS Organisation, in consultation with the Local Clinical Research Network, to build sustainable research and innovation capacity to the benefit of all research partners</td>
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<td>20%</td>
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### INVESTIGATION COSTS

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<tr>
<th>Investigations</th>
<th>Template Value*</th>
<th>Capacity Building*</th>
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<tbody>
<tr>
<td>20%</td>
<td>Distributed to the service support department where the investigation was conducted to cover the cost of their involvement in the research</td>
<td>Collected, collated and reinvested by the NHS Organisation, in consultation with the Local Clinical Research Network, to build sustainable research and innovation capacity to the benefit of all research partners</td>
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### PHARMACY COSTS

<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>Staff Time*</th>
<th>Indirect Costs*</th>
<th>Capacity Building*</th>
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<tbody>
<tr>
<td>70%</td>
<td>Collected and collated for allocation to the NHS Organisation Pharmacy for indirect cost coverage ie the real costs of conducting research within the Pharmacy</td>
<td>Collected, collated and reinvested by the NHS Organisation, in consultation with the Local Clinical Research Network, to build sustainable research and innovation capacity to the benefit of all research partners</td>
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<tr>
<td>20%</td>
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### SET-UP, MANAGEMENT AND CLOSE-DOWN COSTS

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<thead>
<tr>
<th>Department/Task Fee</th>
<th>Template Value*</th>
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<tr>
<td>Distributed to the department where the set-up task was performed/costs incurred, e.g. R&amp;D, service support department, Clinical Research Facility or Primary Care Patient Identification Centre to cover the cost of their involvement in the research</td>
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### Practicalities of Implementation

The following information has been compiled from local network feedback regarding the initial model release in April 2011.

**Communication – discussion is key to implementation**

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<tr>
<th>Who should be involved?</th>
<th>Getting the right people to discuss the guidance has been a big barrier to implementation and making the change happen, eg R&amp;D staff may be receptive to the discussions but Finance staff engagement may be needed to implement.</th>
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<tr>
<td></td>
<td>Involve team members from NHS Organisation management, service support departments and R&amp;D Offices to support open discussions.</td>
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<td></td>
<td>Involve the Speciality Leads, the Local CRN Executive Group and Board as well as the finance leads in the Trusts. The Executive team can help to endorse the model for application across the NHS Organisations.</td>
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<td></td>
<td>Involve the investigator in discussions. Making investigators aware of the potential distribution principles can further support implementation and give support to the splitting of the indirect cost element, but care should be taken not to raise expectations and create conflict between the investigator and R&amp;D.</td>
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<tr>
<th>When should we discuss?</th>
<th>Support the initiation of local discussions with this document as guidance rather than a prescriptive process.</th>
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<td></td>
<td>Local discussions should also take place within the Local CRN to compare and consider a common income distribution model to present to all partner NHS Organisations.</td>
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<td>Frequent discussions and ongoing monitoring can raise the priority.</td>
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<td></td>
<td>Give member trusts time and freedom to consider how the model could work for them.</td>
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<tr>
<th>What should we consider?</th>
<th>Be prepared to invest significant effort and dialogue to encourage NHS Organisations to be transparent with their funding models and costs.</th>
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<tr>
<td></td>
<td>Education regarding the Industry Costing Templates and principle of the tool may be useful introduction to the discussions.</td>
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<td></td>
<td>Relate the benefits of the model to the audience.</td>
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<td></td>
<td>Compare the model to previous cost or distribution approaches eg one NHS Organisation enables consultants to receive 80% of the total per patient fee.</td>
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### Adaptation – flexibility as required

#### When could flexibility be needed?
Hospital structure may dictate requirement for adaption of a locally agree model, eg Large Teaching Hospital vs a District General Hospital; the involvement of a Clinical Research Facility (CRF); or use of University staff and/or facilities.

Depending on the level of commercial income, which may vary over time, affecting the priority of the model within a particular NHS Organisation.

Different numbers of studies may affect the format of the most appropriate model.

Complexity or the size of the study may require bespoke arrangements to ensure principles are applied proportionally.

Different approaches may be needed to accommodate the variety in types of researchers in the NHS Organisation eg some NHS Organisations have experienced that their academic researchers prefer to have the money ring fenced, whilst their NHS researchers want the infrastructure (ie ward space, theatre space, nurse, admin).

#### How could this be incorporated?
Create and document the local version of the distribution model.

If an NHS Organisation wide model cannot be agreed, an alternative is to use a per study approach to generate a study specific document to detail the local distribution for each study which is signed off by R&D and PI once the study contract is signed off.

#### What should we consider?
Recognition of other incentives is important, eg access to CRN infrastructure or gaining pre-selected site status.

### Agreement – consensus approach

#### How could we reach an agreement?
The Local CRN could initially gather information regarding the income distribution status of all member NHS Organisations. This could be used by the Local CRN along with this guidance document to work towards a single common solution, if possible, with agreed areas for potential adaption.

Ask each NHS Organisation R&D Department to confirm whether they are broadly in agreement with the proposed income distribution model.

Consult with R&D departments, NHS Organisation management and investigators of each Partner NHS Organisation to determine if the proposed model can support or improve existing arrangements.

Consult each NHS Organisation to generate an individual policy for their NHS Organisation. This could be the single common solution proposed by the Local CRN, if possible, or a variation as necessary. Without adequate
consultation, it is unlikely a single agreement will be reached.

Approaches may be NHS Organisation wide or on a per study basis depending on what works best for each NHS Organisation.

Acquire high level policy sign off, eg NHS Organisation board approval.

<table>
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<tr>
<th>What support is available?</th>
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<tr>
<td>Utilise support of the Local CRN as necessary for a consistent approach.</td>
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<tr>
<td>The Local CRN may be able to provide contacts in areas where a model has been successfully implemented.</td>
</tr>
<tr>
<td>Understand which Investigators have ‘research’ included in their job plans or descriptions or where this appears in the Directorate’s business plan to help leverage support for agreeing a funding model.</td>
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<thead>
<tr>
<th>What should we consider?</th>
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</thead>
<tbody>
<tr>
<td>Reaching consensus locally on use of monies may be difficult and a default position should be discussed for when this occurs eg if no decision can be reached the funds are transferred to the R&amp;D department.</td>
</tr>
<tr>
<td>Consideration of the NHS Organisations local processes for managing commercial income from NIHR CRN portfolio research should be assessed to ensure the model is workable from a practical aspect.</td>
</tr>
<tr>
<td>The benefits of involving the Local CRN in the decision making for spending of capacity building income.</td>
</tr>
<tr>
<td>Ensure all departments are able to function effectively to support research as this has been identified as a stumbling block when looking to implement a model.</td>
</tr>
<tr>
<td>Investigate if the NHS Organisation are invoicing quickly and accurately for commercial income due.</td>
</tr>
<tr>
<td>Investigate if commercial income can be clearly identified as a separate income line by the NHS Organisation.</td>
</tr>
<tr>
<td>The recovery of network costs is an integral part of a transparent model to avoid duplication of funds and consideration should be given to recover this where possible, or offset where deemed more appropriate.</td>
</tr>
<tr>
<td>Avoid upsetting any current arrangements that were effective, find a way to incorporate them instead.</td>
</tr>
</tbody>
</table>
**Processes – embed the principles agreed**

| How can we embed income distribution? | Following local agreement, the model should be translated into real financial accounting and allocation through the NHS Organisation’s budget management, invoice and credit control systems. For recovery of network costs there should be an agreed invoicing schedule to ensure straightforward management, for example, it may be agreed that Network staff costs would be reconciled and invoiced on a 6 month or 12 month basis.  
Encouraging the NHS Organisation’s departments to work together rather than individually in silos eg avoiding departments invoicing sponsors individually.  
Engaging R&D finance resource helps to build stability and find effective solutions.  
Promote a balance between local recovery of costs while aiming to avoid onerous itemisation and invoicing of study costs.  
Ensure the data systems to support tracking of income are available to the NHS Organisation.  
Implement requirement for the NHS Organisation to report to their own Board and Local CRN with information regarding how the capacity building element has been invested locally or the plans for the expenditure.  
Ensure clinical trial agreements financial appendix or cost tools support the display of costs transparently for support of the income distribution model, eg to support matching to a finance schedule to align with invoices (NOTE: this is addressed via functionality in the NIHR CRN Industry Costing Template). Local tools could be developed as needed to help R&D finance departments how to do this for visits and one off payments. This should be achieved with minimal impact on the Sponsor, ie an internal process.  
Perform an analysis of the resources being used currently on all the commercial studies that are actively recruiting (from financial, operational and workforce development perspective) to determine their effectiveness. Understand their funding streams to help evidence further improvements which could be made when supported by a robust income distribution model. |
|---|---|
| What benefit can we promote? | Recognition of the contribution each stakeholder makes to the health research system.  
Improving research income management benefits all stakeholders.  
Network staff costs can be reimbursed to the NHS organisational budget where they are incurred and reinvested to support non-commercial portfolio activity. |
One NHS Organisation puts all the Industry income into one pooled holding account where investigators can make applications for funds to support research they wish to carry out.

Local arrangements may enable the use of CRN support staff for commercial and non-commercial where the costs are identified but put back into research support rather than direct reimbursement, where appropriate.

Reinforce the need to ensure that public funding is not subsidising commercial activity and how the model could support this (Health Service Guidelines [HSG] 97-32 details the ‘Responsibilities for meeting patient care costs associated with research and development in the NHS’).

Capacity building funds could be used to:

- support clinicians write grants or support clinical study groups to increase studies led by local clinicians
- support Patient and Public Involvement (PPI) members who are key to recruitment
- support dedicated areas, eg ambulance service trust study used the capacity building to support the paramedics get involved in research
- distribute by directorate eg imaging department hires mobile MRI units to avoid delays for the procedures or pharmacy use it to support increase in staffing levels.

**What should we consider?**

Reluctance or capacity restraints may create challenges when considering individual study costing and capacity planning.

Encouragement of self-sufficiency ie looking at commercial income to support future studies rather than the CRN initially which frees up funds to support for other research.

Support NHS Organisations to have a clear idea of their commercial income and ability to account for all elements of this by putting local finance teams in contact across the Local CRN or with other Local CRNs to understand how this could be achieved.

Recovery of network costs from commercial studies may need considerations as to the value in terms of cost effectiveness. As an alternative, some areas have reinvested these costs in local research which has helped to improve the perception of participation in commercial research and moved the region away from reliance on CRN funding and enabled portfolio growth.
NIHR CRN Portfolio studies involving other institutions

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.

Universities should not recover additional indirect costs to those in the Industry Costing Template where the research is taking place on NHS premises, for example applying a University overhead value on top of the costing template total.

Reconciling any discrepancies in staff time costs identified in the Industry Costing Template, for example in line with Full Economic Costing, should be done in accordance with the local agreements referenced above between the NHS Organisation and the University. The University cost recovered should not exceed those agreed by the NHS Organisation with the Sponsor for the University staff.

Clinical Research Facilities and resources

CRFs and NIHR infrastructure are key assets in the clinical research environment. If any activity or review is led by the CRF then the money should flow through to these units and departments where and when the activity has occurred. This should be agreed locally between the CRF and the R&D departments during set-up and should not impact on the Sponsor discussions.

Individual cost centres may need to be created to allocate the funds accordingly and the requirements should be discussed with the CRF to ensure this is fit for purpose.

Feedback from an Income Distribution Survey through the UKCRF group in 2013 demonstrated the majority of respondents would be keen to allocate the costs to the CRF on a visit-by-visit basis, ie visit one takes place in outpatients clinic, visit one in the CRF. Consequently visit one costs go to outpatients department (for further distribution as per the NHS Organisation’s income distribution model for task splits) and visit two costs go the CRF.

The survey also showed that the NHS Organisation’s Finance department, R&D Office or CRF staff are all involved in supporting the invoicing for commercial contract studies against the contract and thus all relevant staff should be involved in the implementation discussions to fully understand the processes already established, and how they can work together.

Consideration may also need to be given to CRFs using the CRF intensity tool, in particular how this can be used to support income distribution.
7. Case studies and income distribution breakdown by stakeholder

Case Study 1

This case study demonstrates the application of the recommended income distribution model for an interventional study running in a secondary care hospital which required the use of a NIHR CRN funded research nurse for the full duration of the study. The NIHR CRN staff costs associated with this work has been deducted from the total staff costs of the study to enable the value to be offset against NIHR CRN costs in the current financial year.

TOTAL STUDY BUDGET (inclusive of indirect costs, Capacity Building and Market Forces Factor)

\[
\text{Per patient budget: £8,100} \times \text{Number of patients: 5} = \text{Total Patient Budget: £42,691} = \text{Total study budget: £48,339}
\]

All values inclusive of Market Forces Factor - in this example 1.054 (5.4% uplift)

- **PROCEDURES:** £30,042
- **STAFF TIME:** £15,812
  - 70% INDIRECT COST: £11,068
  - 20% CAPACITY BUILDING: £3,162
- **INVESTIGATIONS:** £12,649
- **VALUE:** £10,541
  - 20% CAPACITY BUILDING: £2,108

- **Pharmacy costs:** £4,331
- **Set-up costs:** £1,317

Direct staff costs retained by the Hospital
Direct staff costs for NIHR CRN funded research nurse time on study to offset against NIHR CRN costs
Allocated to a research account for the PI & Team
To Hospital for indirect cost coverage
To Hospital for reinvestment in research

Retained by the Hospital to reimburse to provide departments
To Hospital for reinvestment in research

\[ \text{Number of patients: 5} \times \text{Per patient budget: £8,100} = \text{Total Patient Budget: £42,691} \]

\[ \text{TOTAL STUDY BUDGET (inclusive of indirect costs, Capacity Building and Market Forces Factor)} \]

\[ \text{Per patient budget: £8,100} \times \text{Number of patients: 5} = \text{Total Patient Budget: £42,691} = \text{Total study budget: £48,339} \]

All values inclusive of Market Forces Factor - in this example 1.054 (5.4% uplift)
<table>
<thead>
<tr>
<th>Department</th>
<th>Value</th>
<th>As % of total study budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital (direct and indirect costs)</td>
<td>£29,936</td>
<td>61.9%</td>
</tr>
<tr>
<td>Hospital R&amp;D Department</td>
<td>£738</td>
<td>1.5%</td>
</tr>
<tr>
<td>Hospital Support Department(s)</td>
<td>£158</td>
<td>0.3%</td>
</tr>
<tr>
<td>Hospital Pharmacy</td>
<td>£4,331</td>
<td>9%</td>
</tr>
<tr>
<td>NIHR CRN staff costs</td>
<td>£2,372</td>
<td>5%</td>
</tr>
<tr>
<td>Research account for PI &amp; Team</td>
<td>£5,534</td>
<td>11.4%</td>
</tr>
<tr>
<td>Capacity Building</td>
<td>£5,270</td>
<td>10.9%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>£48,339</td>
<td>100%</td>
</tr>
</tbody>
</table>
Case Study 2

This case study demonstrates the application of the recommended income distribution model for an observational study, and therefore no Pharmacy involvement, where no NIHR CRN support was required to deliver the study. However, a University employed staff member did provide administrative support to the study.

TOTAL STUDY BUDGET (inclusive of indirect costs, Capacity Building and Market Forces Factor)

\[
\text{Per patient budget: £4,238} \times \text{Number of patients: 5} = \text{Total Patient Budget: £21,190}
\]

All values inclusive of Market Forces Factor – in this example 1.138 (13.8% uplift)

R&D management Fee: £797

Full fee distributed to the Hospital R&D department where the set-up task was performed/costs incurred

Chief Investigator Fee: £1,366

Full fee allocated to the PI research account

Site initiation Fee: £455

Full fee distributed to the Hospital clinical department where the set-up task was performed/costs incurred
<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
<th>As % of total study budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital (direct and indirect costs)</td>
<td>£15,152</td>
<td>63.6%</td>
</tr>
<tr>
<td>Hospital R&amp;D Department</td>
<td>£797</td>
<td>3.5%</td>
</tr>
<tr>
<td>University (direct costs only)</td>
<td>£1,367</td>
<td>5.7%</td>
</tr>
<tr>
<td>Research account for PI &amp; Team</td>
<td>£3,758</td>
<td>15.7%</td>
</tr>
<tr>
<td>Capacity Building</td>
<td>£2,734</td>
<td>11.5%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>£23,808</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
8. Conclusions

The money generated from industry-sponsored studies is a valuable source of income for NHS Organisations. This income can be used to encourage key research stakeholders to develop capacity for new research within the NHS Organisation and support future income generation.

It is important that investigators are incentivised to carry out commercial research, but this should be balanced with the requirements of the NHS Organisation and NIHR CRN to recover their costs where appropriate.

This document recommends key principles and good practice for the distribution of income from industry-sponsored studies to support local agreement of a suitable approach for each NHS Organisation.

The model proposed in this guidance is based on piloted cases and feedback.

The NIHR CRN aims to ensure that systems to manage and distribute commercial income work towards and achieve the strategic research priorities outlined by 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.

Frequently asked questions:

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why shouldn't the NHS Organisation keep all the indirect costs?</td>
<td>The indirect cost element percentage is set within the NIHR CRN Industry Costing Template at a level which captures these costs incurred by the NHS Organisation but also ensures a margin for flexible financial management. Best practice has shown that there is capacity within this to incentivise investigators if the NHS Organisation also retains the direct costs and delivers an efficient service.</td>
</tr>
<tr>
<td>Do NHS Organisations have to use the Industry Costing Template?</td>
<td>Use of the Industry Costing Template format for display and agreement of costs is recommended for NIHR CRN portfolio industry studies. It is acknowledged that a single template and recommended values cannot reflect the range of research studies and requirements without adjustments. As each NHS Organisation is an individual legal entity and therefore responsible for its own finances, the values within the template are subject to variation where deemed necessary and with supporting justification.</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
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<td>-------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td>Can our NHS Organisation change the distribution percentages?</td>
<td>The distribution percentages utilised in this model can be changed to any equivalent of the 70% indirect costs that works for your local arrangement as demonstrated in the examples provided in this guidance.</td>
</tr>
</tbody>
</table>
| Does our Network have to recover the staff costs funding from the NHS Organisation? | The Local CRN is expected to account for the NIHR CRN funded staff costs utilised in local research to ensure that no “double funding” occurs and to support “value for money” spending initiatives.  

The Health Service Guidelines (HSG) 97-32 ‘Responsibilities for meeting patient care costs associated with research and development in the NHS’ state that “All Costs Associated with Commercial R&D to be met by company concerned” which ensures commercial sponsors pay for the resource requirements of any research that they initiate. This is reflected in the NIHR CRN Industry Costing Template principles to support full cost recovery for the NHS and provide a mechanism through which to recover research monies where it is whole and recognisable within the NHS Organisation’s accounting.

The potential recover of such monies ensures the NIHR CRN upholds a high standard of financial management, due diligence and responsibility for public sector derived monies. Accountability for NIHR CRN funded resource should be be managed through local agreements between the NHS Organisations and Local CRNs, especially in instances where this funding is not required to flow back on a per study or long-term basis (eg, in certain instances where local arrangements may have been made and agreed that income is to “pump prime” research locally). |
| Is there an expectation that some of the money should go to the NIHR CRN for management of the Feasibility and Eligibility Process? | Payment for the management of NIHR CRN Feasibility and Eligibility Process is a separate consideration to the practices outlined in this document. The funding to the NIHR CRN for provision of such cross-cutting research delivery services is provided through the funding allocation from the Department of Health. The involvement of any NIHR CRN staff in the provision of this service for a portfolio study should not form part of NIHR CRN staff recovery costs associated with the delivery of the NIHR CRN Portfolio commercial study. |
9. Key contact

For more information, advice or assistance on implementing this guidance, please contact:

NIHR CRN Industry Team
Email: supportmystudy@nihr.ac.uk

10. Abbreviations

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>CEO</td>
<td>Chief Executive Officer</td>
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<tr>
<td>CRF</td>
<td>Clinical Research Facility</td>
</tr>
<tr>
<td>CRN</td>
<td>Clinical Research Network</td>
</tr>
<tr>
<td>FEC</td>
<td>Application of Full Economic Costing</td>
</tr>
<tr>
<td>I&amp;E</td>
<td>Income and Expenditure</td>
</tr>
<tr>
<td>ISHPs</td>
<td>Independent Sector Healthcare Providers</td>
</tr>
<tr>
<td>mCTA</td>
<td>Model Clinical Trial Agreement</td>
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<tr>
<td>MFF</td>
<td>Market Forces Factor</td>
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<tr>
<td>NIHR</td>
<td>National Institute for Health Research</td>
</tr>
<tr>
<td>PPI</td>
<td>Patient and Public Involvement</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
</tr>
</tbody>
</table>