## Commercial Income Distribution Policy

<table>
<thead>
<tr>
<th>Purpose of Agreement</th>
<th>To outline the rationale behind and process for allocating income earned from commercial research trials between the Trust and the Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Type</td>
<td>Policy</td>
</tr>
<tr>
<td>Reference Number</td>
<td></td>
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<td>Version</td>
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COMMERCIAL INCOME DISTRIBUTION POLICY

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Commercial Income Distribution Policy

1. INTRODUCTION & PURPOSE

1.1. The purpose of this document is to inform stakeholders within the Trust of the income made available through the Industry Costing Template and outlines a process for incentivising stakeholders participating in commercial research.

1.2. Commercial research is defined as research that is sponsored and funded by commercial companies, usually pharmaceutical or device manufacturers, and is directed towards product licensing and commercial development.

1.3. According to health service guidelines (HSG(97)32), NHS Trusts are expected to recover all costs of commercial research and development from the company concerned.

1.4. The Department of Health considers the delivery of industry funded and sponsored research a priority. The benefits of commercial research include the opportunity for Trusts and their patients to:
   - Access new treatments, practices and procedures
   - Access large scale clinical trials
   - Generate income for re-investment back into research, facilities and patient care.

1.5. As a member of the Hampshire and IOW Comprehensive Local Research Network, Solent NHS Trust is required to meet their performance management metrics. In 2012/13 this includes an increase in portfolio commercial research studies. Funding in future years is based on performance according to these metrics.

1.6. It is a key strategic goal within the Solent Research and Service Evaluation Strategy to increase commercial research contracts. This will only be achieved if clinicians are supported to do this research, and are incentivised to do so, in the form of income generation for their teams and departments.

2. SCOPE

2.1. This document applies to all directly and indirectly employed staff within Solent NHS Trust and other persons working within the organisation in line with Solent NHS Trust’s Equal Opportunities Document.

2.2. This policy applies to all income earned from commercial research trials, both portfolio and non-portfolio.

3. DEFINITIONS

3.1. A glossary is provided in Appendix 1 for all definitions and acronyms used in this policy.
3.2 For the purposes of this policy, the Investigator is the lead investigator from within the Trust (normally a Chief or Principal Investigator, or Study Collaborator).

4. INDUSTRY COSTING TEMPLATE

4.1 Commercial life science research commitments in the UK have declined in the UK in recent years. In the context of globally competitive clinical research, the UK has tended to be more expensive that other countries in Europe and Asia for conducting industry sponsored studies. Historically there has been a widely varying cost of conducting a study throughout the UK and the inconsistent and non-transparent methods used by NHS Trusts and Foundation Trusts to calculate commercial prices.

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

4.3 As a remedy to these issues, the NIHR CRN released the Industry Costing Template in May 2008. This research pricing tool has been adopted as the industry standard 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.

4.4 The NIHR CRN Industry Costing process:
   - Provides a clear methodology to calculate consistent and transparent prices associated with industry-sponsored studies to support industry, the NHS and the NIHR Networks
   - Ensures all NHS Trusts are fully reimbursed for any activities associated with industry studies, in accordance with the requirements of the NHS Finance Manual
   - Identifies standard rates for staff time, overheads, capacity building, investigations and costs for departments supporting research, which are acceptable to all parties
   - Speeds up the negotiation process for costing and is one of several tools being introduced to speed up trial initiation and ensure the Networks provide a value for money environment for trials
   - Provides clear guidance for Industry and the public sector

4.5 The NIHR 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).

4.6 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".
4.7 Solent NHS Trust will use this costing template as a default. Should it inherit studies with alternative costing methods, the principles of distribution between Trust and investigator will still be applied.

5 INDUSTRY COSTING TEMPLATE ELEMENTS

5.1 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.

5.2 Per Patient Budget

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

Staff Costs: NHS Trust costs + 70% overhead + 20% capacity building

Investigation costs: NHS Trust costs for investigations (inclusive of Trust’s operating overhead) + 20% capacity building

5.3 Overheads

In the Industry Costing Template a standard overhead rate of 70% is added only to the staff costs 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, 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 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 was an attempt to both standardise terminology and to ensure that there was a mechanism within the Industry Costing Template to capture indirect costs with other utility and efficiency margins for the Trusts.

5.4 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, to ensure a greater volume of research can be delivered in the future.
5.5 Pharmacy costs

Where applicable, 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.

5.6 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 of £700 based on the national average of fees charged. Historically Solent NHS Trust has charged £750 which has been accepted without complaint. It is proposed given the extra management time required for recently introduced metrics that this is increased to £795 from April 2012. 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. The costs of meeting other trial related costs can be documented as needed and should be listed separately from the per patient budget amount.

6 KEY PRINCIPLES

6.1 The principles of commercial income distribution are:

- Departments and individuals are recognised for their contribution to commercial research within the Trust and are incentivised fairly.
- All costs incurred by the Trust are fully recovered
- Commercial research continues to afford both investigators and the Trust the opportunity to fund additional research related activities.
- Income from commercial research can be distributed and carried over financial years in line with the finance control procedures of the Trust, and in accordance with the research priorities agreed between clinical divisions, the research department, service support departments, individual investigators and senior Trust management.
- The Trust will be able to:
  - Set research priorities across the Trust
  - Develop senior investigators within its staff, and attract new staff with highly developed research skills
  - Grow research capacity for the long-term

7 INCOME DISTRIBUTION MODEL

7.1 Staff Costs: Direct costs + Overhead (70%) + Capacity Building (20%)

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

The researchers must be given time to carry out the research, the income will be provided to the department to allow for “backfill” of the researchers post or for staff time to carry out research activity. This time can include additional/ overtime payments for staff working on the research project.

If backfill is not provided the researchers cost will be allocated to the Investigator’s research fund to facilitate future research.
7.2 Distribution of the overhead element – 70% added to NHS Trust direct costs in the Industry Costing Template

a) **25% of the overhead element stays with the NHS Trust** to cover indirect costs. (Suggest this goes either directly to Research to fund support activity or if necessary, the usual overhead percentage goes to the Trust)

b) **75% of this overhead element is designated for the Principal Investigator** (to be allocated to a cost centre through which the PI has a decision making capacity in the use of the funds. The funds will be used for research capacity building in the service)

Good practice observed by NIHR networks has shown that splitting the overhead element provided incentives for investigators and service support departments to participate in research. This followed recognition by Trust management that it has a responsibility to drive research and find efficiencies to incentivise people. The financial incentives are passed through to a PI through a supervised research fund.

7.3 Distribution of the Capacity Building element – 20% within the Industry Costing Template

The capacity building element attributed to investigations and to staff will be reinvested by R&D. This fund can be used to further support activity by the PI of the study, or to increase capacity and research activity across the Trust.

The key to the distribution model is incentivisation, and the opportunity to develop skills and research capacity within the service.

7.4 Investigation Costs: Direct Costs + Capacity Building (20%)

The **Direct costs** are paid to the department which incurs them (generally the department in which the research is carried out, but may be other support departments)

The **Capacity Building** element goes to the R&D account for research development.

8. ACCOUNTING PROCESS

8.1 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 the relevant departmental cost centre. In this way the Study cost centre becomes the “Income & Expenditure” account for the study providing transparency to both the Sponsor and the Trust.

8.2 The 70% overhead charge will be split 25:75 and coded to the Trust R&D budget and an PI account held for the investigator on payment of the invoice to the commercial company.

8.3 The 20% staff capacity building will be credited to the Research cost code on payment of the invoice to the commercial company.

8.4 The 20% investigation capacity building will be credited to Research cost code on payment of the invoice.
8.5 Where the Industry template is not used and only the 70% overheads are applied (no capacity building), the distribution of these overheads will be equally split (50:50) between the Trust and the Investigator.

8.6 The PI will have their own research cost centre against which they will have decision making authority, within certain parameters. The parameters will ensure the protection of the fund for building research capacity within their team and across their service area. As research studies are rarely within year, this fund will be eligible to be carried over at year end provided there is a spending plan against that fund, agreed by the Investigator, the Service Manager, Manager, the Medical Director and the Research Manager. This will act as a guarantee that funds are utilised to discharge the fundamental principle of encouraging key stakeholders to develop capacity for new research within the Trust. Examples of use for the funds are research nurses/staff; training (or backfill to accommodate this); studentships; conferences; research sessions for the PI.

8.7 Annual spending plans must be submitted between Jan – Feb each Financial Year.

9 CONCLUSIONS

9.1 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.

9.2 It is important that investigators are incentivised to carry out commercial research, but this should not be to the detriment of the NHS Trust who must be able to recover their costs.

9.3 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 networks 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.
10. Case Study

Dr Black is a consultant diabetologist working for Seaside Community NHS Trust. He is approached by Mega Devices to take part in a study to test their new infection screening test.

Dr Black agrees to participate in the study and estimates that his service can recruit 35 patients.

He contacts the R&D Department to let them know about the study and completes the necessary forms for approval via the IRAS system.

A representative from Mega Devices forwards the completed Costing Template and model Clinical Investigation Agreement to the R&D Department. They agree the costings and arrange for the mCIA to be signed.

Once R&D Approval has been given by Seaside Hospital, the Trust invoices Mega Devices for £795.00.

At the end of the study, the research team have recruited all 35 patients. In total, Seaside Hospital invoices Mega Devices for £13,405.

R&D invoiced separately for the R&D Set up fee.

Seaside Hospital NHS Trust and the local Network have implemented all elements of the NIHR CRN income distribution model. The Capacity Building element has been collected and retained into an R&D account.

Distribution of the income received from this study can be seen in diagram 1.
Diagram 1: Case Study – Distribution of income using industry template

<table>
<thead>
<tr>
<th>Per Patient Budget</th>
<th>No of patients</th>
<th>Total Budget</th>
<th>Direct Invoicing</th>
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<tbody>
<tr>
<td>£383</td>
<td>35</td>
<td>£13,405</td>
<td>£795</td>
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R&D Set-up fee

Pharmacy costs

Total Study budget

£13,405

Distribution of income

<table>
<thead>
<tr>
<th>Total Study budget</th>
<th>Pharmacy costs</th>
<th>R&amp;D Set-up fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>£13,405</td>
<td>£0</td>
<td>£795</td>
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Total patient budget + Pharmacy costs + R&D Set-up fee

Total patient budget = Investigations + Staff Costs

Investigations = Income to Depts + Capacity Building (20%)

Investigations

<table>
<thead>
<tr>
<th>Investigations</th>
<th>Income to Depts</th>
<th>Capacity Building (20%)</th>
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<tbody>
<tr>
<td>£2,335</td>
<td>£1,868</td>
<td>£467</td>
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Staff Costs = To Dept + 70% Overhead + Capacity Building (20%)

Staff Costs

<table>
<thead>
<tr>
<th>Staff Costs</th>
<th>To Dept</th>
<th>70% Overhead</th>
<th>Capacity Building (20%)</th>
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<tbody>
<tr>
<td>£11,070</td>
<td>£5,826.32</td>
<td>£4,078.42</td>
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70% Overhead = 75% to Investigator + 25% to Trust

70% Overhead

<table>
<thead>
<tr>
<th>70% Overhead</th>
<th>75% to Investigator</th>
<th>25% to Trust</th>
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<tbody>
<tr>
<td>£4,078.42</td>
<td>£3,058.82</td>
<td>£1,019.60</td>
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Capacity building

<table>
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<tbody>
<tr>
<td>£1632.26</td>
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<td>£2,651.86</td>
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<tr>
<td>Distribution Summary</td>
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<td>------------------------------------------</td>
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<tr>
<td>Income to Depts Investigations</td>
</tr>
<tr>
<td>Income to Depts Staff Costs</td>
</tr>
<tr>
<td>Department Income</td>
</tr>
<tr>
<td>Staff Capacity building</td>
</tr>
<tr>
<td>Investigations Capacity building</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
<tr>
<td><strong>R&amp;D Income</strong></td>
</tr>
<tr>
<td>25% Overhead to Trust</td>
</tr>
<tr>
<td><strong>Trust Income</strong></td>
</tr>
<tr>
<td>75% Overhead to Investigator</td>
</tr>
<tr>
<td><strong>Total Budget</strong></td>
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</table>
11. Flow Chart

Departmental Income will be shown in the CSC’s cost centre as R&D Commercial income (check with Paul).

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12. REFERENCES

NIHR Industry Team (2011) Income Distribution from NIHR CRN Industry Portfolio Studies

13. GLOSSARY

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CLRN</td>
<td>Comprehensive Local Research Network</td>
</tr>
<tr>
<td>CRN</td>
<td>Clinical Research Network</td>
</tr>
<tr>
<td>CRO</td>
<td>Clinical Research Organisation</td>
</tr>
<tr>
<td>DH</td>
<td>Department of Health</td>
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<tr>
<td>H&amp;IOW CLRN</td>
<td>Hampshire and IOW Comprehensive Local Research Network</td>
</tr>
<tr>
<td>NIHR</td>
<td>National Institute for Health Research</td>
</tr>
<tr>
<td>Non-PF</td>
<td>Non-portfolio</td>
</tr>
<tr>
<td>NRES</td>
<td>National Research Ethics Service</td>
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<td>PCRN</td>
<td>Primary Care Research Network</td>
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<td>PF</td>
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<tr>
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