Commercial Research Income Distribution Policy

Solent NHS Trust policies can only be considered to be valid and up-to-date if viewed on the intranet. Please visit the intranet for the latest version.

Purpose of Agreement	To outline the rationale behind and process for allocating income earned from commercial research trials between the Trust and the Investigator/ Service
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Amendments Summary:

Please fill the table below:

Amend No	Issued	Page	Subject	Action Date

Review Log:

Include details of when the document was last reviewed:

Version Number	Review Date	Lead Name	Ratification Process	Notes
1.0	May 2017	Sarah Williams	R&D Group, Policy Group, Assurance Committee	Update to reflect update in national document/ process
2	April 2020	Sarah Williams	Approved as part of the Covid-19 review of policies	Expiry date extended to March 2021

SUMMARY OF POLICY

This policy outlines the process for distributing income earned from commercially sponsored research projects. It follows the national guidelines published by the National Institute for Health Research (NIHR, January 2017). The income/ costing for these research projects is calculated using the NIHR Costing Template for Industry Studies.

Income is distributed to ensure that:

1. Direct costs are covered where they are incurred
2. Overheads and the Research Capacity Build Element are used to incentivise staff to be involved in research, and to develop skills and capabilities to enable them to do this safely.

The policy outlines the model for the distribution of this income (see Flow chart in Appendix B).

Table of Contents

Commercial Research Income Distribution Policy

1. INTRODUCTION & PURPOSE

1.1. The purpose of this document is to outline a process for distributing income earned from participation in commercially funded research

1.2. The document is based on the national guidelines issued by the National Institute for Health Research (January 2017) and outlines a process for incentivising research teams and grow research capacity.

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

1.4. As part of its strategic objectives, and as partners with the Clinical Research Network (Wessex), Solent NHS Trust has specific objectives to support commercial research, reflecting the importance and benefits of commercial research which include:

1.4.1. Access to novel compounds, new practices and procedures
1.4.2. Access to well managed and monitored clinical trials for investigators and patients
1.4.3. Access to large scale international trials
1.4.4. Income generation for NHS organisations
1.4.5. Wealth generation for the UK economy.

1.5. The principles which underpin the distribution of income model are:

- Departments and Individuals are recognised and incentives for their contribution
- All relevant costs incurred are recovered from the Commercial Partner
- Commercial research affords opportunities to fund research or research related activities
- Income from commercial research can be distributed and carried over in line with finance control procedures
- Overly onerous itemisation and invoicing of study costs are avoided where possible.
- 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

2. SCOPE & DEFINITIONS

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.

2.3 A glossary is provided in Appendix 1 for all definitions and acronyms used in this policy.

2.4 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).

3. INDUSTRY COSTING TEMPLATE

3.1 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.

3.2 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

3.3 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

3.4 **Direct Costs:**
Direct costs will be reimbursed to the department where the staff member is employed to fully compensate for the work performed.

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.

Investigation Costs: Direct costs of investigations related to the research are paid to the department incurring the costs, or who are carrying out the investigation (examples are phlebotomy, pathology, radiology).

3.5 **Indirect Costs (Overheads)**
A standard rate of 70% will be added to the NHS staff time direct costs. This provides a representative value for the indirect costs when conducting a commercial trial which are not already covered by the direct costs (i.e. 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 (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 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.

3.6 **Capacity Building**

A capacity building rate of 20% is added to both direct staff time costs and investigations. This is designed to build sustainable research and innovation capacity to the benefit of all research partners. This element is separate from the 70% indirect costs to enable it to be easily ring-fenced for maintaining, strengthening, and 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'.

3.7 **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.

3.8 **Pharmacy costs**

Where applicable, pharmacy costs are calculated separately. 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.

3.9 **Set up and other trial related costs**

The pre-trial and on-going 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.

4. INCOME DISTRIBUTION MODEL

1.1 *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.

2.1 *Distribution of the overhead element – 70% added to NHS Trust direct costs in the Industry Costing Template*

a) 50% of the overhead element is allocated to the R&D budget to cover management costs and capacity build.

b) **50% of this overhead element is designated for the Principal Investigator** Fund. This will be managed via the R&D budget, and the PI will have the decision making capacity in the use of the funds. The funds will be used for research capacity building in the service and can be shared with the clinical team. PIs will be required to provide spending plans against the fund.

3.1 *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.

4.1 *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.

5. ACCOUNTING PROCESS

5.1 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.

5.2 The 70% overhead charge will be split 50:50 and coded to the Trust R&D budget and a PI account held for the investigator on payment of the invoice by the commercial company.

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

5.4 The 20% investigation capacity building will be credited to Research cost code on payment of the invoice.

6. CONCLUSIONS

6.1 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.

6.2 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.

7. REFERENCES AND LINKS TO OTHER DOCUMENTS

7.1 (NIHR 2017) Income Distribution from NIHR CRN Industry Portfolio Studies Version 4.0

8. GLOSSARY

Abbreviation	Full term
CRN	Clinical Research Network
DH	Department of Health
NIHR	National Institute for Health Research
Non-PF	Non-portfolio
NRES	National Research Ethics Service
PF	Portfolio
PI	Principal Investigator
R&D	Research and Development

Appendix: A

Equality Impact Assessment

Step 1 – Scoping; identify the policies aims	**Answer**		
1. What are the main aims and objectives of the document?	To outline the process for the distribution of income earned from commercial/ industry funded/ sponsored research		
2. Who will be affected by it?	Staff/ services involved in the delivery of commercial research (research that is funded by industry)		
3. What are the existing performance indicators/measures for this? What are the outcomes you want to achieve?	Increase in research capacity and capability in the Trust – number of studies and participants		
4. What information do you already have on the equality impact of this document?	N/A		
5. Are there demographic changes or trends locally to be considered?	N/A		
6. What other information do you need?	None		
Step 2 - Assessing the Impact; consider the data and research	**Yes**	**No**	**Answer** (Evidence)
1. Could the document unlawfully discriminate against any group?		x	
2. Can any group benefit or be excluded?		x	
3. Can any group be denied fair & equal access to, or, treatment as a result of this document?		x	
4. Can this actively promote good relations with and between different groups?	x		Between research teams and clinical staff
5. Have you carried out any consultation internally/externally with relevant individual groups?	x		Research active clinicians; finance
6. Have you used a variety of different methods of consultation/involvement?	x		Email, meetings – this is a national process being adopted by this Trust
7. Mental Capacity Act implications		x	

8. Will this document require a decision to be made by or about a service user? (Refer to the Mental Capacity Act document for further information)		x	

If there is no negative impact – end the Impact Assessment here.

Step 3 - Recommendations and Action Plans	**Answer**
1. Is the impact low, medium or high?	
2. What action/modification needs to be taken to minimise or eliminate the negative impact?	
3. Are there likely to be different outcomes with any modifications? Explain these?	
Step 4- Implementation, Monitoring and Review	**Answer**
1. What are the implementation and monitoring arrangements, including timescales?	
2. Who within the Department/Team will be responsible for monitoring and regular review of the document?	
Step 5 - Publishing the Results	**Answer**
How will the results of this assessment be published and where? (It is essential that there is documented evidence of why decisions were made).	

****Retain a copy and also include as an appendix to the document****

APPENDIX B:

Flow Chart