Portsmouth Hospitals NHS
NHS Trust

Income Distribution from Commercial Research Activity

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Version Tracking

Version	Date Ratified	Brief Summary of Changes	Author
5	06-08-2017	Reformatted in line with trust policy document, minor changes to text to accommodate reformatting, figures page 3 updated, minor revisions to text, addition of the appendix & flowchart (appendix 1)	DM/AM

CONTENTS

QUICK REFERENCE GUIDE

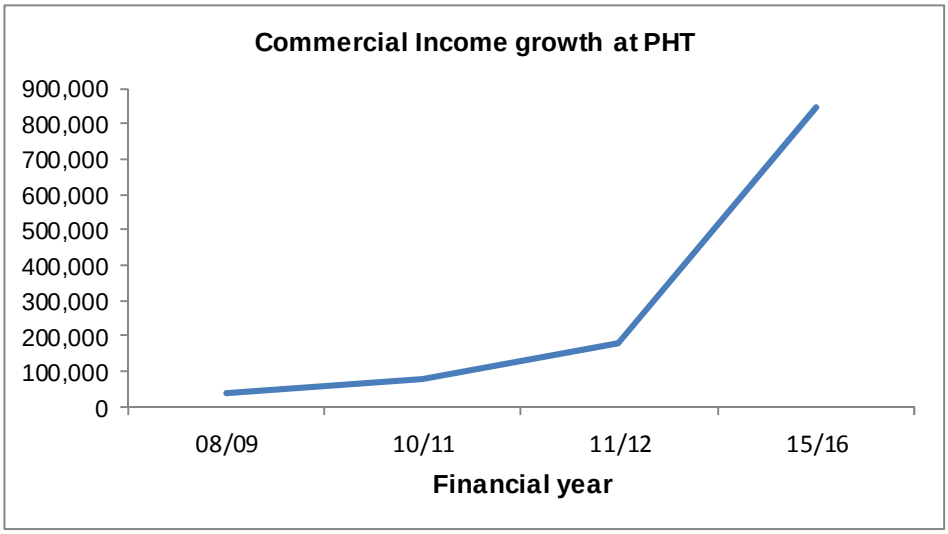
This policy must be followed in full when developing or reviewing and amending Trust procedural documents.

1. The purpose of this document is to inform stakeholders within Portsmouth Hospitals NHS Trust (the Trust) of the income made available via industry sponsored contract trials and specify how to incentivise the research community participating in such commercial research.

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

3. The principles of commercial income distribution are:
    1. Departments and individuals are recognised for their contribution to commercial research within the Trust and are incentivised fairly.
    2. All costs incurred by the Trust are fully recovered (refer to Appendix 1)
    3. Commercial research continues to afford both investigators and the Trust the opportunity to fund additional research related activities.
    4. Income from commercial research can be distributed and carried over in line with the finance control procedures of the Trust.
    5. The Trust will be able to:
        i. Set research priorities across the Trust
        ii. Grow research capacity for the long-term

4. The income generated from industry-sponsored studies has grown significantly since the financial year 2008/09. A policy to recognise the Trust, departments and individuals for their contribution to commercial research is a necessity.



INTRODUCTION

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.

The NHS is encouraged to support commercially sponsored research as it is an opportunity to:

- participate in drug and device development
- evaluate new equipment
- become involved with the development of improved treatment for current and future NHS patients
- generate income for re-investment back into research, facilities and patient care.

The NHS Constitution confirms the commitment of the NHS "to the promotion and conduct of research". The Handbook to the NHS Constitution states "the NHS will do all it can to ensure that patients, from every part of England, are made aware of research that is of particular relevance to them". The NHS Operating Framework states "the NHS must play its full part in supporting health research" and "all providers of NHS care will need to increase their participation in research"

The Department of Health considers the support and delivery of industry-funded and sponsored research to be a priority. To support that priority, it is crucial that all stakeholders are incentivised to participate in industry-sponsored research. The need for incentivisation is reflected in the good practice laid out in this document.

The numerous benefits of commercial research include:

1. Wealth generation for the UK economy
2. Income generation for the Trust
3. Access to novel compounds, new practices and procedures
4. Access to large scale clinical trials
5. Access to well managed and monitored clinical trials for both investigators and patients

In the context of globally competitive clinical research, the UK has tended to be more expensive than 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.

The financial variability, especially for multi-center 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.

As a solution 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.

PURPOSE

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.

This policy is in line with the R&I strategic objective 'Maximise the health and economic benefits of research to improve patient care; ensure that all income from research and research innovation is managed effectively and protected'.

SCOPE

This document applies to all trust stakeholders who are involved in research (e.g. Chief Investigators, Principal Investigators, Research Staff, Finance, Clinical Directors).

'In the event of an infection outbreak, flu pandemic or major incident, the Trust recognises that it may not be possible to adhere to all aspects of this document. In such circumstances, staff should take advice from their manager and all possible action must be taken to maintain ongoing patient and staff safety'

DEFINITIONS

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.

DUTIES AND RESPONSIBILITIES

All stakeholders engaged in research or managing funds from commercial research activities are required to follow the process outlined in the industry costing process and distribution model.

PROCESS

Industry Costing Template

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.

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

The NIHR CRN Industry Costing process:

1. Provides a clear methodology to calculate consistent and transparent prices associated with industry-sponsored studies to support industry, the NHS and the NIHR Networks
2. Ensures all NHS Trusts are fully reimbursed for any activities associated with industry studies, in accordance with the requirements of the NHS Finance Manual
3. Identifies standard rates for staff time, overheads, capacity building, investigations and costs for departments supporting research, which are acceptable to all parties
4. 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
5. Provides clear guidance for Industry and the public sector

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).

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.

Industry Costing Template Elements

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

Per Patient Budget

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

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

Overheads

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&I 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.

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

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

R&D and Other trial related costs
The pre-trial and ongoing R&I 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&I set-up fee based on the national average of fees charged. This R&I 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 within this section.

Key Principles
The principles of commercial income distribution are:

1. Departments and individuals are recognised for their contribution to commercial research within the Trust and are incentivised fairly.
2. All costs incurred by the Trust are fully recovered
3. Commercial research continues to afford both investigators and the Trust the opportunity to fund additional research related activities.
4. Income from commercial research can be distributed and carried over in line with the finance control procedures of the Trust.
5. The Trust will be able to:
   i. Set research priorities across the Trust
   ii. Grow research capacity for the long-term

Income Distribution Model

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.

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

Overheads attributed to staff costs will be divided between the Investigator and the Trust - 75:25 split

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

Capacity Building attributed to investigations will be reinvested by R&I.

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

Accounting Treatment

Staff costs, investigation costs and pharmacy charges will be coded directly to the income distribution cost centre. The income will be distributed to the department, investigator and R&I via a Departmental Transfer.

The 70% overhead charge will be split 75:25 and coded to overheads and an R&I account held for the investigator on the invoice to the commercial company.

The 20% capacity building will be credited to R&I on the invoice to the commercial company.

Funds held in the R&I accounts for either the Investigator or R&I can only be accessed with the agreement of the R&I Director.

The two capacity building accounts (75% overhead investigator and 20% capacity building cost centres) will be held under the R&I accounts hierarchy.

Annual spending plans must be submitted to Trust R&I finance between Jan – Feb each Financial Year. Annual spending plans will be agreed with the Director of R&I to guarantee that funds are utilised to discharge the fundamental principle of encouraging key stakeholders to develop capacity for new research within the Trust.

Where the activity is attributed to clinicians in areas where R&I already support existing staff such as research fellows, income generated will be utilised to contribute to this cost. Each approved study will be supported by the inclusion of a financial distribution template.

Conclusions

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.

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

The NIHR CRN wants to ensure that systems to manage and distribute commercial income work towards and achieve the strategic research priorities outlined by the local research community and the Department of Health. A critical part of achieving these objectives will be making sure that investigators and service support departments in the research system are sufficiently incentivised and reimbursed.

Case Study

Dr Black is a consultant diabetologist working for Seaside Hospital NHS Trust. He is approached by Mega Devices to take part in a study to test their new blood glucose monitor.

The study has been adopted onto the NIHR CRN portfolio. Dr Black discusses the study with his research team and agrees that they can recruit 35 patients. He contacts the Seaside Hospital R&I Department to let them know about the study and so they can begin study set up.

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

Once R&I Approval has been given by Seaside Hospital, the Trust invoices Mega Devices for £707.00.

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

R&I invoiced separately for the R&I 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&I account.

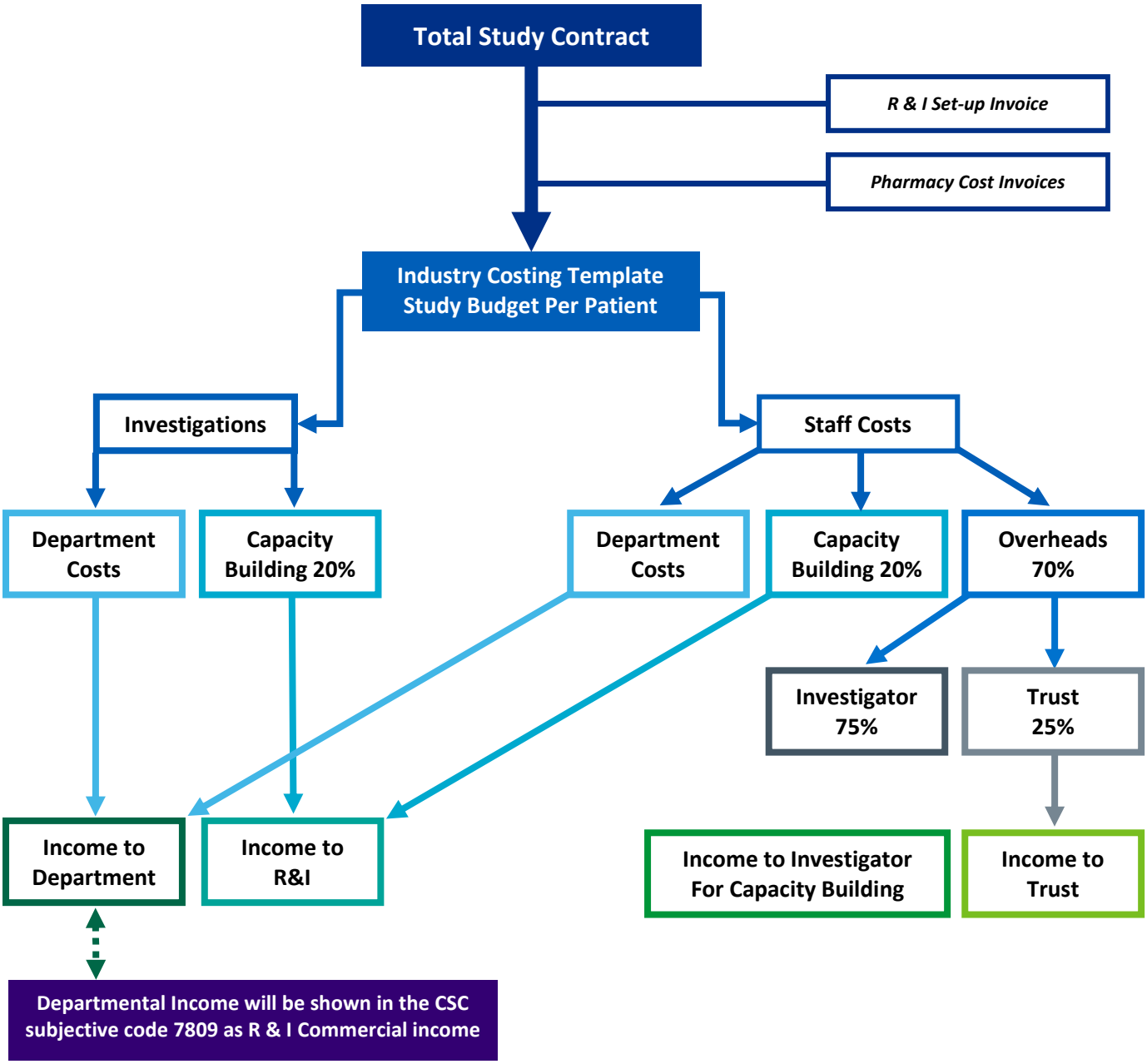
Distribution of the income received from this study can be seen in diagram 1.

Diagram 1

Case Study – Distribution of income

Per Patient Budget		No of patients		Total Budget		Direct Invoicing
£383		35		**£13,405**		
R&I Set-up fee						**£762**
Pharmacy costs						**£0**
Total Study budget				**£13,405**		
Distribution of income						
Total patient budget		Pharmacy costs		Total per Patient Income		
£13,405	+	£0	=	**£13,405**		
Total patient budget		Investigations		Staff Costs		
£13,405	=	£2,335	+	£11,070		
Investigations		Income to Depts.		Capacity Building		
£2,335	=	£1,945.83	+	£389.17		
Staff Costs		To Dept		70% Overhead		Capacity Building
£11,070	=	£5,826.32	+	£4,078.42	+	£1,165.26
70% Overhead		75% to Investigator		25% to Trust		
£4,078.42	=	£3,058.82	+	£1,019.61		
Distribution Summary						
Income to Depts. Investigations		Income to Depts. Staff Costs		Total		% Income
£1,945.83	+	£5,826.32	=	**£7,772.15**		**58%**
Department Income						
Staff Capacity building		Income to R&I Capacity building		Total		% Income
£1,165.26	+	£389.17	=	**£1,554.43**		12%
R&I Income						
25% Overhead		25% Trust Income		Total		% Income
£1,019.61		£1,019.61		**£1,019.61**		8%
75% Overhead to Investigator				Total		% Income
£3,058.82				**£3,058.82**		23%
Total Budget						
				£13,405.00		

Flow Chart

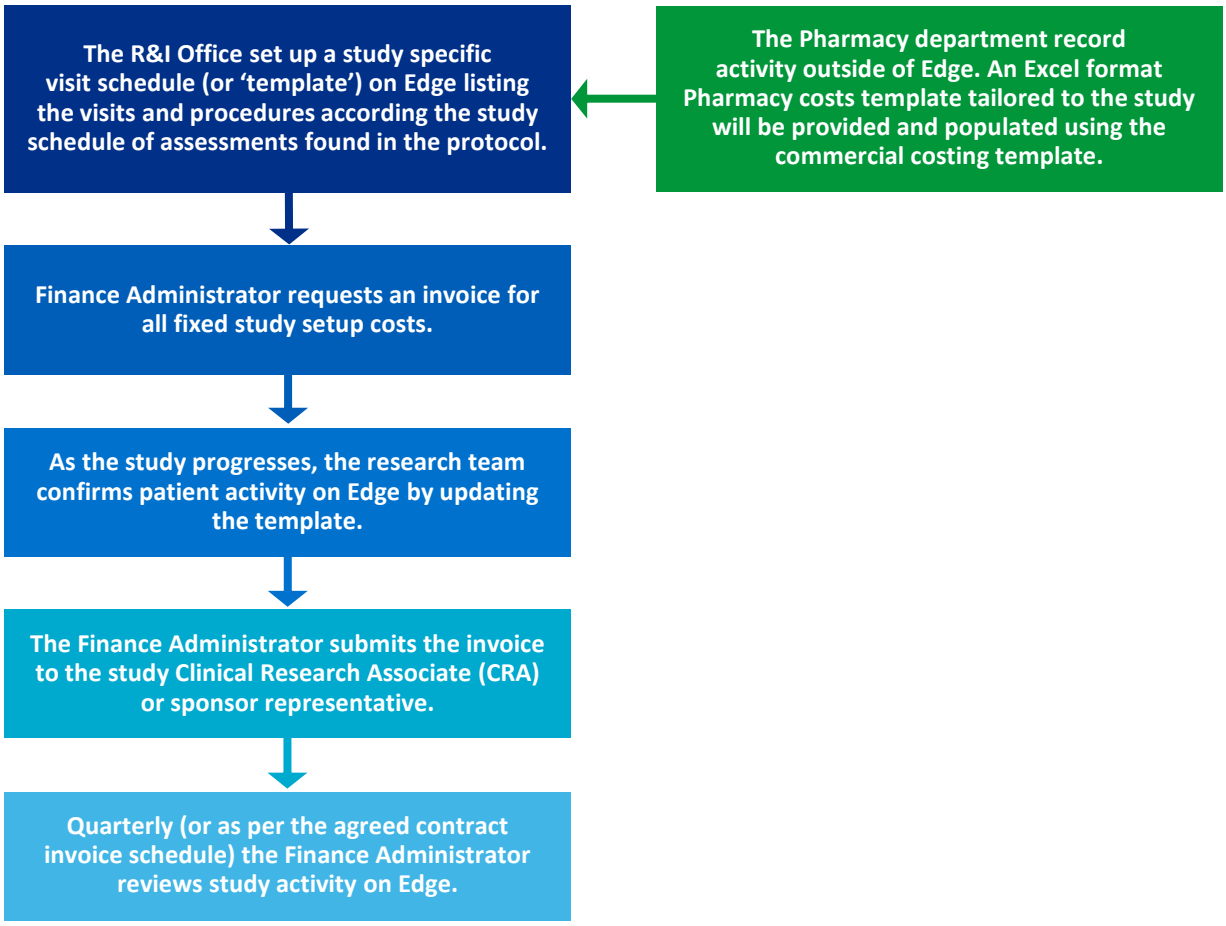

Total Study Contract
R & I Set-up Invoice
Pharmacy Cost Invoices
Industry Costing Template
Study Budget Per Patient
Investigations
Staff Costs
Department Costs
Capacity Building 20%
Department Costs
Capacity Building 20%
Overheads 70%
Investigator 75%
Trust 25%
Income to Department
Income to R&I
Income to Investigator For Capacity Building
Income to Trust
Departmental Income will be shown in the CSC subjective code 7809 as R & I Commercial income

Appendix 1

The process for invoicing commercial and non commercial partners was reviewed and updated in autumn 2016 in order to ensure all individual study activity is invoiced for in an efficient and timely manner.

For commercial studies or those that involve additional payments, the R&I office will set up a study template on Edge reflecting patient activity. The study template will be populated by research teams during the course of the study and used by the R&I finance administrator to track activity and prepare invoices. The system, outlined in more detail below, was designed to be as simple as possible and provides an efficient and watertight process to track, record and invoice for all chargeable activity.

How the process works:



TRAINING REQUIREMENTS

It is the responsibility of all PHT investigators and research management staff to read and understand the policy. Individual training can be provided as required and requested through the Trust R&I office.

REFERENCES AND ASSOCIATED DOCUMENTATION

Gateway No 12153
July 2009
Professor Dame Sally Davies — Director General of R&D
David Flory — Director General of NHS Finance

Income Distribution from NIHR CRN Industry Portfolio Studies
April 2011
Christopher Burdette — Industry Costing & Contracts Manager

Commercial Research Activity R&D/POL001
August 2011
Priya Shimoga — Cambridge University Hospitals Foundation Trust

MONITORING COMPLIANCE WITH PROCEDURAL DOCUMENTS.

Minimum requirement to be monitored	Lead	Tool	Frequency of Report of Compliance	Reporting arrangements	Lead(s) for acting on Recommendations
Annual review of PHT investigator accounts and spending plans	R&I SMT	Spending plans and investigator account balances	Annual	Policy audit report to: R&I SMT	R&I Office

This document will be monitored to ensure it is effective and to assurance compliance.

The effectiveness in practice of all procedural documents should be routinely monitored (audited) to ensure the document objectives are being achieved. The process for how the monitoring will be performed should be included in the procedural document, using the template above.

The details of the monitoring to be considered include:

- The aspects of the procedural document to be monitored: identify standards or key performance indicators (KPIs);
- The lead for ensuring the audit is undertaken
- The tool to be used for monitoring e.g. spot checks, observation audit, data collection;
- Frequency of the monitoring e.g. quarterly, annually;
- The reporting arrangements i.e. the committee or group who will be responsible for receiving the results and taking action as required. In most circumstances this will be the committee which ratified the document. The template for the policy audit report can be found on the Trust Intranet Trust Intranet -> Policies -> Policy Documentation
- The lead(s) for acting on any recommendations necessary.
- recommendations necessary.

Portsmouth Hospitals NHS
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EQUALITY IMPACT SCREENING TOOL

Stage 1 - Screening			
Title of Procedural Document: Commercial Income Policy			
Date of Assessment	June 2017	**Responsible Department**	Research and Innovation Dept
Name of person completing assessment	Alice Mortlock	**Job Title**	Research and Quality Manager

Does the policy/function affect one group less or more favourably than another on the basis of :	**Yes/No**	**Comments**
• Age	No	
• Disability Learning disability; physical disability; sensory impairment and/or mental health problems e.g. dementia	No	
• Ethnic Origin (including gypsies and travellers)	No	
• Gender reassignment	No	
• Pregnancy or Maternity	No	
• Race	No	
• Sex	No	
• Religion and Belief	No	
• Sexual Orientation	No	
If the answer to all of the above questions is NO, the EIA is complete. If YES, a full impact assessment is required: go on to stage 2, page 2		
More Information can be found be following the link below www.legislation.gov.uk/ukpga/2010/15/contents		

Stage 2 – Full Impact Assessment			
What is the impact	**Level of Impact**	**Mitigating Actions** (what needs to be done to minimise / remove the impact)	**Responsible Officer**

Monitoring of Actions

The monitoring of actions to mitigate any impact will be undertaken at the appropriate level

Specialty Procedural Document:	Specialty Governance Committee
Clinical Service Centre Procedural Document:	Clinical Service Centre Governance Committee
Corporate Procedural Document:	Relevant Corporate Committee

All actions will be further monitored as part of reporting schedule to the Equality and Diversity Committee