NHS
Gloucestershire Hospitals
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Management of Research 05 – Distribution of Commercial Income

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the Research & Development Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive version of all Gloucestershire Hospitals NHS Foundation Trust SOPs appear online. If you are reading this in printed form, check that the version number and date below is the most recent one as shown on the R&D website:

http://www.gloshospitals.nhs.uk/en/About-Us/Research--Development/

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Author:	Janet Forkes	signature
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Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP was R&D 16	06/12/2013
1.1	Updating typographical errors and layout	09/12/2014
2.0	Reviewed and Updated along with reorganisation into the Gloucestershire R&D Consortium suite of SOPs	22/11/2016
3.0	Change of priority for the monies generated from commercial trials (GHNHSFT)	19/07/2017
4.0	Rebranding to GHNHSFT, updating contact details and reference documents	31/03/2018

This SOP will be reviewed every two years unless changes to any relevant legislation require otherwise

Contents

1. Introduction, Background and Purpose

All Commercially Sponsored Clinical Trials and Research Projects should be cost-neutral to the hosting Trust. Part of the R&D Review Process will ensure that there is adequate funding to cover the costs of any Commercially Sponsored Study seeking approval within Gloucestershire

The income will vary from trial to trial and the costings involved will also vary according to whether the study has been adopted to the National Institute for Health Research Portfolio.

This Standard Operating Procedure outlines the processes for costing Commercially Sponsored studies and how the income should be distributed.

2. Who should use this SOP?

The Trust R&D Team will follow this SOP when any new commercially sponsored study seeks approval.

Principal Investigators (PI) and Local Collaborators (LC) will adhere to the model for costing trials and for disbursement of funding. They will provide timely accounts of recruitment activity to allow accurate calculation of costs and invoicing to trial sponsors.

3. When this SOP should be Used

Timely costing and identification of income will be carried out to ensure trial feasibility as soon as possible after a new study is submitted for review.

4. Costing Commercially Sponsored Research

4.1 NIHR Commercial Costing Template (NIHR CCT)
The NIHR CCT will be used wherever possible for all NIHR Portfolio adopted studies, see appendix 1.

For any studies, whether portfolio or non-portfolio, where there are no submitted costings, the NIHR Template will be used to ascertain costs.

4.2 For low-activity studies where the costs to the Trust are likely to be minimal, local costing can be determined without the use of the commercial template. This will be agreed through discussion with the Associate Director of R&D and the R&D Finance team. See Appendix 2.

5 Checking Costs

5.1 Where a project is submitted with an NIHR CCT:

- The template will be checked against the study protocol to ensure all trial activity is accounted for.
- The trial activity will also be discussed with the local PI to ensure that they are correct represented on the NIHR CCT.
- Any pharmacy activity will be reviewed and checked with the research pharmacist.
- Support department costs included, but not limited to, Radiology and Pathology, will be checked and reviewed with the appropriate departmental representatives.
- The template will be checked to ensure the R&D fee has been included.
- The template will also be checked for additional, optional costs, such as participants travel expenses and archiving costs. Any additional/ optional costs will be reviewed with the appropriate department.
- If there are discrepancies found the Commercial Trial Facilitator will negotiate the changes with the Sponsor.
- A final approved NIHR CCT will be filed in the R&D Folder and copied to the R&D Office Manager and the R&D Finance Officer.

5.2 Where a project does not include an NIHR Costing Template:

- An NIHR CCT will be created or in circumstances where the study involves little activity/costs, the costings can be outlined on a spreadsheet and reviewed with the local PI/support departments as appropriate.
- A final agreed version of the costings will be filed in the R&D Folder and sent to the R&D Office Manager and the R&D Finance Officer.

6 Clinical Trial Agreements

The Clinical Trial Agreement (CTA) will be expected to include financial details which match the NIHR CCT and trial Schedule of Events.

For portfolio studies it is expected that the Model Clinical Trial Agreement (MCTA) will be used.
Regardless of which agreement is used, it will be checked by the R&D team for suitability and/or changes from standard wording before being sent for signature by the Trust designated signatory(ies).

A fully signed agreement must be in place before Trust Approval is given.

7 Invoicing

Invoicing for studies will be undertaken in conjunction with the R&D Office Manager and R&D Finance Officer in accordance with the instructions detailed in the Trial Agreement.

8 Components of Commercial Trial Income

Commercial Trial Income is made up of 3 main components:

- **Actual Costs** – this is the basic costs of the study that go together to give the actual costs of running the study per patient. It can include items such as the costs of Investigations (blood tests, ECGs, CT Scans etc) as well as staff time for informed consent, screening and completing data collection tools. All of these costs are clearly indicated on the costing template
- **Indirect Costs** – indirect costs are added to the Actual Costs automatically by the template and equate to 70% of the actual costs. They are added only to Staff Time costs on the costing template. They are NOT applied to clinical investigations such as ECGs/XRAYS/MRIs.
- **Capacity Building** – Capacity Building is an additional "overhead" levied for supporting future research projects and is levied on both staff time costs and clinical investigations.

The costing template also includes a **Market Forces Factor (MFF)** that is applied to the total cost and this is around 5% depending on the Trust hosting the research.

Once the costs are calculated the disbursement of income and any surpluses will be arranged (see section 9).

9 Income Distribution

The income from commercial studies will be distributed as follows:

9.1 Actual Costs – The income related to the actual costs will be distributed to the appropriate budget line where the costs have been incurred unless this activity is already fully supported by the NIHR Delivery funding budget. In this case, the costs will be paid into the R&D budget for re-investment.

9.2 Indirect costs - The indirect cost of 70% will be distributed in equal thirds to :

- the Trust main budget,
- the department where the research is taking place.
    - However within GHNHSFT this third will also be held by the R&I Forum to pay for any shortfall in the research delivery team's budget to

maintain a viable workforce, unless monies have already been committed for research specific purposes ie. posters/ conferences and so on.

- Consultants will receive payment as additional payments to their job plan for their time spent on Commercial Trials once the income has been received - no longer prospectively. This will mean that consultants will be working on studies without the time recognition in their programmed activities but there will be an agreement to pay for this work once the funding has been received.

- the Trust's research budget (For example GHNHSFT R&I Forum Fund)

The host department will be obliged to account for the spending of this income to ensure that it is used to support research or research-related activity.

9.3 Capacity Building – The 20% Capacity Building income will be transferred to the Trust's research budget once the study is complete to ensure that any unforeseen costs can be covered. It will then be available to support research-related activity.

9.4 MFF – Payment by Results Market Forces Factor - this will be paid to the trust to cover associated Payment by Results costs.

Any surplus from the income will be distributed on a case-by-case basis at the end of the study. Appendix 1 includes a worked example for a recent study, indicating costs and showing how the income will be distributed, included a potential surplus.

This is based on a study involving staff time costs only. Clinical Investigation costs/income would be distributed in the same way, but only in relation to ACTUAL COSTS, CAPACITY BUILDING and MFF as overheads are not applied in the costing template.

Appendix 1 Worked example for research without an NIHR Costing template

Staff Costs		Full year	Feb 2013- Sept 2013 hrs	Hourly Rate £	Total £	
DOCTOR			22.5	£19.77	£444.83	
DOCTOR			26.25	£21.36	£560.70	
DOCTOR			116.25	£25.40	£2,952.75	
DOCTOR			41.25	£22.08	£910.80	
ADMIN			61	£15.03	£916.83	
DOCTOR			57	£8.48	£483.36	
Total Staff			324.25	£112.12	£6,269.27	A
Consultant - 1 session	PI	£1,633.75			£1,633.75	B
Consultant - 1 session	PI	£10,268.00			£5,134.00	C

APPENDIX 1
Worked Example

			Distribution: Departmental Budget	TRUST	R&I FORUM
	Division of Costs				
	Total Staff Costs (A+B+C)	£13,037.02	£13,037.02		
	overheads 70%	£9,125.91	£3,041.97	£3,041.97	£3,041.97
	Capacity Building 20%	£2,607.40			£2,607.40
	Total	£24,770.33			
	Payment by Results MFF	£1,414.39		£1,414.39	
D	Total inc PBR	£26,184.71			
	Income				
E	Q1	£25,560.50			
F	Q2	£22,135.00			
	Total Income to date	£47,695.50			
	Profit (E+F)-D	£21,510.79	£21,510.79	(as discussed on a case by case basis)	
	Totals		£37,589.78	£4,456.36	£5,649.37

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Appendix 2 NIHR website Costing Guidelines and spreadsheet

http://www.nihr.ac.uk/funding-and-support/documents/Study-Support-Service/Early-contact-and-engagement/Costing-Templates/GUIDE with FAQs Industry Costing Template FINAL UPDATED NOV 2016.pdf

https://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0ahUKEwi02u-4pZLSAhVnJcAKHTYFBrsQFggjMAE&url=http%3A%2F%2Fwww.nihr.ac.uk%2Ffunding-and-support%2Fdocuments%2FStudy-Support-Service%2FEarly-contact-and-engagement%2FCosting-Templates%2FSecondary%2520Care%2520CTIMP%25202016-17%2520Final%25202_4_2%2520.xls&usg=AFQjCNGgOrDiPhXE0iqXajg1C1LmEUnQWA&bvm=bv.147134024,bs.2,d.d24

Appendix 3

NIHR Costing Template Terminology

Capacity Building
A 20% capacity building element has been added to direct staff costs and investigation prices. This surplus should be ring fenced to build research resources.

Direct Staff Costs
Direct staff costs include salary and employer's contributions presented as an hourly rate. They contain no overheads for indirect costs, capacity building or any other increment. For an individual study, the total direct staff costs are calculated by identifying the time required for study specific activities.

Investigation Pricing Index
The index contains investigations which are commonly used in clinical trials and are presented with a price which already includes indirect costs or overheads. Capacity building and MFF will also be added to this price.

Indirect Costs
The term 'indriect costs' replaces the previously used 'overheads' to provide greater transparency of what these costs are i.e. the indirect running costs incurred by an organisation. They have an impact on all aspects of the organisation's business and include heating, lighting, building maintenance, security, finance, general admin, human resources, corporate management and all other resources which allow the organisation to function. Indirect costs are applied to direct staff costs only.

Market Forces Factor (MFF)
MFF is a location based multiplier used to create a final price for each individual NHS Trust reflective of local costs for services e.g. land or labour costs.

Per Patient Budget
The per patient budget is the price calculated for the completion of data for an individual patient within a clinical trial. The price includes overheads and capacity building and is adjusted for each Trust using MFF.

Costs for Departments Supporting Research
These are the costs for departments within an NHS Trust providing specific services for a trial. For example, pharmacy charges.