SOP 14: Distribution of Study Income

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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 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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 Research website:

https://www.gloshospitals.nhs.uk/about-us/research-our-hospitals/

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

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
5.0	See section 6 - clarification of what signed agreements / Summary of Activities / Trust C&C will be required See section 9.1.2 payments for running Commercial trials rewording for clarification See section 9.2 Indirect cost allocation rewording for clarification	Xx/06/2018 Not implemented
6.0	Change of SOP title Correction of typographical errors Implementation of the NCVR process Removal of non NHIR costing template appendix Removal of SOP categories and change of reference codes Change to the income distribution model Departmental name change to R&I from R&D Insertion of webpage for NCVR Clarification of PI allocation of indirect costs	13/05/2024

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

Glossary

CI	Chief Investigator
CTA	Clinical Trial Agreement
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
iCT	interactive Costing Tool
LC	Local Collaborators
MCTA	Model Clinical Trial Agreement
MFF	Market Forces Factor
NCVR	National Contract Value Review
OID	Organisational Information Document
PI	Principal Investigator
R&I	Research & Innovation

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&I Review Process will ensure that there is adequate funding to cover the costs of any commercially sponsored study seeking approval within GHNHSFT.

The income will vary from study to study 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?

GHNHSFT R&D Team will follow this SOP when any new study seeks approval.

Chief Investigators, (CI) Principal Investigators (PI) and Local Collaborators (LC) will adhere to the model for costing studies 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 study feasibility as soon as possible after a new study is submitted for review.

4. Costings

Costing Commercially Sponsored Research:

The National Contract Value Review (NCVR) supported by the NIHR interactive Costing Tool (iCT) will be used for all NIHR Portfolio adopted studies, that are not early phase (1-2a) or primary care studies. Early phase and primary care trials which are NHIR Portfolio adopted will continue to use the iCT process.

Costing non-commercial portfolio or non-portfolio research:

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

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 Senior R&I team and the R&I Assistant Management Accountant.

5. Checking Costs

NCVR stage 2 commenced in October 2023 making NCVR mandatory for all late phase commercial trials in secondary care (phase 2b and above) taking place in NHS organisations

A study's costings will be reviewed by an NHS costing expert (the study resource review) in collaboration with the sponsor. Once released to sites it is expected that there will be no local negotiation of costs between site and sponsor.

At site, the iCT should be checked against the study protocol. If errors are noted within the iCT, this should be escalated through the Industry Team at the LCRN.

Where a project is submitted currently with an NIHR iCT (early phase and primary care studies):

- The tool 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 correctly represented on the NIHR iCT.
- Any pharmacy activity will be reviewed and checked with the Clinical Trial 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&I 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 Research Portfolio Manager will negotiate the changes with the Sponsor.
- A final approved NIHR iCT will be filed in the R&I Folder and copied to the R&I Assistant Management Accountant.

Where a project does not include an NIHR Costing Template:

- An NIHR iCT (interactive Costing Tool) 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 CI/PI/support departments as appropriate.
- A final agreed version of the costings will be filed in the R&I Folder and sent to the R&I Assistant Management Accountant.

6. Clinical Trial Agreements

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

For commercial portfolio studies it is mandated that the Model Clinical Trial Agreement (MCTA) will be used, non-portfolio commercial studies may choose to

use a MCTA. For other studies if the Sponsor choses, the Organisational Information Document (OID) will be used as the contract between the Trust and the Sponsor.

Regardless of which agreement is used, it will be checked by the R&I team for suitability and/or changes from standard wording before being sent for signature by the Trust designated signatory(ies).

7. Invoicing

Invoicing for studies will be undertaken in conjunction with the R&I Research team and R&I Assistant Management Accountant in accordance with the instructions detailed in the Trial Agreement.

8. Components of Commercial Study Income

Commercial Study Income is made up of 3 main components:

- **Activity Costs** – these are the basic costs of the study that go together to give the direct cost 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 study procedures, such as informed consent, screening and completing data collection tools.
- **Indirect Costs** – A standard rate of 70%, added only to the staff time direct costs, provides a typical value for the real cost of carrying out a research activity. These indirect costs include physical aspects (e.g., heating, lighting, building maintenance etc.) and support functions required to deliver a clinical trial (e.g., finance, general administration, human resources etc.) They are NOT applied to clinical investigations such as ECGs/XRAYS/MRIs.
- **Capacity Building** – Capacity Building rate of 20% is an additional "overhead" designed to build sustainable research and innovation capacity

at the research site. This is levied on both staff time costs and clinical investigations.

The NCVR costing template also includes a Market Forces Factor (MFF**)** that is applied to the total cost. The MFF will be reviewed at least annually with the percentage applied changed accordingly.

NB: Departmental costs (e.g., Set-up costs, archiving, amendment fee, additional pharmacy fees) are included separately in the iCT, and are already inclusive of all indirect costs and capacity building – therefore only the MFF element is applicable to these costs.

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:

Activity Costs: The income related to the activity costs will be distributed to the appropriate budget line where the costs have been incurred unless these costs have been pump-primed by the R&I department The only exception to this is pharmacy, with the high level of block funding allocated. R&I take the financial risk of not receiving commercial income to fully cover costs.

- Consultants/medic time costs are transferred to the relevant budgets unless this has been negotiated with departmental managers as part of their job plan or has been pump-primed in advance.

Indirect Costs: The indirect cost of 70% will be distributed in the following way:

- 32% Trust main budget.
- 32% to the R&I department to enable the department to cover their initial outgoing costs & risk and support growth to expand the portfolio.

- 36% to the Principal Investigator. 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 Principal Investigator should follow these guiding principles to support utilisation of funds:
  - Collaboration with and recognition of the department involved in the delivery of the research activity.
  - Opportunities to enhance and develop research skills and expertise across the research team.
  - Consideration for fixed term appointments to support growth in research delivery and delivery of active studies where capacity is limited across research teams.
  - Exploration of opportunities to expand the research portfolio across new clinical areas and embracing innovation.
  - Collaborative partnerships across research teams where cross-specialty activity is required.
  - Enabling protected time to support applications for funding/grants.

Capacity Building: The 20% capacity building element will be ringfenced to build research resources

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

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 indirect costs are not applied in the iCT.

10. References:

NIHR website Costing Guidelines: interactive Costing Tool (iCT): Getting started | NIHR

Costing and contracting using National Contract Value Review (NCVR) | NIHR

Appendix 1 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 'indirect 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.