Gloucestershire Hospitals
NHS Foundation Trust

SOP 14: Distribution of Study Income

SOP reference:	SOP 14	
Version:	9.0	
Author:	Chris Ford	
Approved by Trust Senior Responsible Officer for RIG:	Noel Peter 08/07/2026	
Implementation date of current version:	12/08/2026	
Date of Review:	12/08/2029	

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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
7.0	Further clarification of indirect costs Inclusion of use of iCT on EDGE and Template NCVR escalation email	01/10/2024
8.0	Further updates regarding the NCVR review and escalation process. Including further details on non-commercial costs as not previously covered	24/11/2025
9.0	Change to the Indirect cost split Information regarding externally sponsored non-portfolio non-commercial studies Change to departmental email address	12/08/2026

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

Glossary

CI	Chief Investigator
CTA	Clinical Trial Agreement
EDGE	Clinical Trials IT management system
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
GOG	Governance Oversight Group
ICB	Integrated Care Board
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
RDN	Research Delivery Network
RIG	Research, Innovation and Genomics
ATMP	Advanced Therapy Medicinal Products
PS	Professional Services
SoECAT	Schedule of Events Costing Attribution Tool
ETC	Excess Treatment Cost

Contents

1. Introduction, Background and Purpose

All clinical trials and research projects should be cost-neutral to the hosting Trust. Part of the Research, Innovation and Genomics (RIG) Review Process is to ensure that there is adequate funding to cover the costs of any 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 (NIHR) Portfolio.

This Standard Operating Procedure outlines the processes for reviewing the costs for studies and how the income should be distributed from commercial and non-commercial studies.

2. Who should use this SOP?

The GHNHSFT RIG 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 for invoicing to trial sponsors by the RIG team.

Divisional management teams and Trust finance staff responsible for the disbursement of funding.

3. When this SOP should be Used

This SOP should be used as soon as a new study is submitted for review to ensure timely costing and identification of income.

4. Costings

Costing Commercially Sponsored Research portfolio research:

The National Contract Value Review (NCVR) supported by the NIHR interactive Costing Tool (iCT) will be used for all NIHR Portfolio adopted studies.

Costing commercial non-portfolio research:

For any non-portfolio studies, a costing breakdown should be requested from the sponsor. Where there are no submitted costings, the RIG team will use the NIHR Template to ascertain costs and the impact on our Trust to ensure all activity is covered.

Costing non-commercial portfolio research:

For non-commercial portfolio studies a SoECAT should be received from the sponsor and detail the different study activities, cost impacts and potential funding. This document should be the final version which has completed Post Award Triage Authorisation (signed and dated by an authoriser on the Study Information tab).

Costing externally sponsored non-commercial non-portfolio research:

For externally sponsored non-commercial non-portfolio research to proceed, a fee for study set-up must be provided. If there is no tariff set, we will use the commercial set-up fee template selecting the appropriate tier for the study, applying the basic cost only. Research involving Trust staff only will be costed at a lower rate, which will be reviewed annually.

If the PI requests delivery team support for an externally sponsored non-commercial non-portfolio study, the research can only proceed if the proposed funding fully covers the delivery costs involved.

5. Checking Commercial 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. Updates have now been made to the NCVR process to include early phase and Advanced Therapy Medicinal Products (ATMP) studies.

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.

During study set-up at GHNHSFT, access to the iCT should requested to the RIG inbox ghn-tr.researchandinnovation@nhs.net to allow several members of staff access.

At GHNHSFT, the iCT should be checked against the study protocol and NIHR tariff. If errors are noted within the iCT, this should be escalated through the Industry Team at the RDN using the email template in Appendix 2.

A cost is only eligible for escalation if it meets the criteria below:

- The activity is listed in the protocol but is missing from the iCT
- The cost of activity is too low (not the set tariff cost) and is still not covered by the 70% overhead, 20% capacity build or local Market Forces Factor (MFF).
- The items represent >5% of the overall direct costs of the study OR the RDN issues a waiver where the total costs is <5% but there would be a significant impact on the site
- The item is not related to adjustments of staff timing

If the activity cost is more than listed in the iCT due to the activity being outsourced, and the sponsor are happy to pay the extra, then this does not need to be escalated. Further details on the escalation pathway and the timelines can be found in the NIHR SOP saved here: S:\RDSU\3. Commercial\4. NCVR

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 appropriate Model Agreement will be used, non-portfolio commercial studies may choose to use a mCTA and this should be encouraged. For non-commercial studies, if the Sponsor choses, the Organisational Information Document (OID) may be used as the contract between the Trust and the Sponsor.

Regardless of which agreement is used, it will be checked by the RIG team for suitability and/or changes from standard wording before being sent for approval and signature by the Trust designated signatory(ies) as per SOP 11 - Confirmation of Capacity and Capability.

7. Invoicing

Invoicing for studies will be undertaken in a timely manner in conjunction with the RIG PS team and RIG Assistant Management Accountant in accordance with the instructions detailed in the Trial Agreement. Guideline 16 – Study Invoicing should be used to detail these processes.

8. Components of 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/X-rays/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 Force Factor (MFF) that is applied to the total cost. The MFF will be reviewed at least annually by NHS England 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 within the Set-up and Closedown tab. Some of these costs 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).

Non-commercial Study Income is made up of 4 main components:

Research Costs: the costs of the research itself, that end when the research ends. They relate to activities that are being undertaken to answer the research questions. These costs are what we expect to be provided by the sponsor to the site and included in the contract. Do note these costs are not always covered due to funding changes.

Services Support Costs: the additional patient care costs associated with the research, which would end once the research study in question had stopped, even if the patient care involved continued to be provided. These costs are expected to be covered by the NIHR annual funding to sites.

Treatment Costs: the patient care costs, which would continue to be incurred if the patient care services in question continued to be provided after the research study has stopped. These costs are absorbed by the Trust.

Excess Treatment Costs (ETCs): the difference between the treatment costs in a research study and the costs of the existing standard treatment. A per patient ETC cost or saving should be detailed in the summary tab of the SoECAT. Sites have an annual ETC threshold that must be reached before ETC payments are made. Please see the ETC payment timetable for more detailed information. When a provider has reached this threshold, ETC payments will then be made quarterly by the NIHR. The threshold does not apply to individual studies, but to the organisation due to receive the ETCs. Where ETCs are funded by NHS England Specialist Commissioners rather than by the local ICB, the payments may be subject to the provide threshold or be a minimum payment trigger site.

9. Income Distribution

Commercial

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 RIG department. The only exception to this is pharmacy, which has a high level of block funding allocated. In this case, RIG 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% to the Trust main budget.

- 32% to the RIG department to enable the department to cover their initial outgoing costs and risk and support growth to expand the portfolio.

- 36% will be housed within the RIG Forum budget with the aim to support and enable research activity across the Trust. All Trust staff involved in recent research activity (demonstratable activity within the last 12 months of the application call) will be able to apply for access to this research income through an application process. If the RIG department is in financial surplus, an annual request for applications to support activities that enhance research delivery, research capacity, innovation, or future grant competitiveness will be made. Any income not allocated will be deferred to the next financial year. Applications will be reviewed through a panel process; members of the panel will include the senior RIG team and finance.

Accrued income will be transferred in March once the financial position of the RIG department is balanced.

Capacity Building: The 20% capacity building element will be ringfenced by RIG 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.

Non-Commercial

The costing included in the study contract should be compared to the activity details in the SoECAT by the RIG Professional Services team and distributed to the appropriate department based on who performs the activity. The SoECAT functions as a cost attribution template but is not intended as a study costing tool. These costs and distribution should be added to the 'Income Distribution Agreement' document (saved here: S:\RDSU\4. Finance\6. Income Distribution Agreement Template) and signed off by the Research Matron or appropriate study team lead (or Professional Services Manager if a non-delivery run project).

10. References

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

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

ETC Process & Guidance

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.

Appendix 2: Template NCVR escalation email

To: swc.rrdn@nihr.ac.uk
Dear Local RDN/DA,

CPMS ID:
Study Title:

Our site has reviewed the content of the iCT for the above study which has had a review conducted under the NCVR process and we require items to be escalated. I confirm the following:

- The costs are not covered by the descriptions provided of the 70% overhead, 20% capacity build or local Market Forces Factor.
- The costs do not relate to timing adjustments to the per patient budget.
- DELETE AS APPROPRIATE – [The items represent >5% of the per patient budget]/[The items are part of the Schedule of Events in the protocol]/[We request a waiver of the 5% budget threshold due to significant local impact – *provide additional details]*
-

• Tariff Code	Cost Description and Justification	Tariff cost or estimated cost (if non-tariff).*	Frequency of activity**

*For non-tariff procedures add staff grade and time. For non-tariff investigations the activity cost excluding capacity building allowance and indirect costs and MFF

** add each visit, all or some participants, and/or unscheduled activities as appropriate

Kind regards,

Site