Llywodraeth Cymru
Welsh Government

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS R&D Finance Policy Template

Version 02; 01 July 2025

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Health and Care Research Wales

Version Control

Version	Summary of Amendments	Issue Date
01	Initial Issue	April 2017
02	Terminology updated to reflect current funding streams and policies. Sections re-ordered to outline the full processes for costing and income management of non-commercial research separately from commercial research. **Section 5: Costing Research Studies** • Distinction between costing process for lead sites and participating sites for non-commercial studies • Addition of SoECAT to confirm resource requirement at grant application stage. • Explanation of National Contract Value Review (NCVR). • Explanation of the Interactive Costing Template (iCT) and how it calculates direct costs, indirect costs (overheads) and capacity building fee, including application of the updated Market Forces Factor (MFF). **Section 6: Funding streams and sources of income associated with research in the NHS** • Clearer distinction between non-commercial and commercial funding streams **Section 7: Research Accounts** • More concise overview of Research Accounts structure **Section 8: Management of Research Accounts** New section to outline the following: • 8.1 Research Account set-up • 8.2 Account signatories • 8.3 Managing Income and Expenditure through a Research Account • 8.4 Review of a Research account • 8.5 Closure of a Research Account	May 2025

	Section 9: Income Management & Distribution • **9.3 Commercial study income** • **9.3.1 Direct Costs Income Distribution** • **9.3.2 Indirect Costs Income Distribution** • **9.3.3 Capacity Building Income Distribution** Income distribution models expanded, consistent with NIHR recommendations, for NHS organisations to outline their adopted approach across cost types. • **9.3.4 Market Forces Factor (MFF)** Explanation of increased MFF to cover higher local individual itemised costs, ensuring there is no overall shortfall in funding delivery of a study. **Section 10: Invoicing** • Updated invoicing process flow diagram, to reference relevant sections. **Section 11: Deferred Income Rules:** • Updated to strengthen NHS organisations understanding of IFRS15 and their ability to recognise research related income in the appropriate way to allow deferral across financial years. • Reference to model Commercial Trials Agreement (mCTA) which includes a financial appendix and accompanying guidance regarding use of funding across financial years. **Appendix 1: Worked example of commercial income distribution:** • Updated to show the benefits of NCVR and increased MFF for Wales. **Appendix 2: Examples of overheads covered by Interactive Costing Tool (iCT) 70% indirect cost rate:** • Provided for information, as per NIHR guidance.	

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1. Purpose

This policy describes the requirements and systems in place for the costing, management, accountability and distribution of all research related funding and income within NHS organisations across Wales.

2. Scope

This policy applies to:

- All NHS organisations in Wales
- Non-commercial and commercial research activities
- The following types of income/ funding available:
  - Research delivery funding as provided by Welsh Government quarterly
  - Non-commercial research income
  - Commercial research income
  - Charitable funds donated for research
  - Grant income from research led by the organisation
  - Grant income from research undertaken or hosted by the organisation
  - Wales Commercial research delivery funding (VPAG)

Funding related to service evaluation, service improvement projects, innovation projects and audits are not covered by this policy.

3. Policy context

This policy is one of the NHS organisation's research governance policies, focusing on the costing, management and accountability of all research funding in the NHS organisation.

The Managing Public Money[1] document by HM Treasury sets out the principles of financial probity, transparency and accountability and these are reiterated in the Standing Financial Instructions[2] (SFIs) issued by Welsh Ministers to Health Boards, Trusts and other NHS bodies, using powers of direction provided in section 12 (3) of the National Health Service (Wales) Act 2006.

These SFIs are 'designed to ensure that the Health Board's financial transactions are carried out in accordance with the law and with Welsh Government policy in order to achieve probity, accuracy, economy, efficiency, effectiveness and sustainability'. Rules are also set out by the Charity Commission regarding the use of public funds[3].

[1] Managing Public Money May 2023
[2] Standing Orders - NHS Wales Shared Services Partnership
[3] Publication scheme - The Charity Commission - GOV.UK

Financial probity and compliance with the law and other relevant rules are as important in research as in any other area of NHS finance and the use of public funds in Wales.

Supporting NHS research yields real benefits for the NHS, its patients, research sponsors and investigators. Ensuring continued success and investment in research is dependent on putting in place effective and efficient funding flow mechanisms which are consistent, fair and transparent.

The management of research related funding and income requires that comprehensive accountability and transparency can be demonstrated in all research undertaken in NHS organisations across Wales.

The principles for meeting patient care costs associated with externally funded research are covered by various policies and guidelines, which are updated from time to time. These include (but not limited to):

- Health Service Guidelines initially issued by the Department of Health in 1997 (HSG (97) 32)
- Welsh Government Guidance: Attributing the costs of health and social care research & development (AcoRD) [4], which is a set of principles agreed across the UK, building on HSG (97) 32
- Welsh Government commissioned operational guidance document All Wales Support & Delivery Funding - Technical guidance for NHS Organisations & Support & Delivery Centre[5]
- Commercial Research Delivery Framework
- NHS R&D Framework for Research and Developments WHC 2023/026
- UK Policy Framework for Health and Social Care Research[6]
- ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) [7]

NHS organisations have a duty to ensure that income from research covers the costs incurred, without calling on routine clinical service or patient care budgets.

NHS organisations need to be able to demonstrate that they are covering costs and managing accounts in accordance with policy and national standards. Through support from Health and Care Research Wales, NHS organisations across Wales have therefore established a rigorous financial management process for research income and expenditure to ensure that NHS organisations:

- allocate expert accounting input into costing and monitoring of finances related to research
- can demonstrate appropriate use of research related income
- can demonstrate how Research and Development (R&D) offices adhere to the Standing Financial Instructions
- maintain and demonstrate financial probity in all matters concerning research governance

[4] Attributing the costs of health and social care research & development (AcoRD)
[5] All Wales Support & Delivery Funding - Technical guidance for NHS Organisations & Support & Delivery Centre
[6] UK Policy Framework for Health and Social Care Research
[7] ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95)

4. Types of research:

There are various funding streams for NHS research, which are categorised into two main funding streams:

- Non-commercial
- Commercial

4.1 Non-commercial Research

These are research studies that are initiated and led by a non-commercial based research sponsor. Within non-commercial research, this will either be portfolio or non-portfolio, details as follow:

- ### Portfolio

  These are high quality studies, as determined by their funding source (through open national competition) and peer review, and meet the portfolio eligibility criteria[8]. Examples include studies funded by Welsh Government funding streams (e.g. Research for Patient and Public Benefit [RfPPB]); the National Institute for Health Research (NIHR) or other charity partners like Cancer Research UK (eligible funding streams only). These studies may include collaborative research with a range of funders or partners e.g. industry and charities.

- ### Non-portfolio

  These tend to be smaller standalone research projects being conducted as a one off, often with no plans to develop bids for portfolio eligible funders. They do not meet the portfolio eligibility criteria.

4.2 Commercial Research

These are research studies that are initiated and led by an industry-based research sponsor.

[8] portfolio eligibility criteria

5. Costing Research Studies

Researchers must engage with the R&D office at the earliest stage when considering undertaking a research project to ensure that advice and support can be provided on grants, costings and the regulatory requirements.

5.1 Costing Non-Commercial Research

5.1.1 Research grant applications

When grant applications are being prepared, all planned activities within that research study should be attributed with the use of AcoRD[9] in order to ensure that the correct funding is being requested from the funder.

For most grant applications, a SoECAT (Schedule of Events Cost Attribution Template) [10] must be completed to identify all planned activities within that research study and determine the cost attribution of each, with the use of AcoRD in order to ensure that the correct funding is being requested from the funder.

5.1.2 Acting as a participating site

Relevant costing template should be completed for each study accordingly. The template should detail the activity and the cost of the non-commercial activity. The model Non-Commmercial Agreement (mNCA) or Organisational Information Document (OID) should also detail how payments will be managed.

5.2 Costing Commercial Research

The price to be charged for commercially funded contract research should be at least equal to the full cost as determined by the UK wide commercial Interactive Costing Tool (iCT), with all activities over standard care covered by the commercial sponsor.

The iCT provides a clear standard methodology to calculate consistent and transparent prices for the resource associated with delivering each commercially funded contract study to support both the Life-Sciences Industry and the NHS minimise setup time related to cost agreement.

Data relating to the single costing methodology is built into iCT, including per-participant costs in addition to standard of care. The methodology identifies Agenda for Change rates for specific bands of NHS staff time representing the direct costs. Any overheads are covered by the indirect cost and capacity building elements. Prices for investigations and costs for service departments supporting research are also included. These values are all localised with the research Market Forces Factor (MFF). Only tasks performed by sites in addition to normal or routine patient care are captured in the iCT.

Further information and support regarding the iCT and the development of its cost structure and values are available on the How the interactive Costing Tool (iCT) calculates the costs of studies at sites[11] webpage.

[9] AcoRD
[10] SoECAT (Schedule of Events Cost Attribution Template)
[11] How the interactive Costing Tool (iCT) calculates the costs of studies at sites

5.2.1 National Contract Value Review (NCVR)

National contract value review (NCVR) is a standardised, national approach to costing for commercially funded contract research, and in October 2024, it became mandatory for all commercial trials in the NHS across the UK.

It creates transparency and streamlines administrative processes by providing the site-level costs as a financial appendix for direct insertion into localised contracts. Local negotiation of contract value is **not permitted,** and all NHS Organisations must use the fixed financial appendix in the clinical trial agreement.

The NCVR process significantly reduces the time it takes to set-up commercial studies in the NHS and the resource required to cost commercial clinical trials, including staff resources, as the activity and cost negotiation is done once by the lead site in the UK rather than at each study site.

NCVR ensures that the NHS costs (direct and indirect) are covered. The type of income and receiving department should be identified in the study review and set-up stage. Where permitted by financial systems, the relevant departments should be identified on invoices to facilitate the flow of funds to the appropriate budget.

NCVR uses the NIHR Interactive Costing Template (iCT) to:

- determine resource requirements for study delivery at a national level
- calculate site-specific prices, ensuring commercial trials are costed correctly and the NHS recovers the costs
- include a site-specific multiplier that considers local MFF and overheads.

A capacity building rate is added to both direct staff time and investigation costs within the NCVR, to maintain, strengthen and grow sustainable research infrastructure, as well as build capacity, retain skills and strengthen eligibility to deliver future research.

The MFF tariff included in the cost of the study provides an adjustment value to accommodate the unavoidable cost differences of providing healthcare across the country.

The finance appendix for UK templated model commercial agreements, developed as part of the NCVR standardised national approach to costing commercial contract research has been mandated as follows:

- The current mandate to use the appropriate UK template agreement without modification
- Site specific prices generated in the iCT will be included in a standard template for the financial appendix of the model agreements and local modification will not be permitted.

There is an NCVR escalation pathway to understand when and how to escalate issues or errors with the NCVR review, or wider NCVR programme. An infogram[12] has been co-created by the four UK nations which provides information on the UK NCVR escalation pathway.

More information on National Contract Value Review can be found on the Health and Care Research Wales website[13]

[12] NCVR escalation pathway infogram
[13] Faster costing for commercial research in the UK | Health Care Research Wales

6. Funding streams and sources of income associated with research in the NHS

Funding streams and sources of income are divided into non-commercial and commercial.

6.1 Non-commercial

All NHS organisations in Wales receive research delivery funding quarterly from Welsh Government. The funding is intended to support NHS organisations in delivering their non-commercial research portfolio locally, including funding for research delivery staff time. Funding is provided based on the in-year resource needs of the research studies that are to be delivered (including those in follow-up), with funding directed to where and when those resources are needed and to where and when those costs are incurred.

Income from non-commercial studies covers research cost activities, as defined in the AcoRD Cost Attribution policy guidance.

Excess Treatment Costs (ETCs) are funded on a study-by-study basis, from a centralised Welsh Government budget[14].

Centralised support cost funding is available to Powys THB, Public Health Wales and Welsh Ambulance Service on a study-by-study basis.

6.2 Commercial

Income from commercial studies, including overheads and capacity building fees are funded as determined through the NCVR process (as outlined in section 5.2.1 above)

6.3 Other

Programme investment funding including:

- Wales commercial research delivery funding (via the Voluntary Pricing Access and Growth (VPAG) funding allocated to Wales)
- Savings to the NHS and health community
- Charitable funding for research

[14] Make arrangements for support costs and excess treatment costs (ETCs) in the NHS and social care | Health Care Research Wales

7. Research Accounts

All commercially sponsored and non-commercial research income, which is not a genuinely charitable donation and relates to the NHS organisation must be held within ring-fenced research accounts on the NHS organisation's central ledger.

7.1 R&D Office Research Accounts

These accounts must hold all R&D funding types previously described in section 6, for investment on an organisation wide basis. Each type of income should be reported under separate subjective codes within the related budget.

7.2 Investigator/departmental Research Accounts

These accounts are intended to hold research related income for individual research active clinical specialties. Where more than one investigator exists for a specialty, all investigators are encouraged to work collaboratively as a consortium, planning income and expenditure, undertaking overall management of their research account. Where the account is departmental, it is expected that investigators departmental leads/support departments work collaboratively as a consortium, planning income and expenditure, undertaking overall management of their research account.

8. Management of Research Accounts

The set up, management and closure of research accounts should be managed by the R&D office in conjunction with the NHS Finance Department. All income held in a research account is the property of the NHS organisation and is not owned by any individual who may have been involved in securing funding.

8.1 Research Account Set Up

The R&D finance manager and R&D manager are responsible for setting up research accounts on their organisation's general revenue ledger.

To open a research account the NHS finance department need evidence of the funding arrangements. A completed authorised signatory form is required by the finance department to open and activate any type of research account.

The research account budget holders are required to authorise all expenditure from the research accounts and to ensure that the NHS organisation service budget is reimbursed for any research only tests or treatment costs.

Finance departments must maintain a record of all transactions posted to the NHS organisation's ledger and report on a monthly basis to account signatories.

Occasionally, a charitable research grant may be managed via the NHS organisation's charitable accounts systems, where the principles covered by this policy still apply.

The overall budget is the responsibility of the NHS organisation, who will report regularly to the relevant budget holders.

8.2 Account Signatories

Up to three account signatories plus a member of R&D office staff can be assigned to a research account. It is the responsibility of the account signatories to manage the account. One account signatory must be named as the main budget holder. If the main signatory of the research account leaves the NHS organisation the money remains in the control of the NHS organisation.

If the money is linked to a grant, and it has been agreed that control of the grant is transferred to another organisation then this should be arranged by the R&D office in consultation with the finance department.

Money held in research accounts is not the property of the account signatories, and if the money is not linked to a grant, the money must remain at the NHS organisation and new account signatories should be nominated.

8.3 Managing Income and Expenditure through a Research Account

It is the responsibility of all the budget holders to manage the income and expenditure through the research account, support financial forecasting and to ensure that there are sufficient funds to cover the expected outgoings. The NHS finance department should send monthly account statements to assist with this. It is the responsibility of the signatories on the account to review the statements on a monthly basis.

Overspending on budgets is not permitted. The budget holders are responsible for ensuring that projects remain within budget and if not, may be liable for making the necessary arrangements to cover any shortfall.

The management of the financial risks of the project is the responsibility of budget holders. The R&D finance manager should notify the R&D office of any overspend. The R&D office should notify the lead budget holder and request immediate corrective action. Where unsatisfactory responses are received, the matter must be escalated to the department leads and Finance Director.

Expenditure is authorised by the budget holders and in line with current local NHS organisational policies. All expenditure should be in line with the NHS organisation's rules and regulations, policies and procedures.

Invoices are raised through the R&D office and issued through the NHS Finance department. Invoices need to be requested and are not automatically generated.

It is the responsibility of the budget holders to ensure that the invoices are raised in accordance with the contract and the invoice value is correct before the invoice is raised.

8.4 Review of Research Accounts

All research accounts are subject to both internal and external audit review. Only studies approved by the R&D office can incur expenditure against research accounts.

The signatories are required to provide a plan of expenditure, which is reviewed by the R&D office. If there is no agreed plan the account is considered dormant. If the account is dormant, then the account should be closed and the remaining funded transferred the R&D office accounts to enable future R&D activities, infrastructure or resources.

8.5 Closure of a Research Account

Written confirmation from the sponsor that the study is complete must be obtained by the study clinical team. This is retained on file, as documentary evidence of the closure of the research account and that there is no requirement for funds to be returned.

If the research study is closed and money remains in the account, after all money owed to the NHS organisation for research activities has been paid, then the account should be closed, and money moved to an R&D Office research account.

9. Income Management & Distribution

Income distribution models are most effective when all income values are transparent to all departments involved through good local accounting allocations, clear distribution rule application and central oversight by the R&D office. The use of research income should be managed and monitored through spending plans which are reviewed and approved centrally by the R&D office. This approach ensures an integrated approach to research development across the NHS organisation.

9.1 Welsh Government Funding

Welsh Government provides several funding streams to support the delivery of commercial and non-commercial research activities. These include:

- Research Delivery Funding
- Wales Commercial Research Delivery Funding
- Excess Treatment Costs
- Centralised Support Costs

The management of these funding streams must adhere to the terms and conditions outlined in the corresponding Welsh Government funding award letters and guidance documents.

9.2 Non-commercial study income

NHS organisations must review the resource requirements of the study and identify any potential sources of income. For example, there may be funding within the research grant to cover the cost of NHS staff time spent in undertaking data collection or reporting associated with the study at each NHS organisation. There are sometimes lump sums provided to the organisation in recognition of the participation of the organisation in the study.

All research income identified from non-commercial studies must be invoiced for in a timely manner, with income distributed to the relevant research accounts.

Non-commercial research income should be paid into research accounts. The only exception to this is if the income covers staff time that has already been paid for by R&D, in which case this will be retained by R&D for re-investment; or if the income is for specific fees and charges.

All grant income should be paid into a study specific cost centre within a research account. This is used to cover all identified costs as detailed within the research grant application and the contract as signed with the grant funder. At the end of the study, providing that the funding body agrees, any surpluses can be transferred to the specialty research account and used for general research activity. Any charitable research grants are managed via the organisation's charitable accounts system.

Where an NHS organisation sponsors a research study, costs for providing sponsorship activities should be charged (e.g. for pharmacovigilance, contract management and study oversight).

The R&D Office will advise if costs for sponsorship related activities are required to be included in grant applications. All sponsor costs should be paid into the R&D Office budget under a specific income line.

Diagrams 1 and 2 below summarise how non-commercial research income (excluding sponsorship fees) is distributed:

Diagram 1: Distribution of income for non-commercial research investigation costs

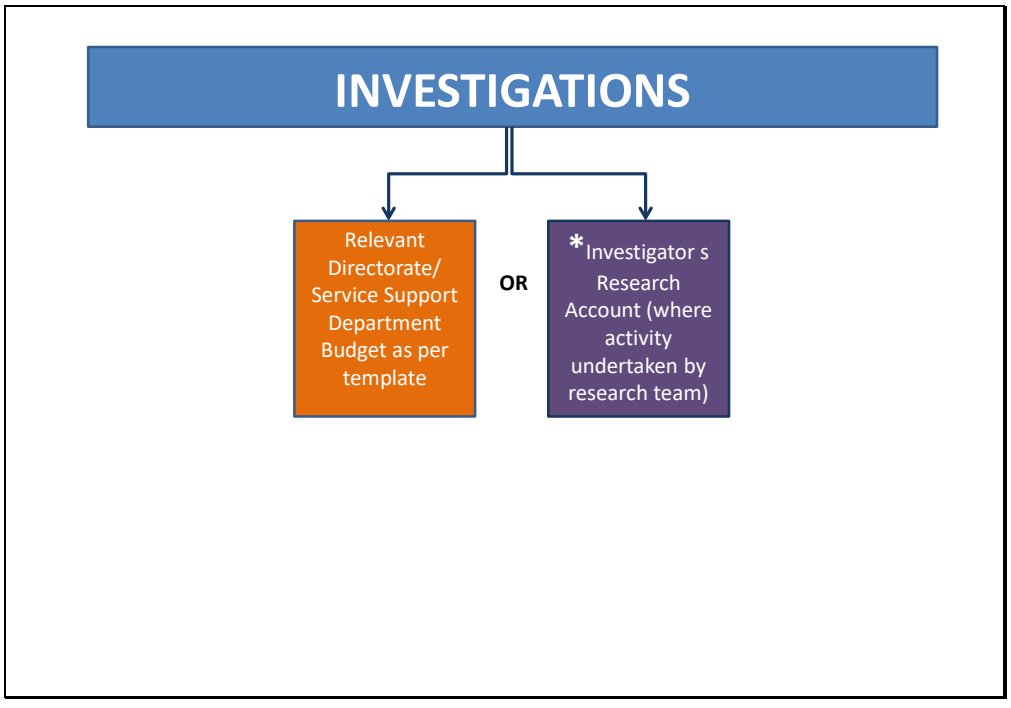
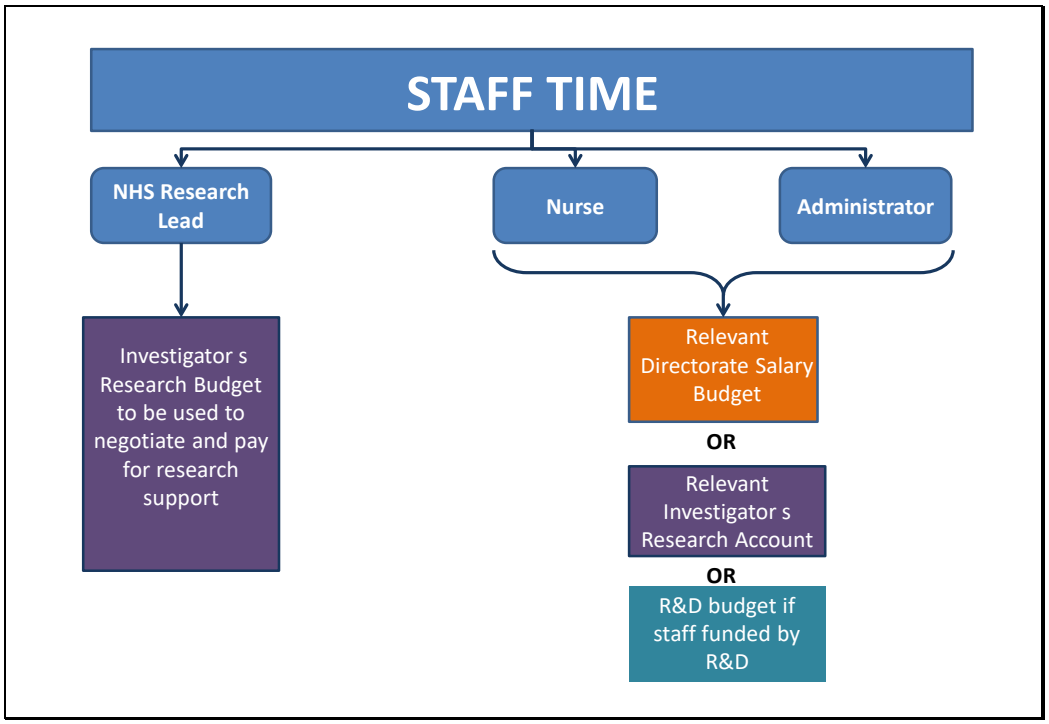


Diagram 2: Distribution of income for non-commercial research staff costs



9.3 Commercial study income

This section outlines the model of fair and balanced distribution of income generated through the conduct of Health and Care Research Wales portfolio commercially funded research within the NHS organisation to incentivise research and grow research capacity.

The principles which underpin this model are:

1. Departments and individuals are recognised and incentivised for their contribution
2. All relevant costs incurred are recovered from the Commercial Sponsor
3. Commercial research affords opportunities to fund additional research or research related activities
4. Income from commercial research can be distributed and carried over financial years in line with the finance control procedures of NHS organisations
5. Involvement of Health and Care Research Wales in the individual NHS organisation's research planning, as required
6. Overly onerous itemisation and invoicing of study costs are avoided where possible

9.3.1 Direct Costs Income Distribution

Research delivery funding used to support commercial research must be cost recovered in full.

Funding for payment of NHS staff time spent undertaking and supporting commercial research studies should be channelled towards the department or service where the staff member is employed to compensate for the work performed.

For commercial studies involving University staff, an agreement must be in place between the NHS organisation and the University to agree suitable distribution of the NHS Staff Time costs calculated by the iCT to take account of HEI based costing methodology, e.g. the application of Full Economic Costing (FEC)

Non-staff costs such as investigations, tests and scans are reimbursed to the directorate budgets unless otherwise declared. For example, if ECGs are done by the study team and not in a support service department, the payment will go to the study team's budget, not the support service department.

The R&D office must hold a specific budget with details relating to trial income. The aim is to use this income to support research activity across the organisation. Key research posts can also be funded from this budget in line with the R&D strategy and long-term plans for increasing the research portfolio. The R&D Director and divisional lead should agree on the spend, in collaboration with researchers as appropriate.

9.3.2 Indirect Costs Income Distribution

An indirect cost rate of 70%, provides a representative value for the running costs of conducting a commercial study that are not already covered by the direct costs (i.e. the real cost of carrying out a research activity).

The wide reach of tasks covered by the 70% indirect costs component (as outlined in **Appendix 2**) supports the splitting of this value to enable representative but practical distribution to the relevant parties involved in delivering the commercial research, via the following approach:

1. Half of the indirect cost element stays with the individual NHS organisation to cover the indirect costs which enable the individual NHS organisation to carry out the underlying operations of conducting research and contribute to any variability between the negotiated prices where required. Additionally, this percentage may be used to supplement or incentivise individual departments.
2. Half of the indirect cost element is designated for the Principal Investigator and provides a method to incentivise participation in commercial research. This amount should be allocated to a commercial research cost centre or similar supervised research account within the individual NHS organisation's finance system, through which the Principal Investigator has a decision-making capacity in the use of the funds in line with individual NHS organisation practices and finance control procedures.

Where local arrangements support different splits to this "equal split" approach these percentages should be developed and agreed based on the organisation's methods for recovering indirect costs and the degree of efficiencies and savings that are realised to make available as incentives. The implication for the organisation of agreeing alternative approaches to the equal split model should be considered, e.g. the impact of reducing the percentage available to the Investigator and team.

NOTE: The distribution split of the indirect cost element assumes that all direct staff costs and the cost of investigations are paid directly to the NHS organisation as per the arrangements of the relevant model Clinical Agreement and where these costs are incurred by support departments or external providers.

9.3.3 Capacity Building Income Distribution

A capacity building rate of 20% should be considered as a 'system optimisation' to deliver research as part of care provision. It is applied to all activity types within the iCT. Capacity building is designed to:

- Build sustainable research infrastructure
- Build capacity to innovate
- Retain skills
- Strengthen organisational capacity and eligibility for projects

The intended use of the 20% Capacity Building element within the NHS organisation should be clearly documented to support and evidence its reinvestment in research in line with the overarching intention to 'improve the health service'. Health and Care Research Wales can support defining the application of this element and ensure consideration and inclusion of the wider research community needs and national research ambitions.

An expenditure plan for the capacity building element is required with supporting accounting processes to manage and evidence the distribution internally and to Health and Care Research Wales. This could be incorporated into existing reports or plans to minimise duplication. The reporting process to Health and Care Research Wales is outlined in the Health and Care Research Wales commercial research delivery framework.

9.3.4 Market Forces Factor (MFF)

The MFF is a multiplier designed to accommodate the unavoidable cost differences of providing healthcare across the country by localising the national rates in the iCT dependent on the specific NHS organisation conducting the activity.

For funding flow, this factor is applied to each element of the costing methodology to provide a true reflection of the cost for that given location (e.g. NHS staff time including MFF; indirect costs including MFF; and Capacity Building including MFF). Ideally, this is not a separate element but an integral part of each cost complement.

Since the mandating of NCVR and the inability to carry out local negotiation, the MFF value present in the iCT for all NHS organisations in Wales increased to act as a buffer to cover any costs that may be higher than an individual itemised cost within the iCT (such as when outsourcing). In this situation, income received as part of the MFF must be used to cover any shortfall. See **Appendix 1** for a worked example to demonstrate distribution in line with NCVR.

10. Invoicing

All invoices or requests to raise an invoice must be sent to the R&D Office. All payments must be made out to the individual NHS organisation and not to individually named accounts or directly to individuals. Failure to follow this process may result in delays, inappropriate or incorrect reimbursement to accounts. Similarly, incomplete and

inaccurate records will be available to auditors and the board, therefore it is critical to ensure that financial transparency, accuracy and probity are always demonstrated.

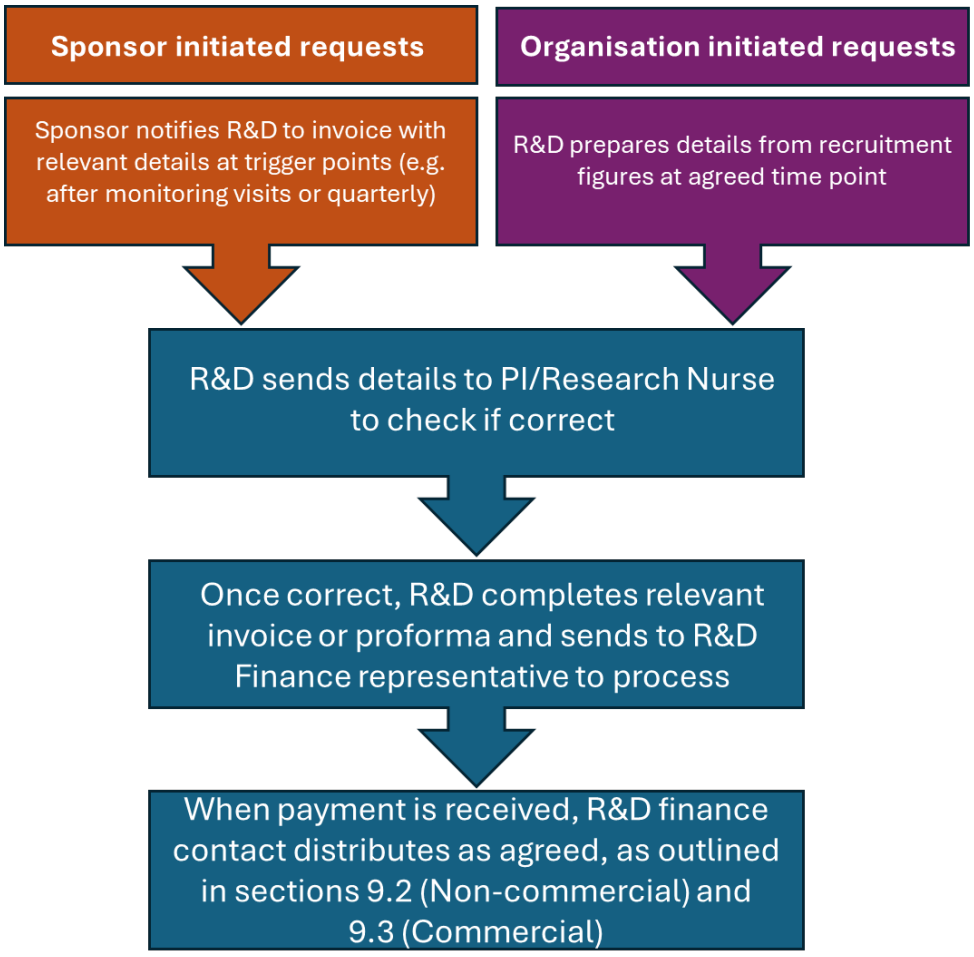
All contracts must stipulate who is responsible for initiating payments, when and how.

Invoicing can be triggered either by a request from the research Sponsor or CRO for commercial studies. [PLEASE ADD DETAILS OF ANY SPECIFIC TOOLS BEING USED AT THE ORGANISATION TO TRIGGER/ CO-ORDINATE INVOICING]

It is preferred that the Sponsor automatically generate payments or to automatically generate a reminder to the organisation to invoice for payment at defined trigger points. However, where automatic invoicing via the Sponsor is not in place, proactive arrangements for invoicing must be undertaken via the R&D Office and through the R&D Finance Manager or Accountant in consultation with the Principal Investigator.

The diagram below summarises the R&D invoicing process:

Diagram 5: R&D invoicing process



11. Deferred Income Rules

Funding/Income from government organisations (Welsh Government, Department of Health, NHS Trusts and Local Teaching or University Health Boards) must not be treated as deferred income. Expenses that have been incurred but are not yet recorded in the accounts at year-end should be accrued and the funding for this expenditure agreed with Welsh Government.

Income relating to commercial trial funding, as calculated via the iCT, can be deferred across financial years, provided plans for expenditure are in place to maintain financial management and oversight. Spending plans must be discussed and agreed with the R&D Office and primarily be intended to cover investment in supporting the delivery of studies, including building research capacity.

11.1 International Financial Reporting Standard (IFRS) 15

IFRS 15 provides the following principles-based 5 step model to be applied to all contracts with customers.

1. Identify the contract(s) with a customer.
2. Identify the performance obligations in the contract.
3. Determine the transaction price.
4. Allocate the transaction price to the performance obligations in the contract.
5. Recognise revenue when (or as) the entity satisfies a performance obligation.

IFRS 15 should not be used as a mechanism to recognise income on a cost accounting basis. The income can be recognised as and when the performance obligations have been completed – for example, agreed research activities have been completed. At that point, the NHS organisation should determine an appropriate measure of progress to determine how much revenue should be recognised as part of IFRS 15.

Income from the delivery of commercial contract studies covers the costs of undertaking the activities required and funds the building of the capacity and capability for further research in the NHS.

Commercial contract research generally falls under IFRS 15. An NHS organisation has a contract to carry out obligations, the research, for a customer for an agreed price. Although Commercial research income is generally received in arrears to pay for activity already completed, it is 'recognised' once the performance obligations have been completed i.e. the end of the study and not when the asset is transferred to the sponsor.

The income should therefore be recognised as or when the NHS organisation fulfils the performance obligations, not when an invoice is issued. **Funding for commercial contract research can therefore be deferred to future financial years**[15] [16]**.**

11.2 Model Clinical Trial Agreement (mCTA) Financial Appendix

As part of the executed mCTA the sponsor acknowledges that the trial site can defer funds paid under this agreement to build research capacity in future financial years. Both parties acknowledge that there is no obligation under this agreement on the trial site to either spend funds paid under the agreement within the same financial year, or to refund the sponsor with any sums not spent within the same financial year.[17]

12. Savings to the health community

Participating in research can provide significant and substantial potential savings to the NHS and should be recognised widely as an additional benefit in supporting high quality research. This is a valuable source of 'potential funding' for investment into both research capacity and infrastructure as well as general clinical service provision.

A large proportion of research studies provide free medication or devices which over time can lead to significant cost savings for the NHS organisation whilst the trial is underway. Additionally, other research studies test more effective treatments, which may save costs on existing patient treatment pathways and provide valuable data for use in appraisal by the All-Wales Medicines Strategy Group (AWMSG) or the National Institute for Health and Care Excellence (NICE).

The overall net effect of a research study must be reviewed. Additionally, the organisation is committed to ensuring that information on the overall effect of the whole research portfolio can be demonstrated in terms of cost savings.

NHS organisations are expected to contribute to national Health and Care Research Wales activities to support the collection of data or other information that demonstrates the value of research through the savings made to the NHS.

[15] NHS England » Managing research finance in the NHS
[16] Microsoft Word - UK Research Finance Guidance-v1.6
[17] IRAS Help - Preparing & submitting applications - Templates for supporting documents

Appendix 1– Worked example of commercial income distribution

The example below demonstrates the application of the income distribution model to be used by the organisation, as described within the policy.

This example is for an interventional study running in secondary care in a hospital.

The table below shows the agreed budget to cover per participant costs, as generated via the Interactive Costing Template, with a 1.2 MFF for Wales and without local negotiation to make amendments where individual costs exceed those determined by the iCT:

Costing element:	Total agreed budget:
R&D set up fee	*£2,508*
Investigation costs	**£25,164**
Staff costs/Procedures	**£602,157**
Total study budget for 25 patients (excluding R&D set up fee, which is invoiced for separately)	**£627,321**

Breakdown of the various elements of the agreed costs (these are clearly identified within the Interactive Costing Template, but presented here for the benefit of working through the example):

Investigation costs have a direct cost and a 20% capacity building fee added to the base rate. For this study, the £25,164 investigation cost breakdown is as follows:

Direct Costs: £20,970

Capacity Building: £4,194 (20% of Direct Cost)

Total Investigation Costs: £25,164

Staff costs (cost of time for carrying out procedures) include the basic cost, 20% capacity building fee and 70% overhead.

Direct Costs: £316,925

Capacity Building: £63,385 (20% of Direct Cost)

Overheads: £221,847 (70% of Direct Cost)

Total Staff Costs: £602,157

Using the principles of income distribution as detailed in Section 8.6.2, the following breakdown will occur:

	Investigation Costs		Staff Costs				
	Direct	Capacity building	Direct	Capacity building	Overheads	Total:	% of total funding
Directorate budget	£20,970					£20,970	3.34%
Research account			£316,925	£63,385	£110,924	£491,234	78.31%
R&D budget		£4,194			£110,924	£115,118	18.35%

For comparison, the table below shows the agreed budget to cover per participant costs, as generated via the Interactive Costing Template using the old 1.09 MFF for Wales, but with local negotiation permitted to make amendments where individual costs exceed those determined by the iCT:

Costing element:	Total agreed budget:
R&D set up fee	*£2,508*
Investigation costs	**£27,168**
Staff costs/Procedures	**£546,960**
Total study budget for 25 patients (excluding R&D set up fee, which is invoiced for separately)	**£574,127**

Breakdown of the various elements of the agreed costs

Investigation costs (have a direct cost and a 20% capacity building fee added to the base rate):

Direct Costs: £22,640

Capacity Building: £4,528 (20% of Direct Cost)

Total Investigation Costs: £27,168

Staff costs (cost of time for carrying out procedures) include the basic cost, 20% capacity building fee and 70% overhead:

Direct Costs: £287,874

Capacity Building: £57,575 (20% of Direct Cost)

Overheads: £201,511 (70% of Direct Cost)

Total Staff Costs: £546,960

Using the principles of income distribution as detailed in Section 8.6.2, the following breakdown will occur:

	Investigation Costs		Staff Costs				
	Direct	Capacity building	Direct	Capacity building	Overheads	Total:	% of total funding
Directorate budget	£22,640					£22,640	3.94%
Research account			£287,874	£57,575	£100,756	£446,204	77.72%
R&D budget		£4,528			£100,756	£105,284	18.34%

As the tables above show, the overall funding received by the site as a whole is increased by £53,194 under NCVR, due the increased MFF for Wales. However, the effect of the inability to amend higher local costs of an individual investigation within the iCT may reduce the amount of income distributed to a directorate, and increase the amount distributed to the R&D Office Budget and Research Account. In order to overcome this, as the organisation as a whole is in receipt of enough income to cover all costs incurred, a simple transfer to the value of the shortfall identified on the iCT for an individual investigation from the procedures/staff costs budget to the Investigations budget will result in the Directorate Account receiving the same reimbursement as under a pre-NCVR costing and distribution while the R&D Office Budget and Research Account continue to benefit from the increased income due to the 1.2 MFF.

Appendix 2 – Examples of Overheads covered by the iCT 70% Indirect Cost rate

An indirect cost rate of 70%, provides a representative value for the running costs of conducting a commercial study that 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
- Security
- Central finance
- Human resources
- Corporate and strategic management of the organisation (adherence to national processes for corporate oversight offered by the CEO, the finance director, R&D director and others to ensure efficiency and cost savings within the organisation/unit)
- General study oversight and administration, including:
    1. Visit management
    2. Investigator, Nurse and coordinator oversight
    3. Medical records/worksheets setup
    4. Category C and contract amendment activities
    5. Change of Sponsor/CRO administration
    6. Financial management of study - invoice generation for all departments
    7. General maintenance of study related paperwork (excluding data management)
    8. Pre-screening (e.g. note searches) that sites may perform where the CI and Sponsor do not feel it is justified (excluding pre-screening activity where the Sponsor and CI/reviewer feel it is necessary to make the protocol work and results in significant workload for the participating organisation)
    9. Pre-site selection or feasibility tasks
    10. Setup and maintenance of standard NHS finance and IT systems (excluding IT support department setup where additional software installation or quality assurance is required by Sponsor for a study)
    11. Study related communications
    12. Arrangement/attendance at any introduction or qualification meetings

13. Time spent preparing or attending inspections by regulatory bodies
14. Medical record retrieval
15. Internal contracts or paperwork for staff, e.g. honorary contracts or University/Health Board agreements for research staff
16. Principle Investigator duty of care responsibilities, including investigator review of safety reporting provided by commercial Sponsor, e.g. annual safety reports
17. Storage space/coordination of equipment/notes

As these costs are already covered within the indirect cost component associated with direct labour activity, the activities listed above should not be added separately to the iCT. Any staff time associated with investigation activities is already included within the investigation cost and therefore should not be charged separately either, e.g. overnight staffing costs are covered in the cost of an overnight stay, ECG nursing and upload time is covered in the cost of an ECG in the tariff data.

The distribution of the indirect cost element is *[retained in full by the R&D Office / divided between the Departmental, Investigator account and the R&D Office] (*Delete as appropriate)*