Reference Number: UHB 487 **Version Number: 2**	**Date of Next Review:** 02.11.2026 **Previous Trust/LHB Reference Number:** N/A

FINANCIAL PROCEDURE FOR SUPPORTING NON- COMMERCIAL RESEARCH

Introduction and Aim

To describe the procedure for costing non-commercially sponsored research projects from the information provided by the Principal/Chief Investigator on the Integrated Research Application System Form (IRAS), study protocol and other relevant documentation.

Objectives

To ensure that non-commercially sponsored research projects are costed appropriately

Scope

This Standard Operating Procedure is for use by the C&V UHB R&D Office and Finance Department, for non-commercially sponsored research. It does not apply to commercially sponsored research where the entire costs are covered by the commercial company (usually a pharmaceutical company or medical device company) and are determined using the NIHR 'Industry' costing template by the Commercials Trials Office of R&D in collaboration with the local research team and support departments and negotiated with the commercial company.

Before confirming Capacity and Capability for an R & D study, the resource implications of delivering research within an NHS care setting must be accurate and clear. This procedure outlines the process for the production of financial information to support study applications but does not consider the process for final study approval.

Equality Health Impact Assessment	An Equality Health Impact Assessment (EHIA) has not been completed because the SOP has been written to support the implementation the Research Governance and the UHB Finance Policies. The Equality Impact Assessment completed for the policy found no impact.
Documents to read alongside this Procedure	NHS R&D Finance Policy Template Version 01 February 2017 *(Expected to be updated during 2023/24)*
Approved by	Joint Research Governance Group
Accountable Executive or Clinical Board Director	Executive Director of Finance
Author	Finance Manager (Resource Management)

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	20/10/2020	20/04/2021	Document updated to reflect the new UHB format Page 1: Scope of procedure clarified. Reference to CaRRs removed Section 1, page 3-4: Minor changes in wording to provide update on: HCRW funding strategy and levels; and refer to the Welsh Government NHS R & D Funding Policy Section 1, Page 4: Move away from SSI to UK Local Information Pack referenced. Section 3; Revised arrangements for funding of Specialist ETC identified. Section 4.4 Reference to Risk assessment form removed. Section 5.2 page 7: Move away from SSI to Local information Pack including schedule of events referenced and summarised. Section 5.3 page 7: Communication of costed schedules clarified. Section 5.3 page 8: Government Accounting rules in respect of deferred income included. Appendix 2 Updated to reflect revised costing template
2	02/11/2023	28.11.2023	Section 1, para 1,3 & 4: Research & Development funding amended to All Wales Research Delivery Funding. Section 1, para 2 Historical context removed Section 1, para 7 reference to HCRW annual report removed

			Section 2, Page 4: reference to AcoRD inserted Page 5 Revised ETC links Section 5, Page 5 Revised ETC links Section 5.5, Paragraph referring to R & D annual report for HCRW removed Appendix 1, Key R & D Contacts has been removed due to consistent changes in staff

1. INTRODUCTION

Cardiff and Vale UHB receives All Wales Research Delivery Funding for the R&D activities it hosts from Health and Care Research Wales (HCRW), Welsh Government (WG).

CAVUHB R&D expenditure budgets which are linked to this allocation are ring fenced so that CAVUHB complies with the Welsh Government NHS Research and Development Finance Policy (WHC 005/2018).

The All Wales Research Delivery Funding is adjusted on an annual basis in line with Welsh Government R&D Funding Policy Template.

In addition to the All Wales Research Delivery Funding, CAVUHB can bid for further funding from HCRW for specific initiatives and costs e.g. National R&D leads; Personal Awards, Integrate funding scheme grants and Excess Treatment Costs (ETC).

The NHS R&D Finance Policy mandates that the management of research related funding and income requires comprehensive accountability and transparency and indicates that 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.

In this context it is essential that every research proposal that is submitted to the CAVUHB R&D Office, which is part of the Cardiff Joint Research Office (JRO) for approval is costed with oversight from the Finance Department accordingly, in relation to staff and tariff costs. Other study research costs are overseen by the pre-awards section within the CVUHB R&D office. The relevant staffing costs for each study are incorporated into standardised costing schedules and are taken into consideration by the CAVUHB R&D Office when assessing the Capacity and Capability of CAVUHB to deliver the study. The costs which will be incurred by CAVUHB as a result of a research study being conducted are identified by both the CAVUHB R&D Office and Finance Department scrutinising each study protocol.

CAVUHB maintains a database of forecast costs identified against each study protocol. The systems used to cost study protocols have been refined as HCRW reporting requirements have grown in order for CAVUHB to demonstrate compliance with both the financial/probity elements of The UK Policy Framework for Health and Social Care Research and the Welsh Government NHS R&D Finance Policy Template.

The ‘UK Local Information Pack’ was fully implemented as the UK-wide mechanism for setting up NHS/HSC organisations participating in HRA/HCRW approved studies on the 5th June 2019. It provides a consistent

package to support study set-up and delivery across the UK and should be used for all non–commercial studies within CAVUHB from this date. A key component of the UK Local Information Pack is the 'Organisation Information Document' which replaces the 'Statements of Activities' previously used to assess non-commercial studies. The Organisation Information Document is used for both commercial and non-commercially sponsored research in the NHS.

2. DEFINITIONS

CAVUHB- Cardiff and Vale University Health Board
CI- Chief Investigator
PI – Principal Investigator
IRAS - Integrated Research Application System
R&D – Research and Development

Costing – A method of identifying all relevant standard NHS costs incurred when a research project is conducted within CAVUHB, or if the project involves CAVUHB Staff, but is conducted at an alternative location.

Costs are categorised as defined by attributing the costs of health and social care research and development (AcoRD) *https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research* in line with the framework for the NHS and its partners to identify, attribute and recover costs associated with research in the NHS:

Research Costs – are the costs of the R&D itself that end when the research ends. They relate to activities that are being undertaken to answer the research questions. These costs are usually met by grant funders through the award of a research grant. Examples are study specific central trial co-ordination and management, patient randomisation and data storage archiving of clinical records (See Annex A of the HCRW AcoRD guidance for a full List)

NHS Support Costs – The additional patient care costs associated with the research which would end once the R&D in question had stopped, even if the patient care involved continued to be provided. This might cover things like additional investigations, assessments and tests where the results are required by the patient's care team to ensure patient safety and where arrangements are in place to feed back the results to the clinician. These costs are met from the HCRW allocation which provides funding for studies that are eligible for adoption to the HCRW Clinical Research Portfolio (CRP).

Sponsor – The person or organisation taking responsibility for the initiation, management and financing (or arranging the financing) of a clinical trial or research project.

NHS Treatment Costs – The patient care costs which would continue to be incurred if the patient care service in question continued to be provided after the R&D study had stopped. Activities that are attributed to NHS treatment costs include, e.g. supplying and administering the medicine/device/therapy being studied. These costs are met through the normal commissioning process.

NHS Excess Treatment Costs - Where patient care is provided which differs from the standard treatment for that condition (either an experimental treatment or a service in a different location from where it would normally be given) the difference between the total NHS treatment costs and the standard costs, if greater, is referred to as the NHS Excess Treatment Costs. These excess costs are nonetheless part of NHS Treatment Costs and are not funded from the HCRW allocation – there is a separate funding arrangement in place.
For non-specialist services the funding for Excess Treatment Costs is accessed through application to HCRW by the lead investigator for the study in question.

The relevant documentation can be found here:

Make arrangements for support costs and excess treatment costs (ETCs) in the NHS and social care | Health Care Research Wales (healthandcareresearchwales.org)

A separate policy governs both study and post study excess treatment cost funding for clinical trials that fall within services commissioned by the Welsh Health Specialised Services Committee (WHSSC). The arrangements are outlined by Specialised Services Commissioning Policy: CP164 - Clinical Trials (all ages): (i) Assessment for participation; (ii) Excess Treatment Costs and; (iii) Funding after Completion of a Clinical Trial. NHS organisations or researchers via the appropriate NHS R&D office can apply for an ETC whilst undertaking other Research Support and Governance processes such as processing R&D permissions.

The detailed policy is available here:

whssc.nhs.wales/commissioning/whssc-policies/organisational/cp164-clinical-trials/

3. RESPONSIBILITIES

Research Governance Team, Research and Permissions Improvement Managers, Income and Control Accountant.

4 PRINCIPLES

4.1 This procedure will be applied to all non-commercial research projects submitted to the CAVUHB R&D Office which are to be carried out within CAVUHB and/or using any UHB resources.

4.2 The Schedule of Events, Local Information Pack and supporting documentation for each proposed research project will be read in detail by the responsible personnel and a costing summary will be produced in spreadsheet format (Appendix 1). To support a consistent approach in the assessment of capacity and capability the same level of costing information is required for single site studies sponsored by CAVUHB. This requires the production of a local schedule of events by the lead researcher in conjunction with the CAVUHB R&D Office to enable the identification of all relevant costs.

4.3 Where the study is a single side study and CAVUHB is acting as sponsor there is no mandatory requirement to provide a completed schedule of events, however the CI should provide a breakdown of study activity in order for the financial impact to be reviewed and understood.

4.3 To assess the capacity & capability to deliver the study, the costing summary will be tabled in the relevant assessment documents for each protocol that is shared with CAVUHB. Any additional detail to inform the financial risk assessment of the study should be noted within the costing summary.

4.4 If there are any Excess Treatment Costs identified in the IRAS form or protocol then Finance will support the CI/PI in their application to HCRW for funding using the forms found at:

Make arrangements for support costs and excess treatment costs (ETCs) in the NHS and social care | Health Care Research Wales (healthandcareresearchwales.org)

4.5 <u>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.</u>

5 PROCEDURE

5.1 Who is responsible for R&D financial costings and who requires the financial information?

Researchers must engage with the CAVUHB 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.

The financial costings are the responsibility of the Income and Control Accountant. The information is required by the CAVUHB R&D Office as part of the assessment of capacity and capability and the project costings are then summarised in the CAVUHB's R&D annual report to HCRW.

5.2 How is the R&D financial costing compiled?

The 'UK Local Information Pack' provides a consistent package to support study set-up and delivery across the UK and should be used for all studies with participating NHS/HSC organisations from this date.

A key component of the UK Local Information Pack which supports study set-up and delivery across the UK is the 'Organisation Information Document'. The Organisation Information Document is used for both commercial and non-commercially sponsored research in the NHS/HSC.

The Organisation Information Document will be localised before sharing with participating NHS/HSC organisations. There are some circumstances where the Organisation Information Document may be shared with participating NHS/HSC organisations without first being localised (e.g. for low risk studies when sharing the document with a large number of potential participating NHS / HSC organisations).

As indicated at paragraph 4.3. to support a consistent approach in the assessment of capacity and capability the same level of costing information is required for single site studies sponsored by CAVUHB

Schedule of Events (SoE) / Schedule of Events Cost Attribution Template (SoECAT)

A Schedule of Events or a SoECAT is provided for all non-commercial studies, where a UK Local Information Pack is required. The SoECAT helps to ensure that the appropriate resources are identified to support

study delivery and that there is clarity for participating NHS/HSC organisations about how the costs associated with participating in a study are attributed. The SoECAT is authorised by an AcoRD specialist, to confirm that the attribution of costs is consistent with AccoRD guidance.

The schedule of events, local information pack and supporting documentation are read in detail to determine key facts. The Income and Control Accountant or the Income and Control Assistant will undertake a full financial costing referring to the PI and CAVUHB R & D Office as and when necessary. The relevant information is initially extracted from the SoECAT or SoE.

The SoECAT includes separate tables to identify general activities and per participant activities. The UHB Finance Department has developed a costing template which applies standard costs to the SoECAT and summarises the projected total cost of a study by AcoRD categories.

5.3 Sections of the SoECAT & Local Information Pack utilised in the costing process:

Details of the PI – used to identify the PI and to clarify whether the PI is employed by the UHB, Cardiff University or another employer.

Title of Research / Proposed start and end date at this site – used to gain a general understanding of the research study and to extract the project start and end dates to determine the duration of the study.

Details of the PI and all other members of the research team at the UHB – identifies the staff that are involved in the project and how much of their time is allocated to the project each week. This information is then used to calculate standard payroll costs and include them in the project costing template sheet.

Details of any non-clinical interventions or procedures to be received by participants as part of the research protocol - used to identify whether there are any additional non-clinical interventions being conducted as a result of the project e.g. consent, follow-up, questionnaires and to allocate a cost to them. This section includes the number of interventions received, how many would have been routinely given, the time taken, location and by whom.

Details of any clinical interventions or procedures to be received by participants as part of the research protocol - used to identify

whether there are any additional interventions being conducted as a result of the project e.g. blood tests, physiological tests, X-rays. This section includes the number of interventions received, how many would have been routinely given, the time taken, location and by whom. This data can inform the R & D investment in support services.

How many research participants/samples is it expected will be recruited / obtained from this site? – used to identify the number of patients involved in the project and how diagnostics, outpatient, inpatient or day case sessions are affected. If the project results in an increase in time or additional visits required then the information in this section is used to cost the impact of this on the NHS and can inform the R & D investment in services.

Details of Cost Classified by AcoRD Categories- Cost categorization is included on the SoECAT and is used to differentiate between Research Cost, Service Support Costs, Treatment Costs and Excess Treatment cost.

What external funding will be provided for research at this site? – used to identify whether the project is funded with help from an external funder or if the project is to be funded in total from the UHB's HCRW R&D allocation and whether there are Excess Treatment Costs. If Excess Treatment Costs are present then the PI must apply to HCRW to obtain additional funding to support these costs via the relevant application forms that can be downloaded from the WG website:

Make arrangements for support costs and excess treatment costs (ETCs) in the NHS and social care | Health Care Research Wales (healthandcareresearchwales.org)

The Income and Control Accountant will provide assistance to the PI in the submission of ETC applications.

Any other relevant documentation is also reviewed to ensure that the information provided by the SoECAT accurately reflects the activities which will be undertaken during the research study.

After any additional relevant information has been extracted from the supplementary documentation, a costing sheet is compiled and stored in the relevant electronic financial folders in the Finance Department and a copy is forwarded to the CAVUHB R&D office. The costing information for each research project is then combined with all the other protocol costings that are open within a financial year for inclusion where required in the CAVUHB R&D annual report to HCRW.

In some instances where clarification of information contained in the SoECAT and Local Information Pack is required for costing purposes further communication may be initiated between the Income and Control Accountant/Assistant and the PI.

Completed costing schedules are relayed to Directorate Accountants for information, feedback and appropriate action. Costing schedules are then relayed to the CAVUHB R & D Office for consideration as part of the Capacity and Capability Assessment.

5.4 Grant applications

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

Applicants must also engage at the earliest opportunity with the R&D office, where help with attribution can be provided, as well as support to ensure that all relevant costs (e.g. sponsorship costs) are included.

In consultation with the Directorate finance manager, the CI or PI must also have clear plans on how the monies will be accounted for, i.e. the account the money will be paid into, the person responsible and how the funding will be distributed to support functions (Diagnostics, Imaging, Pharmacy etc.). The CAVUHB R&D office can also support this.

Confirmation of Capacity & Capability to deliver the study will only be given when it can clearly be demonstrated that the income to support the study is sufficient to cover the costs. All directorates providing additional support to the planned research will need to agree the level of directorate support to proposed research in line with the UHB's scheme of delegation.

Grant applicants should be informed by the CAVUHB R&D office that only income received in advance from organisations outside of government may be deferred from one financial year to another. Funding/Income from government organisations (e.g. Welsh Government, Department of Health, NHS Trusts and Local Health Boards) must not be treated as deferred income and cannot be carried over years (i.e. the income should be used to support expenditure in the year that it is received).

6 REFERENCES

HRA- IRAS Integrated Research Application System
HCRW – Applying to HCRW for Excess Treatment Costs Funding
HCRW - Welsh Government NHS R & D Finance Policy Template.

7 APPENDICES

1. Example of Project Financial Costing Sheet

Appendix 1. Example of Project Financial Costing Sheet

Project Ref:	[redacted]		Start Date:	01/10/19
P.I.			End Date:	01/01/22
Directorate:			Duration:	27
Recruitment Target:				
Service Support Costs:	451.69	Cost to be absorbed by Directorate Ring Fenced R & D Budget		
Research Costs (Part A):	79,627.62	To be obtained from Sponsor		
Research Costs (Part B):	656.09	To be obtained from Sponsor (unless a Charity)		
Excess Treatment Costs	0.00	ETC's to be applied for from HCRW		
Treatment Costs:	0.00	Routine NHS Care, no additional cost		
		80,735.39	CHECK	
Pre-Protocol:	8,073.54	Indicative R&D / Finance Admin Overhead		
Post-Protocol:	103.00	Indicative R&D / Finance Admin Overhead		
Standard Overhead:	310.00	Indicative Standard Overhead		
ISRCTN Registration Cos	0.00	£271.20 cost to be absorbed by Directorate Ring Fenced Budget for C&V-sponsored studies		
Total Costs:	**89,221.93**			
Funding:				
[redacted]	(£1,565,131)	**C&V entitled to:**		
	Research Nurse 1 WTE		£80,000.00	
	Pharmacy Cost		£2,000.00	
	TOTAL		**£82,000.00**	