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Abertawe Bro Morgannwg
University Health Board



Meeting Date	17th May 2018		Agenda Item	3b
Report Title	Health Board NHS Research and Development Finance Policy			
Report Author	Samantha Lewis, Assistant Director of Finance			
Report Sponsor	Lynne Hamilton, Director of Finance			
Presented by	Lynne Hamilton, Director of Finance			
Freedom of Information	Open			
Purpose of the Report	This report requests the Audit Committee ratification of a new Health Board NHS Research and Development Finance Policy. This policy represents the localisations of the All Wales NHS R&D Finance Policy WHC (2018) 005.			
Key Issues	This policy ensures appropriate financial management is applied in support of financial probity.			
Specific Action Required (please ✓ one only)	Information	Discussion	Assurance	Approval
				✓
Recommendations	Members are asked to: <ul style="list-style-type: none"> • Endorse the Research and Development Finance Policy 			

Health Board NHS Research and Development Finance Policy

1. INTRODUCTION

This report requests the Audit Committee ratification of a new Health Board NHS Research and Development Finance Policy. This policy represents the localisations of the All Wales NHS R&D Finance Policy WHC (2018) 005.

2. BACKGROUND

In March 2018, Welsh Government issues the circular WHC (18) 005 'NHS Research and Development Finance Policy' which stated that:

“Ensuring appropriate financial management in support of financial probity is as important in research as in any other area of NHS finance and the use of public funds. Health boards and NHS trusts are expected to have a finance policy that aligns to and is compliant with the principles and process of the NHS Research and Development Finance Policy developed by Health and Care Research Wales.”

3. GOVERNANCE AND RISK ISSUES

The circular also advised that the national policy “describes the systems in place for the costing, financial management and accounting of all research activity undertaken in NHS organisations in Wales. This includes the investment of income and funding available to the organisation to invest in high quality research through the following:

- Local support and delivery funding as provided by Welsh Government annually;
- Commercial research income;
- Non 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
- The NHS Research and Development Finance Policy aligns with the principles of financial probity, transparency and accountability as set out in the Managing Public Money document by HM Treasury and reiterated in the Standing Financial Instructions (SFIs) issued by Welsh Ministers to Local Health Boards, using powers of direction provided in section 12 (3) of the National Health Service (Wales) Act 2006.”

From 1st April 2018 all NHS organisations were expected to be compliant with the NHS Research and Development Finance Policy, and local support and delivery funding would be released on this basis. Compliance will be assessed through a financial audit of non-commercial and commercial research studies which will form part of annual performance management meetings with Research and Development Division Welsh Government.

In order to comply, the health board's Research and Development Committee considered and approved the policy on 30th April 2018 prior to seeing the Audit Committee's endorsement in-line with the health board's policy on policies.

4. FINANCIAL IMPLICATIONS

There are no financial implications for the committee to be aware of.

5. RECOMMENDATION

The Audit Committee is asked to **note** the report and **endorse** the Research and Development Policy.

Governance and Assurance					
Link to corporate objectives <i>(please ✓)</i>	Promoting and enabling healthier communities	Delivering excellent patient outcomes, experience and access	Demonstrating value and sustainability	Securing a fully engaged skilled workforce	Embedding effective governance and partnerships
					✓
Quality, Safety and Patient Experience					
Research and development is essential to developing and trialling innovative and effective new ways of providing patient care, safety and experience.					
Financial Implications					
Ensuring appropriate financial management in support of financial probity is as important in research as in any other area of NHS finance and the use of public funds. Health boards and NHS trusts are expected to have a finance policy that aligns to and is compliant with the principles and process of the NHS Research and Development Finance Policy developed by Health and Care Research Wales.					
Legal Implications (including equality and diversity assessment)					
No implications for the committee to be aware of.					
Staffing Implications					
No staffing implications for the committee to be aware of.					
Long Term Implications (including the impact of the Well-being of Future Generations (Wales) Act 2015)					
No implications for the committee to be aware of.					
Report History	The policy has already been received and agreed at the Research and Development Committee.				
Appendices	The policy is attached at appendix 1.				



Llywodraeth Cymru
Welsh Government



Abertawe Bro Morgannwg University Health Board (ABMU HB)

NHS R&D Finance Policy Template

Version 27 March 2018

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1. Purpose

This policy describes the systems in place for the costing, financial management and accounting of all research activity undertaken in the organisation. It covers the details and mechanisms necessary for the management, accountability and distribution of NHS research funding and income in ABMU HB.

This includes the investment of the following types of income/ funding available to the organisation to invest in high quality research:

- Local Support and Delivery allocations as provided by Welsh Government annually
- Commercial research income
- Non 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

2. Scope

This policy applies to all ABMU HB staff involved with commercial and non commercial research activity.

Service evaluations and audits are not covered by this policy.

3. Policy context

This policy is one of the organisation's Research Governance policies, in particular focusing on the management and accountability of research funding in the organisation.

The Managing Public Money document by HM Treasury sets out the principles of financial probity, transparency and accountability and these are reiterated in the Standing Financial Instructions¹ (SFIs) issued by Welsh Ministers to Local Health Boards, 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 funds².

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.

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.

This document serves as a detailed procedural document for Research and Development (R&D) in ABMU HB.

The management of research related funding and income requires that comprehensive accountability and transparency can be demonstrated in all research undertaken in ABMU HB.

¹ <http://www.wales.nhs.uk/governance-emanual/standing-orders-local-health-boards>

² <https://www.gov.uk/government/organisations/charity-commission/about/publication-scheme>

The principles for meeting patient care costs associated with externally funded research are covered by various policies, which are updated from time to time. These include:

- 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), which is a set of principles agreed across the UK, building on HSG (97) 32
- Welsh Government commissioned operational guidance document 1.2: The appropriate use of Local Support and Delivery Funding
- Research Governance Framework for Health and Social Care in Wales second edition (2009)³

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.

The organisation needs to be able to demonstrate that it is covering costs and managing accounts in accordance with policy and national standards. Through support from Health and Care Research Wales, ABMU HB has therefore established a rigorous financial management policy and process for research income and expenditure to ensure that ABMU HB:

- allocates expert accounting input into costing and monitoring of finances related to research
- can demonstrate how Research and Development (R&D) departments adhere to the Standing Financial Instructions
- maintains and demonstrates financial probity in all matters concerning research governance
- ensures that all projects are reviewed appropriately and signed off by the relevant party, e.g. the Director of Finance, or their delegated representative (e.g. R&D Finance Manager or R&D Manager).

4. Types of research:

The type of research activity determines the level and type of costs associated with research studies that are supported by ABMU HB. This in turn determines the type and level of R&D funding and support available to NHS organisations.

The various types of NHS research are described below and can broadly be divided into two main categories:

- Non commercial
- Commercial

5. Non commercial research

Non commercial research can be further divided into three categories:

³ Work is ongoing to develop a UK policy framework for Research in Health and Social Care – this reference to be updated when this is in place

5.1.1 Portfolio:

These are high quality studies, as determined by their funding source (through open national competition) and peer review. 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).

5.1.2 Pathway to portfolio:

Pathway to Portfolio activities are defined as activities that are undertaken to inform the development of a portfolio study or a grant application for a portfolio study. This can include feasibility and pilot activity along with work to develop a platform for future portfolio studies in health and social care.

5.1.3 Non portfolio:

These tend to be smaller standalone research projects being conducted as a one off, with no plans to develop bids for portfolio eligible funders.

Portfolio studies are given the highest priority for support, followed by pathway to portfolio studies. This is because there is an assurance that the study will be of high quality and will address patient needs as a main focus of their research question. Studies can be led by ABMU HB or led from another NHS organisation or University across the UK, with the organisation acting as a participating site.

5.1.4 Commercial research

These are contract research studies that are initiated and led by an industry based research sponsor, with ABMU HB acting as a single site or one of a number of sites hosting the study.

Note: Occasionally, industry will provide funding to researchers as a grant with which to carry out their own research – in this instance, the study will be classed as non-commercial, as the industry partner is only providing funding (not taking overall responsibility for the design and conduct of the study). This is sometimes referred to as an “investigator-initiated” study

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

All NHS organisations in Wales receive Local Support and Delivery funding allocations annually from Welsh Government. This is a fixed pot of funding that is intended to support NHS organisations in developing their research infrastructure locally, including research delivery staff.

Local Support and Delivery funding allocations are based on previous research activity levels. The formula used to allocate the funding has been agreed by R&D representatives from all of the NHS organisations in Wales.

The funding allocations are provided in two funding streams, which NHS organisations can use flexibly, as viring funding across the funding streams is permitted.

- Delivery Funding
- Research Support and Portfolio Development

The guidance document *1.2 The appropriate use of Local Support and Delivery funding* provides detailed guidance on the use of this funding allocation.

In addition to the funding allocations described above, there are centralised budgets for NHS support costs for Primary Care, Public Health and Emergency Care studies; and Excess Treatment Costs for all eligible studies.

Other sources of funding include:

- Trials income from non commercial studies – research costs covered
- Trials income from commercial studies, including overheads and capacity building fees
- Research grants when ABMU HB leads the study (Chief Investigator employed by the organisation, or organisation sponsors the research study)
- Research Costs recovered from grants when the NHS site is hosting the study
- Savings to the NHS and health community

The type and source of funding will determine how the income must be managed and accounted for.

7. Costs associated with research activity

There are a number of costs associated with leading and/ or supporting research studies. These are summarised below:

Non commercial research projects can include any of the following costs:

- Research costs
- NHS support and delivery costs (*Note that there is a limited budget available, which must be used to appropriately cover support departments involved in research activity. Any up-front allocations not used by support departments may be redistributed to other departments as deemed necessary by the R&D Finance Manager and Associate Director of R&D.*)
- Excess treatment costs (note that cost savings are also delivered through research projects)
- Research staff or infrastructure costs
- Research sponsor costs

Commercial research sponsors are required to cover at least all the study costs above standard of care. The UK wide Commercial Costing Template should be used to support this. In addition, overheads are paid on some elements of the costs and a capacity building fee is also accounted for, aimed at facilitating the growth of research in the organisation through strategic investment of this funding.

Costs will be recovered by the organisation through proactive and timely invoicing. Section 7.6 provides more detail on cost recovery and distribution and use of income generated by research.

8. Research related finance policy and procedures in ABMU HB

8.1 Costing research studies / application information

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.

All costs associated with research must be agreed and signed off via the R&D office. Where costs have not been declared, or where individuals have not followed procedure to gain the organisation's agreement via the R&D office, the lead investigator may be liable to meet cost differences at least; and potentially the full cost from their own research funds where applicable.

Details of how costs are identified and applied for are outlined below:

8.1.1 Studies where ABMU HB is a participating site

Relevant costing templates (non-commercial or commercial), will be completed for each study accordingly. These templates detail the activity and the cost of all study activity at site. Trial agreements may also detail how payments will be managed.

8.1.2 Commercial Research

The price to be charged for industry-funded contract research will be at least equal to the full site /study costs as determined by the UK wide commercial costing template, with all activities above standard care being covered by the commercial sponsor.

Researchers and their teams should ensure that all proposed research related procedures are reflected in the template. This will be checked by R&D to ensure all costs are included.

8.1.3 Research grant applications and ABMU HB led studies

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 costs are being requested from the funder.

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

In consultation with the R&D Finance manager, the chief investigator must also have clear plans on how the monies will be accounted for. A unique account code will be established, with a mechanism for distributing funding to support functions, supported by the R&D department.

Research studies will only be issued R&D approval when it can clearly be demonstrated that the income from the study sufficiently covers the costs.

8.1.4 Pathway to portfolio

Pathway to Portfolio activities are defined as activities that are undertaken to inform the development of a portfolio study or a grant application for a portfolio study. This can include feasibility and pilot activity along with work to develop a platform for future portfolio studies in health and social care. Please contact the R&D department for details on how to access this funding.

8.2 Management of research accounts

All research funding and income will be managed through ring-fenced Research Accounts on the NHS organisation's central ledger and subject to the usual rules and NHS financial standing orders.

The R&D Finance Manager will be responsible for setting up the accounts on the organisation's general revenue ledger.

Occasionally, a charitable research grant may be managed via the ABMU HB Charitable Accounts systems, where the principles covered by this policy still apply.

The overall budget will be the responsibility of the R&D Finance Manager, who will report regularly to the relevant budget holder the Associate R&D Director and to the Financed Director.

Each budget should have as a minimum:

- Two additional authorised signatories (one of which should be the Senior Clinician)
- Two requisitioners (with the ability to order against the account)

8.3 R&D Office Research Accounts

These accounts will hold allocations from Welsh Government and fund support activities as detailed within the Spending plan submitted by ABMU HB.

The budgets will also hold R&D pooled funding for investment on an organisation wide basis in line with the R&D strategy. Each type of income will be reported under separate subjective codes within the budget.

8.4 Investigator Research Accounts

These accounts are intended to hold research related income for individual research active by 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.

Income into these accounts will come from all relevant research, including commercial and non commercial trials activity.

Departmental Research Accounts

Income associated with research activity will be transferred into an appropriate account in each department as follows:

A separate research departmental budget will be set up to hold income for reimbursement to support departments (for example where there is established research activity and/ or a department supporting the delivery of research e.g. Pharmacy). These accounts will be managed and treated equivalent to the Investigator Research Accounts – as above.

These accounts will be managed as revenue accounts, but with special conditions as agreed with the Finance Director.

Transfers will be authorised by the R&D Director, R&D Manager or authorised signatories and managed by the Finance Department and the designated R&D Finance Manager.

8.5 Management and distribution of research funding and income

8.5.1 Local Support and Delivery funding allocations from Welsh Government

Welsh Government Local Support and Delivery funding allocations are a source of non-commercial funding received by the organisation. The funding allocations are provided to ABMU HB based on previous activity (i.e. activity based funding). This policy is based on maximising the use of Welsh Government NHS R&D funding to support and deliver national research strategies at a local level.

For more information on Activity Based Funding, please see operational guidance document 1.1 Activity Based Funding.⁴

Priority is required to be given to support research infrastructure staff, both clinical (e.g. research nurses) and supporting service staff time. The infrastructure must provide essential research capacity, facilitating clinicians to identify, set up, recruit to, conduct and manage clinical trials activity on site.

Such funding will not be prioritised to contribute to consultant clinical research sessions (SPAs), as opposed to generic research support sessions. Alternative models will be explored and implemented. See below re: SPAs.

8.5.1.1 NHS support costs

As well as block upfront payments to provide support for non-commercial portfolio studies only, a per-patient payment can be made, for example for one off studies or for studies requiring reimbursement of test costs. Other examples of such payments can include:

⁴ <http://www.healthandcarereseach.gov.wales/nhs-randd-funding-policy/>

- Covering staff time where not already covered by funding as described in the section above
- Support costs to cover extra tests, scans or visits that are related to patient safety and are over and above standard care, which would be expected to end once the research study ends (see AcoRD⁵ for further information about Support Cost activities)

To access this funding, an All Wales non-commercial resource template should be completed for each portfolio study by [insert local preference; e.g. completed by lead site in communication with local finance team] and ideally submitted as part of the process of confirming that a study can be conducted at site. Alternative costing templates are also acceptable, provided all activities and associated costs are accurately reflected.

The All Wales non commercial resource template uses unit costs based on average tariffs, which have been agreed for use as the base costs for the UK wide commercial costing template, for which prices will be reviewed periodically.

Once the costs are agreed by the R&D office, payment will be made via internal transfer from the NHS Support cost budget to the relevant directorate budget or investigator/ service research account, as authorised by the R&D Director/ R&D Manager or authorised signatory and managed by the R&D Finance Manager in accordance with ABMU HB standard procedures.

Where a tariff is not listed on costing templates for a test or where tests need to be outsourced or undertaken outside of normal hours, R&D and Finance will provide an agreed unit cost for approval. Investigators and individual departments must not negotiate their own tariffs, otherwise the Principal Investigator may be liable to cover the cost difference at least; and potentially the full cost.

Payments are made on the assumption that the patient or participant completes the full range of visits and tests detailed in the protocol, as opposed to what activity is actually incurred. This is because it is impossible to predict adherence of every participant to the protocol and this is therefore the most pragmatic approach in terms of predicting potential costs associated with a study.

Since studies rarely achieve 100% completion per participant, departments in essence are being paid for activity not actually incurred, i.e. are overcompensated. Therefore funding provided for each study recognises the Department's support co-operation, and efforts in conducting the study. In this way, the department and therefore the Health Board should not be at a loss for undertaking high quality portfolio activity⁶.

R&D will only reimburse accounts on condition that robust, accurate and timely recruitment and screening figures are supplied by research teams.

8.5.1.2 Research Support & Portfolio Development (RS&PD) funding

Use of this funding is intended to focus on the development of ideas for high quality research, where researchers will apply for grants from funders likely to meet the criteria for portfolio eligibility.

The process for allocating this funding is through application to the R&D department with supporting evidence of previous trial activity, potential future activity, and funding requirements. Bids will be reviewed by the R&D Senior Management Team, with performance measures identified prior to a decision on R&D support. Funding is issued on a fixed term basis, with further funding requests considered on the basis of performance measures.

8.5.2 Commercial trials income

The UK wide commercial costing template for commercial research studies is used as a basis for negotiation between the NHS organisation and the Sponsor or Clinical Research Organisation (CRO) with regards to

⁵ <http://www.healthandcareresearch.gov.wales/costing/>

⁶ Note that NHS Support costs for Primary Care, Public Health and Emergency care studies are paid through a centralised budget

payments to be made. A finance schedule is included in the contract and invoicing will be undertaken in a timely manner in agreement with the Sponsor or CRO.

The agreed costing based on the template will also determine how income distribution will take place.

The principles that ABMU HB works to in ensuring an effective funding flow model for commercial research include:

- All relevant costs incurred will be recovered from the commercial sponsor and used to cover those costs
- Commercial research affords opportunities to fund additional research or research related activities
- Income from commercial research can be distributed and carried over in line with the finance control procedures of the organisation
- Overly onerous itemisation and invoicing of study costs are avoided where possible

Diagrams 1 and 2 below summarise how income from commercial research studies is distributed. Please see **Appendix 1** for a worked example to demonstrate distribution.

Diagram 1: Distribution of income for commercial research investigation costs

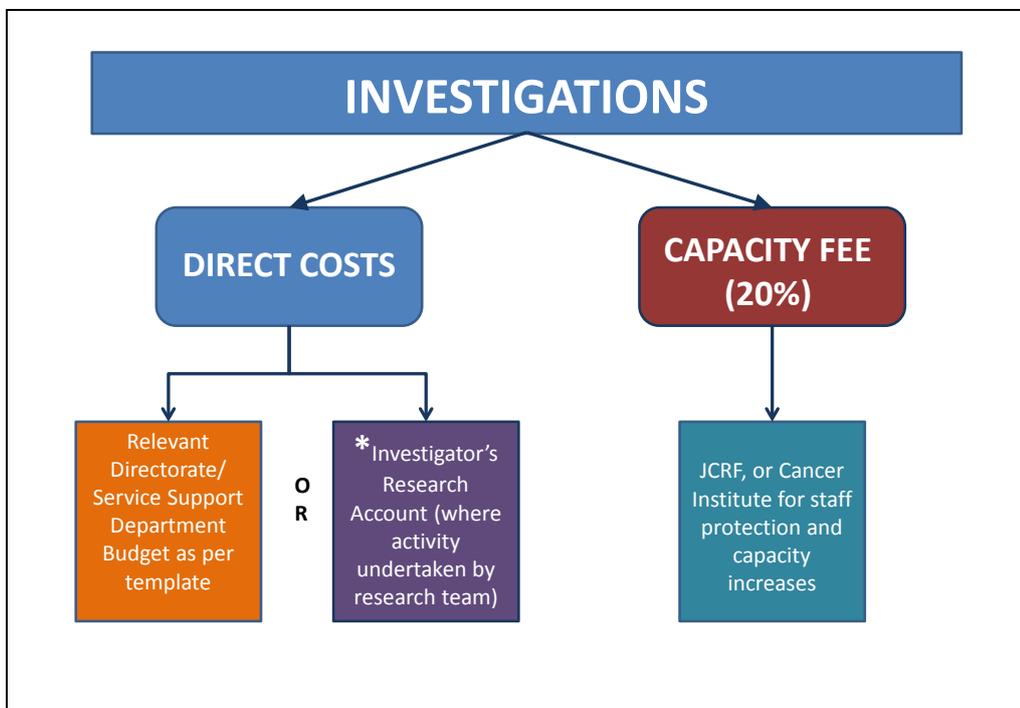
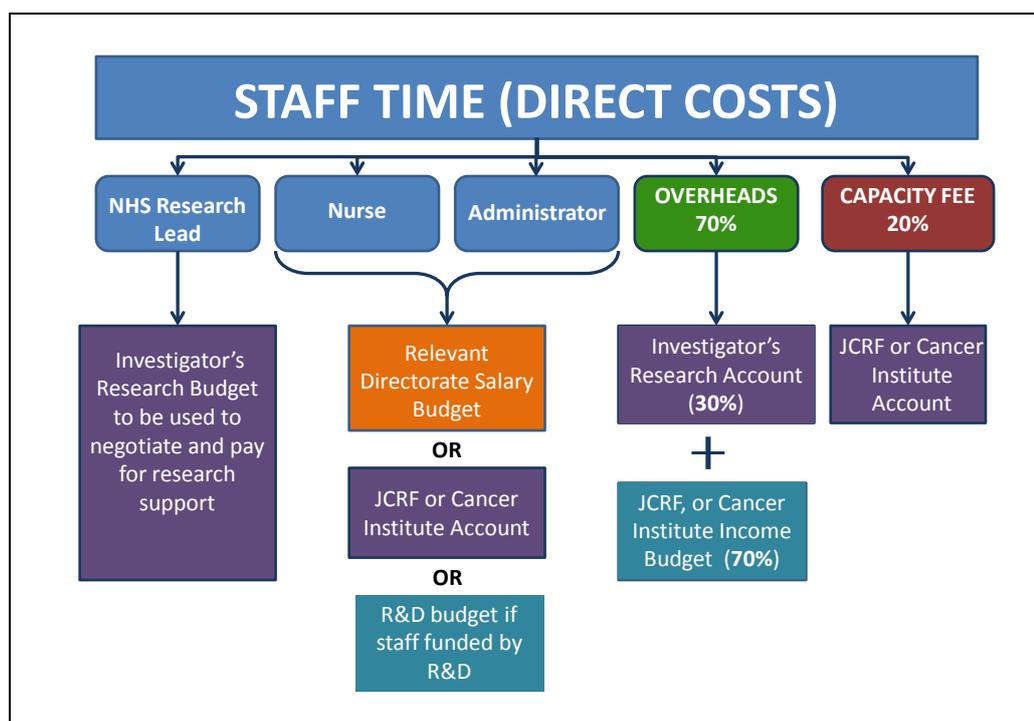


Diagram 2: Distribution of income for commercial research staff costs



Please note the following points with regards to income distribution:

1. Staff payments are made to the budget cost centre where staff are funded from (except for Consultants – see point 2 below)
2. Funding for payment of NHS staff time spent undertaking and supporting commercial research studies will be paid into Investigator's Research accounts and not to Directorate budgets. This funding must be used to contribute to ⁷ research sessions within an agreed job plan agreed by the relevant directorate lead and where necessary in consultation with the R&D office
3. 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 cardiology, the payment will go to the study team's budget, not cardiology).
4. The R&D office will hold a specific budget with details from trials contributing to this funding. The aim is to use this fund to support research activity across the organisation. Key research posts will 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 will agree on the spend, in collaboration with researchers as appropriate.

Commercial set up fees may also be applicable. These will be paid into the relevant department research account. For example, the R&D set up fee will be retained by R&D, the Pharmacy set up fee will be paid to pharmacy and the Investigator set up fee will be paid into the relevant Investigator Research account.

Commercial study overheads will be applied and distributed as shown in the diagrams above. The rates are in line with the UK wide commercial costing template. Note that overheads are already included in the prices for investigations.

Commercial capacity building fees applied to commercial studies will be distributed as shown in the diagrams above, with capacity building against investigations going into the JCRF funding pot; and capacity fees for staff time going to the investigator research accounts.

⁷ <http://www.bma.org.uk/support-at-work/contracts/consultant-contracts/consultants-wales>

Capacity building fees must be used to invest in research infrastructure and capacity building initiatives. Failure to demonstrate such usage may result in the relative proportion of the NHS organisation's Local Support and Delivery funding allocations being withheld, particularly where staff funded through Welsh Government funding allocations have contributed to earning the income.

8.5.3 Non commercial trials income

There may be instances when a costing breakdown associated with non-commercial studies that the organisation is hosting is provided by the Sponsor. The activities that are required to be undertaken by NHS staff that relate directly to the non-commercial portfolio research studies are known as research cost activities⁸ and funding must be accounted for within the research grant to account for this.⁹

However, often, when hosting a non-commercial study, the organisation 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 will be invoiced for in a timely manner, with income distributed to the relevant directorate accounts.

Non-commercial research income will be paid into investigator research accounts. The only exceptions 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.

Where ABMU HB sponsors a research study, sponsorship fees will be charged to cover costs associated with the activities that the organisation is required to undertake to fulfil its role as research sponsor (e.g. pharmacovigilance, contract management and study oversight).

The R&D Manager will be able to advise if sponsorship fees are required to be built into grant applications.

For Clinical Trials of Investigational Medicinal Products (CTIMPs) ABMU HB will charge a minimum of £1000 for single centre studies. For larger scale studies and other types of research studies, the sponsorship costs including monitoring and archiving need to be fully costed in grant applications, as advised by the R&D Finance Manager.

All sponsor fees will be paid into the R&D budget under a specific income line.

Diagrams 3 and 4 below summarise how non-commercial research income (excluding sponsorship fees) is distributed:

⁸ See AcoRD policy for guidance on cost attribution for non commercial portfolio studies

⁹ For other non commercial studies, all associated costs must be covered.

Diagram 3: Distribution of income for non-commercial research investigation costs

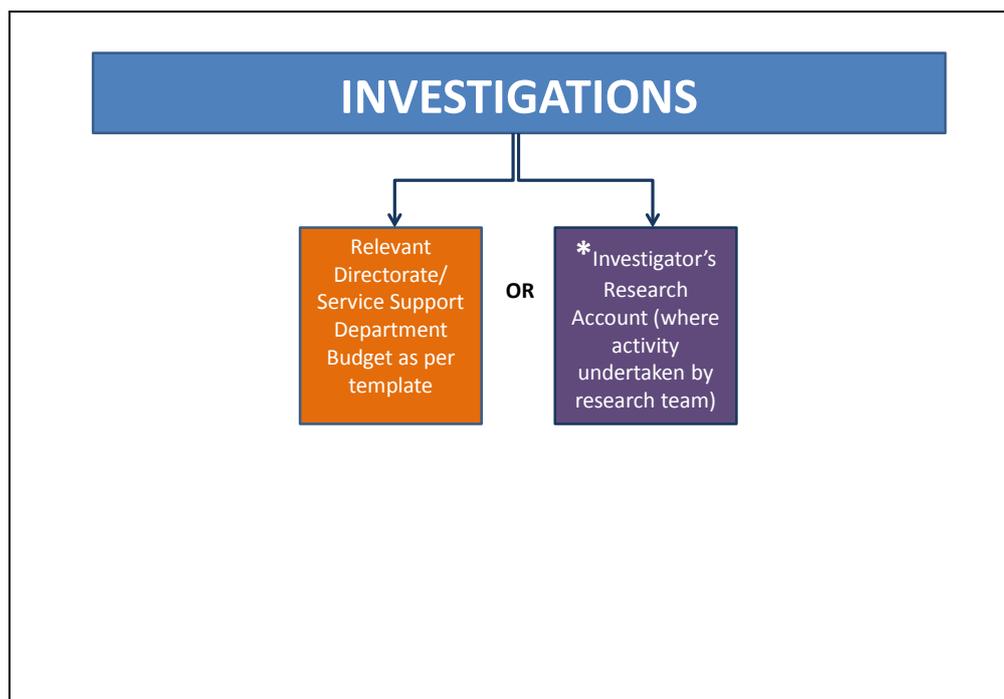
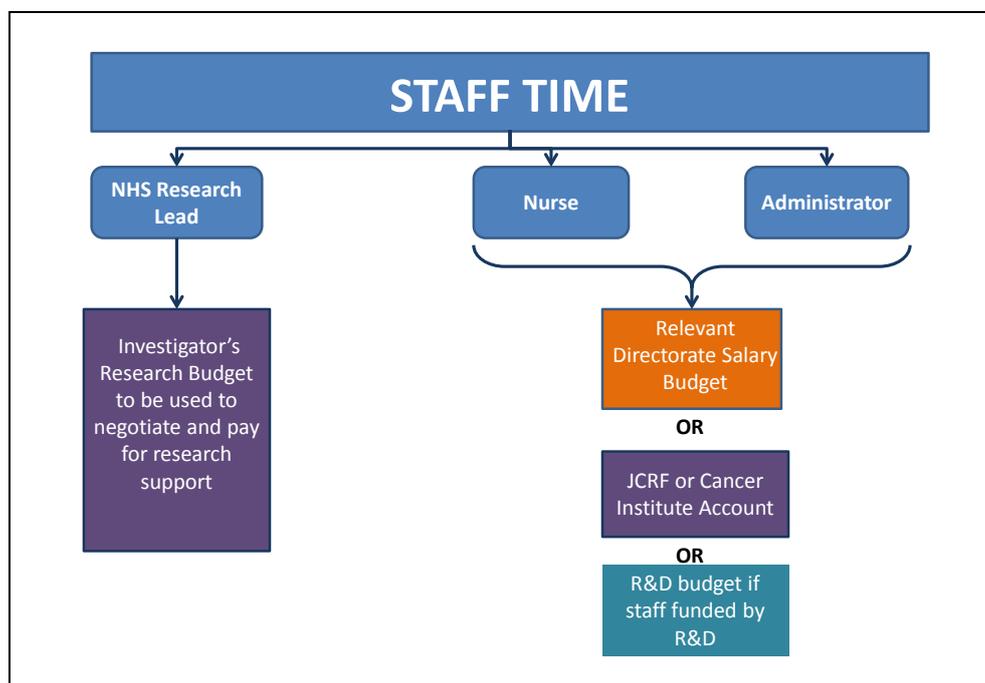


Diagram 4: Distribution of income for non-commercial research staff costs



For both commercial and non-commercial income, funds will be distributed as demonstrated by the diagrams into Investigator Research accounts.

NHS clinical staff play a crucial and important role in research. Research should be undertaken as core NHS business, which should therefore be recognised as an integral part of the employee’s workload and included within agreed working timetable, incorporating research into NHS service provision as well as Directorate or service improvement and development programmes. Time spent engaged in research must be acknowledged. As part of this engagement

and consultation, sessions should and need to be recognised and agreed with the line manager in the working timetables, funded from the relevant NHS salary budgets.

Other methods of increasing capacity for research must also be explored, for example investing in Research Registrar posts or other posts that facilitate the development and delivery of high quality research within the organisation.

e.g. 1 WTE Research Medical post has been agreed by the organisation to support research in Diabetes and 1 WTE in Cardiology. Both posts funded by Overhead and Capacity uplift in Commercial contracts. These are two year fixed term posts, which will be reviewed annually for performance.

8.6 Summary of budgets, intended expenditure and deferred income rules

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.

Only income received in advance from organisations outside of government may be treated as deferred. However, expenditure plans must be in place to effectively oversee the financial management of all research income.

Funding/Income from government organisations (Welsh Government, Department of Health, NHS Trusts and Local Health Boards) must not be treated as deferred income.

Commercial income can be used across funding years, but ABMU HB requires plans for expenditure to be in place in order to effectively oversee the financial management of all research income.

The table below shows a summary of the budgets referred to in this document, along with rules agreed around deferring income from one financial year to another:

Budget:	Intended expenditure:	Rules on use of funding across more than one financial year:
Directorate/ Supporting Services	<ul style="list-style-type: none"> To cover the costs of investigations linked to research activity. The tariffs already include an element to cover overheads 	Deferred income not permitted; Expenditure accruals only
Investigators' Research Account	<ul style="list-style-type: none"> To cover staff costs associated with delivering research Investment in supporting delivery of studies, including building research capacity within the specialty area 	Deferred income permitted, provided spending plans are discussed and agreed with R&D
R&D Department income budget	<ul style="list-style-type: none"> General research capacity and capability building across the NHS organisation Focus on supporting research development and delivery Contributing to building funds to support long term strategic aims 	Deferred income not permitted; Expenditure accruals only

8.7 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).

Welsh Government advises that 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.

8.8 Research grants

All applications for research grant funding must be approved by the R&D department before submission.

All grants will be paid into a study specific line within a researcher's account. This will be 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, any surpluses, providing that the funding body is in agreement, can be transferred to the specialty research account and used for general research activity.

Any charitable research grants will be managed via the organisation's charitable accounts system.

8.9 Invoicing

All invoices or requests to raise an invoice must be sent to the R&D department. All payments must be made out to ABMU HB 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 demonstrated at all times.

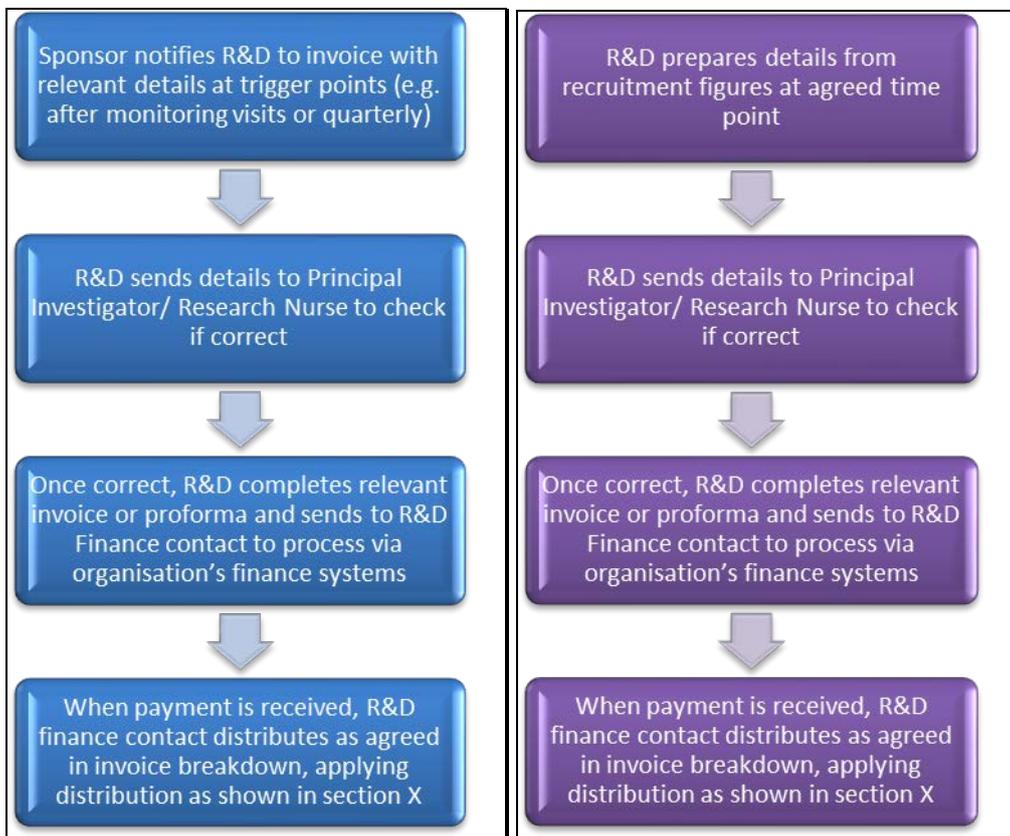
All contracts must stipulate who is responsible for initiating payments, when and how.

Invoicing can be triggered either by a request from the research Sponsor or CRO for commercial studies and supported with data analysis from the Joint Clinical Research Facility (JCRF) or the Cancer Institute.

The organisation's policy prefers a Sponsor to 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 will be undertaken via the R&D office and through the R&D Finance Manager in consultation with the Principal Investigator.

The diagram below summarises the R&D invoicing process:

Diagram 5: R&D invoicing process



Sponsor-initiated requests

Organisation-initiated requests

8.10 Control of funds/ accounts

The R&D R&D Finance Manager and the Associate Director of R&D will undertake regular monitoring and review of R&D finances. Where potential risks are identified, timely and robust remedial action must be taken, following discussion and agreement with relevant investigators and other relevant parties as appropriate.

The R&D Finance Manager will ensure that budget holders/ delegated budget holders and authorised signatories will have access to budget sheets. Regular reports and meetings can be scheduled with the R&D Finance Manager.

Overspending on budgets is not permitted. The delegated budget holder / Principal Investigator will be 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 risks of the project will be the responsibility of the Chief / Principal Investigator with their department. The R&D Finance Manager will provide advice, support and financial information as required.

In addition to the above, specific terms and conditions of investigator research accounts include:

1. Trials income earned from undertaking commercial and non commercial research studies will be paid into the investigator research accounts (after relevant NHS organisation costs and/ or relevant fees have been deducted)
2. The account must be used primarily to support the research agenda within the specialty in accordance with the organisation's overall research objectives and strategy
3. Planned expenditure must never be more than income

4. At the end of each financial year, accounts with accrued income greater than the set threshold must provide spending plans on how investigators intend to use the funding
5. Spending plans are to be provided on a per annum rolling basis and reviewed by R&D at least 6 monthly. Spending plans must detail outline or planned spending / expenditure against income accrued, plus anticipated new income generated per annum
6. Failure to provide spending plans will result in the accrued income not being reinstated at the start of the new financial year. This income will be put into a general research support fund, managed by the R&D Department or be lost and taken to the organisation's bottom line, where relevant supporting evidence cannot be produced.
7. For Investigator research accounts with accrued income at year end less than the organisation's set threshold, provision of spending plans is optional.
8. The threshold will be set by the R&D office in consultation and agreement with the Finance Director
9. Investigator research accounts where there has been no transaction activity for 2 consecutive financial years will be cleared at year end and any accrued income will be transferred to the general R&D income budget line for investment into the general wider research agenda, unless a request is made to the R&D office providing reasonable explanations
10. Principal investigators should be listed as an authorised signatory against a nominated investigator research account. These authorised signatories are responsible for producing spending plans when requested by the R&D office
11. Failure to provide robust remedial action plans will result in any income accrued at the end of each financial year being defaulted automatically to the R&D general account and will not be reinstated to the investigators research account at the start of the new financial year
12. The R&D Director and Senior Management Team, in conjunction with the Finance Director reserves the right to review and change income thresholds and any other terms and conditions associated with Investigator research accounts at any time, associated with an appropriate notice period before enactment
13. Spending must be discussed with and approved by R&D and priority will be given to expenditure that supports the development and delivery of high quality research studies

Income received via BACS transfer will be distributed automatically as per the financial agreements for each study, as advised by the R&D Manager and R&D Finance Manager.

Appointing staff, re-grading staff or increasing staff hours to carry out the support for research studies will be undertaken in accordance with the organisation's HR Workforce and Organisational Development policies and procedures.

Where staff are funded on an ongoing basis from succession of research projects, the department will need to monitor and manage the income and risks carefully to ensure sufficient funds are available to fund the posts.

Expenditure will be authorised by the Investigator or nominated officer in line with the Sponsor and in line with current organisational policies. Such expenditure will follow the study budget and movement between budget lines will be governed by the agreement with the research funder.

All expenditure will be in line with ABMU HB rules and regulations, policies and procedures. The R&D Finance Manager will notify the R&D office of any overspend. The R&D Manager / Director will notify the Investigator and request immediate corrective action. Where unsatisfactory responses are received, the matter will be escalated to the department leads and Finance Director.

This policy will operate within ABMU HB's Standing Financial Instructions and Standing Orders.

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.

Dr Jones (the Principal Investigator (PI)) is a consultant in Diabetes and is approached by Devices Central to take part in a study looking to test a new blood glucose monitor.

The PI discusses the study with his research team and determines that they can recruit 35 patients to the study in the required time period. He contacts the R&D office to advise on the forthcoming study and the team co-ordinates the completion of the relevant paperwork in order to get the study approvals required to start at site.

A representative from Devices Central forwards the completed UK commercial costing template and model contract to the R&D department, which results in agreed payment rates, with the contract signed as required.

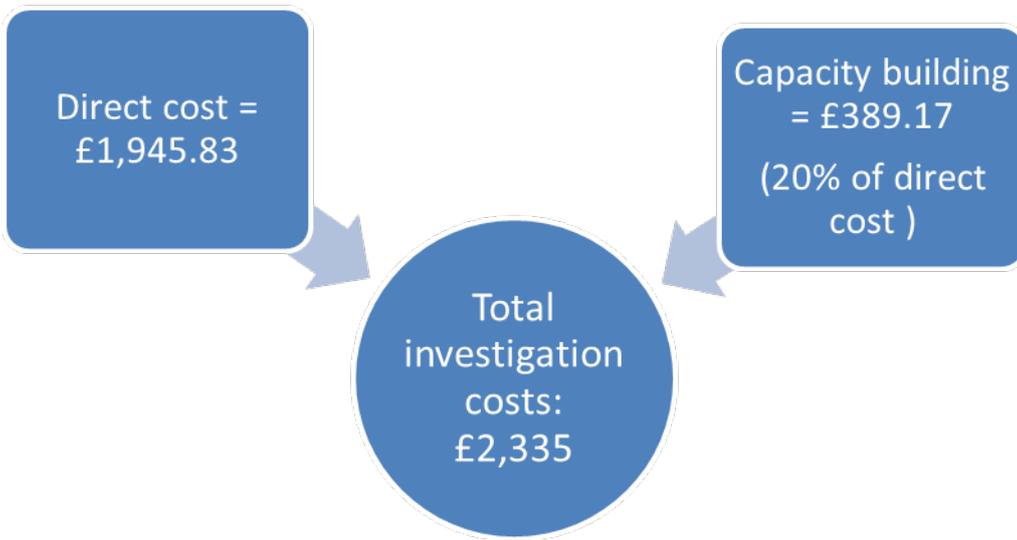
Once the study starts, the R&D office invoices Devices Central for the R&D set up fee. The study team manages to recruit all 35 participants within the given 2-month window. Once the company confirms that they are happy to be invoiced for the participants based on the agreed rates, R&D raises an invoice for £13,405, as per the study budget. This funding goes into the R&D budget.

The table below shows the agreed study budget

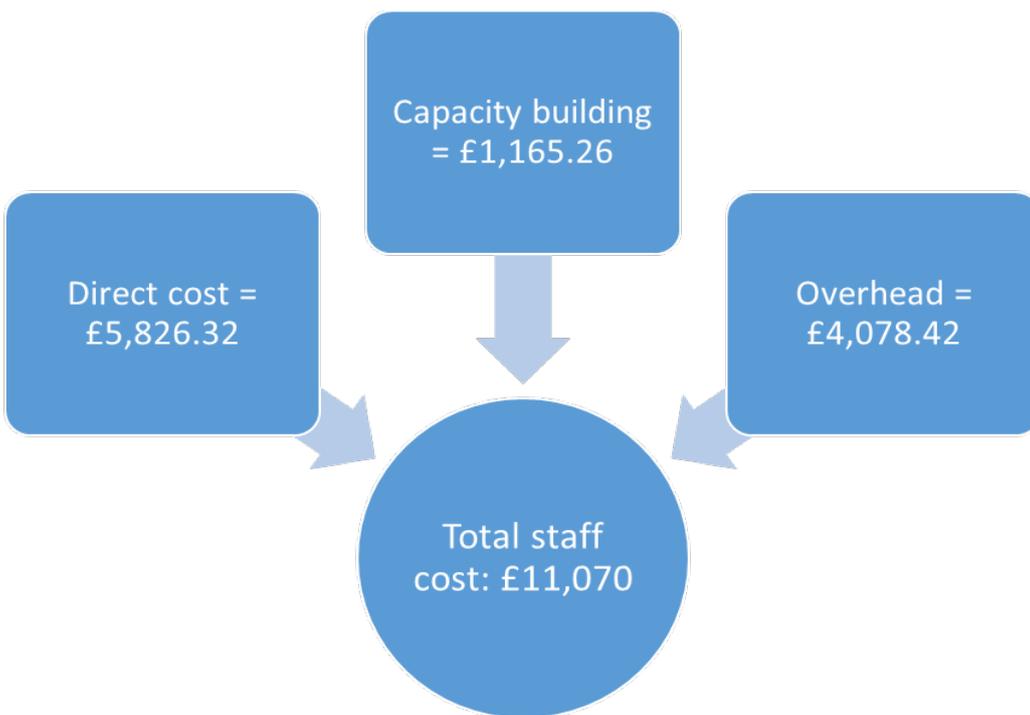
Costing element:	Total agreed budget:
<i>R&D set up fee</i>	<i>£766</i>
Pharmacy set up fee	Not applicable
Pharmacy budget	Not applicable
Investigation costs	£2,335
Staff costs	£11,070
Total study budget for 35 patients (excluding R&D set up fee, which is invoiced for separately)	£13,405

Breakdown of the various elements of the agreed costs (these are clearly identified within the 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 £2,335 investigation cost breakdown is as follows:



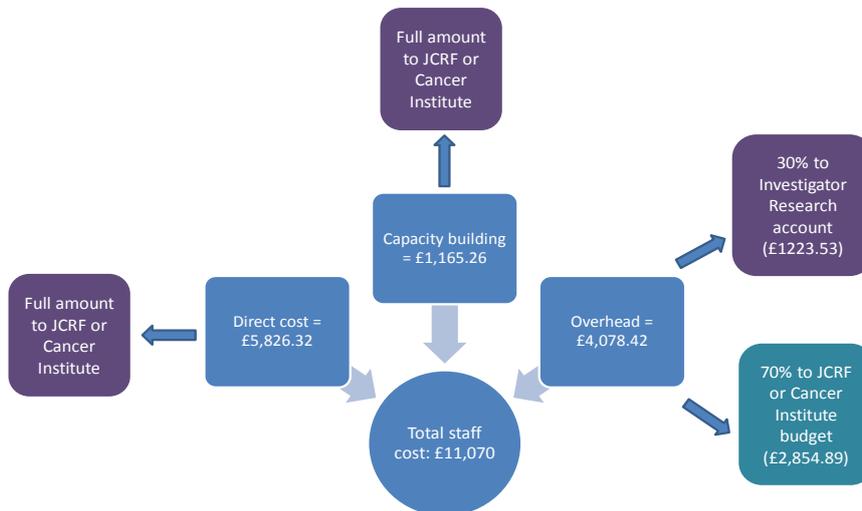
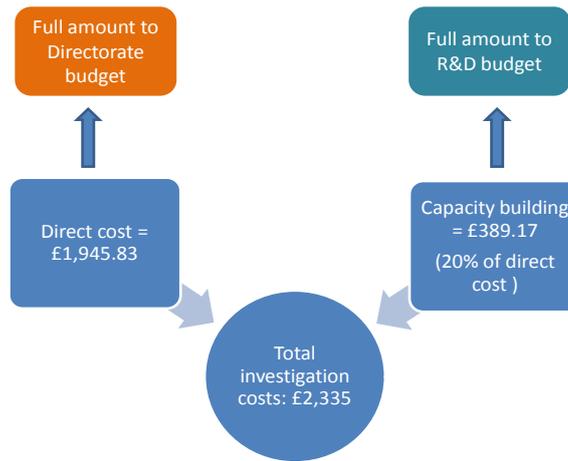
Staff costs include the basic cost, 20% capacity building fee and 70% overhead.



Using the principles of income distribution as detailed in Section 7.6.2, the following breakdown will occur:

Key:

- Directorate budget
- Investigator Research account
- R&D budget



The totals to each budget area are summarised below, along with an indication, for this particular study of what percentage each budget receives:

	Investigation Costs		Staff Costs			Total:	% of total funding
	Direct	Capacity building	Direct	Capacity building	Overheads		
Directorate budget	£1,945.83	-	-	-	-	£1,945.83	14.52%
Investigator Research account	-	-	-	-	£1,223.53	£1,223.53	76.35%
JCRF / Cancer Institute or R&D account	-	£389.17	£5,826.32	£1,165.26	£2,854.89	£10,235.64	9.13%