

Guidance for NHS Organisations 2020/21



The Appropriate Use of Local Support & Delivery Funding

Guidance for NHS Organisations 2020/21

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1. Purpose and Scope of this Guidance

This document has been developed in order to provide NHS organisations in Wales with guidance on the appropriate use of **Local Support & Delivery Funding** provided to them in 2020/21 from Welsh Government.

In line with the national NHS R&D objectives, key indicators and targets outlined in Welsh Government's **Delivery Framework – Funding and Performance Management of Local Support & Delivery Funding**, this guidance document is also based on the expectation that NHS organisations are actively recovering all other costs associated with hosting or leading research studies, both commercial and non-commercial. This includes all costs from commercial sponsors; research costs from grant holders; as well as Excess Treatment Costs (ETCs) identified and agreed for any non-commercial studies in Wales, from the centralised ETC budget. In addition, there is a centralised Support Cost budget for Primary Care, Public Health and Emergency Care studies, which should be accessed as appropriate.

This guidance document should be read in conjunction with the **All Wales Support and Delivery Funding 2020/21 – Technical Guidance** and the AcoRD guidance for Wales¹.

2. Local Support & Delivery Funding- Scope

Local Support & Delivery Funding should be used by NHS organisations to contribute to the investment in NHS based infrastructure, building capacity and capability to support high quality research in a fair and transparent manner, which is linked to national priorities to maximise impact.

Welsh Government's Local Support & Delivery Funding is a proportion of the total funding invested in the research infrastructure in Wales and is intended to support the increase of high-quality research activity in the NHS. NHS organisations are also expected to draw upon and utilise other resources and sources of funding available to build research in their organisations. As such, the NHS organisations are expected to draw on these sources of funding and other appropriate funding for research available to their organisation, to invest in the growth of capacity and capability for NHS research within their organisation. This could include, for example, commercial research income from sponsors of commercial trials and non-commercial research costs recovered from grant holders of non-commercially funded studies as well as charitable funds donated by patients and the public to the NHS organisation.

The diagram below shows how Local Support & Delivery Funding is a proportion of the funding and resources available to NHS organisations to support research.

¹ <https://www.healthandcareresearch.gov.wales/nhs-randd-funding-policy/>

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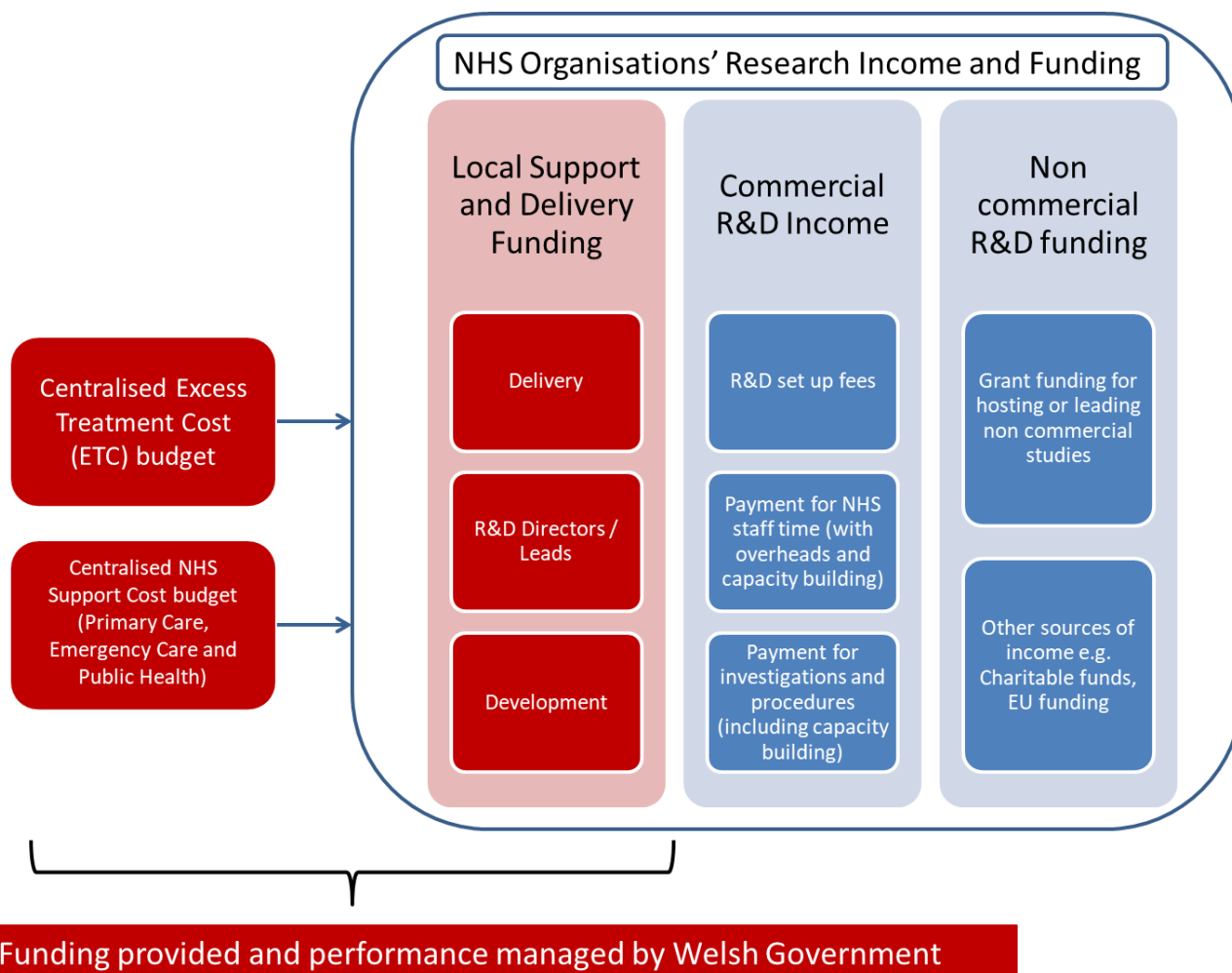


Diagram 1 – Welsh Government Local Support & Delivery Funding and how it relates to other R&D income

The investment of Local Support & Delivery Funding from Welsh Government should be considered in the wider context of other funding and resources that the organisation has secured for research activity.

Examples of other funding and resources for research in the NHS in Wales highlighted by R&D colleagues across Wales have been captured and summarised in Diagram 2 below.

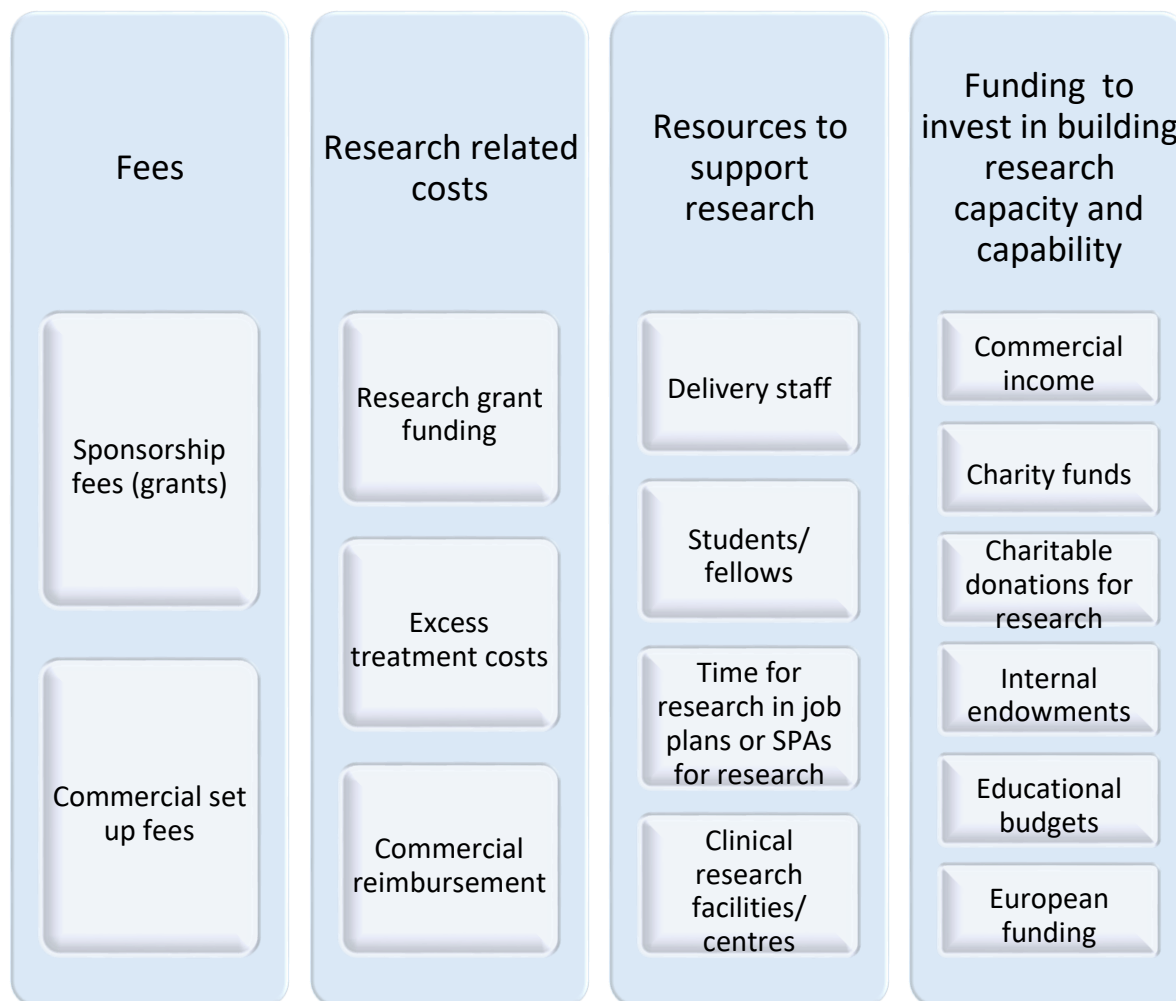


Diagram 2 – Examples of other resources / sources of funding for research for NHS organisations

3. Local Support & Delivery Funding

Local Support and Delivery Funding should be used to provide the appropriate resources required to facilitate and support the local set up and delivery of Health and Care Research Wales Portfolio² studies (non-commercial) at the NHS organisation.

3.1 Delivery Funding

The funding should principally be used to invest in people or posts to support the delivery of research. This could include paying for staff involved in actively supporting recruitment to Health and Care Research Wales Portfolio studies. It could also include

² The Health and Care Research Wales Portfolio is a register of high quality health and social care research studies active in Wales that meet specific eligibility criteria

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paying for staff in departments that are required to provide supporting services for studies.

Local Support and Delivery Funding should be used to cover NHS Support Costs for Health and Care Research Wales Portfolio studies as the priority is to focus on the delivery of Portfolio studies. This may be in the form of research delivery staff costs.

NHS Support Costs – “the additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided”.

As an example, a Research Nurse who is undertaking a patient visit for a study will be undertaking a range of activities, which will be a mixture of standard care, Excess treatment costs, NHS Support Cost activities and Research Cost Activities. The table below demonstrates this:

Example: Visit 1 Day 1 for X study.

Activity	Attribution of activity	Most appropriate funding source for the activity
Explain the study and take informed consent	NHS Support Cost activity	Delivery funding from allocation
Once informed consent received, take bloods – results will be used to ensure the patient fits the research study inclusion/exclusion criteria	Research cost activity	Provision should be made for this in the research grant – should be included in payments to be made from Sponsor to NHS organisation – cost recovery required
Height, weight and vital signs for CRF	Data collection – for research study – Research cost activity	As above, costs need to be recovered
Randomisation – Research Nurse to call a number to get randomisation code	Research cost activity	As above, costs to be recovered
Delivery of intervention that is currently standard care for those patients randomised to the standard care arm of the study	Standard care	Normal NHS commissioning budgets (no action is required in terms of any cost recovery as standard care happens anyway)

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As demonstrated by the example above, even though the Research Nurse salary is funded through Local Support and Delivery funding, some of the activities they will be required to undertake will need costs to be recovered. The research costs would then come back into the R&D office and can be pooled for investment as appropriate.

There are instances where there is no funding for the research cost activities, for example when more sites than initially anticipated have had to be opened. In this case, it is up to the NHS organisation to decide whether to proceed with the study for the benefit of their patients and in line with the organisation's overall R&D strategy. However, it is expected that the financial impact of this is quantified and understood to demonstrate informed decision-making.

This information is also important in feeding back to Welsh Government the impact that this is having on the NHS organisations across Wales.

Local Support and Delivery funding is also intended to cover procedures and investigations that are attributed as NHS Support Cost activities (see above for definition), where these are in addition to other support already in place, or where these are one off activities. However, if the intervention in question were to be assumed to become standard care in the future, NHS Support Cost activities would not be required to be delivered as part of the care pathway involved in the intervention (therefore not a treatment cost activity).

3.2 Research Delivery Staff

On 1st October 2016, staff within the national research workforce were transferred into Health Boards and integrated team structures were established including a number of split posts (i.e. a delivery post working across more than one Health Board) and a number of posts working at one health board only).

3.3 Definition of a “Split Post”:

Following the transfer of the national research workforce, a definition of split post has been developed to allow NHS organisations to consider co-funding posts on an ongoing basis.

Definition: A split post has delivery responsibilities across more than one Health Board. The post holds a substantive contract with one health board but can move when required to the other health boards within the region. This way of working ensures access to delivery resources for all Health Boards in the region. It also ensures flexibility of the resources, allowing them to be moved between Health Boards according to demand and includes the provision of clinical specialist support. An example of this would be a paediatric research nurse working on a study in Cardiff and

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Vale could also support the same study in Aneurin Bevan bringing their knowledge, expertise and lessons learnt into the Health Board. The organisation that employs the post should be the organisation that manages the person.

Organisations who have agreed to a split post arrangement should discuss and agree whether funding needs to transfer between relevant organisations. Organisations should be pragmatic and the value of transferring funding should be considered primarily in scenarios where joint posts are established e.g. 50/50 split. The Regional Planning Groups support the discussions regarding the funding arrangements for split posts.

3.4 Definition of a “Joint Post”:

A joint post is a research related post where the employee holds a substantive contract with one health board but the position is being partly funded by the local support and delivery funding and partly by another source. For Example, a full time (1 WTE) member of staff whose costs are funded 0.6 WTE through Local Support & Delivery funding and 0.4 WTE through a University or Charity, should be reported as 1 WTE with 0.6 of the costs reported as ‘Planned Expenditure from Local Support & Delivery funding’ and 0.4 of the costs reported as ‘funded from another source’.

Examples of Appropriate Use of Local Support and Delivery Funding:

Research Delivery Posts:	
<i>Examples of what is covered</i>	<i>Examples of what is not covered</i>
<input type="checkbox"/> Used to support key posts within the organisation - that are integral to the delivery of Health and Care Research Wales Portfolio studies. This includes posts within Pharmacy, Pathology and Radiology and can also include Research Nurses employed by NHS organisations to deliver research	<input type="checkbox"/> Activities undertaken by these posts that are classed as Research Costs or <i>net</i> Excess Treatment Costs. For such activities, the NHS organisation must put in place an appropriate model for cost recovery from the relevant funding sources and report on these in the monthly financial status report

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<p>□ A proportion of staff time spent supporting study delivery, for example to cover normal clinical care staff in departments actively participating in the delivery of a research study</p> <p>For example: An organisation is undertaking its first Cardiovascular</p>	<p>□ Any activities that are undertaken that fall under research cost or treatment cost categories</p> <p>For example: Extra blood tests where the results are <i>not routinely required</i> to be fed back to the patient or participant’s clinical team, according to the study protocol, these are research</p>
<p>study and clinical staff within that department have agreed to support the research related activity that classes as NHS support in line with AcoRD (e.g. gaining informed consent from the patients/ participants). Some or all of the cost of their time can be covered by this funding stream</p> <p>The same would be the case for a Paramedic, for example, who is supporting a research study by taking informed consent from patients.</p> <p>Individuals working on delivery of portfolio research studies. There is no restriction for the amount of time posts can be funded for, although it is expected for this time to be ringfenced and protected for the delivery of the research in question.</p> <p>=</p> <p>□</p>	<p>costs. This applies even if by exception, some instances may require the results to be fed back to a clinical team. The primary purpose in this instance is to collect research data</p> <p>Any treatment cost activities should also be compared to current standard care to assess whether the activity is excess – if so, the centralised ETC budget should cover these activities, rather than the local support and delivery funding (taking the net effect into consideration).</p>

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Pharmacy Activities and Costs:	
<i>Examples of what is covered</i>	<i>Examples of what is not covered</i>
<ul style="list-style-type: none"> • Pharmacy staff working on research facilitating study delivery, with the understanding that cost recovery is undertaken for any activities where costs should be funded externally, for example for research cost activities and all commercial research activity. <p>Cost recovery for pharmacy staff should cover the majority of their time, as only a handful of activities undertaken by pharmacy staff that relate to patient safety are attributable as support cost activities.</p> <p>Examples include:</p> <ul style="list-style-type: none"> • Un-blinding • Local repackaging of study drug where required by the protocol or for safety purposes 	<ul style="list-style-type: none"> • Cost of the study drug will always be a treatment cost and never attributable as a NHS support cost. This comes under the treatment cost category. If the drug is currently used as part of standard care, this is cost neutral to the NHS (usual NHS commissioning arrangements apply). If the drug is not currently used as standard care, the cost of the drug is covered by the ETC budget. If the cost of the drug is being borne by a commercial company, for example, or provided at reduced cost for the duration of the study, this should be recorded by the NHS organisation as a cost saving. • Placebos - these are always classed as research costs, along with any
<p>□ Individual patient drug accountability</p> <p>Further detail is provided in the AcoRD and IMP Management paper for Wales³</p> <p>Once again NHS organisations will be required to demonstrate how costs have been recovered for the post.</p>	<p>□ associated manufacturing costs and other activities (e.g. pharmacy dispensing placebo is a research cost activity)</p> <p>Any activities that would still be required if the drug became part of standard care, including:</p> <ul style="list-style-type: none"> • Cost of pharmacy staff time to dispense the study drug (treatment cost) • Overall drug accountability • Transport, storage and disposal of IMP

³ <http://www.wales.nhs.uk/sites3/Documents/952/Version%201.0%2021st%20February%2014%20Clinical%20Trial%20Management%20and%20AcoRD%20Wales.pdf>

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Laboratory-based Activities and Costs:	
<i>Examples of what is covered</i>	<i>Examples of what is not covered</i>
<ul style="list-style-type: none"> • Costs of tests that are attributable to the NHS support cost category as defined in AcoRD. This includes lab tests performed by PHW laboratories on behalf of other NHS organisations. In these instances, PHW can claim the NHS Support Costs from the centralised budget as appropriate. • Cost of lab staff time, although not intended necessarily to be on a direct reimbursement basis (i.e. strategic investment could be made in funding part of a post within the support service department to ensure capacity to deliver research in general, with cost recovery in place as appropriate). See Section 2 for the relevant policy context 	<ul style="list-style-type: none"> • Retrieval of tissue blocks where this is for research data purposes only – this is a research cost and should be covered by the grant • Any test or investigation where the results are intended primarily to feedback data to the sponsor, rather than impact on patient care – these are research costs

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Equipment:	
<i>Examples of what is covered</i>	<i>Examples of what is not covered</i>
<ul style="list-style-type: none"> • Non capital equipment under £5k, including VAT) • Items which will support several high quality research studies and directly contribute to recruitment of participants • Items which will overcome blocks from clinical service support for research • Items which are specifically required for research activity <p>Note: A maximum of 5% of the total NHS R&D allocation can be used on appropriate equipment expenditure</p> <p>Examples include:</p> <ul style="list-style-type: none"> • <i>Research fridge/freezer for storage of samples, IMPs</i> • <i>Centrifuge for research use</i> • <i>Thermometers for IMP management</i> 	<ul style="list-style-type: none"> • Any equipment costing more than £5,000 including VAT • Any expenditure over 5% of the NHS R&D allocation for the organisation • Equipment for non-research related activities • Capital costs e.g. refurbishment, furniture, building improvements

Translation costs to comply with Welsh Language Act:	
<i>Examples of what is covered</i>	<i>Examples of what is not covered</i>
<p>□ Translation costs for patient and public facing documentation. These are NHS Support Costs based on the principle that NHS Wales has a duty of care to Wales based patients to provide information in Welsh.</p>	<ul style="list-style-type: none"> • Translation of research related documents that are not patient and public facing • Translation into other languages (not Welsh or English) should be considered as research costs in line with AcoRD policy.

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Governance Activities:	
<i>Examples of what is covered</i>	<i>Examples of what is not covered</i>
<ul style="list-style-type: none"> • <i>Auditing hosted research studies</i> • <i>Provision of ICH GCP training if this is required over and above GCP training provided by the Health and Care Research Wales Support and Delivery Centre</i> • <i>Provision of advice and guidance for compliance with research regulations</i> 	<ul style="list-style-type: none"> • Sponsorship activities, where funding to support the activities should be costed into a grant application as part of the Sponsorship fee, where applicable • Costs of monitoring sponsored studies (this should be covered by the grant if the study receives external research funding)

Research Related Training:	
<i>Examples of what is covered</i>	<i>Examples of what is not covered</i>
<ul style="list-style-type: none"> • Relevant, recognised and widely available training that allows individuals involved in research to conduct, manage and undertake research according to the expected regulatory standards, for example: • ICH GCP training (the preferred provider should be the Health and Care Research Wales Support and Delivery Centre, rather than individual organisations paying for external providers) • Informed consent training 	<ul style="list-style-type: none"> • Training of clinicians and other NHS staff to deliver the treatment - this is a treatment cost activity • Training solely and primarily in the appraisal and application of findings of research • Training on study specific procedures relating to research activities, e.g. training on the inclusion and exclusion criteria, training on filling out the study specific Case Report Forms (CRFs), training on the randomisation process for the study. This includes site initiation visits. These are research cost activities. • Training in research as part of a basic undergraduate or post-basic /

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	<p>postgraduate education for a specific profession</p> <p><input type="checkbox"/> Funding for release time for NHS staff to attend general training, as this should be done in line with all other training individuals agree to attend with their line managers and service managers for their professional development</p>
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Hosting R&D Events and Conferences:	
<i>Examples of what is covered</i>	<i>Examples of what is not covered</i>
<p><input type="checkbox"/> Reasonable costs for locally based events intended to promote research within a specific NHS organisation</p>	<ul style="list-style-type: none"> • Unreasonably high costs • Conferences that are not specifically for NHS R&D promotion

3.5 Development Funding

With the introduction of a new funding approach in 2020/21, Local Support and Delivery Funding is focused on the delivery of research studies in Wales. In agreement with Welsh Government, some organisations will receive a small amount of development funding to cover committed posts and ongoing work that will complete over the year. A revised policy position on development funding will be developed over 2020/21.

3.6 Cost Recovery

NHS organisations should demonstrate that they are aware of the level of activity that should be cost-recovered and are able to demonstrate that effective cost recovery mechanisms are in place through reporting on the monthly financial status reports. For example, the research grant budget should allow for research cost activities that are required at NHS organisation level, with funding being made clear in any contract that is agreed.

Where an NHS organisation has agreed to host a high-quality study for patient benefit where research cost funding is not available, this must also be demonstrated in terms of an informed decision-making process, and the level of impact in terms of how much research funding is being covered should be clear. The purpose of asking NHS organisations to show cost recovered funding is to provide assurances to Welsh Government that where Local Support & Delivery Funding is being used to facilitate

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delivery of studies, there are clear financial mechanisms in place to recoup costs in order to support sustainable growth of capacity for research in the future. This will also support gathering evidence across Wales to demonstrate if there are particular issues in recouping costs for particular activities/studies.

NHS organisations are required to detail commitments against any costs recovered (and planned cost recovery) within their spending plans. It is expected that NHS organisations have in place a robust strategy for use of costs recouped to support local research activities. Any costs recovered, including commercial income that cannot be demonstrated to be committed for in-year spend will be off-set against the Local Support & Delivery Funding received by the NHS organisation and recovered by Welsh Government for re-distribution.

4. Local Support & Delivery Funding- Limitations

4.1 Commercial Research Limitations

There are two main limitations with regards to the use of Local Support & Delivery Funding. These are:

□ Using Local Support and Delivery Funding to cover costs of commercial research

Local Support and Delivery Funding must only be used as an up-front investment to support undertaking commercial research activity if no other resources are available. Where the NHS organisation's R&D Director agrees this is appropriate, clear cost recovery mechanisms must be put in place to recoup the costs, in line with the R&D finance policy. Reporting cost recovery for funds invested to facilitate delivery of commercial research will be required as part of the monthly financial status reports

4.2 Costs not covered by Local Support & Delivery Funding

Local Support & Delivery Funding is **only** to be used to invest in research infrastructure in the NHS in Wales. NHS organisations are expected to manage Local Support & Delivery Funding provided to host, support and undertake R&D in such a way as to achieve maximum benefits in terms of supporting Welsh Government's strategy and to secure long term growth in research activity.

Whilst NHS R&D staff may be funded through Local Support and Delivery Funding, they are employed by NHS organisations in Wales. The Local Support and Delivery Funding is not therefore intended to cover costs that would normally be covered by NHS employers, for example rent charges for space within an NHS organisation for an R&D department, which should be equitable to that charged to other departments. This also applies to aspects like overheads, which should not be charged by the NHS

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organisation to the R&D staff specifically due to the separate ring-fenced Local Support & Delivery budgets. If rent is payable, then this should be a reasonable cost, which can be justified by the organisation.

4.3 Non-NHS Expenditure

The Local Support & Delivery Funding should not be used to cover *any* costs incurred by non-NHS organisations, e.g. University based costs. This includes funding university posts or offices or software for use by University staff. Whilst Local Support & Delivery Funding cannot be used for this purpose, the NHS organisations are encouraged to use other sources of R&D income to cover these to complement the Local Support & Delivery Funding.

There may be instances where a clinical academic may be employed by the University but has an honorary contract with an NHS organisation, with an agreed number of clinical sessions. The Local Support & Delivery Funding can be used to fund these individuals for research activities relating to the NHS aspect of their contract only.

The local support and delivery funding received from Welsh Government should remain in the NHS organisation to which it was allocated. If funding is transferred to another NHS organisation, which should only happen if there has been a previous agreement to fund split posts (see section 3.3) or in exceptional circumstances, and there must be a clear reason and a transparent auditable process reported in the monthly financial status reports.

4.4 Research Costs

Local Support & Delivery Funding should not be used to cover research costs for Clinical Research Portfolio studies that should be funded by grant income and, therefore, claimed from the grant holding organisation. Details of amounts to be claimed should be agreed as part of the contract sign off process, or if a contract does not exist, as part of the local governance checks when undertaking study review for the organisation. This will ensure that the resource required in order to deliver the study can be identified from all relevant sources. This includes items such as archiving costs, which, under the AcoRD policy, are Part A Research Costs.

In exceptional circumstances, where sites must be opened to meet recruitment targets and grant funds have been depleted, a local decision will be taken about whether or not to support the study.

Please note that Part B research costs are expected to be borne by the NHS organisations. This is intended to be done by agreeing to undertake activities using existing resource (e.g. a Research Nurse undertaking data collection with no cost recovery sought as the funder is eligible for support with Part B research costs). Occasionally, if no existing resource is in place, NHS organisations should provide this support through their Local Support & Delivery Funding. This relates to funders that

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are members of the Association of Medical Research Charities (AMRC) and NIHR partners (making studies funded by their grants automatically eligible for the portfolio). Where the resource is provided for such activities by the NHS organisation, this should be highlighted in the monthly financial status reports.

For research studies funded by portfolio eligible AMRC members, some research costs as identified by the attribution in line with AcoRD (see Annex A, Part B), will need to be met by existing resources or through the Local Support & Delivery Funding at an organisational level. NHS organisations covering primary care should be aware that this also applies to Part B research cost activities undertaken at a GP practice level by practice staff (and therefore planning of expenditure of the budget should take this into consideration).

Further guidance about the specific activities that can be attributed as Part B research cost activities is provided in the *Part B Definition Paper for Wales*⁴

4.5 Further Examples of Inappropriate Use of Funding

Other examples of inappropriate use of Local Support & Delivery Funding include, but are not limited to, the following (as stated previously, other sources of R&D income may be used at the organisation's discretion, e.g. commercial income):

- Activities to support service evaluations
- NHS organisation general library services, which should be provided by the organisation for all staff
- Capital equipment costs (e.g. cost of refurbishments, furniture, property improvement etc.); equipment over £5,000
- Costs of accreditation and licensing where this is required clinically (not research specific). For example, where a laboratory requires accreditation for normal clinical work, or where other clinical accreditation or licences are required, this should be covered by clinical budgets, not Local Support & Delivery Funding.
- Paying for time of members of local committees put in place locally to review research (e.g. local risk, peer review and governance panels). NHS staff attending such meetings should do so in line with arrangements for any other meetings associated with their roles.
- Payment for membership or activities out with the local NHS organisation to wider groups/partnerships, that is not in line with the Welsh Government NHS R&D objectives and indicators. If local support delivery funding are used to fund joint posts across NHS organisations, Welsh Government will expect the NHS organisations to be able to present data to demonstrate the added value of the arrangement. Investment in the research infrastructure of the organisation in receipt of the allocation should take priority.

⁴ <http://www.wales.nhs.uk/sites3/Documents/952/v1.0%20Dec%2013%20Part%20B%20Research%20Cost%20Activities%20provided%20by%20NISCHR%20funded%20infrastructure%20in%20Wales1.pdf>

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- Duplication of national activities already funded by Welsh Government (e.g. funding to support Centres, Units and Research Design Services/ Clinical Trials Units or membership to an existing collaboration).

NHS R&D offices should seek advice from local NHS finance colleagues in relation to the use of the Local Support & Delivery Funding in relation to maintenance costs for equipment. The Local Support & Delivery Funding is a revenue funding stream, therefore local consideration is required to ensure the maintenance costs are not defined as capital funding.