1.2. The Appropriate Use of Local Support & Delivery Funding
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 2019/20 from Welsh Government.

The Activity Based Funding model used for 2019/20 is explained in full in the associated guidance: ‘1.1 Local Support & Delivery Funding 2019/20 Technical Guidance – Activity Based Funding’ and should be referenced for all queries relating to funding streams and the formula underpinning the allocations.

This document includes guidance on using all elements of the allocations, including:
- Delivery Funding
- Development Funding

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.

The aim of this operational guidance is to provide support to NHS organisations in planning for the appropriate use of Local Support & Delivery Funding, offering best practice and examples of specific activities or items along with details about which element of the funding allocation is most appropriate to cover them. The document also provides instances where it is not appropriate to use Local Support & Delivery Funding.

This guidance document should be read in conjunction with other guidance documents relating to Local Support & Delivery Funding, including AcoRD for Wales1.

If any part of the NHS Organisation’s R&D spending plan does not comply with the guidance, the R&D Director should discuss this with Welsh Government. Non-compliance is likely to result in the inappropriate expenditure amount being removed from the allocation of the NHS organisation concerned.

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1 http://www.healthandcareresearch.gov.wales/costing/
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 and local strategic priorities to maximise impact. Investment is expected in all aspects of the research pathway, including support for researchers in the design, set up and delivery of high quality studies, where these services are not already provided by other members of the Health and Care Research Wales infrastructure.

As highlighted in the Welsh Government’s *Delivery Framework – Funding and Performance Management of Local Support & Delivery Funding*, the Activity Based Funding formula is based on a strategic investment model, where funding is based on retrospective research activity. This is used as an indicator for the amount of funding each NHS organisation may need in the forthcoming financial year to support NHS research. This provides the fairest mechanism to share out a finite pot of funding between organisations.

Welsh Government’s Local Support & Delivery Funding is a fixed amount allocated across the NHS organisations in Wales annually. It 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.
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.

NHS organisations in Wales should use Local Support & Delivery Funding to increase their research activity and recover costs from research activity, as well as to work to identify other sources of support to sustain increases in their research portfolios.
Diagram 2 – Examples of other resources / sources of funding for research for NHS organisations

The finite nature of the Local Support & Delivery funding means that a direct reimbursement model is not sustainable, as the budget has not increased since the introduction of Activity Based Funding and is not likely to do so in the foreseeable future.

As a result, the strategic investment model has been adopted, ensuring that Local Support & Delivery Funding is invested in the most appropriate areas, to meet both national priorities and local requirements with R&D Directors making assessments about value for money. As an example this means considering whether individual contributions by departments should be pooled to invest in posts to support research, e.g. funding a post in Pathology, rather than retrospectively reimbursing the cost of a staff member’s time on individual studies on a regular basis.
This would contribute to greater capacity to host further high quality research studies within the organisation. Costs of specific processing of tests may still need to be covered, but staff costs would be viewed in a more strategic way and investment made accordingly. In addition, recouping appropriate funds for net\(^2\) Excess Treatment Costs or primary care, public health and emergency care activities also needs to be undertaken in a timely manner, as there have been instances where Local Support & Delivery Funding have been used to cover these costs with no recovery arrangements made.

### 3. Local Support & Delivery Funding – Appropriate Use

As outlined in 1.1 Local Support & Delivery Funding 2019/20 Technical Guidance – Activity Based Funding, Local Support and Delivery funding is split across 2 funding streams: a Delivery stream and a Development Stream.

#### 3.1 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 Portfolio\(^3\) studies (non-commercial) at the NHS organisation.

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

Aside from R&D Office and Heads of Research Delivery salaries, funded through the core funding element, the first call on Delivery funding should be to 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. If the Delivery element of the NHS organisation funding is not sufficient for this, funding can be vired from the Development element of the allocation to manage this within the NHS organisation.

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**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”.

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\(^2\) Net ETCs refer to the overall effect of the study, rather than focusing on only one element. For example, if the study required additional staff time to deliver an intervention, which is excess, but the Sponsor is providing a drug free of charge, this must be taken into consideration when determining the net effect of the study.

\(^3\) 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.
For all posts funded through the Delivery funding stream, there will be aspects of their input to studies that will be deemed to be delivery activities for which other funding should be available to cover their time. NHS organisations are required to demonstrate cost recovery for any activities that these posts undertake where this is appropriate (e.g. commercial research activity).

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.**

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

As demonstrated by the example above, even though the Research Nurse salary is funded through 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.

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).

These may be required on a direct reimbursement basis, but these should generally be for specific procedures or tests that are attributed as NHS Support Cost activities. For all other expenditure under this funding stream, the overriding principle is that of strategic investment.

To clarify, if the lab in the hospital will need tests processed, it may be that this will not take a lot of staff time, so the actual test costs are paid as direct reimbursement. However, it may also be that the NHS organisation would like to increase the numbers of studies they are hosting, which may impact on the numbers of tests required in the lab, therefore impacting on staff time. In this case, Delivery funding would be used to strategically invest in part of a post working in the lab, in discussion with the relevant directorate manager/s.

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. Included in the transfer were the Heads of Research Delivery (North, South West and South East), 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). The funding for all these posts have been included within the Delivery funding stream for each Health Board in 2019/20. Funding for the Heads of Research Delivery is part of the core element of the Delivery stream. Decisions on the use of Delivery Funding for all other posts is the responsibility of the relevant R&D Director (in discussion with the appropriate Head of Research Delivery).

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 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 Delivery Funding:**

<table>
<thead>
<tr>
<th>Research Delivery Posts:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Examples of what is covered</strong></td>
<td><strong>Examples of what is not covered</strong></td>
</tr>
<tr>
<td>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</td>
<td>Activities undertaken by these posts that are classed as Research Costs or <em>net</em> 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 financial returns</td>
</tr>
</tbody>
</table>

Document produced by Health and Care Research Wales Support and Delivery Centre – March 2019
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. 

For example: An organisation is undertaking its first Cardiovascular 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.

The same would be the case for a Paramedic, for example, who is supporting a research study by taking informed consent from patients.

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.

Any activities that are undertaken that fall under research cost or treatment cost categories.

For example: Extra blood tests where the results are not routinely required to be fed back to the patient or participant’s clinical team, according to the study protocol, these are research 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.

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 allocations (taking the net effect into consideration).

Pharmacy Activities and Costs:

<table>
<thead>
<tr>
<th>Examples of what is covered</th>
<th>Examples of what is not covered</th>
</tr>
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</table>
- 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.

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. Examples include:

- Un-blinding
- Local repackaging of study drug where required by the protocol or for safety purposes

- 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

<table>
<thead>
<tr>
<th>Individual patient drug accountability</th>
<th>associated manufacturing costs and other activities (e.g. pharmacy dispensing placebo is a research cost activity)</th>
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</thead>
</table>

Further detail is provided in the AcoRD and IMP Management paper for Wales.

Once again NHS organisations will be required to demonstrate how costs have been recovered for the post.

### Laboratory-based Activities and Costs:

- Cost of pharmacy staff time to dispense the study drug (treatment cost)
- Overall drug accountability
- Transport, storage and disposal of IMP

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### Examples of what is covered

- 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

### Examples of what is not covered

- 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

### Equipment:

<table>
<thead>
<tr>
<th>Examples of what is covered</th>
<th>Examples of what is not covered</th>
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</table>
Guidance for NHS Organisations 2019/20

• 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

*Note: A maximum of 5% of the total NHS R&D allocation can be used on appropriate equipment expenditure*

Examples include:

• Research fridge/freezer for storage of samples, IMPs
• Centrifuge for research use
• Thermometers for IMP management

• 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:**

<table>
<thead>
<tr>
<th>Examples of what is covered</th>
<th>Examples of what is not covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>Translation of research related documents that are not patient and public facing</td>
</tr>
<tr>
<td></td>
<td>Translation into other languages (not Welsh or English) should be considered as research costs in line with AcoRD policy.</td>
</tr>
</tbody>
</table>

3.5 Core funding
A core funding element is provided within the Delivery funding stream to ensure that a stable function for research support and governance is in place in each NHS organisation.

The core funding element of Delivery Funding should be used to cover costs associated with the local NHS Support and Management of R&D when the NHS organisation is involved in research as a lead site or host site. This covers items as described in document 2.1 R&D Office Functions\(^5\). This includes, but is not limited to:

- Salaries of core staff in the NHS R&D department involved in research support and governance activities. Note that this does not include covering proportions of time for NHS employees across other departments to undertake governance related duties, e.g. sitting on local risk committees or review panels for research.
- Support provided by the core R&D team for researchers in submitting grant applications, including cost attribution and applications for regulatory approvals, ethics favourable opinion and NHS permission
- Reasonable costs for research promotion and dissemination of results (e.g. hosting R&D conferences)
- Office equipment and consumables, provided these are within the criteria for expenditure on equipment, as detailed in Section 5.4
- Reasonable accommodation costs (please refer to section 4.2)
- R&D staff training and development
- Note that for any activities associated with Sponsorship for externally funded studies, costs should be part of the grant funding\(^6\), which will cover activities such as:
  - monitoring and auditing sponsored studies to ensure compliance, reporting to the MHRA on adverse events, breaches and urgent safety measures;
  - negotiation of contracts / agreements with study sites as the lead for the study;
  - development of trial specific documentation as lead site

NHS organisations will be required to use their core funding specifically for the purposes outlined above and report against these in line with the arrangements detailed in the guidance document 1.3. Monitoring the Use of Local Support & Delivery Funding.

If the NHS organisation’s Delivery funding is not sufficient, additional governance activities can be covered through Development and other sources of R&D income as deemed appropriate by the organisation.

Examples of appropriate use of Core Funding

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\(^6\) Note that NIHR funding streams do not accept sponsorship costs as part of applications, but other funders do.
### Governance Activities:

<table>
<thead>
<tr>
<th>Examples of what is covered</th>
<th>Examples of what is not covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Auditing hosted research studies</td>
<td>• Sponsorship activities, where funding to support the activities should be costed into a grant application as part of the Sponsorship fee, where applicable</td>
</tr>
<tr>
<td>• 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</td>
<td></td>
</tr>
<tr>
<td>• Provision of advice and guidance for compliance with research regulations</td>
<td>• Costs of monitoring sponsored studies (this should be covered by the grant if the study receives external research funding)</td>
</tr>
</tbody>
</table>

### Research Related Training:

<table>
<thead>
<tr>
<th>Examples of what is covered</th>
<th>Examples of what is not covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 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:</td>
<td>• Training of clinicians and other NHS staff to deliver the treatment - this is a treatment cost activity</td>
</tr>
<tr>
<td>• 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)</td>
<td>• Training solely and primarily in the appraisal and application of findings of research</td>
</tr>
<tr>
<td>• Informed consent training</td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• Training in research as part of a basic undergraduate or post-basic /</td>
</tr>
</tbody>
</table>
postgraduate education for a specific profession

☐ 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

Hosting R&D Events and Conferences:

<table>
<thead>
<tr>
<th>Examples of what is covered</th>
<th>Examples of what is not covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Reasonable costs for locally based events intended to promote research within a specific NHS organisation</td>
<td>• Unreasonably high costs</td>
</tr>
<tr>
<td></td>
<td>• Conferences that are not specifically for NHS R&amp;D promotion</td>
</tr>
</tbody>
</table>

3.6 Development Funding: is provided to NHS organisations to invest in the development of high quality research activity, including funding researchers and supporting them to submit bids to grant funders. This funding is focused on investment in researchers in order to return grants for high quality studies.

Development Funding should be focused on funding time for NHS staff in the organisation to develop their research activity and careers, including:

- Time for development of bids
- Funding activities for researchers to disseminate findings from their research projects
- Funding for Health and Care Research Wales Clinical Research Time Awardees, in order to support continuity in their research endeavours or activities
- Time and other funding to support running pilot or feasibility studies to enable data gathering to support high quality grant applications (pathway to portfolio studies)

Pathway to Portfolio activities are defined as Health and Care Research Wales funded activities that are undertaken to inform the development of a portfolio study or a grant
application for a portfolio study. As well as feasibility and pilot studies, this can include work to develop a platform for future portfolio studies in health and social care.

Development funding can also be used to cover Part B research costs (as defined under AcoRD), if the resource for this is not already provided elsewhere.

**Examples of Appropriate Use of Development funding**

<table>
<thead>
<tr>
<th>Pre-protocol (pathway to portfolio) Activity:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Examples of what is covered</strong></td>
<td><strong>Examples of what is not covered</strong></td>
</tr>
<tr>
<td>Release time or sessions for NHS staff to:</td>
<td>• Small scale own-account research activities that are unlikely to lead to research that is high quality and eligible for adoption onto the portfolio; no wider or significant potential impact on provision of evidence for improved care for patients</td>
</tr>
<tr>
<td>• Undertake database searches</td>
<td></td>
</tr>
<tr>
<td>• Perform literature searches</td>
<td>• Funding for other members of the Health and Care Research Wales infrastructure (no double funding should occur)</td>
</tr>
<tr>
<td>• Co-ordinate and undertake early feasibility assessments</td>
<td></td>
</tr>
<tr>
<td>• Develop research questions / proposals</td>
<td></td>
</tr>
<tr>
<td>• Search and apply for grant funding</td>
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</tr>
<tr>
<td>• Secure support from Statisticians in order to develop their grant application/ research proposal. This could also entail providing study by study funding for statistical support from RDCS/CTUs.</td>
<td></td>
</tr>
<tr>
<td>• Cover costs associated with involving patients and the Public in research and research study development</td>
<td></td>
</tr>
<tr>
<td>• Conduct pilot/feasibility studies</td>
<td></td>
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<tr>
<td>• Secure access to expertise and expert advice e.g. health economics or other leading experts in the field of interest</td>
<td></td>
</tr>
</tbody>
</table>
General Funding for NHS Staff Time for Research:

<table>
<thead>
<tr>
<th>Examples of what is covered</th>
<th>Examples of what is not covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Funding staff time between grants. This is for a maximum of 6 months</td>
<td>• Costs of time for staff employed by the NHS organisation to sit on internal R&amp;D committees or research panels – e.g. committees put in place by NHS organisations to review individual studies as part of the governance process. Staff time is already covered by the NHS employer and this activity should be undertaken as part of their role.</td>
</tr>
<tr>
<td>• Covering the cost of a clinician and other NHS staff time for involvement in regular endeavours to increase and support research. This can include clinical academics with an honorary contract related to providing NHS clinical services e.g. agreed number of sessions who also support research in the NHS. Examples include:</td>
<td>• Costs of time for staff that should be covered from other funding sources e.g. CI from grants (if this is covered); time spent undertaking research cost activities or excess treatment cost activities – cost recovery from the appropriate sources must be undertaken. In certain circumstances a local decision may be taken to host a study even if research cost budgets have been depleted.</td>
</tr>
<tr>
<td>• Membership of peer review panels outside of the organisation e.g. for MRC, NIHR, funding streams</td>
<td></td>
</tr>
<tr>
<td>• Attendance at key regional and national meetings to represent the NHS organisation’s interest and commitment to research (if not already funded from another source)</td>
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</tr>
<tr>
<td>• Contribution to the wider research endeavour in line with the local NHS organisation’s R&amp;D strategy</td>
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</table>

Dissemination of Research Findings (non-commercial studies):

<table>
<thead>
<tr>
<th>Examples of what is covered</th>
<th>Examples of what is not covered</th>
</tr>
</thead>
</table>
3.7 Virement between Delivery and Development funding streams

Whilst the Activity Based Funding formula distinguishes between Delivery and Development, the allocations can be used flexibly across the funding streams to meet local needs, with the priority given to Delivery costs required for Portfolio studies. NHS organisations can vire funding across the whole allocation amount to meet their needs, as authorised by the R&D Director.

NHS organisations are permitted to vire funding between both streams (Delivery and Development) in order to manage demand, provided that NHS organisations ensure their expenditure is aligned as follows:

- First, to Delivery Costs of Portfolio studies and
- Second, to support NHS clinicians and other staff in undertaking development activities that have the potential to lead to Portfolio studies (Pathway to Portfolio). It is the R&D Director’s responsibility to determine which activities are deemed suitable for support and are defined as “Pathway to Portfolio” activities.

The first call on the funding allocation should be any NHS Support Costs or investment to support delivery of Portfolio studies hosted by the organisation. This conforms to the arrangements which the NHS via Welsh Government has entered into with external R&D funders. These studies should be registered on the Health and Care Research Wales Portfolio.

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NHS organisations should use their existing resources or their Local Support & Delivery Funding to meet Part B research costs as defined under AcoRD when the study is funded by an organisation that is an eligible member of the AMRC. This should also include any resources provided by other members of the Health and Care Research Wales infrastructure. Further detail on specific activities that classify as Part B research costs are provided in the Part B Paper for Wales.  

For all NHS organisations, Delivery funding related to studies in primary care, public health Wales and emergency care (via the Welsh Ambulance Service Trust) is available from a centralised budget as outlined in the Delivery Framework – Funding and Performance Management of Local Support & Delivery Funding. Funding is allocated on an application basis and is managed and administered by the Health and Care Research Wales Support and Delivery Centre.

3.8 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 financial returns. 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. This can be done using the noncommercial costing template, which quantifies the time required for research cost activities. 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 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.

For NHS organisations that are integrated Health Boards covering primary care, the centralised support cost budget is available to cover NHS Support Costs incurred at the GP level. In addition, any tests performed by Public Health Wales (PHW) laboratories that are attributed as NHS Support Costs should be flagged to them so that PHW can claim the NHS Support Costs directly from the central budget. Welsh Ambulance Services NHS Trust (WAST) studies incurring NHS Support Costs will also be funded through the central budget, as their allocation does not include a Support Cost element.

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 allocations to cover costs of commercial research**

  Allocations 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 annual returns process. Where an NHS organisation has indicated in one year’s return that allocations were used to cover commercial activity, follow up information will be sought in subsequent annual returns about the recovery of the initial investment made using Local Support & Delivery Funding. Failure to demonstrate this may lead to reduced subsequent allocations.

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 the core funding element of the Delivery funding stream, they are employed by NHS organisations in Wales. The allocations are 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 organisation to the R&D staff specifically due to the separate ring-fenced Local Support Funding.
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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 funding allocations 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 financial mid-year and annual returns.

4.4 NHS Support Costs for other NHS Organisations

In 2013/14, a detailed exercise was undertaken to quantify the impact of NHS Support cost activities undertaken on behalf of other organisations in Wales. In particular, this applies to studies which involve patients from one organisation, where part of the standard care pathway results in them being seen in another NHS organisation (for example Cancer studies, where patient care is delivered across a range of organisations in the area). In these cases, where the patients are recruited into Clinical Research Portfolio studies, the delivery of the study procedures will generally follow the standard clinical pathway, in terms of where the patients are seen and where investigations will take place. It is, therefore, likely that the other NHS organisations will be required to take samples and process tests for the same patients. Where these activities classify as NHS Support Costs, it has been agreed that the organisation undertaking the activities will cover the cost of the activities from their own Delivery funding element of the Local Support & Delivery Funding, particularly as the monetary amounts that were identified during the exercise were relatively small.

An exception would be when laboratory tests undertaken by PHW are attributed as a NHS Support cost. In this instance, PHW should claim the costs directly from the centralised support cost budget.

Agreement reached by Activity Based Funding Advisory Group in 2014.
Welsh Government expects all NHS organisations to take a pragmatic and facilitative approach to research activity across the NHS in Wales, with a focus on the patient. In the main, research activity will naturally follow the standard patient care pathway, with additional procedures and research specific investigations undertaken as additional elements in the context of that pathway (i.e. where the patients attend clinics and have standard treatment across several NHS organisations in Wales). Therefore, an NHS organisation that is normally part of this standard pathway should not decline to undertake the research related support activities for these patients.

With regards to primary care studies, a Health Board will support their general practices with their research activity. There may be situations where, for example, samples taken in GP surgeries are sent to hospital labs for processing. Whilst the cost of time for individuals to process the samples may already be covered by the Local Support & Delivery Funding, there may be some costs, e.g. the test costs that need to be covered. These can be recovered by the Health Board accessing the primary care NHS Support Cost budget, when the activities are attributed as NHS Support Cost activities under AcoRD. Please note that this should be done in collaboration with the appropriate party (i.e. trial manager or GP practice staff member) applying for primary care support costs at the study set up stage.

4.5 Research Costs

Local Support & Delivery Funding from either funding stream 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 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 financial returns.
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\(^{10}\)

### 4.6 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 the allocations 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.
- 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.