



All Wales Support & Delivery Funding 2020/21 Technical Guidance

1. Purpose and scope of this guidance document

The aim of this document is to advise NHS organisations and the Support & Delivery Centre of the technical description and methodology for the distribution and monitoring of **Support & Delivery Funding** in 2020/21.

This document also gives an overview of the local and national decision-making processes for requesting amendments to Support & Delivery budgets during 2020/21.

This guidance is being evaluated in use and therefore updates may be issued during 2020/21 as process is refined. The current version is published on the Health and Care Research Wales website.

2. Definitions

- 2.1. Support & Delivery Funding refers to funding provided by Welsh Government to NHS organisations (termed 'Local Support & Delivery Funding') and the Support & Delivery Centre (National 'Support & Delivery Funding') to support the development and delivery of research in Wales.
- 2.2. 'Delivery Funding' is the funding that is made available to cover the support costs associated with the set-up and delivery (or to support the set-up and delivery of) research studies.
- 2.3. A new approach to distributing Local Support & Delivery Funding is being implemented in 2020/21, requiring transition from the previous formula based 'activity-based funding' model.
- 2.4. From 2020/21, delivery funding is provided based on the needs of research studies, and funding is directed to where and when those resources are needed and to where and when those costs are incurred.
- 2.5. The definition of 'delivery' is the local and national activities that facilitate and support the set up and delivery of Health and Care Research Wales Portfolio studies (non-commercial and commercial) in health and social care settings in Wales. This includes the study-specific activities as detailed in the research protocol, and the wider support (local and national) that facilitates or supports the study to be set up and delivered. Therefore, delivery activities include workforce planning, early engagement and study feasibility assessment, site selection, study set-up, screening, undertaking the study, participant follow-up and ensuring regulatory requirements are maintained throughout e.g. study oversight and monitoring.
- 2.6. "Support costs" are the additional care costs associated with the research, which would end once the research study in question had stopped, even if the care involved continued to be provided.
- 2.7. Research Delivery Funding can only be used for activities relating to research delivery and cannot be used to cover research study development costs.
- 2.8. Research Development costs are those associated with the development of research funding applications which includes time to write (or support the writing of) applications or

undertaking preliminary studies to support a future funding application and/or to support chief investigators. These are identified as part of the Local Support & Delivery funding.

3. Scope of guidance

- 3.1. Included in the scope of this guidance is Support & Delivery Funding that is made available to meet the costs associated with:
 - NHS organisation activities that support the set-up and delivery of research studies
 - National roles that are funded via NHS organisations e.g. Wales Specialty Leads
 - Support & Delivery (S&D) Centre activities that support study set-up and delivery of research studies
 - Support for studies undertaken by independent contractors commissioned to provide health or social care (e.g. general practices, dental practices, care homes etc)
 - Funding to support the development of research grants and/or to support chief investigators ("development funding")
 - Funding for R&D Directors/R&D Leads or equivalent leadership roles are captured on a separate tab within the delivery spending plan for ease of reporting.
- 3.2. Out of scope of this guidance (as guidance is provided separately on each of these types of funding) is the process for accessing:
 - Funding for Excess Treatment Costs
 - Funding for the Support & Delivery Centre activities that do not support study set-up and delivery those activities that support the wider HCRW infrastructure e.g. the communications service; or are part of a UK infrastructure e.g. Approvals Service
 - Funding for research and wider HCRW infrastructure i.e. the research development infrastructure, programmes and grant schemes

4. Implementation of a new approach to Support & Delivery Funding in 2020/21

- 4.1.2020/21 will be a transitional year in terms of the approach to budget setting and management, to ensure smooth implementation of the new research delivery funding approach. A priority in 2020/21 will be to maintain stability for existing staff in post and to ensure adequate support for studies that are already underway, whilst allowing time to develop and embed the operational systems and processes to support the new approach.
- 4.2. The length and nature of the transition period required beyond 2020/21 can only be determined accurately once the submission for resources has been assessed on an all Wales basis. This will provide information that demonstrates whether the move to the new approach results in a big difference in funding required at each NHS organisation, or if it is close to allocations provided previously via the 'activity-based funding (ABF)' formula-based model. It will also determine if the Health and Care Research Wales Support & Delivery Funding budget is sufficient overall. If there is a significant change in resources that are required nationally or locally using the new approach, a longer transition period may be required for some organisations or overall.
- 4.3. For 2020/21, organisations will be required to negotiate a spending plan that matches their ongoing committed expenditure and based on the actual resource required to deliver the active in-year needs.

- 4.4. The following sections of this guidance describe:
 - How initial spending plans for 2020/21 will be developed with NHS organisations and agreed, and in doing so how budgets will be confirmed. This will be based on a combination of committed expenditure and known in-year research study needs.
 - How identification of any gap between actual resource needs (assuming no fixed commitments) versus the initial spending plan will be determined, and how that analysis will inform the length and nature of transitional arrangements.

5. Initial Spending Plan/ budget setting for 2020/21

5.1. NHS organisations and the Support & Delivery Centre will be initially reserved a budget for 2020/21 that matches their ongoing committed expenditure. Budget setting will be undertaken through the following process:



Step 1: Draft spending plan provided to NHS organisations/Support & Delivery Centre (by 12 February 2019)

- 5.2. A draft 2020/21 spending plan will be created by the Research Funding Team for each NHS organisation and for the Support & Delivery Centre. This will be based on the actual expenditure detailed within the 2019/20 Quarter 2 financial returns, which have been reviewed and agreed by Welsh Government. Inclusion of posts/expenditure in the draft plan in Step 1 does not necessarily indicate a commitment by Welsh Government to maintain funding at this level, but is intended to create a building block for the NHS organisation to adjust from.
- 5.3. The draft 2020/21 NHS organisation spending plan will include:
 - R&D Office staff costs (R&D Director/R&D Lead posts will be included as a separate tab
 and separate guidance will be developed in the longer term)
 - Research delivery team staff costs i.e. research nurses, trials officers, administrators etc
 - Principal Investigator time (policy to be confirmed but included as per currently)
 - Clinical support staff costs and/or clinical service support costs i.e. pharmacy, pathology, microbiology, radiology etc
 - R&D Office running costs (non-pay) a standardised list of headings will be included but will not have a budget completed in Step 1.

- Research development staff costs i.e. grant development support posts
- 5.4. The draft 2020/21 Support & Delivery Centre spending plan will include:
 - Support & Delivery Centre staff and non-pay costs associated with functions that support the set-up and delivery of research.
- 5.5. Posts that will be included initially are only those with permanent contracts and fixed-term contracts that extend beyond 1 April 2020. Fixed-term posts that are planned to end before 1 April 2020 will be highlighted for reference in Step 2, but will not be included within the draft spending plan initially.
- 5.6. The draft 2020/21 spending plan will contain cost recovery achieved in Q2 2019/20 as an indication of likely income expected but will need to be reconsidered fully for 2020/21 in Step 2. No bank staff costs will be included but these can be added in Step 2.
- 5.7. If a major organisational change has taken place since Q2 2019/20, the organisation can request Q3 financial information is used to create the initial spending plan. This will be by exception.

Step 2: Amendments submitted (by 28 February)

- 5.8. On receipt of the draft 2020/21 spending plan, each NHS organisation / Support & Delivery Centre will review their individual spending plan and respond with any amendments, which may include, but is not limited to:
 - Addition of any new posts already agreed locally that will commence during Q3 and Q4 2019/20. This includes staff appointed through interview but who have not yet taken up post. It does not include costs for vacant posts where invitations to interview are made after 31st March 2020.
 - Removal of posts that have been vacated and where there is no intention to replace
 - The addition of fixed-term posts stated previously as ending on or before 31st March 2020 that have since been extended i.e. from the list highlighted in Step 1.
 - Forecasted bank staff costs required in year
 - Cost recovery expected against specific posts (based on predicted income in 2020/21 from commercial trials or from other sources)

Operational guidance for the amendment process will be provided by the Research Funding team with the draft spending plans.

- 5.9. In addition to identifying commitments already made, NHS organisations and the Support & Delivery Centre will also be asked to identify risks in the plan where committed resources is known to not be currently justified by 2020/21 activities planned, based on the actual resources required/costs that would be incurred to support the delivery of the active study portfolio in year (including studies in set-up or follow up).
- 5.10.NHS organisations and the Support & Delivery Centre will also be asked to add in additional costs that can be justified (and include that justification), based on the actual resources required/costs that would be incurred to support the delivery of the active study portfolio in year (including studies in set-up or follow up).
- 5.11. During Step 2, the Research Funding Team will be available to support NHS organisations to answer queries, and can also help NHS organisations make changes to the draft spending plan if required (either remotely or by a face-to-face meeting).

- 5.12. If any adjustments are made, the NHS organisation/Support & Delivery Centre must provide a reason against each change made, or as a separate narrative to cover a series of changes. The level of resource required can be defined in a number of ways and it will be for the NHS organisation to determine which method is best suited to their needs:
 - Utilising the experience of research delivery leads in workforce planning to determine resource needs with reference to the research portfolio
 - Utilising individual study schedules and/or costing schedules (ICT or SoECAT)
 - Utilising validated workforce planning tools

Step 3: Spending plans reviewed (by 13 March)

- 5.13. During this transitional phase, draft spending plans will continue to be reviewed according to the process already established i.e. reviewed by Welsh Government and the Director of Support & Delivery, supported by the Research Funding Team (see Section 9). Any queries will be raised with organisations and a spending plan will be agreed.
- 5.14. This will produce a spending plan which will include the level of resource that would be required to support the known activities to be undertaken for 2020/21 and beyond, based on the lifetime of the known research studies currently in set-up, actively recruiting or in follow-up.
- 5.15.2020/21 agreed spending plans:
 - <u>Support & Delivery staff:</u> Costs for those staff already appointed (delivery and development) will be met. This will include staff appointed through interview but who have not yet taken up post. No funding will be approved for vacant posts where invitations to interview are made after 31st March 2020.
 - <u>Non-pay costs</u>: Costs will be met as submitted (or amended following queries). <u>Principal Investigator costs:</u>
 - Principal Investigator sessional time for medical consultants will not be funded.
 Protected time for research should be honoured through SPAs and patient recruitment in normal clinic time should form part of a consultants' usual care provision.
 - Principal Investigator costs for Associate Specialists and Dental Consultants will be funded in 20/21, as the contract differs from the medical consultant contract. This position will be reviewed as part of a wider project.
 - O Principal Investigator costs for nursing, midwifery, allied health professional (NMAHP) consultants e.g. Consultant Nurse, Consultant Psychologist, posts will not be funded. The Agenda for Change national role profiles for NMAPs include R&D activities as major job requirement to co-ordinate, implement R&D activity, initiate, develop R&D activities, conduct research in specialist area, participation in research steering group developing trust wide research

NB: A project to determine the agreed approach for consultant sessional time will be undertaken and this position may change as a result of that

- Bank staff: Requests as submitted are agreed and will be included
- Specialty Leads: Funding is routed via Local Support & Delivery Funding. These will be included in the relevant host NHS organisation plan including sessional time and nonpay allowance.
- 5.16. Once agreed, no funding can be repurposed locally for another type of spend e.g. underspend in bank staff cannot be repurposed for new delivery posts without request.

- 5.17. Once agreed, the spending plans will then form the basis for discussions regarding:
 - Decisions relating to requests for changes to agreed initial budgets
 - Agreeing a plan to narrow the gap between agreed initial budgets and actual needs
 - Total Support & Delivery funding required

Step 4: Agreed budget confirmed (by w/c 30 March)

5.18. Budgets for 2020/21 will be confirmed and this will become the "live budget/spending plan". Expenditure will then be monitored and reviewed on behalf of Welsh Government (see Section 9).

6. Funding for support costs in primary, community and social care settings

- 6.1. Primary care locations (general practices, community optometry, community pharmacy & general dental practices) and social care providers will continue to receive direct reimbursement for any support costs incurred on a per-study basis. This approach is already in line with the new funding approach. The amount of costs to be reimbursed will continue to be agreed during study set up and trigger automatic payments. Where appointed direct by the independent contractor, direct reimbursement for the costs of posts or part funding of research delivery posts that have been pre-agreed will continue to be provided.
- 6.2. As described in Section 5, provision of funding for any posts (including to support, coordinate or oversee primary care research delivery) within the Health Board or Support & Delivery Centre will initially be based on Q2 2019/20 committed expenditure, and adjusted based on in-year known research study delivery needs and the model of research delivery within the health board.
- 6.3. This aligns with the overarching principle of taking a research study needs-based approach, but within the context of the developing All-Wales Primary Care Research Delivery Network (PCRDN) and the planned review of the Support & Delivery service.

7. Decisions regarding changes to agreed spending plans 2020/21

- 7.1. During transitional arrangements in 2020/21, NHS organisations/Support & Delivery Centre will retain local autonomy for decisions to reappoint to posts where vacancies arise or to cover maternity leave/other long-term absences, where active studies (including those in set-up and follow-up) continue as planned. This is on the basis that justification for the need for the post has already been established during the initial budget setting process and is within the agreed spending plan. In making that decision, the NHS organisation/Support & Delivery Centre will consider if the post can be covered by capacity from elsewhere in their teams, ensure that the research study delivery needs continue to justify the post being replaced, and be mindful that the gap between actual resource justified and resource committed will need to be closed as transitional arrangements end.
- 7.2. All changes made to the agreed spending plan as a result of local decisions must be notified to the Research Funding team on a monthly basis (see Section 9).
- 7.3. Where new posts (or expenditure) is no longer required as planned, it cannot be repurposed without discussion this may result in underspends/slippage to the agreed

plan. The NHS organisation/Support & Delivery Centre will notify the Research Funding team through the monthly reporting arrangements, and the quarterly schedule of payments to the NHS organisation will be adjusted. This may be due to changes in the study delivery, timescale, target or performance expected, or where changes across a wider team result in efficiencies in skill-mix required. It may also be due to the number of tests or scans undertaken (if this was used to justify need initially) being different from expected or for slippage or changes in requirements for use of non-pay.

- 7.4. Where new posts (or expenditure) is required to meet additional unplanned needs to support a study, or where new studies arise through the year which were unknown at the start of the year, a request must be submitted by email to the Director of Support & Delivery who will discuss the request with Welsh Government. Requests will be reviewed within the context of agreed spending plans and research delivery performance data, and response provided (either a decision or further clarification required) within 5 working days.
- 7.5. Organisations are required to use the national research delivery job descriptions without amendment (currently Research Nurse Bands 5 and 6, Clinical Research Officer Bands 5 and 6) for new appointments which are to be funded, or part funded by Local Support & Delivery funding. During 2020/21, NHS organisations should ensure all existing staff that are to continue to be funded by Local Support & Delivery funding (in part or full) in the future are moved to the All-Wales job descriptions. The national research delivery job descriptions have been reviewed and approved by the All-Wales banding panel. Work is underway to expand the list of national research related job descriptions.

8. Pump-priming capacity to deliver research

- 8.1. The priority for Support & Delivery Funding will be to ensure research studies already setup in Wales can successfully deliver. However, subject to the total Support & Delivery Funding required as a result of initial budget setting not exceeding the total Support & Delivery Funding available, funding will also be available to support the pump-priming of research capacity in new or expanding teams.
- 8.2. Pump-priming capacity is defined as being where costs cannot be expected to be initially justified by the research studies undertaken but where initial investment in capacity is required to enable a pipeline of studies to be expanded or established.
- 8.3. During transition, the established process will continue a request for access to funding to support pump-priming of capacity must be submitted by email to the Director of Support & Delivery who will discuss the request with Welsh Government.
- 8.4. The frequency and funding available to support requests will be determined once the initial budget setting process has been completed, thereby enabling the total resource needs for the delivery of active studies to be calculated. This will also enable a process to be developed for managing such requests.
- 8.5. Each approved funding request would be time-limited and performance actively managed in order to demonstrate a case for more sustained funding as part of the routine spending plans.

9. Monitoring use of Support & Delivery Funding

9.1. Consistent with the locally implemented NHS R&D Finance Policy, and the NHS Research and Development Finance Policy Welsh Health Circular, Local Support & Delivery Funding is to be managed via ring-fenced Research Accounts on each NHS organisation's central ledger, subject to the usual accounting rules and NHS financial standing orders.

9.2. Monitoring will ensure:

- Funding is used according to spending plans based on research study delivery/support needs and is linked to performance in a national context
- Costs associated with research delivery are being attributed appropriately
- Prompt discussion and action of in-year changes to spending plans to maintain Support
 Delivery funding forecasts
- Prospective discussion and action of any change in funding requirements to those forecasts in a national context e.g. distribution of funding where need has changed or cannot be met or new need is identified
- Identify whether NHS organisations are predicting any variance against their total delivery funding budget within the financial year
- Provide an opportunity for NHS organisations/Support & Delivery Centre to highlight any challenges that they are facing in managing their Research Delivery Funding and whether any additional support is required
- 9.3. The Support & Delivery Funding spending plan template can be used by NHS organisations/ Support & Delivery Centre as the local day-to-day financial management tool for recording Support & Delivery income and expenditure, allowing for straightforward monthly financial status reports to be submitted to the Research Funding team.
- 9.4. The purpose of the monthly financial status report is to:
 - Report on how Support & Delivery Funding has been spent in the previous month (actual expenditure compared to planned)
 - Report on how the NHS organisation/Support & Delivery Centre have utilised other sources of funding in the previous month (actual cost recovery / funding from other sources – actual income compared to planned)
 - Identify local changes made to the spending plan that maintain research delivery as forecasted and are justified, for information
 - Identify changes to the spending plan that present a risk to research delivery as forecasted and require review and action
- 9.5. Changes highlighted in the monthly status report will require justification. Where there is continued research delivery need that has been justified, the NHS organisation is required to refer to previously submitted evidence to justify the resource. This evidence may include local vacancy justification; local business case or evidence from research delivery workforce planning activities. Where need has changed or cannot be met or new need is identified, the NHS organisation is required to provide new evidence to justify the resource. This evidence may include local vacancy justification; local business case or evidence from research delivery workforce planning activities.
- 9.6. Once the process is established, it is expected that spending plans will evolve to capture known ongoing planned spend, profiling known needs for a rolling period past the end of the current financial year.

Operational Reference Group

- 9.7. The reference group will meet monthly to monitor and guide research delivery performance in a national context. The group will provide oversight and escalation at a national level in order to facilitate research delivery to time and target across Wales.
- 9.8. The group will provide peer review, data and recommendations to inform decisions regarding spending plans and expenditure requests. The group will discuss and make recommendations from an operational perspective on the use of delivery resources to meet priorities and optimise research delivery in a national context.
- 9.9. The initial task of the group will be to determine if current committed staffing is justified by the research activities undertaken by the organisation i.e. by reviewing workforce agreed in the spending plan against the actual delivery undertaken. The group may be asked to review and make recommendations in relation to pump priming applications.
- 9.10. Membership will comprise: Director of Support & Delivery (Chair), Head of Research Delivery, a nominated delivery lead for each NHS organisation (a delivery lead can be nominated to cover more than one organisation), the Head of the Support & Delivery Centre

10. Monitoring and review of this guidance

10.1. This guidance is being evaluated in use and as processes are further defined and other projects conclude during 2020/21, this guidance will be expanded/updated as required.