



All Wales Support & Delivery Funding

Technical Guidance v1.4

Guidance for NHS Organisations & Support & Delivery Centre

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**.

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

This guidance is being evaluated in use and therefore updates will be issued as process is refined. The current version is published on the Health and Care Research Wales website. Please see Appendix one for a list of changes made to this document to date.

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 was implemented from April 2020, 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.

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- 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.

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 for 2020/21 only (“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

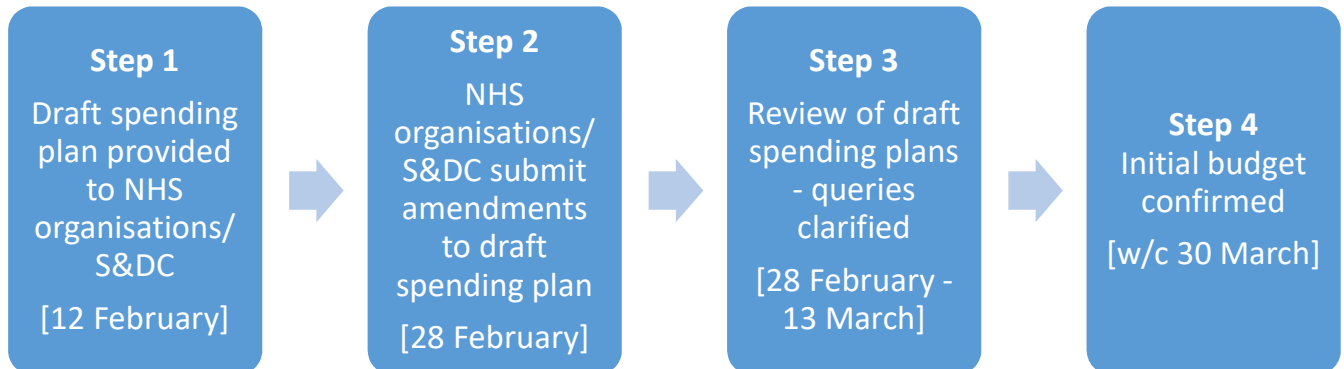
4. Implementation of a new approach to Support & Delivery Funding in 2020/21

- 4.1. 2020/21 was 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 was 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. The impact of the pandemic on income generation will also be factored into this decision making.

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5. Phase one - Initial Spending Plan/ budget setting for 2020/21

- 5.1. NHS organisations and the Support & Delivery Centre were initially reserved a budget for 2020/21 that matches their ongoing committed expenditure. The initial budget setting process is described in Appendix 2 – in summary this involved:



- 5.2. For 2020/21, organisations were 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. Expenditure is being monitored and reviewed on behalf of Welsh Government (see Section 12).

6. Phase two - Review of actual ongoing needs versus committed spend

- 6.1. The second phase of implementation of the All Wales Research Delivery Funding Model is to determine if the spend/posts that are currently committed locally meets the actual resource needed to deliver the studies active during the forthcoming year.
- 6.2. The intention had been to progress this stage of implementation immediately after spending plans had been agreed, however due to the COVID19 pandemic creating significant and sustained disruption to active studies, it had not been possible. The restart of research that had been paused to recruitment due to COVID19 (prioritised in accordance to the NIHR Restart Framework) enables this stage of implementation to proceed. The ongoing uncertainty in restarting research and any subsequent re-pausing of recruitment will be taken into account in assessing prospective need for resources.
- 6.3. Towards the end of 2020/21 financial year 21, work will be undertaken to understand:
- if there are gaps in the actual resources that are needed to deliver the active research portfolio through 2021/22 compared to the Local Support & Delivery funding provided
 - if any over commitments have been made that are now not justified – either currently (in which case may indicate capacity to support other NHS organisations) or anticipate in the future once the pre-COVID19 local portfolio is fully re-established. If there are any NHS organisations where ongoing commitments are significantly higher than

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future research delivery need then, as per the original implementation guidance, a plan will be required to reduce spend or increase activity in 2021/22.

- 6.4. This step will focus initially on delivery staff and study-specific costs. Other recommendations will be covered in subsequent updates to this guidance once decisions have been made on implementation e.g. costs/process for NHS study set-up and oversight, funding for R&D Directors etc. This will continue to inform how Local Support & Delivery funding will be allocated across Wales in 2021/22.
- 6.5. To support evaluation of future 'in-year' need, additional information on the specialties that delivery staff are currently working in was included from month 4 financial reporting.
- 6.6. Information from the financial returns, along with data from LPMS on level of restart priority will provide insight about the portfolio demands and capacity needs in each organisation for the remainder of 2020/21 and beyond.
- 6.7. Collated data from LPMS and the monthly financial status reports will be discussed with each NHS organisation to enable an agreed evaluation of actual in-year needs based on forecasted activity.
- 6.8. The Research Delivery Operational Group (RDOG) will play a key role in supporting discussions and informing how and where that funding can be used for greatest impact from an all Wales perspective.
- 6.9. Where there is a significant gap between what funding is committed (via the agreed spending plan process) and the funding required (either way) discussion will include identification of a plan to rebalance resources against future needs. Uncertainty relating to COVID19 and future portfolio restart and new studies will be taken into account, in addition to the normal fluctuations in activity. Final assessment of in-year need 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.

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

- 7.1. Funding of support costs incurred on a study by study basis for primary care locations (general practices, community optometry, community pharmacy and general dental practices) has been undertaken through direct reimbursement since 2015/16. As this is already in line with the principles of the new funding model, this arrangement will continue. The reimbursement costs will continue to be agreed during study set up and trigger automatic payments. Where appointed directly 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.
- 7.2. As described in Section 6, provision of funding for any posts (including to support, coordinate or oversee primary care research delivery) within the Health Board or Support & Delivery Centre was initially based on Q2 2019/20 committed expenditure, and was

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adjusted based on in-year known research study delivery needs and the model of research delivery within the health board. This aligns with the overarching principle of taking a research study needs-based approach.

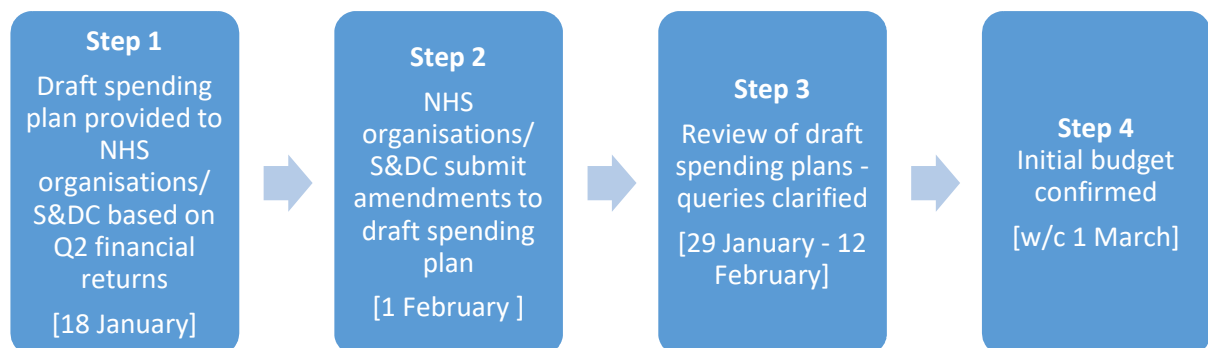
7.3. Non-study Specific Activity:

Funding will be provided for non-study specific research activity to research active practices to cover:

- Expressions of Interest (Eoi) review (see below) and responses to the Support and Delivery Centre
- Monthly LPMS data proforma completion (see below) and return to the Support and Delivery Centre
- Backfill time for GCP/ research training attendance
- Attendance at Support and Delivery primary care engagement events
- Any other reasonable non-study specific costs related to research involvement in line with national funding guidance (E.g. undertaking work to develop searches to identify eligible patients on behalf of multiple GP practices)

8. Initial Budget Setting for 2021/22

- 8.1. Draft spending plans for 2021/22 will be prepared by the Research Funding Team as per the process undertaken in 2020/21 (see appendix one) - i.e. based on known committed expenditure (staff in post) at the end of March 2021. Budget setting will be undertaken through the following process and timescales:



- 8.2. Prioritisation of Urgent Public Health (UPH) studies on an all-Wales basis continues (referenced in the NHS Planning Framework 2021/22). This means resources (staff or funding) may be redirected across NHS organisations to support the priority studies.

9. Decisions regarding changes to agreed spending plans

- 9.1. 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 12).
- 9.2. 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

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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.

- 9.3. 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.
- 9.4. Once work to understand whether committed resource matches required resource based on study delivery needs in year, it is expected that NHS organisations will agree a plan for in year increases/decreases expenditure, increasing local autonomy to make decisions aligned to that plan.
- 9.5. 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.

10. Managing a reduction in commercial trial income

- 10.1. Most NHS organisations have a spending plan for 2020/21 that relies on cost recovery from commercial trial income and, to a lesser degree, income from other sources. For some NHS organisations, commercial trial income covers a significant amount of the committed spend. During COVID19 up to 55% of commercial studies were paused to recruitment which will result in a loss of commercial income for some NHS organisations. The Support and Delivery Centre have been working with local R&D teams to identify this risk for 2020/21 through the monthly financial returns process. This was becoming clearer as Restart plans for individual studies were being made, although the second wave may disrupt that again.
- 10.2. All loss of commercial income will need to be reflected in wider NHS organisation financial plans - Local Support & Delivery Funding will not be increased or used to cover this loss of income and so any gap in funding for specific posts will need to show as 'funded from another source'. Slippage from Local Support & Delivery funded expenditure cannot be repurposed locally to cover any element of lost commercial income. However, recognising 2020/21 has been an unusual year, an exception will be

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made and NHS organisations will not be asked to cover the full loss of commercial income in 2020/21 only if commercial capacity building income has had to be used to offset the in-year loss.

- 10.3. From 2021/22, any reduction or loss of commercial income against the original spending plan agreed must be met by the NHS organisation unless there is evidence of a national decision to allow the repurposing of Local Support and Delivery funding for a specific reason.

11. Pump-priming capacity to deliver research

- 11.1. The priority for Support & Delivery Funding will be to ensure research studies already set-up in Wales can successfully deliver. During the pandemic, UK wide guidance on the prioritisation of studies will be followed. 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.
- 11.2. 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.
- 11.3. 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.
- 11.4. 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.
- 11.5. 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.

12. Monitoring use of Support & Delivery Funding

- 12.1. 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.
- 12.2. 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

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- 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

12.3. The Support & Delivery Funding financial status reports 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.

12.4. 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
- Highlight changes to the full year forecast each month, particularly in the context of the pandemic where e.g. cost recovery amounts have fallen compared to initial forecasts
- Provide a summary of the level of staffing resource allocated across specialty areas and Covid activity (including research, clinical and vaccine trial delivery)

12.5. 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.

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.

13. Monitoring and review of this guidance

13.1. This guidance is being evaluated in use and as processes are further defined, this guidance will be expanded/updated as required.

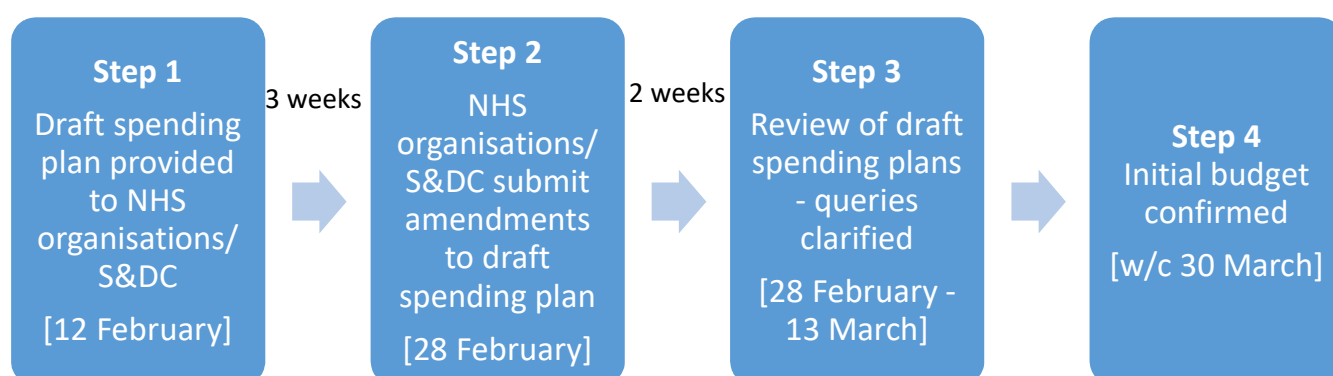
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Appendix One: Summary of changes/amendments

Version	Summary of changes/ amendments	Issue date
1.1	<ul style="list-style-type: none"> Release of the first technical guidance 	February 2020
1.2	<ul style="list-style-type: none"> Clarification that Principle Investigator sessions will not be funded Impact of COVID19 on reporting 	May 2020
1.3	<ul style="list-style-type: none"> Summary of impact on COVID19 on research income Addition of non-study specific costs for primary care studies Updated plan for the implementation of phase two of the all Wales support and delivery funding model (as agreed at the S&D collaboration meeting in October 2020) Clarification on how the loss of commercial income will be met Clarification on the role of the Research Delivery Operational Group (RDOG) (as agreed at the S&D collaboration group in October 2020) Addition of version control summary 	November 2020
1.4	<ul style="list-style-type: none"> Changed the order of section to allow the guidance to become an evolving, live document Timelines for developing and agreeing 2021/22 spending plans Adding information regarding local autonomy once the need for resource is understood 	January 2021

Appendix Two: Phase one - Initial Spending Plan/ budget setting for 2020/21 detailed process

NHS organisations and the Support & Delivery Centre were initially reserved a budget for 2020/21 that matches their ongoing committed expenditure.



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

- 13.2. A draft 2020/21 spending plan was created by the Research Funding Team for each NHS organisation and for the Support & Delivery Centre. This was based on the actual expenditure detailed within the 2019/20 Quarter 2 financial returns, which were reviewed and agreed by Welsh Government. Inclusion of posts/expenditure in the draft plan in Step 1 did not necessarily indicate a commitment by Welsh Government to maintain funding at this level, but was intended to create a building block for the NHS organisation to adjust from.
- 13.3. The draft 2020/21 NHS organisation spending plan included:
- R&D Office staff costs (R&D Director/R&D Lead posts were 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
 - 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 was included but did not have a budget completed in Step 1.
 - Research development staff costs i.e. grant development support posts
- 13.4. The draft 2020/21 Support & Delivery Centre spending plan included:
- Support & Delivery Centre staff and non-pay costs associated with functions that support the set-up and delivery of research.
- 13.5. Posts that were included initially are only those with permanent contracts and fixed-term contracts that extend beyond 1 April 2020. Fixed-term posts that were planned to end before 1 April 2020 were highlighted for reference in Step 2, were not included within the draft spending plan initially.
- 13.6. The draft 2020/21 spending plan contained 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.
- 13.7. If a major organisational change has taken place since Q2 2019/20, the organisation were able to request Q3 financial information and use this to create the initial spending plan. This was an exception.

Step 2: Amendments submitted (by 28 February)

- 13.8. On receipt of the draft 2020/21 spending plan, each NHS organisation / Support & Delivery Centre reviewed their individual spending plan and responded with any amendments, which may include, but was not limited to:
- Addition of any new posts already agreed locally that commenced during Q3 and Q4 2019/20. This included staff appointed through interview but who have not yet taken up post. It does not include costs for vacant posts where invitations to interview were made after 31st March 2020.
 - Removal of posts that were vacated and where there was no intention to replace
 - The addition of fixed-term posts stated previously as ending on or before 31st March 2020 but had since been extended i.e. from the list highlighted in Step 1.

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- 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 was provided by the Research Funding team with the draft spending plans.

- 13.9. In addition to identifying commitments already made, NHS organisations and the Support & Delivery Centre were asked to identify risks in the plan – where committed resources were 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).
- 13.10. NHS organisations and the Support & Delivery Centre were also be asked to add in additional costs that could 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).
- 13.11. During Step 2, the Research Funding Team were available to support NHS organisations to answer queries, and also helped NHS organisations to make changes to the draft spending plan when required (either remotely or by a face-to-face meeting).
- 13.12. When adjustments were made, the NHS organisation/Support & Delivery Centre provided a reason against each change made, or as a separate narrative to cover a series of changes. The level of resource required could be defined in a number of ways and it was for the NHS organisation to determine which method was 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)

- 13.13. During the transitional phase, draft spending plans continued 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 were raised with organisations and a spending plan was agreed.
- 13.14. This produced a spending plan which included the level of resource that was required to support the known activities to be undertaken for 2020/21 and beyond, based on the lifetime of the known research studies that was currently in set-up, actively recruiting or in follow-up.
- 13.15. 2020/21 agreed spending plans:
- Support & Delivery staff: Costs for those staff already appointed (delivery and development) was met. This included staff appointed through interview but who had not yet taken up post. No funding was approved for vacant posts where invitations to interview are made after 31st March 2020.
 - Non-pay costs: Costs were met as submitted (or amended following queries). Principal Investigator costs:

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- Principal Investigator sessional time for medical consultants were not funded. Protected time for research should be honored 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 were funded in 20/21, as the contract differs from the medical consultant contract. This position will be reviewed as part of a wider project.
- Principal Investigator costs for nursing, midwifery, allied health professional (NMAHP) consultants e.g. Consultant Nurse, Consultant Psychologist, posts were not 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 were agreed and were included
- Specialty Leads: Funding is routed via Local Support & Delivery Funding. These were included in the relevant host NHS organisation plan including sessional time and non-pay allowance.

13.16. When the spending was agreed, no funding can be repurposed locally for another type of spend during 2020/21 e.g. underspend in bank staff cannot be repurposed for new delivery posts without request.

13.17. When the spending plan was agreed, the spending plans formed the basis for discussions regarding:

- Decisions relating to requests for changes to the agreed initial budgets
- Agreed a plan to narrow the gap between agreed initial budgets and actual needs
- Total Support & Delivery funding required

13.18. During transitional arrangements in 2020/21, NHS organisations/Support & Delivery Centre retained 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 was 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 needed to consider if the post could be covered by capacity from elsewhere in their teams, ensure that the research study delivery needs continued to justify the post being replaced, and be mindful that the gap between actual resource justified and resource committed needed to be closed as transitional arrangements end. Any local decisions made for appointments that go beyond 31st March 2021 were made at the risk by the NHS organisation.

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

13.19. Budgets for 2020/21 were confirmed and this became the "live budget/spending plan". Expenditure is being monitored and reviewed on behalf of Welsh Government during 2020/21 (see Section 9).