Delivery Framework for the performance management of NHS R&D 2016/17

1. PURPOSE

This Delivery Framework sets out how the Welsh Government will performance manage the NHS organisations in Wales in relation to R&D, through the provision of the R&D funding allocations provided to each NHS organisation¹.

The Welsh Government will specifically performance manage the NHS organisations’ performance against the national NHS R&D objectives, key indicators and targets. The allocations will be performance managed at an individual NHS organisational level.

Welsh Government’s Strategic vision for research within the NHS

Welsh Government’s strategic vision is for Wales to be internationally recognised for its excellent health and social care research that has a positive impact on the health, wellbeing and prosperity of the people in Wales.

Welsh Government’s ambition is that Wales is a place where research prospers as a vehicle for health and social care wellbeing. To achieve this ambition the Welsh Government is committed to funding a research

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¹ NHS organisation for the purposes of this paper is defined as a Health Board or a NHS Trust. Currently there are 7 Health Boards and 3 NHS Trusts in Wales
infrastructure and capacity that will facilitate improvements to the health, wealth and well-being of the people of Wales.

Since 1 April 2015 an integrated and coordinated research Support and Delivery Service was established to achieve maximum efficiency, effectiveness and international competitiveness of the research environment in Wales. The functions of the service are delivered through the ten NHS organisation’s R&D Offices (including the Health and Care Research Wales Workforce) and Health and Care Research Wales Support Centre.

This development is expected to contribute towards achieving better outcomes for patients and the public by increasing the opportunities to participate in high quality research. Welsh Government expects the Support and Delivery Service to work within the principles of prudent healthcare.

Funding is provided to each of the 10 NHS organisations to facilitate their contribution to this ambition. The funding is specifically intended to help NHS organisations to meet the national NHS R&D objectives, key indicators and targets as set out in this Delivery Framework.

2. NHS R&D FUNDING STREAMS

In order to assist NHS organisations in delivering against the national NHS R&D objectives, Welsh Government provides NHS R&D funding to Health Boards and Trusts. Funding is provided through three funding streams to each NHS organisation.\(^2\) This funding is termed the NHS R&D allocations.

The NHS R&D allocations are based on a Strategic Investment Model. The funding follows activity based on three year rolling averages, which is used as an estimate for the amount of funding the NHS organisation may need in the

\(^2\) Except for the Welsh Ambulance Services Trust who’s funding is provided outside of the funding formula.
forthcoming financial year. NHS organisations are expected to make strategic decisions to maximise the use of the funding and create a research environment which promotes and encourages high quality Welsh led research within NHS Wales.

The three R&D funding streams are:

i) **NHS Research Support and Governance (RS&G):** core funding is provided to ensure that a stable function for research support, governance and management is in place in each NHS organisation. This is in the form of the NHS R&D office, which is a key service for researchers in Wales. RS&G funding covers activities including advice and support for researchers, from costing to governance and regulatory applications, processing studies in order to give NHS permission, as well as overall support for the NHS organisation to meet their sponsor responsibilities as appropriate.

ii) **NHS Support Costs (NHS SC):** NHS SC are provided for Clinical Research Portfolio\(^3\) research studies (non-commercial) to be able to access the resources required to facilitate delivery of these studies at a local level. The NHS Support Cost element within the allocation covers relevant activities taking place in secondary care. For Primary Care, the centralised NHS Support Cost budget is available to support activity at practice level. This may be in the form of payment for specific procedures, as well as time for clinical staff supporting activities involved in actively supporting recruitment to portfolio research studies. Due to the focus on high quality studies, the first call on funding should be to NHS SC for clinical research portfolio studies. As such, funding can be vired between the NHS SC and the other elements of the allocation to manage this within the NHS organisation.

iii) **NHS Researcher Support and Portfolio Development (RS&PD):**

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\(^3\) The Health and Care Research Wales Clinical Research Portfolio is a register of high quality health and social care research studies active in Wales that meet specific eligibility criteria.
RS&PD funding is provided to NHS organisations to invest in health care staff who are committed to developing and undertaking high quality research studies. “Pathway to portfolio activities”\(^4\) are intended to be supported in this way and can include Chief Investigator time and/or costs involved with setting up and delivering early activities associated with a study’s pathway to portfolio (e.g. feasibility studies providing data to support a grant application to funders that meet the eligibility criteria for adoption onto the Clinical Research portfolio). In addition, Part B Research Cost activities in Health Boards (primary and secondary care) and other NHS organisations for eligible non commercial funders can also be covered through RS&PD.

For more detail on the purpose and use of RS&G, NHS SCs and RS&PD, please see the guidance on *The Appropriate Use of NHS R&D Allocations*\(^5\).

In addition, the Research Delivery Workforce will provide study delivery support to researchers, to enable research to be undertaken across NHS and social care settings for patient and public benefit. The Research Delivery Workforce Operational Strategy details that the “delivery funding streams will be simplified with the previous national *Health and Care Research Wales* workforce budget and NHS R&D budget being combined and distributed directly to NHS organisations. This will enable NHS R&D Directors to be fully accountable for research delivery activity, reporting expenditure and meeting delivery performance indicators. Oversight will empower NHS R&D Directors to make decisions from a fully informed perspective of the resources to hand within their organisation to maximise their use.” Work will be undertaken with respect to this during 2016/17 as part of a review of the Activity Based Funding formula.

\(^4\) These involve activities that are undertaken to inform the development of a portfolio study or a grant application for a portfolio study. This can include feasibility and pilot activity along with work to develop a platform for future portfolio studies.

\(^5\) The Appropriate Use of NHS R&D Allocations guidance can be found at: http://www.healthandcareresearch.gov.wales/nhs-randd-funding-policy/
In addition, NHS organisations are eligible to apply for Centralised NHS Support Costs, Excess Treatment Costs and to utilise the Health and Care Research Wales Workforce.

**Centralised NHS Support Costs**

In 2009/10, the Welsh Government established a central application scheme for NHS Support Costs in primary care. This was expanded in 2011/12 to include emergency Care NHS support costs (via the Welsh Ambulance Service NHS Trust) and service support costs accrued by Public Health Wales NHS Trust research. From 1 April 2016 this centralised service will be provided by the Health and Care Research Wales Support Centre. More information on this can be found at: http://www.healthandcareresearch.gov.wales/nhs-rannd-funding-policy/

**Excess Treatment Costs**

From 1 April 2016 the Health and Care Research Wales Support Centre will take over responsibility from the Welsh Government in administering a central application scheme for Excess Treatment Costs (ETCs) for externally funded non-commercial R&D in NHS Wales. The budget meets the *difference in costs between the standard treatment and the additional treatment costs resulting from R&D activity*. The centralised process enables a streamlined approach to be taken with regards to ETC decision-making and monitoring.

Further information: *Attributing the costs of health and social care Research & Development guidance (AcoRD)* sets out what is a research cost, NHS support cost, treatment cost and excess treatment cost.

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6 The AcoRD guidance can be found at: http://www.wales.nhs.uk/sites3/page.cfm?orgid=952&pid=62653
Other funding sources

Welsh Government’s funding is a fixed amount allocated annually. However, NHS organisations also have the ability to draw on other sources of funding to invest in the growth of capacity and capability for NHS research within their organisation. This could include, for example, commercial R&D 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.

3. NATIONAL R&D OBJECTIVES, KEY INDICATORS AND TARGETS

Context

Integrated Medium Term Plans

The NHS Wales Planning Framework 2016/17 sets out that each NHS organisation is expected to produce an Integrated Medium Term Plan to cover the period 2016/17 – 2018/19.

There is a clear intention and expectation that the Integrated Medium Term Plan is the key overarching organisational document for each NHS organisation. Welsh Government expects each NHS organisation to set out their organisation’s plan for research and development in their Integrated Medium Term Plan. Research and Development is specifically identified as one of the ‘enablers’ which will provide a key resource to enable the organisation’s Integrated Medium Term Plan to be delivered.8

The NHS Wales Planning Framework 2016/17 sets out what the IMTP must deliver to be successful. The research-related criteria are to:

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7 http://gov.wales/topics/health/nhswales/circulars/subjectname13/?lang=en

8 “It is expected the Integrated Medium Term Plans will demonstrate the importance of research within the NHS organisation and set out a structured approach to research, teaching and innovation”
• demonstrate how the NHS organisation will improve patient outcomes through participation in research and maximising impact from research results;

• demonstrate the active promotion of the value of research through clear communication strategies with a range of audiences, i.e. patients, clinicians etc.;

• describe the arrangements in place to ensure research feeds into an organisation’s mechanisms for uptake of best practice, innovation and service change;

• demonstrate how the organisation will meet the key indicators and targets set out in this Delivery Framework

• demonstrate how the organisation will set expectations for appropriate inclusion of children and young people into research programmes and proposals.

In relation to the third bullet point the Welsh Government is particularly looking at how NHS R&D Directors have aligned themselves and their R&D departments to other parts of the NHS to promote R&D and maximise the potential for the uptake of findings across their organisations, including, as appropriate, primary care.

**NHS Outcomes Framework (Public facing document) and NHS Delivery Framework (NHS facing document) - (Overarching outcome measures)**

*The NHS Outcomes Framework*, and *NHS Delivery Framework* published on 29 March 2016 in the Effective Care domain states – “People in Wales receive the right care and support as locally as possible and are enabled to contribute to making that care successful”. The relevant performance outcome measures for this domain relating to R&D are:

• Increase in research activity for people of all ages
  • Number of Health and Care Research Wales Clinical Research Portfolio studies and commercially sponsored studies
- Number of participants recruited into Health and Care Research Wales Clinical Research Portfolio studies and commercially sponsored studies

Welsh Government will report on these outcome measures on a quarterly basis. The performance reports produced by the Health and Care Research Wales Support Centre for performance monitoring will be used to meet this reporting requirement. Note that for Health Boards, ‘research activity’ referred to in the key indicators includes activity across both primary and secondary care, covering all services within the Health Board’s remit.

**National Objectives, Key Indicators and Targets**

Welsh Government has set national objectives for NHS organisations to guide the effective use of R&D allocations and to help inform the development of local R&D strategies. Welsh Government has also set key indicators to enable measurement of NHS organisations’ performance against the national objectives, as well as provided targets that these NHS organisations should aim to achieve.

The national NHS R&D objectives are set out below:

a) To increase the profile of research and development within NHS Wales
b) To ensure the effective provision of a NHS research infrastructure to develop research capacity and capability through the appropriate use of NHS R&D allocations
c) To increase the quantity of high quality research being undertaken in NHS Wales
d) To increase the opportunity for NHS patients to participate in, and benefit from, clinical trials and other well designed studies
e) To improve the efficiency of processes for research permissions, study set-up and delivery of research in NHS Wales
f) To create a research environment which promotes and encourages commercially funded research activity within the NHS

The key indicators and targets set by Welsh Government to measure NHS organisations’ progress against the national objectives are set out in Table 1. Please note that following feedback from the NHS organisations some of the key indicators have now been grouped together to improve monitoring and managing reporting requirements. The numbering of the key indicators has however, remained the same as in previous financial years to enable a year-on-year comparison of performance to be undertaken.
Table 1: Welsh Government NHS R&D Objectives, Key Indicators (KIs) and Targets for R&D in NHS Wales

<table>
<thead>
<tr>
<th>Objective</th>
<th>Key Indicators (KIs)</th>
<th>Target/ Measurement</th>
<th>Implementation Date</th>
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<tbody>
<tr>
<td>A. To increase the profile of research and development within NHS Wales</td>
<td><strong>A1.</strong> NHS research data tabled at the NHS organisation’s Board meeting</td>
<td>Minimum of twice a year. Confirmation of data being tabled</td>
<td>2013/14</td>
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<td></td>
<td><strong>A2.</strong> R&amp;D representation at the NHS organisation’s Board meeting</td>
<td>Confirmation of Board member representing R&amp;D</td>
<td>2012/13</td>
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<td></td>
<td><strong>A3.</strong> Up-to-date R&amp;D strategy for NHS organisation</td>
<td>Confirmation that the R&amp;D strategy is up-to-date. Copy of current R&amp;D strategy provided, signed off by the organisation</td>
<td>2012/13</td>
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<tr>
<td></td>
<td><strong>F1.</strong> A Commercial Research Strategy/ Policy in place</td>
<td>Confirmation of current up-to-date commercial research strategy or policy in place, signed off by the organisation (this could be stand alone or part of the R&amp;D strategy, see A3)</td>
<td>2014/15</td>
</tr>
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<td></td>
<td><strong>A4.</strong> Inclusion of research in the NHS organisation’s annual report</td>
<td>Confirmation that R&amp;D is included. Copy of annual</td>
<td>2012/13</td>
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<tr>
<td>A5. Up-to-date Research Capability Statement for the NHS organisation</td>
<td>report provided, showing inclusion of research</td>
<td>2016/17</td>
<td></td>
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<td></td>
<td>Updated annually. Copy of current Research Capability Statement provided</td>
<td>To note - A paper will be developed with NHS R&amp;D in terms of how the individual capability statements will feed into an all Wales Capability Statement</td>
<td></td>
</tr>
<tr>
<td>A6. Appropriate inclusion of plans for research included within NHS organisation's Integrated Medium Term Plan</td>
<td>Confirmation of R&amp;D included. Copy of section of Integrated Medium Term Plan provided, showing inclusion of plans for research</td>
<td>2015/16</td>
<td></td>
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<tr>
<td>B. To ensure the effective provision of a NHS research infrastructure to develop research capacity and capability through the appropriate use of NHS R&amp;D allocations as well as investment of other R&amp;D income that the organisation generates (DSCHR will only performance manage against the allocation it provides)</td>
<td></td>
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<tr>
<td>B1. Documented up-to-date R&amp;D finance procedure or policy for the NHS organisation</td>
<td>Confirmation of current, up-to-date policy. Copy of current finance policy provided, signed off by the organisation (this could be stand alone or part of other R&amp;D related policies e.g. the R&amp;D strategy, see A3)</td>
<td>2014/15</td>
<td></td>
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<tr>
<td>B5. Cost recovery model in place for commercial and non-commercial research</td>
<td>Confirmation of current agreed model in place for</td>
<td>2014/15</td>
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<tr>
<td><strong>B6.</strong> Income distribution model in place for commercial and non-commercial research</td>
<td>cost recovery, signed off by the organisation (this could be stand alone or part of other R&amp;D related policies, e.g. the documented R&amp;D finance policy, see B1)</td>
<td>2014/15</td>
<td></td>
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<tr>
<td><strong>B7.</strong> Use of costing templates for commercial and non-commercial research (where applicable)</td>
<td>Confirmation of current agreed income distribution model in place, signed off by the organisation (this could be stand alone or part of other R&amp;D related policies, e.g. the documented R&amp;D finance policy, see B1)</td>
<td>2014/15</td>
<td></td>
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<td><strong>B2.</strong> Appropriate use of NHS R&amp;D allocations in accordance with the DSCHR, Welsh Government guidance</td>
<td>All expenditure reported in annual returns are aligned to the guidance</td>
<td>2012/13</td>
<td></td>
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<tr>
<td><strong>B4.</strong> Implementation of AcoRD</td>
<td>All expenditure reported in annual returns demonstrate accurate</td>
<td>2012/13</td>
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<tr>
<td><strong>B3.</strong> Timely and accurate reporting in accordance with the financial monitoring cycle for NHS R&amp;D allocations</td>
<td>Attribution, in line with AcoRD</td>
<td>Submission of all annual returns, mid year financial returns and spending plans by deadline provided</td>
<td>2012/13</td>
</tr>
<tr>
<td><strong>C.</strong> To increase the quantity of high quality research being undertaken in NHS Wales</td>
<td><strong>C1.</strong> Number of Health and Care Research Wales Clinical Research Portfolio (CRP) studies</td>
<td>Increase of 10% per annum</td>
<td>2012/13</td>
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<tr>
<td></td>
<td><strong>C2.</strong> Number of commercially sponsored studies(^9)</td>
<td>Increase of 5% per annum</td>
<td>2012/13</td>
</tr>
<tr>
<td><strong>D.</strong> To increase the opportunity for NHS patients to participate in, and benefit from, clinical trials and other well designed studies</td>
<td><strong>D1.</strong> Number of patients recruited into Health and Care Research Wales Clinical Research Portfolio (CRP) studies</td>
<td>Increase of 10% per annum</td>
<td>2012/13</td>
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<tr>
<td></td>
<td><strong>D2.</strong> Number of patients recruited into commercially sponsored studies</td>
<td>Increase of 5% per annum</td>
<td>2013/14</td>
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<tr>
<td><strong>E.</strong> To improve the efficiency of processes for research permissions, study set-up and delivery of research in NHS Wales</td>
<td><strong>E1.</strong> Percentage of Health and Care Research Wales Clinical Research Portfolio (CRP) studies receiving NHS research permission within 40 calendar days</td>
<td>80% of studies</td>
<td>2013/14</td>
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</tbody>
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\(^9\) *Commercially Sponsored Studies are those studies that are industry funded and industry sponsored*
<table>
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<tr>
<th></th>
<th>Percentage of commercially sponsored studies receiving NHS research permission within 40 calendar days</th>
<th>80% of studies</th>
<th>2013/14</th>
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</thead>
<tbody>
<tr>
<td><strong>E2.</strong></td>
<td>Percentage of commercially sponsored studies recruiting the first patient within 30 calendar days of approval/site initiation</td>
<td>80% of studies</td>
<td>2014/15</td>
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<tr>
<td><strong>E3.</strong></td>
<td>Percentage of Health and Care Research Wales Clinical Research Portfolio (CRP) studies recruiting the first patient within 30 calendar days of approval/site initiation</td>
<td>80% of studies</td>
<td>2014/15</td>
</tr>
<tr>
<td><strong>E4.</strong></td>
<td>Percentage of commercially sponsored studies recruiting to time and target</td>
<td>80% of studies recruiting 100% of target</td>
<td>2015/16</td>
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<tr>
<td><strong>E5.</strong></td>
<td>Percentage of Health and Care Research Wales Clinical Research Portfolio (CRP) studies recruiting to time and target</td>
<td>80% of studies recruiting 100% of target</td>
<td>2015/16</td>
</tr>
<tr>
<td><strong>E6.</strong></td>
<td>Percentage of non-recruiting Health and Care Research Wales Clinical Research Portfolio (CRP) studies within NHS organisations</td>
<td>No more than 10%</td>
<td>2015/16</td>
</tr>
<tr>
<td><strong>E7.</strong></td>
<td>Percentage of non-recruiting commercially sponsored studies within NHS organisations</td>
<td>No more than 10%</td>
<td>2015/16</td>
</tr>
</tbody>
</table>
5. ROLES AND RESPONSIBILITIES

R&D Directors within NHS organisations are accountable for the NHS R&D funding within their NHS organisation. Welsh Government expects all NHS R&D Directors to decide strategically how to meet the national NHS R&D objectives and how to subsequently spend their NHS R&D allocation within their NHS organisation.

R&D Directors are responsible for ensuring that their NHS organisation makes progress against the national NHS R&D objectives, key indicators and targets. They are also responsible for ensuring that their R&D allocations are utilised in line with Welsh Government’s guidance (please see The Appropriate Use of NHS R&D Allocations for more information), as well as demonstrating that their NHS organisations attribute costs correctly in line with AcoRD for Wales, (including recovery of costs as appropriate, e.g. research costs from a University or full recovery of costs for commercial trials, the first call on which is to pay for the full costs incurred in running commercial trials).

Welsh Government will performance manage R&D within NHS organisations in Wales against national NHS R&D objectives, key indicators and targets; and administer and manage the NHS R&D allocations as part of the overall NHS R&D funding programme. Welsh Government performance manages all NHS R&D Funding in Wales.

Viring funding

As detailed above there are three NHS R&D funding streams (RS&G, NHS SC and RS&PD); although funding is allocated to each of these three strands, it is for each R&D Director to maximise the use of the allocations alongside other funding streams such as charitable and commercial funding in order to support high quality research and meet the set targets. Welsh Government permits funding provided through the NHS R&D allocations to be vired between the three funding streams to meet local needs and delivery.
Expenditure, however, will be performance monitored and performance managed against the three funding streams.

Under the direction of Welsh Government, Health and Care Research Wales Support Centre will:

- monitor NHS organisations’ progress against the national objectives, key indicators and targets by monitoring R&D activity;
- review whether NHS organisations are spending their R&D allocations (for RS&G, NHS SCs and RS&PD) in line with Welsh Government’s guidance, by monitoring R&D expenditure;
- review whether NHS organisations are demonstrating accurate cost attribution in line with AcoRD for Wales.
- manage the Health and Care Research Wales Clinical Research Portfolio (CRP) and provide research activity data in support of performance monitoring.

6. PERFORMANCE MANAGEMENT ARRANGEMENTS

Welsh Government will performance manage progress against national NHS R&D objectives and the use of R&D allocations, on an on-going basis, through the following process:

i) Commission the Health and Care Research Wales Support Centre to monitor progress against national NHS R&D objectives and the use of NHS R&D allocations (for RS&G, NHS SCs and RS&PD) by monitoring R&D expenditure and activity. The performance monitoring arrangements for R&D expenditure are outlined in the guidance on Monitoring the Use of NHS R&D Allocations and the arrangements for monitoring progress against national NHS R&D objectives is outlined in the guidance on Monitoring NHS R&D Activity. The data provided by the Health and Care Research Wales Support Centre will be used to performance manage the NHS R&D allocations.
ii) Welsh Government will assess progress against national NHS R&D objectives, key indicators and targets on a quarterly basis, particularly on the number of studies and number of participants recruited to studies on the Health and Care Research Wales CRP and commercial studies (to meet the reporting requirements for the *NHS Outcomes Framework and NHS Delivery Framework*).

iii) Welsh Government will formally meet with each NHS organisation on an annual basis to undertake a performance management meeting. Welsh Government will compare year on year how each NHS organisation is meeting the key indicators and targets. Red-Amber-Green (RAG) reports will be prepared for each NHS organisation to be used by Welsh Government as part of the annual performance management meetings.

iv) Welsh Government and the Health and Care Research Wales Support Centre will meet formally three times a year following the submission by NHS Organisations of their Spending Plan, Mid Year financial Return and Annual Return to review these returns and discuss any issues arising.

7. OPERATIONAL GUIDANCE

A suite of operational guidance has been developed by the Health and Care Research Wales Support Centre to explain to NHS organisations how the performance monitoring will be undertaken. These guidance documents are titled:

1.1 Activity Based Funding
1.2 The Appropriate Use of NHS R&D Allocations
1.3 Monitoring the Use of NHS R&D Allocations
1.4 Detail on National NHS R&D Objectives, Key Indicators and Targets
1.5 Monitoring NHS R&D Activity
All of these operational guidance documents are available on the Health and Social Care Wales website. (http://www.healthandcareresearch.gov.wales/nhs-rannd-funding-policy/)