Appendix C – Basis for the Revision to the Commercial Income Distribution, and Worked Example

C.1 Revised Model Structure

With the restructuring of research accounts, alongside new guidance from Welsh Government, a revision has been required to ensure compliance with financial rules and regulations, government guidance, and the internal operational demands of the health board.

As such, the revised model closely follows the construction of costs as per the iCT to ensure that the funds are distributed as closely as practically possible to contracted performance obligations. From the NCVR we have that the income elements should be treated as follows:

- Direct: The funds are the directly attributable staff time for the R&D activity. These are set by the iCT and form the basis of the other income elements.

- Capacity Building: The funds that are to be designated for system optimisation to deliver research as part of care provision. This may include building sustainable research infrastructure, building capacity to innovate, retaining skills, and strengthening organisational capacity and eligibility for projects. This is currently set at 20% of the direct costs.

- Indirect costs: The portion of the income that represents the real cost of carrying out a research activity, outside of the direct costs. These indirect costs include traditional overheads, such as human resources and management oversight, but also general study oversight and administration. The indirect cost element is only applied to procedural costs as per the iCT. The distribution of the indirect cost is to cover both NHS organisational overheads as well as the support that is provided through the investigator specialty accounts. The combination of all indirect costs is set at 70% of the direct costs. With this policy the indirect cost element is split evenly between an overhead account for the health board, and the investigator specialty accounts.

- Market Forces Factor: The MFF is a multiplier designed to accommodate the unavoidable cost differences of providing healthcare across the country. It is applied to the aggregate of the direct, capacity building, and indirect elements. The all-Wales MFF is 20%, however historically has been lower, with the previous MFF being 9.43%. The MFF was drastically increased with the mandating of NCVR to act as a buffer to cover any costs that may be higher than an individual itemised cost within the iCT. As such, when arriving at the income distribution, the MFF element of the income has been further disaggregated into a 10% factor to be applied to each of the other income elements, and the residual 10% of the MFF to supplement the R&D capacity building element in order to support the any such itemised costs that are misaligned

This additional contribution to the capacity building element is to be used to cover any shortfall in the contract value.

C.2 Application of Procedural Costs and Comparison to the Old Policy

When producing the overall billable amount for procedural costs, the initial activity pricing is grossed up by 90% (being 20% for capacity building and 70% for indirect costs, comprising of both the overhead and investigator specialty amount), and subsequently this total is grossed up by an additional 20%, giving an overall cost of 228% of the initial activity cost as per the iCT.

Then, when internally distributing this income, we split each element into its base cost, multiply each of these by 10%, representing the disaggregated MFF portion, and then add the residual MFF portion into the R&D capacity building account, as seen in the table below:

	Base Amount	Adding Split MFF Element (10%)	Adding Residual MFF Element (10%)
Direct (Research Activity Account)	100	110	110
Capacity Building Account	20	22	41
Investigator Specialty Account	35	38.5	38.5
Overhead Allocation	35	38.5	38.5

The old policy acted as a rough approximation of this system, and whilst the overall amount that was billed was constructed the same way, due to the requirements of the NCVR, the way it has been distributed within the Health Board is different.

The overall amount billed had the MFF element removed, to be held by the R&D office, and then split the residual amount up according to the following percentages:

Research Team	40%
R&D Office	25%
PI Account	25%
Overhead Allocation	10%

Comparing the two policies results in the following distributions, represented here as the percentage of the overall bill:

	Old Policy	New Policy
Research Team	33.3%	48.2%
R&D Office / Capacity Building Account	37.5%	18.0%
PI Account / Investigator Specialty Account	20.8%	16.9%
Overhead Allocation	8.3%	16.9%

It is worth highlighting that the overhead portion here would only be allocated centrally under the old policy if the research took place outside of one of the dedicated research facilities and be passed on to the dedicated research facility if the research activity occurred there instead. Under the revised policy this would be allocated centrally for all commercial trial activity.

C.3 Application of Investigational and Comparison to the Old Policy

When producing the overall billable amount for investigation costs, the initial activity pricing is grossed up by 20% for capacity building and subsequently both the direct element and capacity building element are grossed up by a further 20% for the MFF. This gives an overall cost of 144% of the initial activity cost as per the iCT.

As with the distribution of the income for procedural costs, the base elements are to be grossed up by 10%, with the residual 10% of the market forces factor being added to the capacity building element, as seen in the table below:

	Base Amount	Adding Split MFF Element (10%)	Adding Residual MFF Element (10%)
Direct (Research Activity Account)	100	110	110
Capacity Building Account	20	22	34

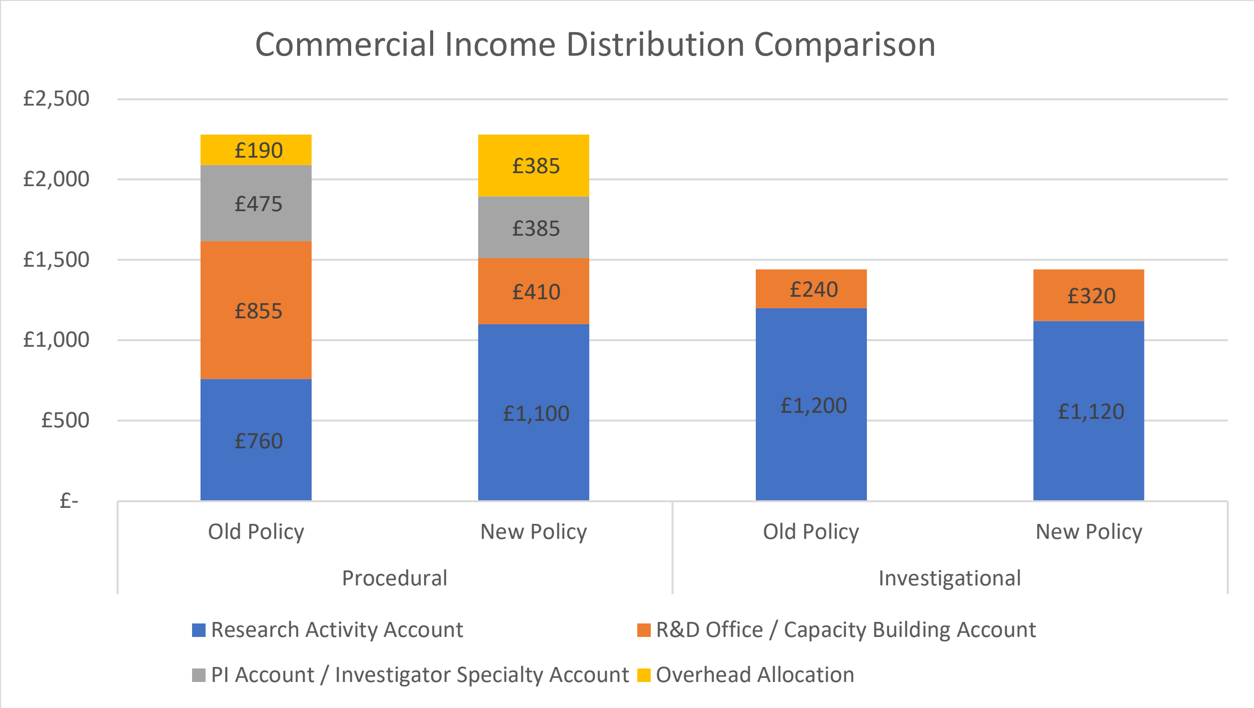
The old policy acted as a simpler version of this system, with the MFF element being allocated to the R&D office, and the remaining amount being allocated to the area where the research activity had taken place.

Comparing the two policies results in the following distributions, represented here as the percentage of the overall bill:

	Old Policy	New Policy
Research Team	83.3%	76.4%
R&D Office / Capacity Building Account	16.7%	23.6%

C.4 Example & Key Points

For a simple example, consider the scenarios where we have an investigation activity and a procedural activity that both have a direct cost of £1,000 in the iCT. Then by following both the old policy and the new proposed methodology, the following amounts would be billed and distributed:



The key movements here focus around two areas:

1) A larger and more consistent contribution to general overheads with both the removal of the different treatment of specific research facilities, and the even split of the indirect cost element being applied between the PI/research specialty account and the overhead contribution.

2) Redistribution between the R&D central allocation and the research activity accounts, with a significantly smaller portion of the income landing in the central R&D fund, and more being placed in the applicable research activity account. This should allow teams to run more independently with less reliance on central support and funding. With the research activity account seeking to be brought centrally, the risks around potential overspend, alongside the benefit of underspend, would land collectively alongside the central R&D costs, allowing for management of the consolidated R&D position and more efficient utilisation of collective R&D funds.

Building this into a more complex scenario, consider a fuller scenario, where the following costs are presented as billable following the NCVR and study activity:

Costing Element	Total Billable Amount
Total Investigation Costs	£25,164
Total Procedural Costs	£602,157
R&D Set-Up & Archiving Fee (Other Costs)	£2,508
Total	£629,829

This would get split up as follows:

	Investigation	Procedural	Other	Total
Research Activity Account (Procedural)	-	£ 290,514	-	£ 290,514
Research Activity Account (Investigation)	£ 19,223	-	-	£ 19,223
R&D Office Cost Account	-	-	£ 2,508	£ 2,508
R&D Capacity Building Account	£ 5,942	£ 108,283	-	£ 114,224
Investigator Specialty Account	-	£ 101,680	-	£ 101,680
R&D Overhead Account	-	£ 101,680	-	£ 101,680
Total	£ 25,164	£ 602,157	£ 2,508	£ 629,829

Meanwhile under the historic convention, it would be split up as follows:

	Investigation	Procedural	Other	Total	Surplus/(Deficit) from New Allocation
Research Activity Account (Procedural)	-	£ 200,719	-	£ 200,719	(£ 89,795)
Research Activity Account (Investigation)	£ 20,970	-	-	£ 20,970	£ 1,748
R&D Office Cost Account	£ 4,194	£ 225,809	£ 2,508	£ 232,511	£ 115,778.76
PI Account	-	£ 125,449	-	£ 125,449	£ 23,769
Corporate Overhead / Research Facility Overhead	-	£ 50,180	-	£ 50,180	(£ 51,500)
Total	£ 25,164	£ 602,157	£ 2,508	£ 629,829	-