Work place instruction for distribution of commercial trial income (HMH June 2016)

This document should be read in conjunction with the costing template and distribution for an example commercial trial CT-060-2014 S:\Commercial Trials\WPI folder

1. General background

Determining the costs of commercial trials

Costs for commercial research studies are calculated using the NIHR costing template. The template generates set-up, per patient and additional costs which are based on the time taken to perform a task using standardised staff hourly rates and recommended price lists for investigations (e.g. lab tests, radiological scans, ECGs, ECHOs. etc). The template applies an 'overhead' cost to direct staff time and a 'capacity building' element is added (to both staff rates and investigations) to create a commercial rate. To account for location cost weighting when using a standardised national rates, the costs are multiplied by the *All Wales Multiplier* (AWM) of 1.0943 to reach the final figure.

The sponsoring commercial company, or their agent, provide an initial populated costing template specific for the trial. This template should then be reviewed and worked on at the Directorate level (as appropriate by the research team who have experience of conducting trials and the timings required for the composite elements) before being forwarded to the R&D Office for approval. It is important to include all costs and to determine the appropriate research staff to cost for each study. The following link provides information on commercial study costing templates: https://www.crn.nihr.ac.uk/can-help/life-sciences-industry/setup-service/

Commercial trial income distribution

Commercial income is distributed within C&V UHB as indicated in the Table 1* below:
**Source- UHB Board Paper February 2012 S:\Board Papers*

Table 1

	Study with UHB PI[1]	Study with CU PI[1]
R&D	Set up fee of £1000 plus 25% of total template UHB staff costs	Set up fee of £1000 plus £500-£2000 continuation service fee if patients are recruited to the study[2]
R&D Research Fund managed by R&D Office	AWM for total study income (~9%)	AWM for total study income (9%)
Directorate of PI	40% of total UHB template staff costs[3]	N/A[3], [4]
UHW Corporate	10% of UHB template staff costs	N/A[4]
Pharmacy/Labs/ Radiology	Full costs less AWM	Full costs less AWM
Principal Investigator UHB Account	25% of total template staff costs[7]	N/A[5, 7]

frequently or occasionally sponsoring companies require monthly invoicing and/or direct debit type payments. The details of the invoicing/payment process will be agreed at trial set-up. Additional invoicing can occur as and when necessary.

Travel and subsistence of trial participants

These expenses are paid by the sponsor of the study via a UHB account that has been set up specifically for travel and subsistence payments for patients involved within commercial clinical trials. Participants should claim expenses from the UHB Cash Office in the usual way and these expenses will be reimbursed to the Cash Office from the UHB central generic commercial trial travel and subsistence account. Details of all travel expenses claimed by participant should be sent by the research team, on a study by study basis, to the Commercial Trials Office, at least quarterly, so that the sponsoring company can be invoiced in a timely manner for all travel and patient related expenses.

2. Worked example of distribution of commercial income (CT-060-2016)

S:\Commercial Trials\WPI folder

In order to distribute commercial income the agreed costing template (between the UHB and Sponsor) and the final SSI form are required.

1. Start a distribution spreadsheet such as the example, and save to the electronic study folder. Include CT ref or R&D ref, PI, Sponsor, full study title, protocol version version and date of agreed costing template and the target number of trial participants as quoted in the costing template and the mCTA (IMP trials) or mCIA (medical device trials). If the costing template and contract differ in the number of target trial participants (sometimes, the sponsor requests that a single participant is used to calculate fees) the contract takes precedent. The version and dates of costing templates and protocols are important and should be included because if there is a subsequent protocol and/or contract amendment that alters the trial cost it is important that the correct costing template/distribution are applied for the trial activities up to the point of notification and a new distribution (if required) for activities after the notification.

2. Determine, using the SSI form, the research staff involved in delivering the trial namely: PI, Co –Investigators, research nurses, administrators etc.

3. Confirm whether they are UHB or CU employed (should state within the SSI if not enquire directly with the individual) and if the latter what UHB directorate(s) they are affiliated with.

4. Determine using the WTE ratios, or other timing information provided in the SSI, the relative contribution each individual will make within their own staff group (clinician, research nurse or equivalent, administrator) to the delivery of the trial. For the purposes of the distribution it is assumed that the ratio stated on the SSI is the contribution throughout the life time of the trial. Also if there are staff for which an UHB salary charge apply. The % contribution the UHB pays is applied to the individual's contribution to the trial and this revenue element is distributed to the UHB.

Cardiff University	Nil	100% of total CU template staff costs[6]

1. When both CU and UHB employees are working on a study, funds will be distributed through a combination of the UHB and CU PI algorithms according to the mix of staff and recharges where applicable.

2. Charged to CU to cover all aspects of trial servicing provided by the R&D Office, primarily the Commercial Trials Office.

3. Income received by directorates will be used to cover commercial research costs to the directorate including the staff costs of all individuals involved and overheads. The 40% would rise to 65% of total UHB non-PI staff costs for CU PI studies.

4. For CU PI studies involving UHB staff, the UHB template staff costs minus 10% that will go to UHW corporate and the AWM that will go to a R&D managed fund, will be paid to the appropriate UHB directorate(s)

5. 25% of the PI's template cost staff time who are 100% recharge to the UHB will be allocated to Cardiff University as an incentivisation payment for the PI.

6. This money is distributed within CU by its Research, Innovation and Enterprise Services and appropriate School.

7. Travel and subsistence expenses for all study will be held in a UHB central generic commercial research travel and subsistence expense account.

The above table and footnotes may be applied to other external staff with honorary contract with C&V UHB.

PI trading accounts

A new PI account is created by the UHB Finance Department when a new commercial study with a UHB PI is approved. The UHB PI trading account is held within the PI's Directorate and can be used for various activities to support research. These along with details of how to apply to use money are detailed in *Spending Surplus Research Income Guidance* S:\Commercial Trials\00 Spending of commercial income rules and forms. The money in the PI trading account is available until 18 months after the date of the official close out of the trial as notified to the R&D Office by the commercial Sponsor. The PI will be notified by the Commercial Trials Office approximately 1-2 months prior to the 18 month date that the account is due to closure. At 18 months post close out, 80 % of any residual PI funds within the trading account are transferred into the appropriate Directorate Research Legacy Fund and 20% transferred to the Central Research Legacy Fund to support Directorate R&D initiatives (overseen by the Directorate R&D Lead) and UHB-wide R&D initiatives (overseen by the Director of R&D), respectively.

Cardiff University employed PIs are not allowed to hold PI trading accounts within the UHB. CU destined income, flows from Commercial Sponsor to UHB to CU on a quarterly basis. The internal distribution of income within Cardiff university is determined by the Research Innovation and Enterprise Services and individual Schools.

Invoicing of commercial income

The Finance and R&D Department have developed an Invoicing Pathway whereby all trials are usually invoiced quarterly throughout their life time; registries may be invoiced less

In the given example, there are 4 clinicians (Healy, Jones, Howe and Hughes) involved. All are externally employed, by Public Health Wales employed, and as such will follow the rules for CU employed clinicians (refer to Table 1 for over view).

Two of the clinicians have UHB salary recharges associated with them i.e. they perform clinical sessions for the UHB for which they are paid by the UHB. (Healy 65% UHB recharge and Hughes 25% recharge.
According to the SSI, the clinical contribution in WTEs was Healy 0.1; Jones 0.2, Howe 0.1 and Hughes 0.1. Converting this to % (assuming sum of the whole time equivalents is 100%), the contributions of clinicians to the delivery of the trial are Healy 20%, Jones 40%, Howe 20%, and Hughes 20%.

However, because the UHB pays 65% of Healy's salary , the commercial fees associated with 65% of the 20% contributed by Healy UHB, similarly 25% of the 20% contributed by Hughes, needs to allocated to the UHB. Thus 13% plus 5 % = 18% of the total commercial clinician fees (after the AWM has been removed and allocated to the AWM fund within the UHB) is due to the UHB and/or 18% of the clinical fee component of each visit. This 18 % is subject to the standard distribution rules for CU/external PIs within the UHB i.e.65% affiliated UHB directorate (paying the salary recharge), 25 % UHB R&D office and 10 % UHB corporate. The affiliated UHB directorate for both recharged clinicians (Healy and Hughes) is Internal Medicine

In the case of the research nurses there is only one, Richmond Russell who is 100% PHW employed and so all of these fees should flow to PHW after the AWM component has been removed (and allocated to the AWM fund within the UHB). Had there been a mixture of UHB and PHW nurses, the scenario as for the clinicians should be applied. In the case of Health and Care Research Wales Work research nurse or administrator involvement within the trial the staff fees would be re-imbursed to HCRW at actual cost plus 25% overhead and should be treated as a support department cost .

5. Set up fees
The distribution and salary recharge rules apply to the research team set up fees. In the given example it was established that it was the PI and Research Nurse who were responsible for the trial set with no or minimal co-investigator contribution. Therefore the £400 set up fee minus the AWM (always take off first before distribution rules applied except for patient travel and subsistence allowances) was allocated in monetary value -50% Research nurse and 50% PI and the recharges for the PI applied. Thus, there was 13% of £200 for distribution within the UHB using the std. formula for external PIs namely 25% R&D office, 65 % affiliated UHB directorate meeting the salary recharge (Internal Medicine) and 10 % UHB corporate. All other set up fees are (R&D Office, UHB Pharmacy, UHB Labs and PHW R&D Office are treated as support departments. The salary contribution element for PHW for both the research nurse and PI (£374) was itemised separately to the PHW R&D set up fee, at PHW's request.

6. Per visits fees- determination of clinicians fees to be retained by the UHB
It has been established that 13% of the clinician fees for each visit needs to be retained within the UHB in accordance with the recharge rules. The next section of the distribution spreadsheet determines that monetary value of this element for each visit e.g. visit Baseline/screening £47.47 through visit 6/ EOS £10.32.

7. Per visit fees distribution

   The per visit fees are distributed in the following order: total fee (as per contract and costing template), AWM component (total – (total /1.0933), UHB support departments (Biochemistry and Haematology labs total cost as per costing template minus AWM), UHB clinician recharge component distributed between affiliated directorate 65% , R&D office 25% and corporate 10%) and PHW (remainder of the clinician and Research nurse fee element) by applying an appropriate formula within the excel cell.

   Thus the total expected revenue for each visit to the contributing stakeholders is established and also the total revenue for the completed visits for the total number of trial participants (n=24).

8. Additional itemised costs
   For procedures i.e. staff time only the above rules/steps apply. For investigations the total fee as per costing template/contract minus the AWM are allocated directly to the providing support department.

9. Pharmacy fees are a support department cost therefore 100 % (after AWM deducted from total costing template fee) are allocated to Pharmacy.

10. Other fees
    In this example these are advertising and patient travel & expenses both of which are through costs and allocated accordingly (no AWM component). There is also an R&D fee for review of amendments. £164.15 minus the AWM (£14.15) = £150 goes to the R&D office..

Additional useful tips/information (to be added to)

1. For studies that have all UHB staff from the same directorate the easiest way to distribute income is in the following order. Remove AWM, assign income to support departments/third parties and apply the distribution formula (40% Directorate, 10 % Corporate, 25 % PI Trading account and 25% R&D) to the remainder.
2. Where the research staff are CU with a single UHB, determine this component and the UHB support departments first. The remainder/majority will be due to Cardiff University.
3. CU require total estimated CU research staff time for the trial, the total expected revenue to CU based on set up fees and per patient visits for the target number of participants. Not the additional itemised costs. They also require the UHB servicing fee amount and whether this has been met b the Sponsor or not.

4. Patient travel and subsistence do not attract AWM therefore if these form part of the payment these should be assigned first before removing AWM and applying the distribution formula.

5. For third party suppliers the AWM component is still charged to the sponsor and retained by the UHB. The third party supplier will receive their required 100%.

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