Annex B – Wales

Contents

Frequently Asked Questions for Wales
(Updated December 2018)

1. Introduction

Q1.1 Why have you revised the guidance on attributing Research Costs, Support Costs and Treatment Costs in the NHS?

A. This FAQ document has been updated to reflect the introduction of the Schedule of Events Cost Attribution Tool (SoECAT) to provide a standardised approach for attributing the costs of health and social care research and development (AcoRD). Researchers should note that this impacts studies led from England and Wales as well as from other Devolved Administrations.

2. Schedule of Events Cost Attribution Tool (SoECAT)

Q2.1 A new cost attribution tool that is similar to the commercial costing template has been developed to support the cost attribution of non-commercial Health and Social Care Portfolio eligible studies in line with the AcoRD guidance. Do I have to use it?

A. The SoECAT has been created to provide a standardised approach for cost attribution to allow consistency across the UK. The SoECAT is a UK-wide tool that allows researchers to access ETCs in England and Wales in a more streamlined way. As part of their funding applications, researchers will be required to complete the SoECAT.

The SoECAT is a template that captures and calculates the different activities and costs associated with relevant research studies. This Excel spreadsheet is based on the existing HRA Schedule of Events and has numerous tabs designed to allocate costs according to the specific activities undertaken in a research study. From the 1st October 2018, the use of the SoECAT has become mandatory for a number of portfolio eligible grant applications which affect both England and Wales-led applications. This applies to:

- New calls for single stage applications issued after 1 October 2018
- Invitations to submit the second and final stage of an application where the invitation is issued after 1 October 2018 (the call for the first stage application may have been issued prior to 1 October).

Applications need to be reviewed and signed off by an AcoRD specialist in Wales prior to grant submission.

The tool and supporting guidance can be found here:

SoECAT

SoECAT guidance

Q2.2 How do I find an AcoRD specialist?

A. There are a number of AcoRD specialists based in Wales with two based in the Health and Care Research Wales Support & Delivery Centre:

- Mike Holloway Michael.holloway@wales.nhs.uk
- Dr Helen Hodgson helen.hodgson@wales.nhs.uk

Or contact funding-research@wales.nhs.uk for more information

For grant applications led by another nations the SoECAT needs to be reviewed and approved by one of the AcoRD specialists within that nation. There is no need to re-review the SoECAT by sites outside of the lead nation

Q2.3 What impact does the introduction of the SoECAT have on cross border studies?

A. The SoECAT is a UK-wide tool to allow a consistent approach for applying the principles of AcoRD across the UK. The introduction of the SoECAT will allow applicants to access ETCs in England and Wales in an easier and more streamlined process.

Q2.4 Do I need to fill in a SoECAT even if my study doesn't involve ETCs?

A. Clinical research that is not thought to involve ETCs will still need to provide a SoECAT signed off by an AcoRD Specialist at funder submission to ensure the attribution has been carried out correctly and consistency.

3. Funding sources

Q3.1 How are NHS Treatment Costs and Excess Treatment Costs funded in Wales?

A. NHS Treatment costs associated with research studies are the responsibility of the NHS and should be funded through the normal commissioning arrangements. In Wales the funding for Excess Treatment Costs can be accessed through a central mechanism. Applying for ETCs in Wales can be done via a completed SoECAT or through an application process; for more information please see the Health and Care Research Wales' Guidance on applying for Excess Treatment Costs (ETCs). This is available on the Health and Care Research Wales website: NHS R&D Funding Policy under Excess Treatment Costs - Guidance for Secondary Care. https://www.healthandcareresearch.gov.wales/nhs-randd-funding-policy/

Neither the NHS organisations nor Health and Care Research Wales will fund non-NHS Treatment Costs i.e. the cost of interventions relating to services that if commissioned at the end of the study would commissioned by non-NHS funding bodies such as Social Care

For information that involves ETCs in England or one of the other devolved administrations please visit:

England

Scotland

Northern Ireland

Q3.2 How are the NHS Support Costs of non-commercial studies funded in Wales?

A. NHS Support funding for studies that are eligible for adoption to the Health and Care Research Wales Portfolio, is paid to Health organisations in Wales as part of their NHS Local Support and Delivery funding.

Wales also operate a centralised NHS Support Cost budget for studies taking place in Primary Care, Emergency Care and Public Health Wales settings (Public Health Wales is an NHS organisation in Wales). Applying for centralised NHS Support Costs can be done via a completed SoECAT or through an application process; for more information please see the Health and Care Research Wales' Guidance on applying for Support costs. This is available on the Health and Care Research Wales website: NHS R&D Funding Policy under Excess Treatment Costs - Guidance for Secondary Care. https://www.healthandcareresearch.gov.wales/nhs-randd-funding-policy/

Q3.3 My study will meet the eligibility criteria for NHS Support but how do I access the resources that I need?

A. It is important to consult with the NHS organisations regarding costings prior to the submission of a grant/research funding application to help ensure that all eligible direct research costs are included in the grant/research funding application. For advice on how to access NHS support for secondary care, please contact your local NHS R&D office. NHS Support for Primary, Emergency care and Public Health Wales studies can be accessed through a central mechanism in Wales. Further information on this can be found on the Health and Care Research Wales website: (https://www.healthandcareresearch.gov.wales/nhs-randd-funding-policy/)

Q3.4 Managing the sharing of money between universities and the NHS is sometimes difficult – is any national guidance planned?

A. Research costs applied for on grants/research funding held by universities, but incurred in the NHS should be recovered by the relevant NHS organisation from their partner university, and vice versa where the grant/research funding is held by an NHS organisation. This is the national policy, no further guidance is planned.

Q3.5 My research study is being funded by an AMRC charity. How will I access the NHS resources needed for data collection?

A. For studies funded by a charity that is a member of the AMRC, data collection performed by existing members of staff employed by an NHS organisation will be met through funding allocated through NHS Local Support and Delivery funding. Funders may require you to demonstrate that funding for NHS resources is available. Applicants are advised to consult with the NHS R&D Departments prior to the submission of the grant/research funding application to ensure all relevant costs are calculated correctly and will be met.

Q3.6 Is there a searchable list of AMRC members?

A. The AMRC has a searchable list of members at www.amrc.org.uk. Some AMRC members are not classified as NIHR non-commercial partner organisations and will not be eligible for Research Part B

Cost funding because they do not award via open national competition. The AMRC will be able to provide an up to date list of these charities on request.

Q3.7 What does the guidance mean for Welsh charities that are not members of the AMRC?

A. Under the guidance, a Welsh charity which is not a member of the AMRC is liable to meet Part B research costs. However, Health and Care Research Wales is content for NHS organisations to exercise discretion in terms of meeting Part B research costs for studies funded by Welsh charities which are not members of the AMRC. Such charities are advised to contact the local NHS R&D office to discuss. Please note that any provision of funding must be in line with '*The appropriate use of NHS R&D Local Support and Delivery funding'* guidance available here: https://www.healthandcareresearch.gov.wales/nhs-randd-funding-policy/

4. Research Conduct and Design Service/ Application advice services / Health and Care Research Wales Permissions Service

Q4.1 I will be seeking advice from the Research Ethics Service (RES). Do I need to include the cost of RES time advising me on my study on my grant/research funding application?

A. No. There is no need to include the cost of the time that Ethics committees spend advising you on the research grant/research funding application as the service is funded and supported through Health and Care Research Wales.

Q4.2 I will be using the Health and Care Research Wales Permissions Service for gaining NHS Research Permission. I think that this is a NHS Support activity, but do I need to include the cost within the NHS Support Cost section of my grant/research funding application?

A. Obtaining NHS research permission co-ordinated by the Health and Care Research Wales Permission Service and through R&D staff in NHS organisations does not need to be included as a cost on the research grant/research funding application as the services are funded through Health and Care Research Wales.

Q4.3 My NHS organisation are in receipt of Local Support and Delivery funding. Can I use some of this funding to cover research costs?

A. Where NHS organisations are in receipt of Local Support and Delivery funding, this funding may be used to meet the costs of some activities defined as research costs in Part B of Annex A only if the funder is a member of the AMRC. Existing staff resource may be used depending on the activities that need to be supported. It is advised that researchers engage the R&D Office to ensure that they have the resources to cover research costs Part B,

5. Clinical Trials Unit Costs

Q5.1 I am applying for a research grant for a study that will be run through a Clinical Trials Unit. Should I include the costs that will be incurred by the Clinical Trials Unit on my application form?

A. Most grant funders have their own rules about what should or should not be included on a grant application in relation to studies run through Clinical Trials Units to which they contribute funding. Funders do not expect to fund a cost that they have already funded. You will need to check with the Clinical Trials Unit and with the grant funder about which costs should be included within the grant funding section of the application form.

6. MHRA inspection

Q6.1 How should Medicines and Healthcare Products Regulatory Agency (MHRA) inspection fees (not the MHRA set up or annual fee), which should be paid if a Clinical Trial of an Investigational Medicinal Product (CTIMP) is inspected by the MHRA, be attributed?

A. Routine MHRA inspection is a research management and governance cost that would need to be picked up from funding that NHS organisations receive for this purpose.

7. Patient recruitment/consent

Q7.1 A research study looking at a public health intervention plans to recruit participants from a large number of GP lists. The only practical means of recruiting sufficient numbers of participants is to conduct a mass-mail-out with the support of GPs. How do I attribute the costs of this aspect of study recruitment?

A. The mass-mail out does not form part of NHS patient care service. The primary purpose is to recruit patients into a research study to answer the research question. The mail-out and its associated costs are research costs and should be met by the research funder.

Q7.2 Patients attending an outpatient clinic to receive standard care for high blood pressure are informed by their clinician of a research study looking at cholesterol levels in blood. Patients who express an interest in hearing more about this research study are referred on to a research nurse who can discuss the study in more detail. Is this initial contact a research cost?

A. Once again, the primary purpose is to recruit patients to a research study. However, for practical purposes the conversation between the clinician and patient falls within the NHS patient care service. Therefore, for non-commercial research studies, this cost activity will be funded by the NHS organisation as a NHS Support Cost. This decision reflects the context within which the activity takes place and the juxtaposition of research and patient care.

It may on occasion be difficult to see where the boundary for recruitment research costs sits – those that should be met by research funders and those that will be met by a NHS Organisation. The suggested delineator is whether or not the specific recruitment activity can be regarded as an integral part of a NHS patient care service. If the specific recruitment activity sits outside of a NHS patient care service, it should be met by the research funder.

Q7.3 All patients need to be consented as part of the overall recruitment process, before entering a research study, why is this a NHS Support Cost?

A. The activity of obtaining an informed consent from a patient before they enter a research study is primarily concerned with a patient's rights and safety under Research Governance. The consent is

regarded as part of an NHS patient care service and is undertaken specifically to facilitate a research study and address the NHS duty of care to a patient. Consent is therefore attributed as a NHS Support Cost.

Q7.4 Consent-taking is a Support Cost, but what about placing public adverts, e.g. for healthy volunteers?

A. The placing of public adverts aimed at recruiting patients or healthy volunteers is a Research Cost Part A because there is no direct patient benefit.

Q7.5 If the person taking consent will be a university employee, how should these Support Costs be recovered?

A. Taking the consent of patients that will be participating in a clinical research study taking place in the NHS is an NHS Support activity, no matter who takes the consent. Taking the consent of study participants for non-clinical research studies that are not taking place in the NHS is a research activity, no matter who takes the consent. In general it is the latter type of study for which university employees would take consent.

Q7.6 Does recruitment for funded studies have to be carried out specifically by research nurses whether funded through Health and Care Research Wales or not?

A. No. The person recruiting patients should be the most appropriate for the task and not all recruitment activities are support activities.

Q7.7 Is taking the consent of healthy volunteers a Research or a Support activity?

A. Consenting healthy volunteers to participate in a clinical research study that involves medical interventions which incur and NHS duty of care is an NHS Support activity. However, if healthy volunteers are being recruited to participate in a study that is not clinical research, then the activity is a Research Cost activity.

Q7.8 When attributing the cost of approaching patients to invite them to participate in a study, is writing to, or telephoning, potential participants identified through a primary care practice encompassed by the 'processing of the patient record' and therefore considered a Support activity?

A. The reviewing of patient records and taking the consent of patients are Support activities. The time that staff spend sending out letters inviting patients to participate in the study, the cost of the stationary and the postage costs of sending the letter are Research Part A activities. If the letter that is sent out contains information for patients in addition to the invite to participate and study description, cost attribution of the time spent stuffing envelopes and postage etc would need to be determined by the primary purpose of the letter.

If patients are telephoned to ask if they will participate in an NHS study and at the same time they are consented, the whole cost can be attributed as a Research Cost because the primary purpose of the telephone call is to ask the patient if they wish to participate. There is no need to disaggregate the cost of the call into inviting to participate and consent. However, if there are two separate telephone calls, the call to obtain consent would be a Support Cost.

Q7.9 Opportunistic recruitment during routine consultations is often used to enter patients into research studies. How should this activity be attributed?

A. The primary purpose of the appointment time is consultation. If explanation of the study and consent taking can be achieved within the normal consultation time, in addition to the clinical consultation, this should be considered part of the normal consultation and no further attribution is required.

However, when research sites are anticipating opportunistic recruitment into studies and they provide considerably longer time slots per surgery session to take into account the additional time that will be required over and above the consultation for the condition, the additional time required is attributed as a NHS Support Cost.

Similarly, where there is some kind of triaging system e.g. the patient phones a receptionist or triage nurse, who identifies that the patient is potentially eligible for a study, and therefore books the patient into a considerably extended appointment slot to cover the clinical consultation as well as confirming eligibility, explanation and consent, the additional time booked over and above the clinical consultation time is attributed as a NHS Support Cost.

8. Patient assessment

Q8.1 All patients will need to undergo an assessment prior to their entry into the study to determine their eligibility to participate. The assessment will be performed by their clinician and involves questions about their medical history, a physical examination, ECG, x-rays and blood tests. Is this a research activity or a NHS Support activity?

A. Assuming these activities relate to screening and identifying patients for study eligibility, that are **in addition to** any assessment required for standard care or any assessment that would be needed in the intervention arm should the intervention being studied become standard care and they are only taking place because the patient may be recruited to a research study and the results of the assessment are **primarily** being used to determine study eligibility. The activities would be research activities and would need to be funded through the research grant/research funding.

Q8.2 How should I attribute screening or assessment activities that would form part of routine practice if the intervention being studied became standard care?

A. Screening or assessment activities that would form part of routine practice if the intervention being studied became standard care are attributed as Treatment activities that are funded through normal commissioning arrangements.

Q8.3 All patients recruited to the study need to undergo a baseline assessment by a clinician or nurse involving various tests that are in addition to routine or standard care. The patient also has a similar assessment at the end of the intervention so that we can compare results and measure the effectiveness of the intervention. Are these research activities?

A. These are research activities because whilst the clinician will know the results of the tests, the primary purpose for performing the assessments is to answer the research question by identifying how the intervention/procedure has impacted on the patient.

Q8.4 My study requires participants to participate in a range of cognitive, motor, and quality of life assessments (including questionnaires) where the data generated by these activities is required by the research team to answer the research question. The primary purpose of these activities is research, but do I attribute them as Research Part A or Part B activities? Can I

attribute these activities as data collection as the data is needed to answer the research question?

A. Research Part A Costs encompass the following:

- Any screening tests/assessments to determine whether a patient is eligible to participate in a study, performed after the patient has been approached to ask if they wish to participate in the study, but before they are accepted onto the study.

- Investigations, assessments and tests relating to if, how, why and when an intervention/procedure works - in other words, activity which is intended to answer the research question.

- Investigations, assessments and tests where the results are anonymous and unlinked to a patient identifier, or where the individual results will not be reported back to study participants or their clinicians, since such information is collected primarily for the purpose of answering the research question. However, exceptional circumstances may arise where there is an overwhelming clinical need to convey results to the clinician providing care. The possibility of such exceptional circumstances does not change the primary purpose.

Performing any of these tests or assessments, assuming they are in addition to those required as part of standard care or would not be needed if the intervention in question became standard care, is a Research Part A activity. Collating these assessments and providing them to the research team for analysis is a data collection activity and would be attributed as a Research Part B activity.

9. Patient records and other databases

Q9.1 If nurses collect patient data for research, how should this be costed into a grant/research funding and how should the organisation incurring the cost receive payment?

A. The collection of patient data is a Research Part B activity that should be included in the research grant/research funding as a Part B Research activity and funded by the grant/research funding funder unless the funder is an eligible AMRC member. The NHS organisation delivering this activity will need to recover the costs from the organisation holding the Attributing the costs of health and social care Research & Development (AcoRD) research grant whether that organisation is a university or another NHS organisation.

Where the funder is an eligible AMRC member or other eligible charity that is not required to fund these activities as part of their grant/research funding award, the costs should be shown separately as a Research Part B Cost and the resource will be met via the NHS Local Support and Delivery funding. It is advised that researchers engage the R&D Office to ensure that they have the resources to cover research costs Part B,

Q9.2 My study requires a review/search of resident records held by care homes to identify potential study participants. Is this an NHS Support activity?

A. Reviewing the **NHS records** of patients in care homes with a view to identifying patients who would be suitable to approach to take part in a clinical research study is a NHS Support activity. Reviewing **care home or other non-NHS records** is a Research activity because these records are not NHS patient records.

Q9.3 Are all database searches an NHS Support activity?

A Reviews of patient records, whether in electronic form or hard copy, to identify patients eligible to participate in a research study is a NHS Support activity –see FAQs 9.2. The review of other

electronic databases to extract data required by researchers to answer the research question is a Research Activity Part A.

10. Patient travel

Q10.1 If my study is trialing a treatment that requires additional trips to hospital, are the participants' travel expenses a Research Cost?

A. The participant's travel cost is a research cost because it is not something that would be met by the NHS if service were provided outside the context of research. NHS support funding should not be used to fund patient travel costs for the same reason.

11. Early Phase Studies

Q11.1 My study is a Phase I research study that is primarily about the development of a new intervention and testing its safety. Are these early phase intervention activities Research or Treatment activities?

A. Up to and including "first in man" (or equivalent for research that was not a Clinical Trial of an Investigational Medicinal Product) the development of an intervention is a research cost. However, the administration of the intervention and all other activities would follow the normal rules of attribution.

12. Training

Q12.1 How is GCP training funded for NHS staff involved in research studies?

A. GCP training is part of NHS staff overall training and development and should not be included in applications for research funding as either a Research, NHS Support or a Treatment cost. It is for the employing organisation to fund the training and development needs of the staff it employs. Health and Care Research Wales provide a range of training events locally all of which are free for NHS staff and researchers in Wales.

13. Interviewing staff and patients

Q13.1 My study requires me to interview NHS staff and patients as part of a service evaluation. I understand that the time I spend interviewing is a research activity, but what about the time of the NHS staff or patient that is being interviewed?

A. NHS staff being interviewed as part of a research study should be treated the same as any other study participant. In most cases, study participants are not reimbursed for their participation, but where there is a need to incentivise participation in the study the cost is a research cost.

14. Changes to standard care

Q14.1 We believe that the patient care intervention in question will be delivered differently if it became standard practice than it is being delivered during the research study. As the ongoing patient care costs will be less than the patient care cost required during the study, should we calculate the Treatment costs based on the ongoing costs?

A. Yes. If the intervention will be delivered differently if it became standard practice, only the on-going costs are Treatment Costs. This is because the definition of a Treatment Cost is a cost that would continue after the end of the study if the service/intervention continued to be provided. If the

researcher can demonstrate that the experimental intervention would always be delivered differently if it became standard practice (without compromising the efficacy of the intervention), the additional costs incurred during the Research study would be attributed as Research Costs.

Q14.2 I am testing more than one experimental intervention (i.e. in a three arm clinical study) and I am not sure which intervention would continue to be delivered after the study has finished. Should I attribute the cost of each experimental intervention as a NHS Treatment Costs?

A. Yes.

Q14.3 How should the intervention under review be attributed in a feasibility study where an intervention currently provided in a NHS setting is to be re-provided in a community setting or care home? And, in this case, is consent attributed as an NHS Support activity?

A. Under AcoRD the interventions that would continue after the end of the research study if they became standard care are attributed as a Treatment activity (Regardless of where the treatment will take place in the future). The cost of these treatment activities must be funded during the study by the organisation that would be responsible for commissioning and funding the service/intervention if it became standard care. The location for delivering the service and the provider of the service is irrelevant. In the case of interventions provided in a care home setting, the funder may be the NHS if the service or intervention would ultimately be commissioned by the NHS, or the funder may be the local authority or the care home itself. Consent, in this case, is an NHS Support activity.

15. Adverse research event

Q15.1 Clinicians are usually required to report an adverse event in research subjects to the research team and may need to provide additional care to the research subject because of these events. Are these care activities NHS Support activities?

A. No. The provision of care to a research subject that is required because of an adverse or serious adverse event is a NHS treatment activity. However, central monitoring of adverse or serious adverse events in research subjects is a research activity.

16. Diagnostics

Q16.1 In a study researching a new diagnostic tool, the results of the diagnostic tool will not be shared with the patient. How should the cost of the diagnostic tool be attributed?

A. The collection and analysis of samples to see if they are able to inform diagnosis is too early in the development process to be considered a treatment and therefore are Research Costs. If there is a subsequent study (or second phase of the same study) where researchers are comparing whether the (same) analysis is better than standard diagnosis then, at this point, the activity is a Treatment Cost.

Q16.2 My study requires patients to undergo a scan the primary purpose of which is to provide data to answer the research question. The scans are sent to the research team to be read and the results are not routinely shared with the patient's clinicians because they are not to be used to influence the care of the patient. I understand that under these circumstances both the scan and the analysis by the research team is a Research Cost. However, if the research team's review of the scan finds something that would have an adverse impact on the patient's health if not treated and this is reported to the patient's clinician, does this change how the scan and its analysis are attributed? What if the scans, but not the analysis are shared with patient's clinicians and the patient's clinicians chose to have the scan read locally?

A. Where the primary purpose of a scan is to provide data to answer the research question and the results of the scan analysis is not shared routinely with the patient's clinician, both the scan and the

analysis are attributed as Research activities. If the analysis identifies incidental findings that are critical to the patient's care and which need to be shared with the patient's clinicians, both the scan and the analysis are both still attributed as Research activities. However, any care provided to the patient because of the incidental findings is an NHS Treatment activity.

Similarly, if the research team shares the scan with the patient's clinician, but not its analysis of the scan, and the patient's clinician decides, outside of the protocol to have the scan analysed locally with a view to using the results to determine patient care, the scan and research team analysis remain Research activities. However, the local analysis of the scan and any subsequent patient care are NHS Treatment activities, and these Treatment activities are separate to the research study.

17. Room hire

Q17.1 Can sites be provided with funding to cover room hire costs incurred in the course of a research study?

A. As research is a core function of the NHS, it is not normally expected that room hire costs will be reimbursed.

However, where payments have to be made to hire space not normally used for clinical purposes (e.g. a church hall) the costs can be reimbursed. The attribution of the room hire costs will follow the attribution of the activity taking place i.e. for activities attributed as NHS Support activities, the associated room hire will also be attributed as a NHS support activity: for activities attributed as Research, the associated room hire will also be a Research activity.

Where independent contractors can demonstrate a loss of income, or opportunity cost, because use of their premises is necessary for research, consideration will be given on a site by site basis as to whether a room hire charge is appropriate. The attribution of room hire costs will be as described above.

18. Drugs and pharmacy activities

Q18.1 I know that the cost of dispensing the intervention medicine for a study is a NHS Treatment Cost, but the drug has to be repackaged locally at each recruitment site specifically for the trial. Is the repackaging a NHS Treatment Cost even though it would not need to repackage the drug once the study ended even if we continued to dispense the drug to patients?

A. The repackaging of an intervention drug is a research activity where it is performed centrally either by a single NHS organisation or by a non-NHS supplier for use by all recruitment centres. However, where a NHS organisation repackages a drug locally for its own use, the activity is a NHS Support activity.

Q18.2 How should costs be attributed if the repackaging of drugs is done locally on the instruction of the central team or if, due to new sites coming on board, drugs are moved from one site to another and have to be repackaged locally.

A. Any repackaging done locally for the Trust's/organisation's own use is a Support activity even if the repackaging is done on instruction from the research team. If drugs have to be repackaged locally because they have been moved from one site to another this would also be attributed as a Support activity.

Q18.3 All costs associated with placebo or sham treatments are Research Costs. My study is a blind trial where the dispensing organisation will not know whether it is dispensing the placebo or the active drug. How do I apportion the costs and how are the dispensing organisations funded?

A. For studies where the intervention drug is blinded the cost of dispensing the placebo is a Research Cost and the cost of dispensing the active drug is a NHS Treatment Cost. In a blinded study the dispensing costs should be the same or very similar for the placebo and the active drug. Assuming there are two arms to the study, with half of patients recruited to each arm, recruiting organisations should assume that half of the patients they recruit receive the placebo and half receive the active drug. The dispensing organisation would recover the cost of dispensing the placebo from the research grant/research funding and cover the cost of dispensing the active drug from its patient care funding.

Q19 Treatment Costs

Q19.1 If a Welsh patient is treated across the border / in another country, is the cost of treatment in a hospital outside of Wales covered by ETC's in Wales? Would it make any difference if the study is lead from Wales or a country outside of Wales?

A If this practice becomes standard care after the study has completed, then this would be considered as an ETC cost.

Q19.2 Sometimes standard care involves sub-contracting to private sector. Therefore if the study requires the services of the private sector, then is this an ETC?

A If this practice becomes standard care after the study has completed, then this would be considered as an ETC cost.

Q19.3 The intervention being tested is standard care in England, but not standard care in Wales. Can we apply for ETC's in Wales even if it's not going to be adopted as standard care?

A No. As this is not standard care in Wales then it cannot be considered as a treatment, and therefore cannot be funded from ETCs