Annex B - Scotland

Frequently Asked Questions

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

A. The definitions of Research Costs, NHS Support Costs and NHS Treatment Costs were first set out in 1997. However, since that time the practical interpretation of these principles and definitions has become less clear. In particular, ARCO[1] blurred the boundaries by introducing consideration of where the activity is performed and by whom rather than basing it solely on nature of the activity itself. The revised guidance reinstates the principles of the 1997 guidance, focusing on the primary purpose of the activity being performed. By providing comprehensive guidance including lists of exemplars and FAQs, it is hoped that the new guidance will make attribution more straightforward and consistent.

Q2. How are the NHS Support costs of non-commercial studies funded in Scotland?

A. NHS Support funding for studies funded by eligible funders or adopted to the UKCRN Portfolio Database, is paid to NHS Boards as part of their NRS Funding allocation. From April 2013 this allocation will be based on an agreed 'per-patient' cost and the number of patients recruited to the study in the relevant Board. Please note that NHS Support funding is not a form of secondary grant application i.e. it cannot be used to supplement direct research cost elements, which were omitted from the original grant application or rejected by the grant funder, nor can it be used to supplement non-NHS Service Support elements. For this reason it is important that studies are correctly costed at the grant application stage.

Q3. How are NHS treatment costs and excess treatment costs (ETCs) funded in Scotland?

A. The background principles to the funding of excess treatment costs were established in the Departmental letter MEL(1997)31 in June 1997 and further reinforced in HDL(2005)2 in January 2005. Under these instructions NHS Scotland is obliged to ensure that patient care services associated with R&D are provided and funded efficiently through normal arrangements - this includes excess treatment costs. Consideration to grant a subvention is only given when the costs are considered to be disproportionately expensive. Further information on this can be found at http://www.cso.scot.nhs.uk/nrs/nrs-funding-2/excess-treatment-costs-for-research/

[1] **A**ttributing **r**evenue **co**sts of externally funded non-commercial research in the NHS guidance published in 2005

Q4. How are NHS organisations expected to fund Research Part B activities?

A. Such costs are by definition marginal in that they should be able to be met through existing resource. For studies funded by members of the AMRC the costs of part B activities should be met by NHS Boards from the funds already allocated by CSO. For example, NRS Researcher Support allows for Part B activities including item 14 in Annex A to be met, some costs can be met from NRS Infrastructure funding or indeed some may be met through Research Management funding.

Q5. Managing the sharing of money between Universities and NHS is sometimes difficult – is any national guidance planned?

A. Research costs applied for on grants 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 is held by an NHS organisation. This is the national policy, no further guidance is planned.

Q6. 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.

Q7. 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 Board or Scottish Clinical Research Network will met from the NRS funding allocated to Boards/Networks annually. Grant applicants will need to identify the resources required to perform this activity separately within the research costs section of the application form. To ensure that the Board/Network has the capacity to deliver the resources required, applicants should consult with their local NHS R&D Department(s) prior to the submission of the grant application to ensure that all relevant costs are calculated correctly.

Q8. I will be seeking advice from the National Research Ethics Service (NRES) and the Regulatory and Governance Advice Service. Do I need to include the cost of time these organisations spend advising me on my study on my grant application?

A. No. There is no need to include the cost of the time these organisations spend advising you on the research grant application as the services are funded through other funding streams.

Q9. Medicines and Healthcare Products Regulatory Agency (MHRA) inspection fees (not the MHRA set up or annual fee), which should be paid if a CTIMP is inspected by the MHRA, were included in NHS Support Costs under the previous ARCO guidance. Is this still the case with AcoRD?

A. MHRA inspection fees are not usually study specific. However, if they are study specific they would be Research Costs and would come under Research Part B Costs. If the cost is one that relates to research generally, it is a research management and governance cost and would need to be picked up from funding that the Board receives for this purpose.

Q10. 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 or which has been funded already through another source. 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.

Q11. 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 as such should be met by the research funder.

Q12. 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 the 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, the cost of this research activity will be funded by the Health Departments. 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 funder and those that will be met by a Health Department. The suggested delineator is whether or not the specific recruitment activity can be regarded as an integral part of an 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.

Q13. All patients will need to undergo an assessment prior to their recruitment to 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. These activities relate to screening and identifying patients for study eligibility. They 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 tested become standard care. They are only taking place because the patient may be recruited to a research study and the results of the assessment are only being used to determine study eligibility. The results will not be used to determine patient care. The activities are therefore research activities and would need to be funded through the research grant.

Q14. 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 now clearly identified as Research 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.

Q15. 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 Costs, funded through normal NHS arrangements.

Q16. All patients need to consent as part of the overall recruitment process, before entering a research study, why is obtaining consent an NHS Support Cost?

A. The activity of taking 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 an NHS Support Cost.

Q17. 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.

Q18. 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 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 activity.

Q19. 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. If University employed staff take consent for the former type of study, reimbursement will usually need to be sought from the appropriate Board.

Q20. 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.

Q21. 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 an NHS Support activity. Reviewing **care home or other non-NHS records** is a Research activity because these records are not NHS patient records.

Q22. 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 person 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.

Q23. If nurses collect patient data for research, how should this be costed into a grant application and how should the organisation incurring the cost receive payment?

A. The collection of patient data is a Research cost that should be included in the research grant application as a Part B Research activity and funded by the grant funder unless the funder is an eligible member of the AMRC. The NHS organisation delivering this activity will need to recover the costs from the organisation holding the research grant whether that organisation is a university or another NHS organisation.

Where the funder is an eligible AMRC member that is not required to fund these activities as part of their grant award, the costs should be shown separately as a Research Part B Cost and the NHS organisation delivering the activity will need to meet the costs from its NRS funding.

Q24. 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.

Q25. 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. Intervention activities within a Phase I study are usually too early in the development process to be considered a Treatment activity and are therefore Research activities. These research studies are usually about developing a new intervention and testing its safety in a small number of patients.

Q26. 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.

Q27. 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 Board'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.

Q28. 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 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 and cover the cost of dispensing the active drug from its patient care funding.

Q29. 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 activities NHS Support activities?

A. The provision of care to a research subject 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.

Q30. 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 an NHS Treatment Costs?

A. Yes.

Q31. 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. Performing any of the tests or assessments detailed in Annex A items 1,4 and 5, 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.

Q32. 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.

Q33. 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 as a result 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.

Q34. 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, the time spent would constitute a treatment cost.

However, if research sites are anticipating opportunistic recruitment into studies and they provide longer time slots per consultation to take into account the additional time that will be required to take consent 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 an extended appointment slot to

cover the clinical consultation as well as confirming eligibility, explanation and consent, the additional time booked is attributed as a NHS Support Cost.

Q35. 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.

Q36. I am unsure what the term 'data collection' referred to under Part B research costs covers

A Where data collection requires the retrieval of materials (tissue specimens / samples / scans / blocks / tests / patient records) for a central researcher; (usually stored samples or results for central review or analysis), the retrieval/preparation of these materials are Part A research costs. The task of extracting data to complete a Case Report Form at the local site, as well as completing the form itself, is a Part B Research cost activity.

Q37. How should Secondary Care Pharmacy activities in relation to Clinical Trial Management be attributed?

A The below lists Secondary Care Pharmacy tasks in relation to Clinical Trial Management and attributes these activities as either Research (Part A or B), Support or Treatment in line with AcoRD.

Activity Group	Attribution
1. All costs associated with Placebos	Research Cost Part A
2. Manipulating the drug in such a manner that requires a MIA(IMP) licence The MHRA defines these as **"Manufacturing", or "Assembly"**	Research Cost part A
	Exception: Treatment cost if assembly is part of standard treatment (e.g. standard treatment = chemotherapy assembled by an external contracted supplier)

Activity Group	Attribution
3. Manipulating the drug as an additional activity to local dispensing under an exemption of regulation 37 of SI 2004/1031 ('Regulation 37 exemption') E.g. Assembly (packaging and labelling) or Small Scale Repackaging in an NHS provider organisation also a Trial Site.	NHS Support Cost **Exception**: **1.** Assembly is part of standard treatment = NHS Treatment cost **2.** Where Assembly is carried out centrally on Sponsors behalf under an MIA (IMP) under regulation 37 exemption - for other investigator sites it becomes a Research Cost Part A (see 2 above)
4. Dispensing of the IMP /NIMP including reconstitution, serial dilution as part of the act of the act of physically dispensing and aseptic dispensing. *Note* separation of act of dispensing/ supply from associated patient level CT drug accountability record keeping.	NHS Treatment cost
5. Activities to ensure the safety of the Patient E.g. Unblinding, patient level record keeping /documentation.(i.e. record of drug accountability)	NHS Support Cost
6a. All activities associated with the supply chain Including Shipping/Transporting, storing, disposal.	NHS Treatment Cost Note Placebos as an exception have been ignored here for simplicity and practicality.

Activity Group	Attribution
6b. Supply chain non routine costs Exceptional transportation costs where these are evidenced Special/ non routine disposal for duration of research study where cost is evidenced *Note* any excessive costs in this category relate being able to answer the research question and are therefore Research Costs Part A.	Research Cost Part A
7. Local site administrative preparations and IMP delivery tasks including Study specific paperwork Standard Operating Procedures Temperature monitoring and reporting Allocation of patients to treatment at site using a centrally set up system *Note* costs in this category are outside of business as usual arrangements and are Research Costs.	Research Cost Part B
8. Training which is study specific i.e. over and above usual expected levels of competence for a research site	Research Cost Part A