Department of Health

DH Attributing the costs of health and social care Research & Development (AcoRD)

Frequently asked questions

July 2016

Annex B

Frequently Asked Questions

Updated July 2016

Contents

1. Introduction

Q1.1 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 attribution solely on the 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.

2. Funding sources

Q2.1 How are the Support Costs of non-commercial studies funded in England?

A. For studies that meet the eligibility criteria for NIHR Clinical Research Network (CRN) Support[2], resources for meeting NHS Support Costs are provided primarily through the Local Research Networks of the NIHR Clinical Research Network. However, some NIHR grant funding schemes, such as grants awarded for Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) and Biomedical Research Centres and Units, include funding for NHS Support Costs as part of the grant award. Studies where the research costs are funded via these NIHR grant funding schemes will not be entitled to additional Support funding via the NIHR CRN. The NHS Support Costs for studies outside the NIHR Clinical Research Network Portfolio costs must be met by the study sponsor or funder, although NIHR CRN funded infrastructure (e.g. trial nurses) may be used to support these studies on a full-cost recovery basis.

Q2.2 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 and the Network Service regarding costings prior to the submission of a grant application, to ensure that all eligible direct research costs are included in the grant application. Advice on how to access NHS Support is provided by the NIHR Clinical Research Network Co-ordinating Centre (NIHR CRN CC) *study support service*.

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

[2] Refer to Eligibility Criteria for NIHR Clinical Research Network Support, October 2011 https://www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-portfolio/which-studies-are-eligible-for-clinical-research-network-support/

Details can be found on the CRN CC website at:
https://www.crn.nihr.ac.uk/can-help/study-support-service/

Please note that NHS Support 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.

Q2.3 How are NHS Treatment Costs and excess treatment costs funded in England?

A. NHS Treatment Costs associated with research studies, including Excess Treatment Costs, are the responsibility of the NHS and should be funded through normal commissioning arrangements. Further guidance on funding NHS Treatment Costs is provided in *HSG(97)32 Responsibilities for meeting patient care costs associated with research and development in the NHS* and is available at:
http://www.nihr.ac.uk/documents/policy-and-standards/Health-Service-Guidance-Patient-Care-Costs-97_32.pdf.

NHS England has also published guidance on its website on meeting Excess Treatment Costs resulting from non-commercial research where the services being researched would be commissioned by Clinical Commissioning Groups (CCGs) or commissioners of specialised services. It can be found at: https://www.england.nhs.uk/ourwork/research/etc/. Questions on this guidance should be addressed to: england.etcs@nhs.net

Neither the NHS nor DH R&D will fund non-NHS Treatment Costs i.e. the cost of interventions that if put into practice at the end of the study would be met from non-NHS funding bodies such as Social Care or Education. Public Health England is developing guidance on funding public health research where the services being researched would be commissioned through Local Authorities or other non-NHS organisations.

The AcoRD guidance relates to funding ETCs during the research study only and post-study funding of interventions is a matter for commissioners. Where provision of post-study treatment is offered to patients when they agree to participate in the study, the arrangements for funding that treatment beyond the duration of the study must be in place prior to commencing the research. Researchers must ensure the arrangements for post-study care are reviewed by the Research Ethics Committee.

Q2.4 If NHS organisations do not receive any Research Capability Funding (RCF), how are they to fund Research Part B activity?

A. For Association of Medical Research Charity (AMRC) funded studies only, Networks in England can use their RCF, at the Network's discretion, to help Trusts that have not received RCF because they have recruited insufficient patients during the preceding year to qualify for RCF funding. All NHS organisations that accrue a set number of patients to studies that are eligible to receive NHS Support are awarded some RCF.

Q2.5 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.

Q2.6 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, a Clinical Research Network or by an organisation funded by the NHS to provide patient care services on its behalf will be funded by the Department of Health via its Clinical Research Networks (CRNs). 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 CRN has the capacity to deliver the resources required, applicants are advised to consult with NHS R&D Departments and the CRN prior to the submission of the grant application.

Q2.7 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 from DH 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.

Q2.8 My organisation receives Research Capability Funding (RCF). Can it use some of this funding to cover research costs?

A. Where NHS organisations are in receipt of RCF, this funding may be used to meet the costs of some activities defined as research costs in Part B of Annex A. Guidance on how RCF can be used is contained within RCF annual funding agreements and on the NIHR website at: http://www.nihr.ac.uk/policy-and-standards/research-capability-funding.htm RCF should never be used as a substitute for grant funding.

3. Clinical Research Network funding

Q3.1 Are any Research Costs funded via the Clinical Research Networks and, if so, should I record them on my research award application form

A Tables 1 and 2 below set out Research activities that are funded by DH:

Table 1 sets out the Research activities that are funded by DH and provided by the NIHR CRN **for all NIHR CRN Portfolio studies**. These activities should **not** be included in your funding application

Table 2 sets out Research activities and tasks provided by NIHR CRN under Annex A, Part B **for NIHR CRN Portfolio studies funded by a medical research charity that is a member of the AMRC**. These activities should be included in your funding application.

Table 1: Research Cost activities and tasks provided by NIHR Clinical Research Network for ALL NIHR Portfolio studies

Activity	Task
Feasibility assessment	- Read Protocol - Support and advise funders and research teams to identify suitable sites, approach and assess capability of these sites - Initial assessment of feasibility by the site research team and feedback to funders - In house meetings to assess feasibility and deliverability of study - Work with funders/research/clinical teams to establish recruitment targets
Support regulatory submission for local approval and resource allocation	- Support Principal Investigators, where required, in preparation of the study documentation and submission through IRAS for processing in the CSP system for NHS Permission - Support investigators, where required, with preparation of the study documentation, submission, attendance/presentation to other local committees or liaison with NHS colleagues - Allocation of local resources based on nationally agreed attribution of Service Support Costs
Performance Management of study delivery	- Work with funders and study/clinical teams to monitor progress against recruitment targets - Work with funders and study/clinical teams to identify blocks/barriers to achieving recruitment targets at site level - Work with funders and study/clinical teams to develop and implement action plans to overcome barriers to recruitment at site level

Table 2: Research Cost activities and tasks provided by NIHR Clinical Research Network under Annex A, Part B for NIHR Portfolio studies funded by a medical research charity that is a member of the AMRC

	Activity	Task	Funding
Study Set Up	Preparing for study initiation	- Attending external investigator meeting - In house meetings for information and activation of study - Preparation for site initiation visit - Promotional activities to raise awareness of study	Trust Research Capability Funding
	Local site administrative preparations	- Preparation, maintenance and distribution of Site File - Collection and filing of study specific documents (e.g. delegation log, file notes) - Development of study specific paperwork (e.g. screening log, flow sheets, visit schedules, SOPs for local processes) - Coordination and ensuring sufficient local study supplies (e.g. CRFs, blood sampling kits) - IT preparation (i.e. Databases, tracking systems, remote data capture etc.)	Clinical Research Network
Study Delivery	Contact patients	- Time of staff to mail out to identified patients and liaison with central trial/study team regarding replies	Clinical Research Network
	Monitoring/Audit visits	- Plan and prepare individual patient files/notes for site-visit monitoring and audit visits - Participate in external and internal monitoring and audit visits - Resolve queries post monitoring and audit visit -	Clinical Research Network
	Protocol Amendments	- Work with the study teams to prepare (regulatory) local documentation to submit protocol amendments through IRAS for processing within CSP - Work with study teams to update study files and implement revised documents following amendments (site file) - Participate in in-house meeting to discuss protocol amendments	Clinical Research Network
	Local Financial Management (but not making payments)	- Work with Trust R&D offices to raise and resolve financial queries about local study conduct - Work with study teams to organise payment of sites where appropriate (e.g. GP practices) - Organise payment of study participants where appropriate -	Clinical Research Network
	Other Study Administration	- Maintain site file/ensure file is maintained - Work with study teams to compile and send annual report to local R&D office	Clinical Research Network Trust Research Capability Funding

	Activity	Task	Funding
	Data collection	- Document eligibility/non-eligibility in screening log/ notes/ database - Review and record adverse events and toxicity - Review and record serious adverse events - Obtain, review and record results of treatment/visits/ investigations - Complete Case Report Forms and other listed forms as appropriate - Review and obtain signatures for Case Report Forms - Photocopy, send and file study documents - Resolve routine data queries	Clinical Research Network
Study Closure	Procedure for study closure	- Inform local R&D office of study closure - Review study documents prior to archiving - Collect study documentation and materials from wards/departments/units - Pack and label study materials for archiving - Organise final shipment of study specific samples - Prepare for sponsor close out visit	Trust Research Capability Funding

These tasks include activities conducted by departments supporting the conduct of clinical research in the NHS such as pharmacy, radiology, pathology, medical physics, nuclear medicine etc.

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 Annex A, 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 an Annex A, Part B Research cost activity.

Activities listed in Table 2 must be included on research funding application forms in the appropriate section. For non-AMRC funded studies, the cost will be met by the funder of the research award and should be included in the research costs section of the application form.

4. Application advice services/NHS permissions

Q4.1 I will be using services provided by the Research Design Service (RDS) in putting together a research grant application. Do I need to include RDS' costs on my grant application?

A. No. RDS is funded centrally by the NIHR to provide advice to researchers so there is no need to include the cost of this research activity on a research grant application.

Q4.2 I will be seeking advice from the Health Research Authority (HRA). Do I need to include the cost of time these organisations spend advising me on my study?

A. No. There is no need to include the cost of the time this organisation spends advising you on your study as the services are funded through other funding streams.

Q4.3 I will be using the NIHR Coordinated System for gaining NHS Permission (NIHR CSP). I think that this is an NHS Support activity, but do I need to include the cost within the NHS Support Cost section of my grant application as the service is co-ordinated nationally by the NIHR CSP Unit?

A. Obtaining NHS permission using the NIHR Coordinated System for gaining NHS Permission process is an NHS support activity but there is no need to include this cost on the research grant application as the services are funded through other funding streams.

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. Yes, Clinical Trials Unit costs should be included. However, it is expected that costs are proportionally related to the design and size of the study proposed. Funders also do not expect to fund a cost they have already funded or which has already been funded through another source. Most funders have their own rules about what should or should not be included on the application form in relation to studies run through Clinical Trial Units to which they contribute infrastructure funding. You will need to check with the Clinical Trials Unit and with the funder about which costs should be included.

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 and would need to be picked up from funding that the Trust receives 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.

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, 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 an NHS patient care service, it should be met by the research funder.

Q7.3 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 obtaining 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.

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.

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.

In England, NHS Support is provided mainly via CRNs. If University employed staff take consent, reimbursement will usually need to be sought from the appropriate Network, but NIHR funding for Biomedical Research Centres and Units and ECMCs also include some Support funding and may be an appropriate funding source for studies taking place in these organisations.

Q7.6 Does recruitment for funded projects have to be done by Clinical Research Network research nurses?

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 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.

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 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.

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, the time spent would constitute a treatment cost, funded through normal commissioning payments.

However, when research sites are anticipating opportunistic recruitment into studies if 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.

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 an NHS Support activity?

A. 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. 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.

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 application 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 application as a Part B Research activity and funded by the grant funder unless the funder is an eligible AMRC member (or other eligible charity in Northern Ireland). 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 or other eligible charity 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, in England, need to approach the local Clinical Research Network for the resources required.

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 an 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 (FAQ 3.1, Table 2).

10. Patient travel

Q10.1 If my study is trialling 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 should form 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. NIHR provides a range of e-learning courses that are free to access. NIHR also provides training events locally. See Activity 8 in table 3 below.

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 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.

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 an 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 an 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. 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 an 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 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.

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 an NHS Treatment Cost, but the drug has to be repackaged locally at each recruitment site specifically for the trial. Is the repackaging an NHS Treatment Cost even though a NHS site would not need to repackage the drug once the study ended even if it 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 an NHS organisation repackages a drug locally for its own use, the activity is an 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 the active drug is an 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.

Q18.4 How should Secondary Care Pharmacy activities in relation to Clinical Trial Management be attributed?

A. Table 3 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.

Table 3 Summary detail of attribution for tasks related to local management of IMP as applied to NIHR CRN Portfolio studies

Activity Group	Attribution	Funding for the Activity	
		AMRC funded studies	Non AMRC funded studies
1. All costs associated with Placebos	Research Cost Part A	Research Grant	Research Grant
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	Research Grant	Research Grant
	Exception: Treatment cost if assembly is part of standard treatment (e.g. standard treatment = chemotherapy assembled by an external contracted supplier)	NHS	NHS
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	Clinical Research Network (or other NIHR infrastructure where applicable)	Clinical Research Network (or other NIHR infrastructure where applicable)
	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)	NHS	NHS

Activity Group	Attribution	Funding for the Activity	
		AMRC funded studies	Non AMRC funded studies
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	NHS	NHS
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	Clinical Research Network (or other NIHR infrastructure where applicable)	Clinical Research Network (or other NIHR infrastructure where applicable)
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.	NHS	NHS

Activity Group	Attribution	Funding for the Activity	
		AMRC funded studies	Non AMRC funded studies
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	Research Grant	Research Grant
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	Clinical Research Network (or other NIHR infrastructure where applicable)	Research Grant
8. Training which is study specific i.e. over and above usual expected levels of competence for a research site	Research Cost Part A	Research Grant	Research Grant

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