Annex B – Northern Ireland

Frequently Asked Questions for Northern Ireland

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 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.

Q2. How are the NHS Support Costs of non-commercial studies funded in Northern Ireland?

A. NHS Support Costs are included as part of HSC R&D Division awards provided any NHS Support Costs are detailed and verified as part of the normal HSC R&D Division application/evaluation process. For research studies adopted onto the Northern Ireland Clinical Research Network (NICRN) or the Northern Ireland Cancer Trials Network (NICTN) research portfolios, NHS Support Costs will be met by HSC R&D Division either through the deployment of existing network resources, or by additional direct payments. For non-network studies HSC R&D Division may fund the HSC Support Costs for eg Research Council, NETSCC, or AMRC awards providing these are agreed by HSC Division during the application process on a case by case basis. However, the funding of HSC Support Costs, in any one year, is always subject to budgetary constraints. Equally clinical network resources are finite. Therefore in all cases individual requirements must be discussed with the relevant co-ordinating centre, Trust Research Office or HSC R&D Division at the earliest opportunity. NHS Support Costs not funded by HSC R&D Division should be met by the study sponsor or funder.

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

A. NHS Treatment Costs associated with research studies, including Excess Treatment Costs are the responsibility of the NHS and should be funded through normal commission arrangements. However, given the pressures on clinical resources it is essential that researchers wishing to undertake non-commercial research discuss their proposals with Trust Research Offices at the earliest possible opportunity.

[1] Attributing revenue costs of externally funded non-commercial research in the NHS guidance published in 2005 by the Department of Health England.

Q4. 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 ARMC, or that has signed a partnership agreement with HSC R&D Division, data collection may be performed by existing members of staff employed in the HSC where there is sufficient capacity. Grant applications will need to identify the resources required to perform this activity within the research costs section of the relevant application form. It is essential that applicants discuss these requirements with the relevant HSC organisation at the earliest opportunity to ensure there is sufficient capacity to deliver the relevant activity.

Q5. My charity is not a member of the AMRC, can I benefit from the new arrangements to reduce research costs that my charity has to fund?

A. Northern Ireland based charities have the option of entering into a partnership agreement with the HSC R&D Division whereby the research costs identified in Part B of Annex A will not be recovered from your charity. Partners are required to demonstrate that the charity funds HSC research and that any such research is subject to a rigorous peer review process.

Q6. I will be seeking advice from the National Research Ethics Service (NRES) and HSC Trust Research Offices. Do I need to include the cost of time these organisations spend advising me on my study or 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.

Q7. 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.

Q8. 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.

Q9. 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 funders 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.

Q10. 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 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.

Q11. 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. 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.

Q12. 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.

Q13. 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.

Q14. 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.

Q15. 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.

Q16. 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 fundi

Q17. 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 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.