Managing Research Costs for Studies recruiting in Northern Ireland

Introduction

This guidance relates to the processes for managing funding associated with health and social care research studies taking place in Northern Ireland. You should read this guidance if you are involved with the preparation of a funding application for a study that proposes to recruit participants through a health and social care (HSC) organisation in Northern Ireland, or an organisation commissioned to provide services on behalf of the HSC [1] - this could be as a Chief Investigator, local Principal Investigator/Co-Applicant, representative of Sponsor or partner organisation e.g. research finance representative, research governance representative, study manager, project manager etc. The funding of Excess Treatment Costs (ETCs) and Service Support Costs (SSCs) is dealt with herein.

1. AcoRD Guidance and Research Costs

It is important that the costs of health and social care research in the United Kingdom are properly identified and appropriately funded by the right organisations. For this purpose, guidance on **A**ttributing the **c**osts **o**f health and social care **R**esearch and **D**evelopment (AcoRD) was introduced in 2012. The AcoRD guidance provides a framework for the NHS and its partners to identify, attribute and recover the various costs associated with research in the NHS, in a transparent, robust and consistent manner. It applies to all NHS[2] research covered by the UK Policy Framework for Health and Social Care, and most funders will ask applicants to identify and attribute costs in line with the guidance. The principles of cost attribution are similar across all four nations of the UK; some differences in certain aspects of the funding mechanisms operating in England, Northern Ireland, Scotland and Wales do exist; further information can be found in the country-specific guidance (England; Scotland; Wales).

Researchers wishing to access funding for their research in the UK must attribute the costs across three categories:

- **Research costs**: research costs are met by the research funder, unless that funder is an Association of Medical Research Charities (AMRC) member charity. Where the funder is an AMRC member charity, Research Costs are further categorised as Part A (paid by the research funder) and Part B (see Section 2 and Figure 1 for details).
- **Support costs (sometimes referred to as Service Support Costs)**: support costs are generally met from the budgets of the government health funding organisations, either directly to the organisation incurring the costs, or through existing supportive infrastructure, such as research networks.
- **NHS treatment costs**: NHS treatment costs are funded by the NHS through normal commissioning arrangements for patient care. Excess Treatment Costs are dealt with below.

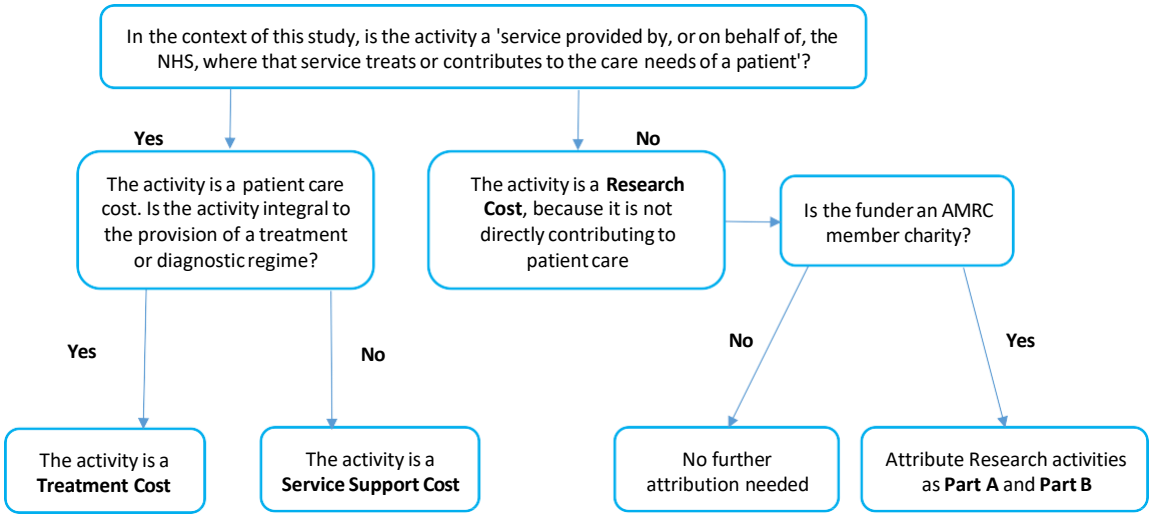
[1] For example: Health and Social Care Trusts (HSCTs), general medical practices, general dental practices, community organisations, residential care organisations, or charitable organisations.

[2] For the purposes of this document, references to the NHS also include the HSC

AcoRD training and documentation include specific examples of these costs, and provide detailed guidance on how to attribute all the costs of health and social care research. E-learning provided by the National Institute for Health Research (NIHR) is available here.

Figure 1 illustrates the attribution process.

Figure 1 Attribution Flowchart



Terminology explained:

Research costs are the costs of the research and development itself that end when the research ends. They relate to activities that are being undertaken ***to answer the research question.***

Support costs are the additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided. They are often associated with safety.

NHS treatment costs are the costs of patient care, which would be incurred if the care/treatment under review became standard care. For the purpose of attributing costs during a research study, an assumption is made that the care/treatment under review will become standard, but whether this happens in practice is dependent on the results of the research and on the desire of the health service to commission it.

2. Sources of funding for studies recruiting in Northern Ireland

In Northern Ireland, the costs of non-commercial research are met from a number of sources, depending on the type of cost involved:

- **Research costs**: research costs are met by the research funder, unless that funder is an Association of Medical Research Charities (AMRC) member charity. Where the funder is an AMRC member charity, the Research Costs are further categorised as Part A and Part B. Where the research activities are categorised as Part B, and are being carried out by existing members of staff employed by the HSC, a Clinical

Research Network or by an organisation funded by the HSC to provide patient care services on its behalf, these are supported by the Department of Health (NI) through HSC R&D Division funding. Part A activities are funded by the research funder. Further details of Part B activities can be found here.

- **Support costs**: support costs may be met from the HSC R&D budget, administered by the HSC R&D Division of the Public Health Agency; resources may be provided by the HSC R&D Division via research infrastructure, such as the Northern Ireland Clinical Research Network (NICRN) or the Northern Ireland Cancer Trials Network (NICTN), or additional resource may be provided directly to the organisation incurring the costs.
- **NHS treatment costs**: NHS treatment costs may be funded by the HSC through normal commissioning arrangements for patient care.

3. Excess Treatment Costs

A research study may result in care that differs from standard treatment, or is delivered in a different location from where it would normally be given. The associated NHS treatment costs may be less, or may be greater, than the cost of standard treatment. If greater, the difference between the NHS treatment costs and the cost of the standard treatment is referred to as the Excess Treatment Cost.

These costs are part of the NHS Treatment Cost, not the NHS Support Cost, and would be met as part of the normal commissioning process if the treatment under investigation became standard care. It is therefore important that researchers identify such costs and initiate early discussions with relevant commissioning organisations about the cost implications and potential implementation of the treatment under investigation. There are also circumstances where the cost of care in a research study results in a treatment cost saving. It is also important that these are recognised and recorded.

Focus on Excess Treatment Costs

Excess Treatment Costs are the difference between the total treatment costs and the cost of standard treatment. Excess Treatment Costs should be identified at an early stage of a study, preferably prior to an application for research funding being submitted. Researchers should seek to minimise these through study design and management of costs.

In Northern Ireland, the funding of Excess Treatment Costs incurred during a research study may be met from the R&D budget managed by HSC R&D Division. The current process of approval of Excess Treatment Costs for studies recruiting participants in Northern Ireland is described below.

Will your study run in more than one Devolved Administration?
Whilst the processes for managing Excess Treatment Costs in the Four Nations has been aligned, there are differences in how they are approved and administered. If your study plans involve recruitment in more than one of the UK nations, ***you should refer to the country-specific guidance*** (England; Scotland; Wales).

4. Eligibility for ETC and SSC funding in Northern Ireland

Eligibility of studies for ETC funding and SSC support/funding will be considered on a case by case basis, and will take into account the following:

- Eligibility for adoption by a Northern Ireland research delivery support body (e.g. NICRN and NICTN).
- Eligibility for support by a national funder in another devolved administration e.g. NIHR CRN.
- Eligibility for subvention funding through the Public Health England ETC subvention process.

5. Mechanisms of Approval

Non-commercial research Sponsors have a responsibility to ensure that the activities to be undertaken through studies are appropriately costed and attributed. The **S**chedule **o**f **E**vents **C**ost **A**ttribution **T**emplate (SoECAT) is a cost attribution tool that has been developed in partnership with charity funders and research sponsors to provide a standardised approach to the recording of different costs associated with clinical research, and attributing them accordingly. As part of their funding applications to most funders, researchers will now be required to complete a SoECAT. It is the responsibility of the Sponsor to ensure that the SoECAT is completed.

Under new arrangements, sign off via the SoECAT by an AcoRD Specialist is required to confirm the study attribution complies with AcoRD guidance. Completion of the SoECAT will be requested by research funders during the funding application process, and approved before funding is agreed separately.

The SoECAT will be reviewed and approved by an AcoRD Specialist in the Lead Nation where the Sponsor is based, and accepted by other nations where participant recruitment is proposed.

6. Review Processes

- If a study is led **from NI**, the SoECAT will be reviewed and approved locally by an AcoRD Specialist:
    - Willingness to sponsor the study should be sought from and confirmed by an appropriate person with the Sponsor organisation.
    - A representative of the Sponsor organisation (probably the CI) should complete the SoECAT in consultation with appropriate stakeholders (research

development, research grants teams and/or, research finance etc) and representatives of healthcare the lead delivery organisation(s)/recruiting site(s) (research managers, service delivery leads, PIs etc).
    - Contact should be made with HSC R&D Division to identify an AcoRD Specialist to review the SoECAT.
    - Contact should also be made with any research delivery support organisation (e.g. research networks) that may be involved to discuss the support required for delivery of the study.
    - A minimum of **ten working days** before the grant deadline will be required by the AcoRD Specialist to review a completed SoECAT, accompanied by the application and study protocol.
    - The SoECAT will be reviewed and, if approved, signed off electronically by the AcoRD Specialist.
    - The SoECAT can then be submitted to the funder in accordance with the funder's processes.

- If a study is led **from outside NI**, and an organisation in Northern Ireland is being proposed as a site,
    - The SoECAT will be reviewed and approved in the Sponsor Organisation's lead nation, and will be considered as part of the funding approval process.
    - Once funding is approved, and sites are being identified, the SoECAT will form part of the Local Information Pack being considered as part of Capacity and Capability Review at site level.
    - To discuss the support required for delivery of the study, contact should be made with HSC R&D Division and with any research delivery support organisation (e.g. research network) that may be involved.
    - In some circumstances, further information may be requested to allow an appropriate decision about resources to be made.

Resource Management and Funding Arrangements

- If **any** study proposes that participants are recruited through sites in NI, the Trial Manager and local Co-Investigators/Principal Investigators should make the following contacts:
    - HSC R&D Division (researchsupport@hscni.net) to discuss the study resource requirements.
    - The appropriate research delivery support infrastructure (e.g. Northern Ireland Clinical Research Network, Northern Ireland Cancer Trials Network) to discuss support and/or portfolio adoption.
    - The Research Office(s) in the relevant organisation(s) (e.g. HSCTs) to discuss support, resource requirements and local governance approval requirements.
- The local infrastructure may share details of requests in order to coordinate local support and set-up.

- The funding of **Excess Treatment Costs** will be managed centrally by the HSC R&D Division of the Public Health Agency.
- Funding is subject to availability of budget and local feasibility considerations.

An ETC Application Form will be used as the tool for ETC approval in NI. An ETC Application Form must be completed by any organisation wishing to claim ETCs. It is the responsibility of the Study Lead to ensure that ETC Application Forms (which can be fund on our website) are completed and submitted to HSC R&D Division.

- For the majority of eligible studies, **Support Costs** may be funded through existing research infrastructure such as the Research Networks.
- If support cannot be provided through the deployment of existing resource, HSC R&D Division will consider other options for delivery of the study at NI sites on a case by case basis.
- In some circumstances, further information may be requested.

Good Practice

- All applications should be shared with, discussed and agreed with relevant HSCT Research Office(s).
- Any application involving service delivery organisations outside of the HSCTs should be shared with, discussed and agreed with appropriate representatives of the organisation.
- All applications for studies proposing to recruit patients in NI with potential ETCs or Support Costs should be discussed with HSC R&D Division (researchsupport@hscni.net).

7. During your Study: Financial Management Processes

- Once agreed, the Service Support Costs and Excess Treatment Costs will be managed through normal HSC R&D Division payment processes, which will vary depending on the organisation receiving costs.
- Alternative arrangements for managing payments may be put in place in exceptional circumstances.
- Budgets will be based on proposed recruitment rates, and payments calculated on the basis of the per patient value from the SoECAT.
- An appropriate representative of the delivery organisation will verify the recruitment information on which payments are based.
- Evidence in support of recruitment figures must be available if requested.
- To facilitate this, study teams should consider the use of EDGE for study management, regardless of adoption by local clinical research networks.
- It is hoped that, in the future, this system can be replaced with an automated payment system based on recruitment data entered into the Local Portfolio Management System.
- Further details of the operational processes are provided in the document *Financial Management of Costs Associated with Research in Northern Ireland*.