

# **Attributing revenue costs of externally-funded non-commercial research in the NHS (ARCO)**

**Gateway reference: 5956**

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## Introduction

1. This document aims to clarify the distinction between Research Costs, NHS Support Costs and Treatment Costs in relation to activity specified in the research application/protocol; and to help the attribution between the NHS and the external funder of:

- patient-related activity;
- clinical staffing;
- placebos and medicines.

2. Although research in primary and community care settings may have specific features, these notes are intended for all NHS research covered by the *Research Governance Framework for Health and Social Care*. They should be read in conjunction with HSG(97)32: *Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS*.

## Basic principles

3. The costs of R&D in the NHS are split into three categories:

- Research Costs are the costs of the R&D itself. They include the costs of data collection and analysis and other activities needed to answer the questions that a piece of R&D is addressing. They can include pay and indirect costs of staff employed to carry out the R&D (but see below on NHS Support Costs), registration of trials, and costs associated with making the results accessible.
- NHS Support Costs include the additional patient-related costs associated with the research, ***which would end once the R&D activity in question had stopped***, even if the patient care service involved continued to be provided.<sup>1</sup> These costs might cover items such as extra patient tests, extra in-patient days, and extra nursing attention. NHS Support Costs might also cover informed consent obtained from participants where active treatment is delivered as part of the research, or where consent is necessary in the context of the NHS retaining its duty of care. NHS Support Costs may also cover the research activity, such as managing and undertaking a portfolio of projects, of Research Active Professionals employed in the NHS.<sup>2</sup>
- Treatment Costs are the patient care costs ***which would continue to be incurred if the patient care service in question continued to be provided after the R&D activity had stopped***. Where patient care is provided that is either an experimental treatment or a service in a different location from where it would normally be given and it differs from the normal, standard treatment for that condition, the difference between the total Treatment Costs and the costs of the standard treatment (if any) is called Excess Treatment Costs. These costs are nonetheless part of the Treatment Costs, not an NHS Support or Research Cost. The term Treatment Costs covers all types of patient care services, including diagnostic, preventive, continuing-care and rehabilitative-care services, and health promotion.

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<sup>1</sup> In Scotland known as Service Support Costs.

<sup>2</sup> In Scotland known as Investigator Support funding.

4. Research Costs will be met by the research funder(s); NHS Support Costs will be met from NHS R&D Support Funding<sup>3</sup>; Treatment Costs will normally be met through commissioning arrangements for patient care.

## Patient-related activity in R&D

5. Will the results or outcome of the activity (test, measurement or procedure) be needed for the care of the participants in the research? As part of the prudent monitoring of the research activity, will the results or outcome be reported to the participants' clinicians where necessary to alert the clinician to clinically significant events (e.g. abnormal test results)?

<b>Yes</b>	<b>NHS Support<sup>1</sup> or Treatment Cost</b>
Systematic reporting arrangements will be in place for normal and/or abnormal test results from this activity; new and amended protocols will need to state the rationale and route of reporting.	
<b>No</b>	<b>Research Cost</b>
Results will be anonymised and unlinked, and/or the protocol states that the individual results of this particular activity will not be reported back to study participants or their clinicians.	

## Clinical staffing

6. NHS-funded staff (doctors including GPs, dentists, nurses, pharmacists, allied health professionals and others) may be involved in R&D. Are the staff:

<b>Engaged in research alongside their other clinical duties</b>	<b>NHS Support Cost<sup>2</sup></b>
<b>Employed specifically for a research project</b>	<b>Research Cost</b>

Specific Issues:

<b>Identifying patients eligible to participate, explaining the study to participants, obtaining informed consent</b>	<b>NHS Support Cost<sup>1</sup> (please see Section 1)</b>
<b>Providing the intervention</b>	<b>Treatment Cost</b>
<b>Collecting clinical data for research</b> (unless the collection of data is onerous and accounts for a significant proportion of a member of staff's time, or the professional is not normally deployed in the service setting, e.g. consultant on a home visit)	<b>NHS Support Cost<sup>1</sup></b> <b>(Research Cost)</b>
<b>Following up:</b> - Contemporaneous with clinical care - Not contributing to individual patient management	<b>Treatment Cost</b> <b>Research Cost</b>
<b>Training:</b> - To carry out the treatment under investigation - time out being trained - NHS staff time in training clinicians - non-NHS staff time in training clinicians - Where the new skills are required to carry out the R&D activity	<b>Treatment Cost</b> <b>Treatment Cost</b> <b>Research Cost</b> <b>Research Cost</b>

<sup>3</sup> In Scotland known as NHS Support for Science funding.

## Placebos and medicines

7. Medicines as interventions are normally treatment costs, but industry often provides a contribution in cash or kind.

**Clinical trials where a medicine may be compared to a placebo, and/or other active drugs already used in the condition concerned.**

Cost of the medicine being researched	If not funded by Industry, Treatment Cost
Cost of the placebo itself	Research Cost
Cost of active comparator medicine(s)	Treatment Cost
<b>Additional cost of formulating, disguising, storing or distributing placebo or medicine</b>	
When undertaken or incurred on NHS premises	NHS Support Cost <sup>1</sup>
On non-NHS premises	Research Cost

If the activities can be undertaken conveniently in an NHS hospital pharmacy along with normal routine pharmacy preparation, storage and distribution, without incurring significantly greater cost than normal handling of other medicines, they may be included as **NHS Support Costs**<sup>1</sup>.

However, if the activities are particularly time-consuming and involve, for example, formulating placebo injections, and/or manufacturing and assembly in a unit with an “investigational medicinal product” authorisation, then they are a **Research Cost**.

8. The Medicines for Human Use (Clinical Trials) Regulations 2004

The cost of compliance with the above is an eligible NHS cost. If no other funding source is available, this cost can be met from NHS R&D Support Funding<sup>3</sup>.

## Other costs

9. NHS Support Costs include provision for researchers employed through a contract with the NHS who work up proposals into cogent studies (commonly called pre-protocol work). This includes activities up to consideration by the funder, and includes drafting the protocol and preparing the application for ethical review.<sup>2</sup> From the time the funder issues a grant-awarding letter, further non-patient-related activity to begin the work is considered a Research Cost.

10. NHS R&D Support Funding<sup>3</sup> may also cover revenue costs of maintaining the NHS base for research in the NHS. These costs include, for example, fees paid by the NHS for “good clinical practice” inspections in relation to clinical trials of medicinal products, as required under the Medicines for Human Use (Clinical Trials) Regulations 2004.

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