Guidance on Excess Treatment Costs
NHS England has been working in consultation with the Department of Health and other key stakeholders to develop an NHS England guidance on Excess Treatment Costs (ETCs).
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Equality and Health Inequalities statement
Promoting equality and addressing health inequalities are at the heart of NHS England’s values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and

- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Prepared by: Joint NHS England and Department of Health Research and Development Directorate Working Group

The National Health Service Commissioning Board was established on 1 October 2012 as an executive non-departmental public body. Since 1 April 2013, the National Health Service Commissioning Board has used the name NHS England for operational purposes.
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1 Introduction

The value of Excess Treatment Costs is not a large sum in the context of overall NHS funding but anecdotal evidence suggests that the (non) payment of Excess Treatment Costs has become a point of friction between providers and commissioners, both of whom want to support research in the interests of healthcare for patients.

This guidance on meeting Excess Treatment Costs resulting from research is provided by NHS England for Clinical Commissioning Groups (CCGs) and commissioners of specialised services. It relates specifically to non-commercial research (i.e. research funded by the National Institute of Health Research (NIHR), other areas of central Government including Research Councils, NIHR non-commercial Partners and also Investigator-initiated, commercial-collaborative studies (Industry-funded, non-industry sponsored studies). It covers the following topics:

- Meeting the costs of research
- Excess Treatment Costs
- Excess Treatment Savings
- The responsibilities of commissioners, providers and researchers in the funding of Excess Treatment Costs

Where there are Excess Treatment Costs arising from public health research, guidance issued by Public Health England (PHE) should be followed.

NHS England guidance should be read in conjunction with the following policy documents:

- Health Service Guideline - HSG (97) 32
- Attributing costs of health and social research and development (AcoRD) - Department of Health (October 2012)

This guidance reflects the policies and principles set out in these documents in relation to Excess Treatment Costs. It does not seek to change these, but is intended to provide guidance on how such costs should be identified and how the payment of those costs can best be managed by NHS bodies, in accordance with the established policy.

2 Background

Research evidence can help transform the way the NHS cares for people, leading to better health outcomes. It may involve developing and evaluating new diagnostics, more effective drugs and other therapies, or different ways of delivering services. Research also contributes to promoting the economic prosperity of the country.

The National Institute for Health Research (NIHR) is the main funder of research (and research infrastructure) in the NHS. The NIHR is funded by the Department of Health and its focus is on improving the health of patients and the public, and working with the NHS to ensure that NHS Research and Development (R&D) is a world-class environment for conducting and using NHS research. Other major funders of research in the NHS include the Medical Research Council, medical
research charities, and pharmaceutical or other companies. The Health Research Authority (HRA) promotes and protects the interests of patients and the public in health research, and ensures research is ethically reviewed and approved. It does not fund research.

Only around 20 percent of applications made to funders of medical research are awarded funding, and only a proportion of those funded will impact NHS treatment costs. Funders are very mindful of the quality and scientific merit of the study and the extent to which it offers potential future value for money to the funder and the NHS, as well as taking into consideration the funding priorities of government and the NHS, and their own research agenda.

In determining priorities for research, research funders engage with key stakeholders in the NHS (including NHS England), public health, policy makers, and health professional organisations such as the Royal Colleges, patient groups and charities. In addition, the NIHR takes account of recommendations for research from organisations such as the National Institute for Health and Care Excellence (NICE), and the Cochrane Collaboration.

An illustration of the funding application process can be found at Appendix 1.

3 Meeting the costs of research

Under the National Health Service Act 2006 NHS commissioners have the power to conduct, commission, and assist the conduct of research by themselves or others. This power expressly includes the power to assist by providing financial assistance or making other resources available.

Under the Health and Social Care Act 2012, NHS England also has a general statutory duty to promote and support research on matters relevant to the NHS when exercising its core functions. It also has a responsibility to ensure that the treatment costs of patients, involved in non-commercial research, funded by the Government and research charities, are met.

These statutory powers and duties are reflected in the Department of Health’s Health Service Guideline HSG (97) 32 which sets out responsibilities for meeting the costs of research including patient care costs resulting from research and development, and in its 2012 guidance ‘Attributing the costs of health and social care research and development’, known as AcoRD that provided greater clarity on attributing the costs of health and social care research studies.

The Secretary of State’s Mandate to NHS England also reflects these powers and duties and includes a specific requirement to ensure the payment of treatment costs for NHS patients taking part in research. The Mandate to NHS England for 2015–16 says that it has to:

“…ensure that the new commissioning system promotes and supports participation by NHS organisations and NHS patients in research funded by both commercial and non-commercial organisations, most importantly to improve patient outcomes, but also to contribute to economic growth.”
This includes ensuring payment of treatment costs for NHS patients taking part in research funded by Government and Research Charity partner organisations.” (page 27, paragraph 7.2)

As part of their authorisation process, CCGs were required to make a declaration about their understanding of, and compliance with, their statutory obligations to support research. This declaration states:

“We declare that our CCG understands and will comply with our statutory responsibilities regarding promoting research; and that we are committed to following the policy of ensuring that the NHS meets the treatment costs for patients who are taking part in research funded by Government and research charity partner organisations.” (pages 2-3)

In addition, the NHS Standard Contract 2015–16, clause 26.4, specifically states that ‘In respect of any Approved Research Study the Parties must have regard, as applicable, to NHS Treatment Costs Guidance’

Health and social care research is a core NHS activity and, as such, the NHS is committed to supporting a portfolio of high quality commercial and non-commercial funded research.

4 Understanding the costs of research

In England, funding for the costs of non-commercial research is met from a number of sources. Researchers wishing to access funding for their research must therefore attribute the costs across three categories:

- **Research costs**: research costs are met by the research funder
- **Support costs**: resources are generally provided by the NIHR usually via the Local Clinical Research Networks
- **NHS treatment costs**: NHS treatment costs are funded by the NHS through normal commissioning arrangements for patient care

AcoRD provides specific examples of these costs (see Appendix 2 for relevant extract) and provides detailed guidance on how to attribute all the costs of health and social care research including Excess Treatment Costs for non-commercial research

**Terminology explained:**

**Research costs** are the costs of the research and development itself that end where 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
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 NHS’ desire to commission it.

5 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 Costs. These costs are however part of the NHS Treatment Cost, not an NHS Support Cost, and should be met as part of the normal commissioning process. It is important, therefore, to identify early on the commissioning route for treatments delivered as part of a research study (see section 8).

Terminology explained:

Excess Treatment Costs are the difference between the total treatment costs and the cost of standard treatment.

Excess Treatment Costs are part of treatment costs and therefore normal commissioning arrangements apply.

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.

6 Excess Treatment Savings

Clinical research can also generate substantial cost savings for the NHS. For example, over a two-year period (April 2011 to April 2013), the cost savings to the NHS of haemophilia trials and an evaluation of clinical research activity across the Kent and Medway Health Economy identified an overall saving of nearly £400,000.

Despite this, the tendency has been to focus on the additional costs of supporting clinical research rather than the potential savings. Savings made during the course of a study are known as Excess Treatment Savings. These may be made on patient care costs during a study where the cost of care/treatment under review is less than standard care or where industry provides the drugs or devices under review.

Commissioners should consider the extent to which providers have offset any Excess Treatment Costs incurred by a study against treatment savings incurred in
their other on-going studies when determining whether to provide additional funding for Excess Treatment Costs. Commissioners should not seek to recover savings, resulting from participation in research, from providers without consideration of the Excess Treatment Costs they are incurring and the need to incentivise provider participation in research.

7 Subvention funding

In exceptional circumstances, where Excess Treatment Costs are very high, the Department of Health Research and Development Directorate (DH RDD) may provide a contribution towards funding them via what is referred to as subvention funding.

Applications for subvention funding can only be made by a Chief Investigator of a research study once they have received notification of funding (at least in principle) from the research funder. Further guidance on applying for subvention funding can be found in the AcoRD guidance.

8 Accessing funding for Excess Treatment Costs

Funding to pay for Excess Treatment Costs is contained within National Tariff for those services for which there is a Tariff price. Where there is no Tariff covering a service, provider organisations should clarify their funding and contractual position with their commissioners. As health services can be funded via a number of organisations including Clinical Commissioning Groups, Specialist Commissioning and Local Authorities, it is important that the commissioning route for treatments provided within a research study is understood at the outset so that the correct commissioner(s) are approached.

Circumstances for applying for and accessing funding for Excess Treatment Costs may differ between commissioners or in each area as NHS localities have sought to develop their own processes. Where research active provider organisations make a request to commissioners for additional funding for Excess Treatment Costs, commissioners will usually expect providers to:

- demonstrate that Tariff or contractual payments for activity are insufficient to cover the cost of the excess treatment, and
- savings accrued as a result of lower NHS Treatment Costs for other ongoing research studies are insufficient to cover the shortfall.

The introduction of the costing template should help providers to calculate these figures.

The identification and selection of suitable NHS organisations to participate in a research study is a joint decision between the sponsor of the research and the NHS organisation that should be made once funding is in place, when the capacity and capability of the provider organisation can be taken into consideration. However, it is important that researchers engage with the NHS well in advance of the study commencement so that adequate financial planning can take place within provider and commissioning organisations. Research funders usually seek assurance from
researchers that such engagement has taken place before making research funding available.

The Department of Health expects researchers to engage with the R&D office for their employing NHS organisation or their NIHR Local Clinical Research Network prior to making their research application to ensure that NHS costs have been assessed correctly.

Where it is possible to identify potential research sites at the funding application stage, the researcher should seek to identify the capacity and capability of the site(s) to undertake the research as well as consider the availability of financial support. Researchers should contact the Local Clinical Research Network, which provides an Early Contact and Support Service for researchers, to facilitate study set up. The employing NHS organisation R & D department will also be able to provide support. NHS commissioners and providers may find it helpful to establish a formal mechanism that enables commissioners to be aware of the research portfolio of providers and any proposed studies.

Despite best efforts, it will not always be practicable for researchers to engage with all potential NHS organisations likely to be involved in a research study prior to the research funding application being submitted, particularly if the study is being undertaken across multiple centres. Commissioners cannot therefore expect to be consulted in every single case, on the development of all research studies for which they are subsequently asked to fund Excess Treatment Costs. Commissioners and their providers cannot refuse to meet Excess Treatment Costs, on the sole basis of affordability or prioritisation, where a legitimate funding request for these costs is submitted for a research project that has been awarded research funding by NIHR or one of its research partners.

To arrive at the correct cost attribution, it is important to recognise that the NHS bears the cost of caring for its patients even when they are involved in a research study. AcoRD provides detailed guidance on attributing costs.

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.

Commissioners in NHS England Regional Teams, and in CCGs, should be aware of their local or regional approaches to funding Excess Treatment Costs. In some areas, joint arrangements exist between a number of commissioning and provider organisations and most research active NHS organisations will have in place processes and procedures for applying for, reviewing and approving Excess Treatment Costs. Local Clinical Research Networks may be able to help facilitate understanding of the local processes in place in different areas.

Where joint arrangements and processes are not in place, commissioners are encouraged to work with their provider organisations, finance departments and R&D offices, to develop processes to manage Excess Treatment Costs. Commissioners and providers need to agree on the funding that is available within contracts to meet Excess Treatment Costs and agree a threshold up to which providers should fund
them from within the contract. Generally, this should be considered on the basis of net Excess Treatment Costs i.e. excess treatment costs less any excess treatment savings across the whole non-commercial research portfolio of the provider rather than on the basis of individual studies. The threshold needs to be set at a realistic level where the risk is shared between the commissioner and provider.

An example of a shared agreement between organisations for funding Excess Treatment Costs for non-commercial research studies can be found at Appendix 3.

Processes for managing and administering Excess Treatment Costs should be underpinned by the following good practice and principles:

- A clear, consistent and transparent approach that enables the commissioner to deliver their mandate responsibilities and is not a barrier to research which has already been through a competitive process and peer review;
- Transparent and auditable costing for treatment costs and savings produced on a consistent basis;
- Sharing of information between commissioners and providers in relation to the research portfolio;
- A process which is aligned, as far as possible, to decisions about funding research and financial planning in the NHS;
- Regular discussions take place between commissioners and providers, as part of usual contract monitoring, about the research portfolio and Excess Treatment Costs - this could include a process whereby provider organisations identify known forthcoming studies in discussions relating to annual contractual agreements;
- A defined process for the funding of Excess Treatment Costs and clear guidance on the roles and responsibilities of those involved in the process of attributing and costing Excess Treatment Costs;
- A system that ensures Excess Treatment Costs are not a disincentive to research nor a threat to service provision;
- A standard reporting system;
- A process whereby providers can, in conjunction with researchers, ask for reconsideration of a decision where an application to a commissioner for Excess Treatment Costs is unsuccessful;
- Inclusion of the responsibility for collecting and sharing data relating to Excess Treatment Costs in the contracting process or service level agreement;
- Named individuals with responsibility for managing the Excess Treatment Costs funding process in each organisation;
- The local process for managing Excess Treatment Costs funding is published on commissioner and provider websites;

9 Process for researchers applying for research funding and Excess Treatment Costs

The typical process that researchers/investigators will undertake in applying for research funding and securing Excess Treatment Costs funding can be found at Appendix 1.

When inviting sites to participate in their research study, researchers/investigators should supply sites with the following information:
• A costing template with:
  o Details of the Excess Treatment Costs/Excess Treatment Savings including cost/saving per patient per study
  o Details of any cost savings that may be generated during the study
  o Level of Excess Treatment Costs/Excess Treatment Savings generated in each year of the study
  o Targets for recruitment for each year of the study
• Details of any requests for subvention support
• A copy of the study protocol
• A copy of the grant application including full costing information (but excluding researcher CVs)

Providers require this information so that they can assess whether they are able to meet these costs from their existing resources or whether they will need to apply to their commissioners for additional resources. Guidance can be sought on securing funding for Excess Treatment Costs from Local Clinical Research Networks.
Appendix 1 - Application process for costs associated with research where Excess Treatment Costs & Excess Treatment Savings are identified

**NHS Commissioners**
Commissioning process: Commissioners and providers agree a mechanism for funding ETCs locally

**NHS Providers of secondary care:**
For **Primary care** (and where services are not provided by the NHS)
NHS Commissioners, CCGs, Specialist Commissioning

**NIHR CRNs**

**Higher Education Institutes**

**Researcher**
Researcher develops proposal:
- Research question
- Methodology
- Costings (including attribution of research, support and treatment costs)
Researcher engages with NHS to access funding for treatment costs

**Funder’s engagement with health system:**
- Advisory committee (commissioners, DH, charities, MRC)
- Strategic consultation
- Specialist consultation

**Research funder:**
- Guidance to researchers
- Question setting for commissioned research

**Outline application to funder (where required)**

**Internal review/peer review**

**Full application to funder**

**Additional questions**

**Rejected**

**Funding panel (VFM)**

** Asked to submit full application**

**Funding panel**

**Rejected**

**Funded with changes**

**Funded**

**Researcher applies for HRA approval (where study eligible) &/or ethical approval**

**Researcher agrees resources & financial requirements with NHS & Networks**

**Researcher makes required changes in consultation with stakeholders**
Appendix 2 - Extract from ‘Attributing the cost of health and social care Research & Development (AcoRD) Annex A’

List of common research activities attributed to the Research Costs, NHS Treatment Costs and NHS Support Costs

Activities that are attributed to Research Costs include:
The costs of activities listed in Part A should be funded in full by all grant funders. The costs of activities listed in Part B will also need to be funded in full by grant funders except where the funder is a medical research charity that is a member of the Association of Medical Research Charities (AMRC) and the activity is undertaken by existing staff employed by the NHS, NIHR Clinical Research Network or other organisations funded by the NHS to provide patient care services. Under these circumstances, the cost of the activities in Part B will be met by the Department of Health.

Part A
1. 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.
2. Study specific central trial co-ordination and management.
3. Patient randomization.
4. 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.
5. 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.
6. Patient follow-up where the follow-up is not a part of individual patient clinical management.
7. Cash reimbursements or payments to volunteers to participate in the study.
8. All costs associated with placebos including but not limited to producing, formulating, disguising, shipping, storing and dispensing placebos, including administering sham treatments, since these costs do not form part of the patient’s care and would not continue to be incurred once the study is finished.
9. Registration of trials, including MHRA clinical trial authorisation fees.
10. Data storage archiving of clinical research records.
11. Costs associated with making the results accessible.
12. Training where new skills are required to carry out the R&D activity, but not training in obtaining informed consent, or training to deliver the treatment under investigation.
13. Data analysis needed to answer the questions that the research study is addressing.
Part B
14. Local study trial co-ordination and management.
15. Data collection needed to answer the questions that the research study is addressing (including collecting data for and completing the report).
16. Regulatory preparation and compliance including obtaining ethical approval and complying with the Medicine for Human Use (Clinical Trials) Regulations 2004.
17. The time taken by Chief and Principal Investigators (CI and PI) to explain the study to professional colleagues, and to understand, the research elements of a study. For example the time taken to explain the criteria for patient eligibility or to explain the randomisation protocol.

Activities that are attributed to NHS Treatment Costs include:
1. Supplying and administering the medicine/device/therapy being studied.
2. Supplying and administering any active comparators - including medicines, devices or therapies, but not placebo or sham treatments.
3. Training of clinicians to deliver the treatment.
4. Investigations and tests which would continue to be incurred if the patient care service in question continued to be provided after the R&D study has stopped.
5. Patient follow-up where this is required as part of the clinical management of a patient. If the primary purpose of the follow-up is to inform the long-term evaluation of an experimental treatment, the activity should be attributed as a Research Cost. If the primary purpose of the follow-up is to monitor patient safety rather than efficacy, the activity should be attributed as an NHS Support cost.

Activities that are attributed to NHS Support Costs include:
1. The processing of the patient record to identify NHS patients who may be suitable to approach to ask if they wish to participate in a research project.
2. Obtaining informed consent from patients where the study is a health research study, taking place within the NHS.
3. Additional investigations, assessments and tests where the results are required by the patient’s care team to ensure patient safety and where arrangements are in place to feed the results back to the clinician.
Appendix 3 - Example of a model of good practice for funding Excess Treatment Costs for non-commercial research studies

Process for funding Excess Treatment Costs for non-commercial research studies

Introduction
Some commissioners and providers find it difficult to assess the extent of the likely demand for ETCs at the start of the financial year and have developed a local or regional funding stream to manage this process (referred to hereafter as ‘the collaborative’). This involves CCGs agreeing to a shared funding stream where funding is top-sliced from their budgets, and held centrally by a host organisation, with decisions on the awarding of ETCs being taken by the collaborative funding or executive group. The contribution from each CCG may be calculated in a number of ways including on the basis of the population they are responsible for and the level of research activity. Research activity is viewed on a portfolio basis rather than an individual study basis. Provider organisations agree with commissioners in advance the amount of treatment costs that the provider organisation will pay from funding awarded in the Contract with the provider only applying to the collaborative if net costs across the research portfolio exceed this. Some collaborations agree thresholds for individual studies where, if the costs for a study exceed the threshold, additional funding can be sought from the collaboration.

Funding process
The Chief Investigator, who is responsible for applying for grant funding, contacts the R & D office of their employing NHS organisation or the Local Clinical Research Network, for assistance in identifying costs relating to their research. The R & D team can help to make the distinction between different costs i.e. NHS support costs, Research costs, and NHS Treatment costs, and ensure they are attributed accurately. The Chief Investigator also contacts other provider organisations that they may wish to invite to participate in the study to discuss capacity and capability issues including financial implications.

Each R & D office maintains a record of all research applications that are likely to incur treatment costs or savings. Once a study is funded, the Chief Investigator formally invites provider organisations to participate in their research study. Where there are ETCs associated with the study, the researcher will need to provide information to enable the provider to approach commissioners for the additional funding. Researchers inviting provider organisations to participate in a research study should submit the following information, highlighting the level of ETC funding required:

- Full details of the ETC funding required including the cost per patient entered into the study;
- The ETC funding required for each financial year of the study;
- The number of patients to be recruited in each financial year of the study;
- Details of any subvention funding awarded by the Department of Health;
- A copy of the study protocol;
• A copy of the funding grant application, excluding personal data such as a CV;
• The Portfolio or IRAS ID number.

Activity for any funding required must be correctly attributed as a treatment activity in line with the AcoRD guidance (Department of Health 2012). The amount required should be the additional cost of the research treatment when the standard care cost has been subtracted.

Provider organisations, being invited to participate in a research study, should consider the ETCs of the study against the costs and savings across its portfolio and consider the need to request additional funding from commissioners. The relevant R & D office will validate the costings for the study. The provider reviews the costing calculations for the study and considers the funding requirements alongside other capacity and capability issues. If no additional resources are required from commissioners to meet the ETCs, and the site has the capacity and capability to conduct the study, the provider will notify the researcher that it is able to meet the ETCs and is able to participate in the study.

If additional resources are required to meet ETCs, the provider makes an application to the commissioner collaborative for additional funding by completing and submitting the collaborative host organisation ETC application form, available from its R & D office, providing evidence to support the application. The collaborative assesses the application for additional funding against its published criteria and makes its decision.

The Trust applying for the ETCs, and the NHS organisations incurring the costs, will receive confirmation in writing of the decision of the CCGs/collaborative. If the application has been rejected the letter will explain the reason for the decision. The provider notifies the researcher of the outcome.

**Payment of ETCs**
Payments for additional funding for ETCs will be made to the NHS provider responsible for the treatment, usually quarterly in arrears based on actual recruitment to its research portfolio.

Funding will be conditional on submission of up to date recruitment information.

**Reporting**
A quarterly report should be submitted to the collaborative that summarises recruitment to the study and spend against the allocated budget.