York Foundation Trust R&D Unit
Guidance Document
R&D/G07

Excess Treatment Costs Guidance for York Teaching Hospitals NHS Foundation Trust April 2019

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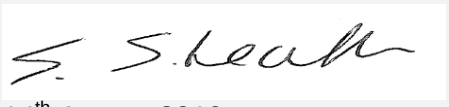
	Signature:	
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This Template will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	14th August 2019	N/A

Contents

1. Summary

This paper sets out the following model for Excess Treatment Costs (ETCs) related to non-commercial research studies (where NHS England Specialised Commissioning and Subvention arrangements are not applicable).

The YTHFT central ETC reserve will be utilised to cover ETCs along with directorate support via the following model

I. **Up to £1,000 per study per financial year**: The relevant Directorate will fund the first £1,000 for each study per financial year.

II. **Up to £5,000 per study per financial year:** The relevant Directorate will fund the first £1,000 and the remainder will be supported from a Trust central reserve.

III. **Greater than £5,000 per study per financial year:** The relevant Directorate and the Head of R&D will discuss such studies on a case by case basis to identify a way forward.

All studies with ETCs must have the Head of R&Ds approval to open. YTHFT will hold a small central reserve each financial year to meet ETCs. Once the reserve has been used, no further ETCs can be incurred in year without approval from the Head of R&D and R&D Financial Manager. This could therefore halt some departments and services in the Trust from being able to open a study due to lack of funds being able to meet ETCs.

2. Background

The Department of Health published guidance which provided a framework for the NHS and its partners to identify, attribute and recover the various costs associated with research in the NHS in May 2012. The guidance, entitled "Attributing the costs of health and social care Research and Development (AcoRD)" became effective from 1st October 2012.

The basic principles of AcoRD are to attribute the cost of clinical research study into three broad categories for the purpose of agreeing the appropriate funding arrangements:

- **Research Costs** – the cost of the Research and Development (R&D) itself that end when the research ends. They relate to activities that are being undertaken to answer the research question.

  Research Costs are usually met by grant funders through the award of a research grant.

- **NHS Treatment Costs** – 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 study had stopped.

  NHS Treatment Costs may be greater or less than the cost of standard treatment. If greater, the difference between the NHS Treatment Costs and the cost of standard care is referred to as the **NHS Excess Treatment Costs**.

NHS Treatment Costs are the responsibility of the NHS and should be funded through normal commissioning arrangements. ETCs used to be funded by the Local CCG (see below for an update)

- **NHS Support Costs** – 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. E.g. additional investigations, assessments and tests where the results are required to ensure patient safety.

  NHS Support Costs are met via the Local Clinical Research Networks.

- **Subventions** – In exceptional circumstances, where the volume or concentration of ETCs associated with a R&D study impacts unfairly on a very small number of NHS organisations and would risk serious disruption to NHS services locally, DH may make available a subvention to cover part of the ETCs. DH will determine the level of subvention offered in discussion with the Chief Investigator(s).

- **NHS England Specialised Commissioning** – On occasion NHS England Specialised Commissioning will reimburse providers directly for agreed ETCs as part of existing contractual arrangements that were negotiated prior to studies opening. R&D will identify and deal with this as part of study set up.

3. Changes to ETC funding from 1st October 2018

Commencing 1st October 2018 there are a number of changes in the way CCGs, NHS England Specialised Commissioning and NHS providers are expected to manage ETCs related to non-commercial research.

The response to the consultation, “Supporting Research in the NHS”, set out on how NHS England, the National Institute for Health Research, the Department of Health and Social Care and the Health Research Authority, working together, would implement changes to simplify arrangements for managing ETCs.

The changes implemented are as follows, any study with ETCs opening after 1st October 2018 has to see the NHS Trust doing the study covering the ETCs, up to a threshold amount set by our local CRN.

Providers are now expected to absorb ETCs to the level of 0.01% of their total operating income, or a minimum of £10,000 per year, whichever is higher. These thresholds have been set in partnership with NHS Improvement, and any agreed ETCs beyond these will be reimbursed. Once the provider threshold has been reached, CRNs will reimburse providers for ETCs relating to CCG commissioned services without the need for an invoice, based on recruitment data held in the central portfolio management system (CPMS).

To assist with this issue DH has informed every NHS Trust that the tariff payment made to providers already includes a value for ETCs. Every NHS Trust has also signed a new contract with the CCGs (from April 2018) in which there is a statement explicitly noting they would be required to following the 'new ETC guidance' in this area.

YTHFT ETC Threshold is approx £50,000 per annum; therefore our Trust cannot apply for ETC support from the CRN until we have breached this threshold.

Currently exceeding our ETC threshold is very unlikely to happen as we have never had that many ETCs in one financial year. So, we will now have to find our own funds to support ETCs.

To allow research to continue YTHFT will hold a small central reserve each financial year to allow studies with ETCs to open, if exceeded no further ETCs can be incurred in year which could see our Trust being unable to open a study. All studies with ETCs must have the Head of R&Ds approval to open.

Once the reserve has been used, no further ETCs can be incurred in year without approval from the Head of R&D and R&D Financial Manager. This could therefore halt some departments and services in the Trust from being able to open a study due to lack of funds being able to meet ETCs.

4. Adopting a study from the Portfolio

After looking at the ETCs incurred in studies undertaken by YTHFT over several years, and working with Finance Managers, YTHFT has agreed the following model for ETCs related to non-commercial research studies (where NHS England Specialised Commissioning and Subvention arrangements are not applicable).

YTHFT will hold a small central reserve each financial year to meet ETCs. Once the reserve has been used, no further ETCs can be incurred in year without approval from the Head of R&Ds and the Head of Finance. This could therefore halt some departments and services in the Trust from being able to open a study due to lack of funds being able to meet ETCs.

The YTHFT central ETC reserve will be utilised to cover ETCs along with directorate support via the following model.

I. **Up to £1,000 per study per financial year**: The relevant Directorate will fund the first £1,000 for each study per financial year.

II. **Up to £5,000 per study per financial year:** The relevant Directorate will fund the first £1,000 and the remainder will be supported from a Trust central reserve.

III. **Greater than £5,000 per study per financial year:** The relevant Directorate and the Head of R&D will discuss such studies on a case by case basis to identify a way forward.

All studies with ETCs must have the Head of R&Ds approval to open.

5. When writing a grant to a National Funder

Research teams are required to complete a Schedule of Events Cost Attribution Tool (SoECAT) at research funding application stage to attribute the research study activity and calculate the likely ETCs associated with the study. R&D will support this activity and validate the attribution of activity in the tool.

It is imperative that the R&D is involved in this application stage and they will support departments and services with the detailed process.

6. Conclusion

This paper sets out to introduce a model for the funding of ETCs that is relatively easy to apply, in what is otherwise a complex process, for grant applications and study authorisations, particularly where a number of collaborating organisations are involved.

This guidance has been approved by Andy Bertram, Director of Finance for a 1st April 2019 implementation and will be kept under review.