PLEASE NOTE THAT THIS POLICY HAS BEEN SUSPENDED

# R&I POLICY: Excess Treatment Costs in Research at NBT

R&I PO3

| Specific staff groups to whom this policy directly applies | Likely frequency of use | Other staff who may need to be familiar with policy |
|---|---|---|
| General managers<br>Directorate finance leads<br>Research leads | As required | R&I department staff |

**Main Author(s):** Alex Ross, Research Operations Manager

**Consultation Route:** R&I Senior Team, NBT Research Committee, Research & Innovation Group, Research Advisory Group, general managers

**Original Date of Issue:** October 2013

**Date of Review:** July 2015

**Current Version Reviewed By:** Dr Rebecca Coad, Research Development Manager

**Ratifying Committee:** Research & Innovation Advisory Group

Summary of changes:

1) General edits have been made, and sections reworded, to provide greater clarity.
2) If ETCs are less than £10,000 per year per study the grant will be submitted even if acknowledgement has not been received from the general manager.
3) Figure 1 has been updated to reflect point 2 (above).
4) Appendix 1 has been replaced with the correct letter template.

**Date of Next Review:** July 2018

## 1. Purpose and Scope

1.1. This policy explains the background and procedure for the review and sign-off of Excess Treatment Costs for research grant applications across North Bristol NHS Trust (NBT)

1.2. A delay in the set-up of some studies at NBT due to unresolved agreement over Excess Treatment Costs can result in reduced or missed opportunities for NBT patients to participate in research.

1.3. Key Risks: Financial, reputational

## 2. Background

2.1. Treatment costs are the costs of patient care delivered during a research project which, if that care continued after the research finished, would continue to be incurred.

2.2. Excess Treatment Costs (ETCs) arise when the cost of the treatment being researched is different to the cost of the standard patient care pathway.

2.3. The ETCs for a research study might be more than that of standard care i.e. there is an additional cost, however, the reverse can also be true and savings may be generated from the proposed research resulting in negative ETCs.

2.4. Treatment costs, including ETCs, are considered by the Department of Health (DH) to be funded through tariff. NHS providers cannot refuse to fund research due to concerns over ETCs. It is the responsibility of directorates to renegotiate tariff income with Clinical Commissioning Groups (CCGs) if, on review, ETCs are consistently not being met:

> *"NHS Treatment Costs related to non-commercial research studies, including ETCs, are the responsibility of the NHS and are funded through normal arrangements for commissioning patient care. This is because funding to cover these costs is allocated to PCTs* as part of their overall revenue allocations. R&D related treatment costs usually make up only a small part of the overall costs of individual providers and are included in the reference costs used to calculate PbR tariffs (PbR tariffs are higher as a consequence). Given that research tends to be time limited, when new activity starts other activity will generally have ended, providers should be able to cover research related treatment costs through existing commissioning arrangements. However, if providers experience material increases or decreases in Excess Treatment Costs between financial years, Trusts should apprise commissioners of this and commissioners should adjust funding accordingly. Where Trusts have made savings on research related patient care costs because industry has donated drugs or devices, the Trust should use these savings to offset ETCs incurred by other research studies."* ***Guidance on Funding Excess Treatment Costs related to non-commercial research studies and applying for a subvention April 2009***
> ** now (CCGs)*

2.5. If the ETCs identified are considered to be significant, then it is possible to apply to the DH for a subvention, where the DH will cover some of the costs of the ETCs. However a subvention will only be provided in exceptional circumstances and will not cover the full amount.

2.6. Although not collected routinely, the total amount of ETCs at NBT are estimated by staff involved in costing research studies to be relatively low (estimated at c£20k-£30k per annum). Current examples include:

2.6.1. A NIHR funded trial which involves an early intervention for patients with chronic fatigue syndrome; ETCs estimated at approximately £6,000 over 2 years.

2.6.2. A NIHR portfolio adopted HTA trial involving use of an ACE inhibitor in Parkinson's Disease and early dementia; ETCs estimated at approximately £13,000 over 2 years.

2.7. Additionally, it is likely that negative ETCs apply to some research studies which may represent significant savings. Current examples include:

2.7.1. A NIHR funded surgical trial involving the use of 2 different devices to treat urinary incontinence; ETCs estimated at a saving of approximately £24,000 over 3 years.

2.8. The Research and Innovation department (R&I) does not receive any funding to cover ETCs.

## 3. Policy

3.1. Directorates will be informed as soon as possible by R&I if there are ETCs arising from a proposed research study via email.

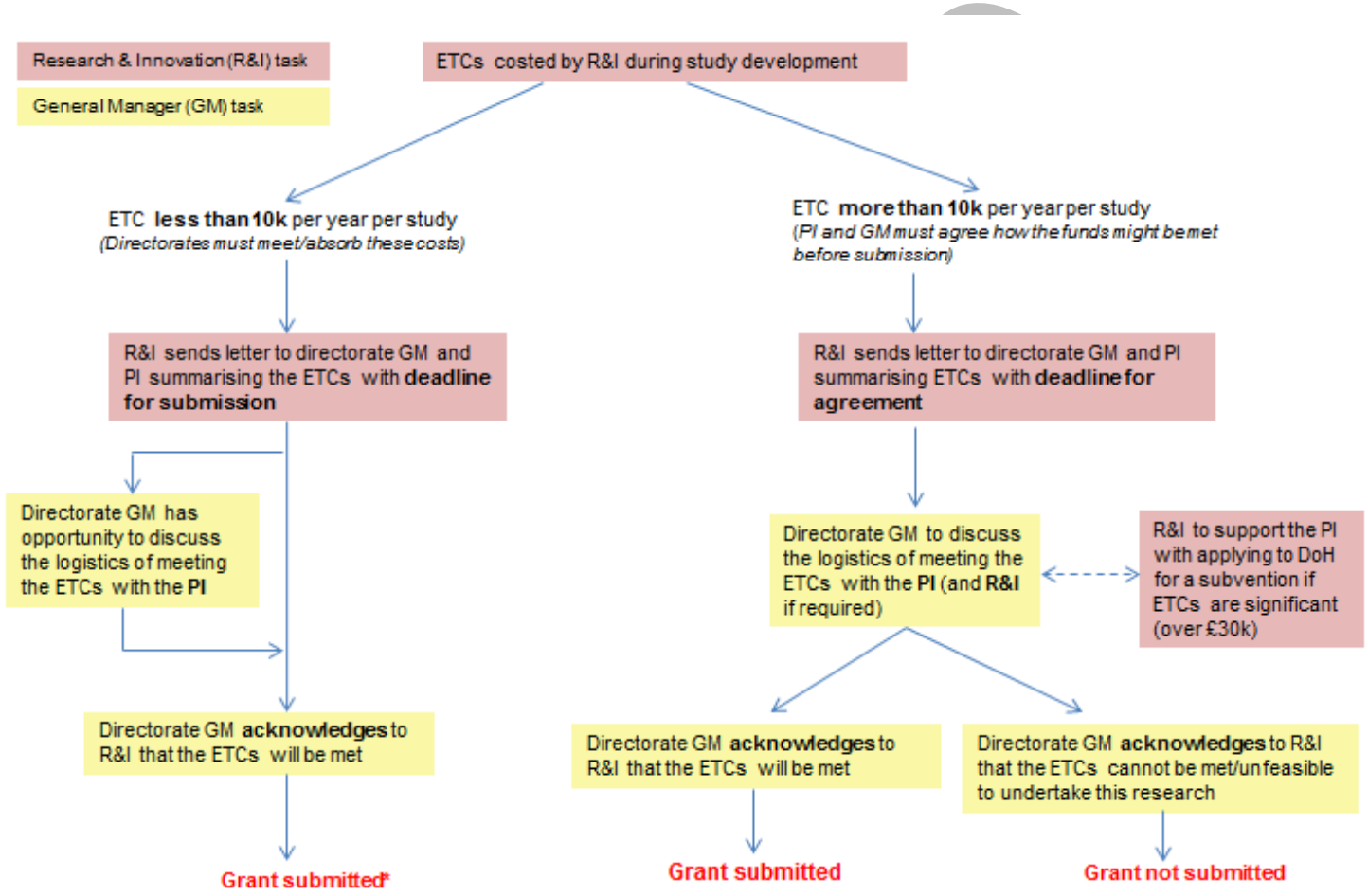
3.2. An R&I representative (research development manager or research development officer) will summarise the ETCs in a standard letter (see Appendix 1) to the directorate general manager and the directorate accountant with a timescale for acknowledgement.

3.3. If the ETCs are costed as being less than £10,000 per year for a study, then the relevant directorate will absorb/meet these costs. Acknowledgement by the general manager to R&I will be sought for our records prior to grant submission. If acknowledgment is not received before the grant deadline, the grant will still be submitted. However this puts NBT at a reputational risk if the grant is successful and it is only at this point that the directorate raises an issue which needs to be addressed before the study can proceed.

3.4. If ETCs are costed as being above £10,000 per year for a study, the required funding/resources will be discussed by the general manager and the principal investigator (PI) to agree the how these costs could be met with support from R&I as required e.g. to apply for a subvention. The PI and general manager must inform R&I of the outcome of their discussions prior to the grant deadline. If agreement cannot be reached on how these costs would be met, the grant will not be submitted.

3.5. R&I will maintain a record of ETCs arising (both costs and savings) to allow provision of information regarding ETCs to directorates on request.

**Fig. 1 Procedure for Managing the Review and Sign-Off of Excess Treatment Costs**




** If R&I do not receive acknowledgement from the GM prior to the deadline, the grant will still be submitted. However, this represents a reputational risk should the study be successful but an issue arises regarding the ETCs post award causing a delay to study set-up.*

## Appendix 1 Template Letter – Notification of Excess Treatment Costs

Date

Dear **General Manager**,

**Re: '**Project Title**'**

**NBT Staff Member* from **Directorate** at NBT is currently [leading] [involved in] a XXX stage **Funding Stream** application which is being submitted on **Submission Date**. Prior to submission of the application, we require an email from you acknowledging the excess treatment costs associated with this study and that they will be met if the grant is awarded.

This project aims to …XXX

It involves …XXX

Excess treatment costs:

- It is anticipated that XX patients would be recruited into this study at NBT; XX to receive standard care and XX to receive XXX.
- The additional cost associated with XXX relates to XXX, which has been costed at £XXX in total (up to XX hours per patient, costed at Band XX).
- If the grant is awarded, the excess treatment cost of £XXX would be incurred from **Date** over an XX month period.

To support the submission of this **Funding Stream** application we require an email from you to confirm that you are aware of the excess treatment cost associated with this study **(£XXX**) and that the directorate would meet this cost should the grant be awarded by **Date**.

I have attached the R&I POLICY: Excess Treatment Costs in Research at NBT (R&I PO2) for your reference.

If have any queries regarding this study and the feasibility of delivering this through your service/directorate, or would like to know more about the rationale and potential impact of this study, please contact **NBT Staff Member**.

Yours sincerely,

**Dr Rebecca Coad**

**Research Development Manager**

cc **NBT Staff Member, **Directorate Accountant**.