Standard Operating Procedure: Excess Treatment Costs for Research

R&D SOP10

V1.1

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EXCESS TREATMENT COSTS (ETC) in Research

1. Background:

Health & social care research is a core NHS activity and as such, the NHS is committed to supporting a portfolio of commercially and non-commercially funded research. This document provides a brief description of the processes for applying for recovery of ETC in Bradford District Care Foundation Trust.

In England, the NHS constitution confirms research as a core function of the NHS which reaffirms the commitment of the NHS, throughout the UK, to promote and conduct research to improve health & social wellbeing and to improve NHS patient care services. The Health and Social Care Act also reaffirms this – for instance through the powers and duty it will place on the Secretary of State and others to support and promote research. While the NHS must play its full part in supporting research, it is important that the cost of that research is identified and properly funded.

For any piece of research there are three types of costs.

- **Research costs**, those costs that occur because of the research, e.g. the costs of employing a researcher to carry out the research, these costs would be covered by the associated research grant
- **Service Support Costs** which are those costs that arise because someone in the NHS is carrying out an activity to support the research taking place. Eg. Identifying and recruiting study participants. These costs are covered by a fund administered by the NIHR and supplied to Trusts vis Clinical Research Networks
- **Treatment costs** can be categorised relating to the commissioning arrangements
    - *Treatment costs* – the cost to the NHS of treating the participant using current standard care
    - *Reduced treatment costs* – the cost of a 'test' intervention is less than the standard care cost. This represents a saving for the Trust.
    - *Excess treatment costs* – the cost of the new intervention over and above the cost of the alternative current standard care. This creates a cost pressure for the Trust.

This document outlines the process for the recovery of ETCs for studies being undertaken within BDCFT.

2. Purpose

The purpose of this procedure is to support high quality research and to ensure that research in the Trust is managed and conducted in accordance with the legislative requirements relating to The UK Policy Framework for Health and Social Care Research (2018) of the Department of Health and the Care Act 2014.

Specifically, this guidance relates to the processes surrounding the claiming of costs for research interventions that exceed those of standard care; Excess Treatment Costs

3. Type of Procedural Document

This is a procedural document describing the "how"; and gives guidance about how R&D authorisation for research in the Trust is obtained. It provides a step-by-step guide, which someone not familiar with the process can follow. It is considered binding, and a breach of a procedure may have contractual consequences for the member of staff. The procedure will ensure research and development activity is carried out in accordance with national standards and guidance.

4. Duties

4.1 Chief Executive

Overall accountability for all R&D activities in the Trust lies with the Chief Executive. Responsibility for specific processes is delegated by the Chief Executive as set out below.

4.2 Medical Director & Caldicott Guardian

The Medical Director has overall delegated responsibility for R&D in the Trust. It is the responsibility of the Medical Director to ensure and give assurance to the Board of compliance with the systems and processes described in this procedure.

The Medical Director will be part of the panel responsible for the authorisation of ETCs from Trust funds as described below.

4.3 Research & Development Director

The R&D Director has the delegated authority and responsibility for providing R&D authorisation for applications for research projects in the Trust, as part of the overall authorisation process.

It is the responsibility of the R&D Director, supported by the Head of Research, BDCFT, to ensure all relevant staff are aware of this Procedure, and to facilitate compliance with its contents.

The R&D Director will be part of the panel responsible for the authorisation of ETCs from Trust funds as described below.

4.4 Head of Research (HoR)

The Head of Research, BDCFT is responsible for the effective implementation and operation of the procedure. They also have responsibility to ensure all researchers working at any Trust site are aware and compliant with the R&D policy and procedures.

The Head of Research will oversee the coordination of the ETC processes to risk assess projects. If further review is required, he/she will facilitate this process, and ensure that reviews of projects are conducted in a timely manner.

The Head of Research is responsible for maintaining up to date knowledge of the ETC Procedure.

The HoR will be part of the panel responsible for the authorisation of ETCs from Trust funds as described below.

4.5 Finance Managers

The designated Finance Manager has the responsibility of:

- Provision of assessments of research project costs and potential financial risks to the organisation, as part of the study feasibility process, in collaboration with the project Lead CSO.
- Facilitate applications for ETCs to the appropriate funder, as required, in collaboration with the study Lead. CSO
- Manage the accounting procedures for the payment of ETCs in support of BDCFT Research Projects, registering them within appropriate R&D Cost Centres before transferring them to the relevant services in a timely manner.
- Providing reports of the above, and other relevant R&D finance issues, to research management meetings as appropriate eg. Research Forum, Research Executive Group etc. These reports will contribute to the information used to provide assurance to the Trust Board.

And in addition:

- Provision of advice and support to researchers for the costing of projects when developing bids for research funding, including ETCs, and the use of Schedule of Events Cost Attribution Tool (SoECAT).
- Review and authorise costings provided by researchers when applying for permission to undertake research within the Trust. The Finance department will provide Feedback to R&D to the Lead CSO as appropriate, in a timely manner to facilitate authorisation within designated timescales.

4.6 Researchers, Clinical Studies Officers and Research Support Staff

There are specific duties and responsibilities as described in The CRN Study Support Service for Activity Attribution Support and Review, NIHR CRN, 2018 for the following research roles, with regard to the attribution of the various costs for research activities:

Chief Investigators
Other Investigators
Project Sponsors
Project Funders

It is expected that these responsibilities will be discharged in line with the guidance prior to a project being submitted to BDCFT for consideration.

These involve the completion of SoECAT and hence the agreement of ETCs as part of the initial HRA and other approval processes, in collaboration with the Sponsor/CI's Lead Clinical Research Network. These agreements should be in place before BDCFT is approached for participation in a research project, so facilitating the local feasibility process.

The completed and agreed SoECAT, and other documents, should be presented to the Trust research team at the point of beginning feasibility assessments to allow timely consideration of costs by the BDCFT Finance Team.

Project Lead Clinical Studies Officers (L.CSO) and other members of the BDCFT research team will facilitate the requests for information form the CI/Sponsor and pass to BDCFT Finance as part of the feasibility process.

5. Procedural Details

5.1. The Cost Attribution Process

Step 1 - Research Costs are derived from the core research activities that are being undertaken to answer the research question(s). They end when the research ends. In practice, it is easier to identify Research Costs by exclusion. If an activity is not directly contributing to an NHS patient care service, then it is attributed as a Research Cost.

Step 2 - Activity that is regarded as part of an NHS patient care service must be split between NHS Treatment Costs and NHS Support Costs.
(see appendices 2 and 3)
The differentiation between these two categories is again driven by primary purpose. If an activity is integral to the provision of a treatment regime, whether this is standard or experimental, then it is attributed as an NHS Treatment Cost.

If a patient care activity is primarily undertaken to facilitate research or is driven by the NHS duty of care to a patient, e.g. to ensure the safety of a patient participating in research then it is attributed as a NHS Support Cost.

A research study may result in an NHS patient care service 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 NHS **Excess Treatment Costs**. These excess costs are nonetheless part of the NHS Treatment Costs, not an NHS Support Cost and are not normally funded from Department of Health R&D budgets.

Where the primary purpose of an activity is to generate data to answer the research question then the activity is not primarily concerned with patient care and is regarded as a Research Cost even where it is a clinical activity.

The split between NHS Treatment Costs and NHS Support Costs is, in some instances, less obvious. Both provide different aspects of an NHS patient care service. However, a key delineator is the residual consequence arising from the cessation of a research study. NHS Treatment Costs would continue to be incurred as long as the treatment regime continued to be delivered; extending beyond the completion or cessation of the particular research study.

In contrast, NHS Support Costs would cease with the completion or cessation of the research study as they are not an integral part of the treatment regime. For the purposes of the attribution process it can be assumed that an experimental intervention/service being tested **will** continue after the end of the study.

The rationale of using primary purpose to determine the attribution of research activity therefore raises the possibility that an individual involved in a research study, a research nurse for example, may carry out a range of activities some of which will be Research Costs, some will be NHS Support Costs and some will be NHS Treatment Costs. The funds required to cover the cost of this one member of staff may therefore need to come from a range of funding sources.

5.2. Sources of Funding for ETCs

NOTE: This document aims to help staff to understand the new process that will begin as a trial period from 1 October 2018 and that will be rolled out in full by April 2019.

Procedure for Application for Payment of ETCs
There will be a mechanism in place for identifying a single, national per-patient ETC for every portfolio study, which will be supported by a new **Schedule of Events Cost Attribution Tool** (SoECAT). This per patient ETC will apply to all patients recruited to that study by all participating sites for ETCs associated with CCG commissioned services. A complementary costing methodology will be introduced for studies with ETCs relating to specialised commissioned services.

- CCG Commissioned services - BDCFT will be expected to cover the payment of ETCs up to a threshold level, beyond which, applications will be made directly to CRN-Y&H
- All other non-CCG Commissioned Services – a process similar to that above is expected, but not in place as of September 2018

5.3. BDCFT Threshold Contributions

NIHR CRN-CC expect Trusts to support ETCs from their CCG commissioned services as a proportion of their annual operating income[1]. This proportion will be reviewed by CRN CC and so Finance Managers should check before allocating ETC funding amounts for any given year.
This amount should be set aside to support ETC at the start of each financial year and calls for ETCs made against that account until all that allocated funding has been spent.
At this point, the 'threshold' will have been deemed to be exceeded and applications can then be made directly to CRN-Y&H to support further ETC.

Details of this application process should be sought directly from CRN-Y&H. It will be based up the following documents, sent from the CI/Sponsor to the site, and as part of their HRA Application:

a. HRA Schedule of Events (SoE) (no costing or standard of care information include – no AcoRD Specialist validation required)
b. Schedule of Events Cost Attribution Tool[2] (SoECAT)(includes functionality to determine cost value of Excess Treatment Costs against standard of care – CRN AcoRD specialist validation required)

NOTE: monetary values contained in the SoECAT are agreed as part of the Sponsor/CI application and approvals process and so are NON-NEGOTIABLE. Whilst it is recognised that this may not represent actual local costs, it is anticipated that over a period of time Trusts will benefit from a 'swings and roundabouts' model of over and underpayments, so making such a national tariffed system equitable.

[1] In September 2018 this threshold was set at 0.01% of 2016/7 Trust Operating Income. This figure is liable to regular review.
[2] SoECAT use is applicable for interventional studies only

5.4. How to submit an application for ETCs

i. During site feasibility (Assess, Arrange, Confirm) processes, the study Lead Clinical Studies Officer (L.CSO) will identify projects with associated ETCs.
ii. L.CSO will then forward details of the study to the relevant BDCFT Finance manager for determination of ETC values relevant for BDCFT.
iii. The results of this assessment will then be passed to **either**:
    a. BDCFT Approval Panel for applications for research in CCG commissioned services within Threshold values
    (this panel will comprise: Medical Director, R&D Director, Head of Research) **OR**
    b. CRN-Y&H Approvals Process for applications for research in CCG commissioned services beyond Threshold values **OR**
    c. The process for ETC payments for research in non-CCG commissioned services if different to the above.

5.5. Determination of awards

It should be noted that awarding of ETCs **IS NOT** automatic. Each application will be judged on merit. For BDCFT Threshold Funds the following criteria will apply:

i. Relevance to the Trust research strategy[3]
ii. Perceived potential benefits to BDCFT services/service users.

5.6. Payment of ETCs

Once agreed, payments of ETCs are directly related to performance of the study in terms of its agreed recruitment credit eg. Whether a project accrual happens at the point of consent or randomisation etc, as defined in the Protocol and SoE.

ETC awards are made:

i. Pro rata per year that the treatment is being delivered in the project, as demonstrated in the relevant project documents eg. SoE
ii. Pro rata per participant accrual recorded within any given period as per 1 above.

Eg. A project is predicted to recruit 10 participants in the year 2018-19. Awarded ETCs are £100.

i. The study recruits 10 participants – all £100 of the award is paid
ii. The study recruits 2 participants – only £20 of the award is paid[4]

Payments will be made monthly, from the Trust or CRN or other body (as appropriate) to the relevant service delivering the intervention and so incurring the cost. For accounting and audit purposes, all payments from all sources will be paid into the relevant R&D Cost Centre before being forwarded to the service/s concerned.

All awards, payments and the information on which they are based will be captured and recorded on R&D Financial Accounts and made available to R&D Managers and or relevant management committees as appropriate.

[3] Available on the R&D Department Intranet Pages
[4] At the time of writing it is unclear if unspent ETCs can be held over into a further recruitment year

6. Consultation, Approval and Ratification Process

6.1 Consultation Process

Stakeholder	Level of involvement
• Research Forum • Medical Director • Information governance • Heads of Service • Senior Clinical Studies Officer • Data, Information Systems and Governance Officer	Consultation
• Research & Development Director • Head of Research • Finance	Development
• Research Forum	Approval and Ratification

7. Review of the Procedural Document

This document will be reviewed every 3 years or when deemed necessary as a result of statutory or operational change in line with Trust policy

8. Dissemination of the Procedural Document

This document will be held in the R&D Department and in the library services across the Trust. It will be available on the R&D Intranet and Internet once ratified.

9. Training and support for the implementation of the Procedure

The R&D department will provide support to individuals as and when required. This will take various means including:

- Procedural documents
- Guidance available on the intranet and internet web sites
- Access to training e.g. Good Clinical Practice (GCP)
- Introduction to Health and Social Research courses
- Circulation of research courses available via the 'Local Clinical Research Network'

10. Monitoring Compliance and effectiveness of the Procedural Document

Criteria	Evidence identified to indicate compliance with policy	Method of monitoring i.e. how/where will this be gathered?	Frequency of Monitoring	Lead responsible for monitoring
Process for checking that staff are compliant with financial governance, good clinical practice and research guidance as outlined by the NHIR Study Support Service (SSS)	Notes in Site Files Finance Reports to related R&D committees	As outlined in this SoP	As outlined in this SoP	Head of Research or delegated member of BDCFT Research Team

11. **References**:

Attributing the costs of health and social care Research and Development (AcoRD) (2012)
https://www.nihr.ac.uk/funding-and-support/study-support-service/early-contact-and-engagement/acord/
https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

CRN Study Support Service for Activity Attribution Support and Review, NIHR CRN, 2018
(web link blocked at present)

HSG (97)32: Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS
http://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthserviceguidelines/DH_4018353

Manual for specialised commissioning services
http://www.england.nhs.uk/wp-content/uploads/2012/12/pss-manual.pdf

NHS RD Forum Briefing Paper
https://gallery.mailchimp.com/442e19d6ae871c5a27d2813bf/files/11312363-863b-4866-84e8-9703960330a1/EXCESS_TREATMENT_COSTS_BRIEFINING_NOTE_FINAL_VERSION_1.0_7th_Sept_2018.01.pdf

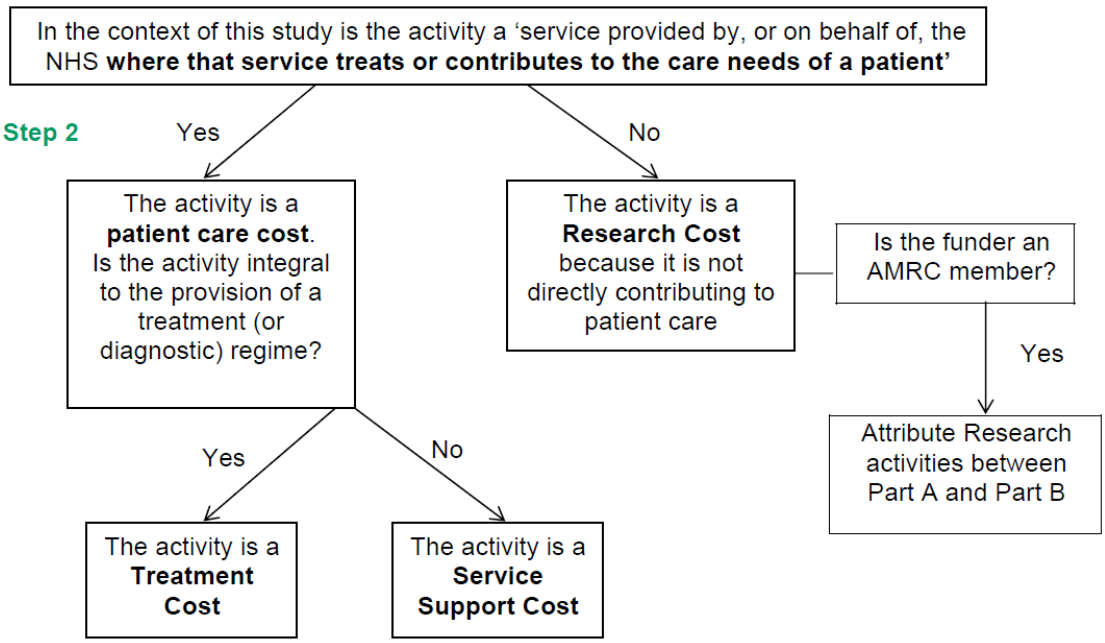
Supporting and applying research in the NHS
https://www.nihr.ac.uk/funding-and-support/study-support-service/resources/supporting-research-in-the-nhs.htm

12. To be read in conjunction with

R&D Registration and Project Authorisation Procedure; R&D Standard Operating Procedure 01
and
Guidance on Research Finance
Z:\R&D\Research Dept Management\SOPS policies and strategies\Approved

Appendix 1 – attribution process

Figure 1: Funding attribution flowchart



Appendix 2- list of common research activities

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.
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

1. Local study trial co-ordination and management.
2. Data collection needed to answer the questions that the research study is addressing (including collecting data for and completing the report).
3. Regulatory preparation and compliance including obtaining ethical approval and complying with the Medicine for Human Use (Clinical Trials) Regulations 2004.
4. 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.
5. Sponsorship fees such as MHRA fees, and CTA annual renewal fees.

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.