Managing Excess Treatment Costs for Research into Public Health Interventions Commissioned by Non-NHS Organisations in England

GUIDANCE FOR RESEARCHERS

1 Overview of the Guidance

This guidance is for researchers who are undertaking research in public health in organisations in England and who are seeking funding for Excess Treatment Costs (ETCs). The term ‘ETC’ refers to the cost of the intervention being researched. It is the difference between the cost of the existing standard care/intervention offered to people eligible to be recruited to the research study and the cost of care/intervention(s) offered as part of the research study where those costs are higher.

Research in PH is funded through the National Institute for Health Research (NIHR) and its partners. These research funders only fund costs that are attributed as research costs (see AcoRD guidance), and do not fund ETCs.

Public health research is undertaken in services that are outside the remit of the NHS that, for the most part, are not commissioned by Clinical Commissioning Groups and are not included in NHS specialised commissioning. An exception to this may be interventions delivered in non-NHS settings that are jointly commissioned by a CCG and a Local Authority (LA). For non-NHS PH research the responsible organisation is usually the LA but could include other non-NHS organisations that have been commissioned to deliver services that are the responsibility of the LA. The Association of Directors of Public Health has published a position statement on the funding of ETCs by LAs. (http://www.adph.org.uk/wp-content/uploads/2016/05/ADPH-position-statement-on-excess-treatment-costs.pdf)

The Department of Health and Social Care (DHSC) has stated as a matter of principle that the organisation responsible for commissioning the intervention being researched should be expected to pay the ETC. If you need to find out which non-NHS organisation is responsible for the commissioning of a PH service in England, please contact PHE.

If it has not been possible to secure funding for the ETCs from the commissioning organisation, in exceptional circumstances the DHSC allows researchers to access its subvention fund for ETCs for PH research. PHE will also consider requests for ETC support for certain studies. To qualify for support from the DHSC subvention fund or from PHE researchers will need the approval of PHE’s ETC Panel.

The PHE ETC Panel will look for evidence that the researchers have worked closely with the commissioning organisation in developing their research funding application in advance of its submission to the research funder. Researchers are advised to have these discussions early in the process of developing the funding application. Specifically, the study lead must demonstrate that they have engaged with LA/commissioning organisation(s) and discussed the following:

- The feasibility, sustainability and affordability of delivering the intervention
- The LA assets required e.g. the organisational infrastructure and facilities.
- The fit of the research intervention with current services delivered by the organisation and any duplication of provision
- Whether the research addresses a priority in the area
- The level of impact of the research - the demonstrable contribution that it will make
- The capacity and capability of the organisation to enable the research to be completed.
- The payment of ETCs

Details of the above discussion(s) must be captured on the funding application form and submitted to PHE with the application for ETCs. PHE can provide details to researchers of contacts in commissioning organisations, if required.

NHS England works closely with PHE and the DHSC to provide and commission a range of public health services such as national immunisation services and screening services. For ETCs for research into the Section 7a services the NHS England process must be followed.

2 The Role of the NIHR Local Clinical Research Network (LCRN)

Support with the submission of the full funding application
The research lead will need to make contact with the LCRN when the research funder has invited them to submit a full funding application. A lead LCRN based in the study lead’s geographical area will provide support for multicentre studies.

The LCRN will support the research sponsor with the completion of the Schedule of Events Cost Attribution Tool (SoECAT). The SoECAT captures details of the activities undertaken in the research study to allow cost attribution. It must be signed off by the AcoRD specialist, and submitted alongside all applications for new single stage calls and invitations to submit a final application that are issued after 1st October 2018. Once the deadline for receipt of funding applications has passed, the research funder will forward to PHE a list of all PH research funding applications.

Support when funding has been awarded
When research funding has been awarded the LCRN can help with inclusion of the research onto the NIHR portfolio and arrange for provision of ongoing support in line with the DHSC eligibility criteria.

For PH research studies, the LCRN will utilise a triage process via PHE to confirm the commissioning organisation(s) that would be responsible for the payment of the ETCs identified in the SoECAT. This aligns with the NHS England triage process.

3 Provision of funding of ETCs for PH research studies and applying to the DHSC Subvention fund and PHE for ETC support

PH research studies with ETCs may be eligible for support from PHE if LAs or other commissioner organisations are unable to fund the ETCs. Studies with high cost ETCs will also need to apply to the DHSC subvention fund (section 4).

When the research funder has confirmed the award, the research sponsor will need to submit the funding application, the SoECAT and completed funding form directly to PHE for
consideration by the PHE ETC Panel if they wish to access support for ETC payment from PHE or from the DHSC subvention fund. Only applications approved by the PHE ETC Panel will be eligible for consideration for ETC funding from PHE and/or the DHSC subvention fund. Applicants must demonstrate that they have worked closely with the commissioning organisation(s) and that the commissioning organisation(s) support the study.

DHSC subventions will be awarded only in exceptional circumstances. Applicants will need to have secured a financial contribution towards the ETCs to apply to the subvention fund. If applicants have not secured a financial contribution, PHE may consider paying this contribution so that the researcher can apply to the subvention fund for the balance, but this will be dependent upon the outcome of the PHE ETC Panel review.

PHE ETC Panel approved applications that require support from the DHSC subvention fund will be sent to the DHSC by PHE and the DHSC will work directly with the applicant.

4 The PHE ETC Panel

When the research funding award for the study is confirmed, studies requiring ETC funding will be considered by PHE. Applicants must submit their funding application and SoECAT directly to PHE. The PHE ETC Panel will determine if the:

- Research is in line with national government priorities
- Research is a priority for the local government and/or local health providers
- Roll-out of the intervention would be feasible and affordable should the research show it to be of benefit
- A commissioning organisation has agreed to pay a contribution to the ETC

The panel will also consider whether the study lead has engaged with LA/commissioning organisation(s) and discussed the following. See funding application form.

- The feasibility, sustainability and affordability of delivering the intervention being researched
- The LA assets required e.g. the organisational infrastructure and facilities.
- The fit of the research intervention with current services delivered by the organisation and any duplication of provision
- Whether the research addresses a priority in the area
- The level of impact of the research - the demonstrable contribution that it will make
- The capacity and capability of the organisation to enable completion of the research.
- The provision of ETCs

The PHE ETC Panel review of research will take up to two months. Following the review, PHE will inform the research sponsor, the research funder and the NIHR LCRN of the decisions of the PHE ETC Panel. ETCs for low cost studies may be paid directly to the researcher by PHE.

If the research study is awarded funding by the research funder but is not supported by the PHE ETC Panel the research lead will not be able to access funding for ETCs from PHE or the DHSC. They will need to independently identify an alternative source of ETC funding.
ETC application Process for Non-NHS Research

The research study is shortlisted for funding by the NIHR or their partner organisation

The research sponsor forwards the completed SoECAT to the NIHR Local Clinical Research Network (LCRN). The LCRN AcoRD specialist ensures the correct attribution of costs by validating the SoECAT.

The researcher forwards a full application and SoECAT to the funder

The funder sends a list of all PH research applications with excess treatment/intervention costs to PHE

The researcher is awarded research funding and informs the LCRN. For PH research studies, the LCRN uses a triage process via PHE to confirm the commissioning organisation(s) that would be responsible for the payment of the ETCs identified in the SoECAT.

If PH research the sponsor submits a copy of the SoECAT, funding application form and funding confirmation letter to PHE

Study is reviewed by the PHE ETC Panel. PHE informs the research sponsor, the research funder and the LCRN of the decisions of the PHE panel

The research study is approved by the PHE ETC Panel.

Low cost studies – ETC paid by PHE

High cost studies – An ETC contribution will be paid by PHE to DHSC if required.

PHE will forward the application and SoECAT to the DHSC subvention fund. The DHSC will then work directly with the research sponsor.

The research study is not approved by the PHE ETC Panel.

The research lead cannot access funding for ETCs from PHE or the DHSC.

The research lead will need to independently identify an alternative source of funding for the ETC

Final contract signed between funder and researcher.

*PHE can provide contact details for the commissioning organisation.
ETC Funding Application Form

Please complete this form to give details of discussions you have had with the LA/commissioning organisation(s) with responsibility for provision of the service you are researching and which would be responsible for rolling out your intervention if it was shown to be of benefit. Your responses will be considered by the PHE panel when they make their ETC funding decision.

This form will need to be submitted to PHE when you apply for support with your ETC. It will need to be accompanied by your funding application, SoECAT and your letter confirming research funding.

Please confirm you have discussed the following with the relevant commissioning organisation:

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