

HEALTH INNOVATION CHALLENGE FUND

Accessing NHS Support & Treatment Costs

1 Introduction

Sections 2) and 3) of this document provide a convenient summary of NHS Support and Treatment Costs.

Applicants should bear in mind that:

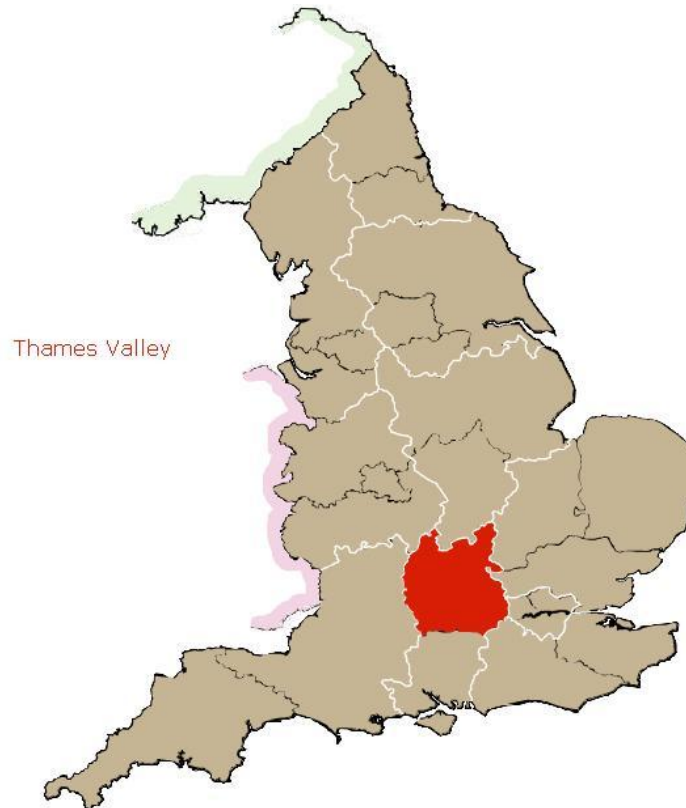
- **NHS Support Costs and Treatment Costs are not covered by this scheme and should not be included in the funding requested from HICF.**
- **Applicants should, however, provide an estimate of NHS Support costs and Excess Treatment costs in the relevant sections of the application.**
- **Reviewers will take into account the estimated NHS Support and NHS Excess Treatment Costs when assessing the overall value for money provided by the proposed project.**
- **Any award will, however, only comprise Research Costs; NHS Support Costs are met by a number of routes, including NIHR Clinical Research Networks, and NHS Treatment costs are met through NHS commissioning arrangements for patient care.**
- **Applicants are encouraged to seek advice from the relevant organisations well in advance of submitting an application.**

Further information on the distinction between Research, NHS Support and Treatment costs is provided in the document [Attributing the Revenue Costs of Externally Funded Non-commercial Research](#) in the NHS (ARCO), available at:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4125280

2 NHS Support Costs & Research Network

The National Institute for **Health Research (NIHR) Comprehensive Clinical Research Network (CCRN)** was created as part of the government's research and development strategy, '[Best Research for Best Health](#)' to provide a world-class infrastructure for clinical trials in all areas of disease and clinical need within the NHS.



- CCRN consists of a number of **Comprehensive Local Research Networks (CLRNs)**, which are managed locally and support participation in the national portfolio of NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC) studies e.g. Thames Valley in map above
- Each CLRN is led by a Clinical Director who provides leadership for all aspects of the CLRNs work, including developing the Network strategy and overseeing its implementation, supported by a CLRN Executive Group and a Senior Manager
- Each CLRN has a broader Network Board which includes representation from all the NHS organisations, and relevant higher education institutions and other stakeholders, within the CLRN area
- The Network Board takes oversight of the activities of the CLRN to ensure that the interests and priorities of the constituent organisations are carefully considered and inform its activities

The CCRN provides those NHS Service Support Costs, which were previously provided through other NHS R&D funding streams.

2.1 Registering Your Study

In order to obtain NHS Service Support Costs, researchers need to register their study to the CRN database. Registration can be initiated in the following ways, depending on the stage your study has reached:

2.1.1 Non-Commercial Studies

If you are just starting out

To be considered for the NIHR CRN Portfolio, new studies should apply, using the [Integrated Research Application System](#) (IRAS), for NHS permission through the NIHR Coordinated System for Gaining NHS Permission (CSP). You will complete a short CSP Application Form, followed by the main R&D Form. Studies are assessed during the CSP process to determine whether they may be included in the Portfolio.

If you have already applied for NRES approval

You should complete the [Initial Study Registration Proforma](#) and email this to crncc.portfolio@nihr.ac.uk. Your study will then be assessed for eligibility and you will receive a letter to confirm whether or not your study has been included in the Portfolio. Studies already being processed by NRES are not able to use CSP.

If you have already applied for R&D approval

You should complete the [Initial Study Registration Proforma](#) and email this to crncc.portfolio@nihr.ac.uk. Your study will then be assessed for eligibility and you will receive a letter to confirm whether or not your study has been included in the Portfolio. Studies already being processed by local R&D offices are not able to use CSP.

If your study is already open

NIHR CRN CC is not currently accepting applications for studies that have already started recruiting patients. Ongoing studies for which an Initial Study Registration Proforma was submitted to NIHR CRN CC before 31 December 2008 will be assessed for eligibility and in due course will receive notification of whether or not the study is to be included in the Portfolio. Refer to the [Industry webpages](#) at the UKCRN website for more information.

2.1.2 Commercially-funded studies

Industry sponsored studies

All Industry sponsored studies need to go through an adoption process to be considered for inclusion in the NIHR CRN Portfolio. We strongly suggest that companies engage with the appropriate NIHR Clinical Research Network at the earliest possible time, to benefit fully from the services available to adopted studies through the networks, including site selection and costing negotiations. Refer to the [Industry webpages](#) at the UKCRN website for more information.

Industry studies are required to complete a short NIHR CRN Industry Submission form, so there is no need to complete the Initial Study Registration Proforma.

Alternatively, the Portfolio adoption process can be initiated through the use of NIHR CSP for gaining NHS permissions. The Industry contact at the appropriate network will receive details of the study and will make the necessary arrangements to consider your study. If you have already applied for NRES Approval or R&D Approval, your study will not be able to access NIHR CSP.

Please note, CCRN Industry studies are currently being considered for adoption on a case-by-case basis until the full implementation of the Comprehensive Local Research Networks (CLRNs) and Specialty Groups is complete, to ensure there is adequate interest and CLRN infrastructure in place to support study set-up and delivery. Consideration of all CCRN Industry studies for adoption will be possible from April 2009.

Industry funded, non-industry sponsored studies

The information above for non-commercial studies (relating to the stage the study has reached) also applies to industry funded, non-industry sponsored studies.

The *Initial Study Registration Proforma*, along with notes for completion, is available to download below:

http://www.ukcrn.org.uk/index/clinical/portfolio_new/P_how/mainColumnParagraphs/00/document/Initial_Study_Reg_Proforma.doc

The *Initial Study Registration Proforma* guidance can be downloaded at the following website:

http://www.ukcrn.org.uk/index/clinical/portfolio_new/P_how/mainColumnParagraphs/01/document/Proforma_guidance_030108.doc

Once registered, researchers will be contacted by a member of the CLRN staff who will help through the access of resources required for the delivery of the study.

3 NHS Treatments Costs & PCTs

In general terms, NHS Treatment costs are those costs related to patients' care that would continue if the treatment under investigation continued after the end of the study. The cost difference between experimental treatment and standard patient care is called Excess Treatment Costs.

Treatment Costs and Excess Treatment Costs are provided by the Trusts where patients are recruited and cared for. It is applicants' responsibility to seek and obtain support for Treatment Costs from the Trusts. Early involvement in the application process of the NHS organisation that would provide the standard and experimental care is crucial for the timely start and the successful delivery of any proposed study. Applicants are strongly encouraged to seek advice from the finance department of the Trusts where the research work will be undertaken.

Further guidance on what constitutes Treatment Costs can be found at the following link:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4125280