Health Technology Assessment Programme

NHS National Institute for Health Research

Call for Expressions of Interest

Funding for Primary Research Using Efficient Study Designs to Evaluate Clinical and Public Health Interventions for the NHS

Specification Document

Introduction

The NIHR Health Technology Assessment Programme funds research to assess the effectiveness of important health interventions and technologies to inform clinical or public health decision making within the NHS.

Focus of this call

Within that broad remit, the focus of this call is for research that will demonstrate particular design features to allow either more rapid conduct or lower costs, or both, when benchmarked against conventional pragmatic multicentre trials, while still providing sufficiently robust data to guide NHS or patient decisions in important clinical areas.

Applications can relate to any area of the health service, with no restrictions on specialty or disease area. The setting may be in primary, community or hospital care.

Some features of in remit studies might be:

- The use of routinely collected data or registries, or electronic health records (eg to identify patients who might participate in a study or for follow up);
- Exploitation of existing cohorts;
- Simple randomised trials allowing rapid recruitment and follow-up;
- Other innovations to promote rapid or more efficient recruitment;
- Simplified design and/or follow up by focusing on a limited number of the most important outcomes;
- Adaptive designs for trials;
- Non-randomised evaluations (retrospective or prospective) where bias can be reduced to acceptable levels;
- Where feasibility has already been demonstrated or where pilot studies have either already been conducted or are underway;
- Reanalysis of existing datasets (eg from other trials or IPD).

Although many HTA studies are multicentre, single-centre studies will be considered where the applicants can demonstrate that its results will be sufficient to answer the question being proposed and be generalisable to the wider NHS.

This call can be an opportunity to apply and/or test new methods of study design/conduct/analysis within the overall context, and there is an opportunity to apply for parallel funding from the MRC-NIHR Methodology Research Programme for methodological work (see later section for further detail). However, it is not intended as solely a call for methods research.

Most studies might usefully incorporate an internal pilot phase, for example to test recruitment against milestones. However, stand-alone pilots or feasibility studies are not appropriate for this call.

How to apply

Please note that for this call only it is <u>not</u> necessary for the Summary of the Research Proposal sections of the form: Rationale for Research, Scientific Abstract and Summary to be completed in an anonymised format.

Expressions of Interest (EoI) are invited on an application form. These should briefly state the research question and study design, and should explain how the results could inform clinical decision making in the NHS and the efficiencies in conduct or design.
Although the form is an Expression of Interest, it is important to convey the importance of the research question and the scientific methodology clearly. Where the form requests only an estimate of costs, the HTA programme accepts that some variance is likely to occur between EoI and the full application, but significant changes will be carefully scrutinised by the funding board. Applicants are advised to discuss their EoI with appropriate methodologists before submission, but detailed involvement of, for example, a clinical trials unit, is not always necessary at this stage.

EoIs will be initially scrutinised by a prioritisation panel. Those deemed of highest importance to the NHS will then proceed to a funding board for review of the scientific quality. Those judged most to be the highest quality will be invited to submit detailed full proposals. The criteria for assessment of proposals are given below.

The prioritisation panel and funding boards will assess applications against the following criteria:

1. The proposed study assesses the effectiveness of a health technology.
2. The importance of the issue to patients, clinicians or the wider NHS.
3. Whether the outcomes chosen are important to patients and the NHS, and whether participants are representative of the case mix treated in the NHS.
4. A demonstrable case for the need for the proposed research with reference to the current evidence base.
5. An explanation of how the results of the study could inform clinical decision making in the NHS.
6. Scientific quality of the proposed methods.
7. Clear demonstration of the features and benefits of the proposed of efficient study design.

Efficient contracting
In keeping with the nature of the call, the programme encourages applicants to consider ways they can move quickly through the contracting process.

Public involvement
Researchers should be aware that all applications will need to demonstrate appropriate involvement of patients and the public in the planning and conduct of the proposed study.

Required expertise
Applicants are recommended to seek advice from appropriate methodological support services. Involvement of relevant specialty groups and research networks is encouraged, where this is appropriate. The HTA Programme expects applicants to use a qualified trial manager for appropriate projects, and clinical, statistical and methodological expertise as is required to successfully deliver the trial being proposed. We do not necessarily require full economic evaluation to be undertaken in these trials, but if one is proposed then appropriate experts must be involved.

Opportunity to apply for a methodology bolt-on award alongside your main study.

NIHR and MRC wish to invite applications for bolt-on methodological projects to run alongside studies funded through this call. Funds are available for the development, evaluation and validation of novel methodologies to support any stage of the study process, which should be intended to further increase the efficiency of the study and allow comparison of methods and demonstration of the preferred approach. This methodological work will be considered as a separate application to the main study, and success of the study funding application will not be contingent on that of the

methodology proposal (and therefore the methods work should not be an essential part of the study).

These methodological bolt-on (MBO) awards can be applied for in one of two phases (each study can be associated with multiple submissions in either or both phases):

1. Applicants should indicate in their Expression of Interest whether they intend to apply for an MBO. The application for a MBO should then be made at the time of submission of the main HTA application (full proposal), which must be a separable but closely-aligned piece of methodological work intended to facilitate the study but also to give insight into the best methods for increasing study efficiency. This MBO must be budgeted separately to the main bid, and review of the main bid will not be contingent on that of the MBO. The MBO will be assessed over the same timescale as the main HTA application.
2. Applications for MBOs can also be made **after** the HTA study is reviewed and funded. Such applications should be submitted directly to the MRC-NIHR Methodology research programme through the normal application procedure, to the June 2016 deadline, or thereafter.

Methodological applications concerning aspects of the early stages of study conduct (eg methods for recruitment) will, by necessity, be submitted to phase 1.

If you would like advice on whether your MBO is appropriate to this call, please e-mail a summary of your proposed research to htatcall@soton.ac.uk.

Making an application and assessment dates

If you wish to submit an EoI in response to this call, the application form will be available at the following location: http://www.nets.nihr.ac.uk/funding/hta-researcher-led

EoIs received by **1pm, Wednesday 18 November 2015** and deemed within remit will be assessed for their importance to the NHS in December 2015. Applicants will be advised of the status of their application by early January 2016. Prioritised applications will progress for review by a funding board in early February.

Shortlisted applications will be invited to submit full proposals by mid-April 2016. These will be peer-reviewed ahead of a second funding board in June 2016. Outcome letters will be sent to applicants in July 2016.

There may be applications where some uncertainties exist. In these cases, a revised EoI may be invited, rather than a full proposal. The timings for these submissions will be communicated in decision letters.

Please note, applicants may submit more than one application. EoIs will only be eligible for consideration if they are within the HTA Programme remit and meet the specification for the call. Those that do not fulfil these criteria will be declined. An EoI is required for applications to progress to the next stage.

Applications within remit for the HTA programme but not for this specific call may be transferred to the HTA Clinical Evaluation and Trials workstream. Out of remit applications may be transferred to another appropriate NETS Programme.

Applications with Methodological bolt-ons

If your main application is supported by the HTA funding board in June 2016 and includes an MBO, this will be passed across to the MRC Methodology programme, for peer review, ahead of consideration by their panel at the end of November. Applicants should bear in mind the two

different dates they will receive notification of the outcomes of their main study and the MBO when preparing their applications.

For any enquiries about this call please e-mail htatcall@soton.ac.uk