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 data sufficiently robust to guide NHS or patient decisions.

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 such 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 already been conducted or are underway;
- Reanalysis of existing datasets (eg. from other trials or IPD).

This call can be an opportunity to apply and/or test new methods of study conduct within the overall context: however, it is NOT intended as a call for methods research.

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

A report of recently completed trials conducted using CPRD will be available from this website in time for outline and full applications, and applicants interested in using CPRD as a vehicle for studies under this call should read this.

Expressions of interest invited

Short 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. It is accepted that costing in an EoI can be only indicative. Applicants are advised to discuss their EoI with appropriate methodologists before submission, but detailed involvement of, eg. a clinical trials unit, is not necessary at this stage.

These Expressions of Interest will be scrutinised by a committee and those judged most suitable will be invited to submit full proposals for research. Some which are of interest but which the committee feel cannot be taken forward quickly at this time, will be asked to submit an outline. Successful applicants' host institutions must be able to sign the contract within eight weeks of receipt of the final funding decision letter and studies should commence recruitment (where this is part of the study) no later than nine months after the final funding decision letter.

The criteria for assessment of full proposals are given below. It is not expected that Expressions of Interest will be able to demonstrate all these, but the committee may decline any that it considers unlikely to be competitive at the next stage.

The Board will assess proposals 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. A demonstrable case for the need for the proposed research with reference to the current evidence base.
4. An explanation of how the results of the study could inform clinical decision making in the NHS.
5. Scientific quality.
6. The outcomes chosen should be important to patients and the NHS and participants should be representative of the case mix treated in the NHS.
7. A demonstration of features of efficient study design leading to reduced duration, and value for money.
8. 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.

Further guidance on applications

The Health Research Authority (HRA) will be updating its guidance on the proportionate governance of studies during the course of this call: applicants are advised to keep up to date on these developments which may influence the design and conduct of studies in this call. See the HRA guidance for this call at: www.nets.nihr.ac.uk/__data/assets/pdf_file/0013/103270/HRAguidanceforHTAv2.pdf

Rapid contracting requirement

Draft contracts will be issued and sent to successful applicants together with the formal funding recommendation letter. It is expected that all contracts will be signed and returned to the HTA Programme within eight weeks of receipt. Funding will be conditional upon adherence to this rapid contracting process.

Public involvement

Researchers should be aware that any full application, when invited, will need to demonstrate appropriate involvement of patients and the public in the planning and conduct of their 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.

Making an application and assessment dates
If you wish to submit an Expression of Interest in response to this call, the application form will be available at the following location shortly: http://www.nets.nihr.ac.uk/funding/hta-researcher-led

Expressions of interest received by **1pm 16 July** and deemed within remit will be assessed for their importance to the NHS in August 2014. Applicants will be advised of the status of their application by late August.

Shortlisted applications will be invited to submit full proposals by the end of October 2014. These will be peer-reviewed and considered by one of our funding boards in December 2014. Questions from peer reviewers will be sent to applicants around 24 November 2014. Decision letters will be sent to applicants in January 2015.

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

Please note that applicants may submit more than one Expression of Interest. Expressions of Interest will only be eligible for consideration if they are within the HTA Programme remit and meet the specification for the call. Those which do not fulfil these criteria will be declined. All eligible Expressions of Interest will be assessed on overall quality and likelihood of meeting the funding criteria. An Expression of Interest is required for applications to be able to progress to the next stage.

Applications not approved for shortlisting as part of this call may be transferred to the HTA Clinical Evaluation and Trials work-stream if appropriate. Out of remit applications may be transferred to an appropriate NETS Programme.

Applicants should note that the usual 12 month resubmission rule (whereby applicants would be required to wait for 12 months before resubmitting an application to the HTA Programme) will not apply to declined Expressions of Interest.

Applicants should consider Ethical, Legal and Social Issues
All those involved in research must adhere to the strictest ethical and legal standards. Ethical, social and legal issues must be considered in relation to all stages of the research cycle. Applicants are asked to consider documents such as the MRC Ethics Guide: Medical research involving children; (DH 2004), Seeking Consent (DH 2001), Direction of Travel for Urgent Care (DH 2006), Mental Capacity Act (2005).

Applicants should follow the Medical Research Council's Good Clinical Practice guidelines (http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416) when planning how studies, particularly RCTs, will be supervised.