Call for Expressions of Interest

Funding for randomised controlled trials to rapidly generate evidence to inform clinical decision making in the NHS

Specification document

Introduction

The NIHR Health Technology Assessment programme funds research to assess the effectiveness of technologies within the NHS. In this researcher-led work-stream grants are available for primary research within the broad method of randomised controlled trials. Studies must generate evidence to inform clinical decision making within the NHS. We expect to make funding decisions on successful applications within 6 months of the initial closing date of expressions of interest.

Remit of this Call

The focus of this call is for randomised controlled trials that will generate evidence in the short to medium term to inform clinical decision making in the NHS. 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. It is anticipated that these trials will be pragmatic in nature, simple to set up and initiate, and rapid to commence recruitment. A health economic component is not essential.

Expressions of interest invited

Short expressions of interest 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. These expressions of interest will be scrutinised by a committee and those judged most suitable will be invited to submit full proposals for research. Successful applicants' host institutions must be able to sign the contract within 8 weeks of receipt and studies should commence recruitment no later than 9 months after the final funding decision letter has been issued.

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 applicants' ability to rapidly commence recruitment to the study, with this being no later than 9 months after receiving funding approval.
8. Although many HTA studies are multicentre, single-centre studies will be considered where the applicants can demonstrate that recruitment will be sufficient to answer the question being proposed and should be generalizable to the wider NHS.
9. Studies should aim to have completed recruitment and follow-up within 3-4 years or fully justify any longer duration.

Further guidance on applications

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/PolicyGuidance/EthicsAndGovernance/GoodResearchPractice/index.htm) when planning how studies, particularly RCTs, will be supervised.

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 with 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. HTA 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

If you wish to submit an expression of interest in response to this call, please complete the electronic application form (http://www.hta.ac.uk/funding) and submit to the NIHR Evaluation, Trials and Studies Coordinating Centre (www.netscc.ac.uk/) by **13.00 hrs on 18th November 2011**. *Expressions of interest received after 18th November 2011 will not be considered.*

Please note that applicants may submit more that 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 rejected. 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. **Shortlisted applicants will be notified by 21st December 2011 and requested to submit a full application by 15th February 2012**.

Applications not approved for short-listing may be transferred to the Clinical Evaluation and Trials workstream if appropriate. Out of remit applications may be transferred to an appropriate NETS programme.