



# National Institute for Health Research

## HTA Researcher-Led Open Call Specification Document Closing date: 1pm, 15<sup>th</sup> May 2019

**Please note that primary research proposal submissions to this call will be on the new NIHR stage 1 application form. This is part of a streamlined application process for researchers applying for funding and is in response to wide user feedback, and as part of the NIHR's continuous improvement culture.**

### 1. Introduction

The Health Technology Assessment (HTA) Programme is part of the National Institute for Health Research (NIHR). The secretariat function of the Programme is managed by the NIHR Evaluation Trials and Studies Coordinating Centre (NETSCC) based at the University of Southampton under a contract with the Department of Health.

The HTA Programme is funded by the NIHR, with contributions from the CSO in Scotland, NISCHR in Wales, and the HSC R&D Division, Public Health Agency in Northern Ireland.

The NIHR HTA Programme funds research to assess the effectiveness of technologies within the NHS. In this researcher-led workstream, grants are available for primary research and evidence synthesis on topics proposed by the researchers.

### 2. Remit

Proposals should normally evaluate the clinical and cost effectiveness of a health technology. For diagnostic technologies, researchers may suggest equivalent evaluations.

We are interested in receiving proposals addressing any health problem in areas not otherwise well covered in our [portfolio](#). Please note that proposals should be within the scope of the [HTA Programme](#). Proposals to investigate the organisation of health services, or services entirely outside the NHS will not be eligible.

The NIHR programmes currently have the following two highlight notices open:

- 1. Complex Health and Care Needs in Older People.** This highlight notice indicates the continuing interest of NIHR in receiving research proposals in this area, and particularly those addressing Frailty; Transitions in care, service delivery and models of care; Medicines management/polypharmacy; Promoting healthy ageing/preventing ill health; Patient-centred decision making.
- 2. Brain Tumours.** This highlight notice indicates the continuing interest of NIHR in receiving research proposals in this area, and it encourages collaborative applications that demonstrate how they build on recent initiatives and investment in the area made by the NIHR, the MRC and other research funders.

For further details of these highlight notices, please see <https://www.nihr.ac.uk/themedcalls>

Please note that the HTA Programme researcher led call is open to all relevant research areas, and does not just include these highlight notices. If you are responding to the highlight notices, please indicate this in the application form in Section 6, Question 1 'What is the problem being addressed?'

### **Technologies to be investigated**

The HTA Programme undertakes research for the benefit of patients and the NHS. Health technology covers any method used to promote health, prevent and treat disease and improve rehabilitation or long-term care. 'Technologies' in this context are not confined to new drugs or equipment, but include procedures, devices, tests, settings of care, screening programmes and any intervention used in the treatment, prevention or diagnosis of disease. They should be currently used in the NHS, or likely to be used if supported by the results of the research. Technologies being evaluated should have had some assessment of efficacy already. For less well evaluated technologies consider the EME Programme. Proposals to evaluate public health interventions in other settings may be eligible to apply to the Public Health Research Programme.

### **Study designs**

The Programme does not restrict the study designs it will consider, but they must be the most suitable to answer the specific HTA research question. Applicants should justify their design and note that we are unlikely to support single centre studies that are less likely to give results applicable in a large number of NHS settings.

For primary research projects, which generate new data, the most suitable study design is often a randomised controlled trial, but this is not the only type of trial we fund. Other study designs may be appropriate, for instance cohort or other observational studies, or adaptive designs. All should be adequately powered and the results should be relevant across the UK population.

Feasibility and pilot studies are eligible. We expect that when pilot or feasibility studies are proposed by applicants, a clear route to the substantive study will be described.

Evidence synthesis projects are also eligible. These should investigate clinical and cost-effectiveness. They are likely to include one or more systematic reviews and economic analysis, but other well designed studies are eligible. Researchers can also apply to the Research for Patient Benefit Programme for evidence synthesis studies. Researchers

should justify why the HTA Programme is the most appropriate to fund this study, rather than other Programmes.

### 3. Application process

We accept stage 1 proposals on an on-going basis. There are three deadlines per year.

The Programme reserves the right to review and develop potentially important research areas for the NHS that are highlighted during the assessment of unsuccessful researcher-led applications. Research topics may be further developed with the aim of openly funding further research to address NHS priorities. Research assessed as an NHS priority will be advertised as a commissioning brief (i.e. a call inviting research proposals in a specified topic area addressing an NHS need). All briefs are openly advertised and proposals submitted to address a brief are considered in direct competition.

The Programme obtains topic suggestions from a wide range of sources and, on occasion, proposals may be submitted to the researcher-led streams, which are on a similar topic area as one in development via our commissioned stream. Please note that **commissioning briefs take priority over applications to researcher-led funding calls**. If an application is submitted on a similar area to a commissioning brief in development, it will not be considered.

### 4. Criteria for assessment of proposals

Primary research applications to the HTA Researcher-Led call are checked for eligibility and competitiveness for:

- a. The need for the evidence in the NHS.
- b. The scientific rigour of the research.

If successful at the above competitiveness assessments, the applications will be considered at a HTA Funding Committee.

#### Scientific rigour

Selected proposals are then considered by a HTA Funding Committee. The Funding Committee uses the following criteria:

- i. *The importance of the research*, taking into account national priorities, policy considerations, prevalence of disease and any social or ethical considerations.
- ii. *Scientific quality of the proposal*. The proposal should be carefully designed to ensure good internal and external validity.
- iii. *Demonstration of the necessary skill mix, experience, project management and infrastructure for success*. High quality proposals need a multi-disciplinary team. The HTA Programme expects research teams to have an appropriate mix of skilled people, such as partnerships between research clinicians and methodologists. For clinical trials, applicants are encouraged to include input from an accredited clinical trials unit, or one with equivalent experience and should plan to engage an experienced trial manager. A commitment to team working is important and a collaborative approach between institutions is welcome.
- iv. *Explanation and justification for estimated recruitment rates in primary research*. Studies should achieve their aims, including recruiting the necessary participants. In the case of clinical trials sample sizes are likely to be large. Researchers should demonstrate that they can recruit the necessary number of participants. The HTA Programme welcomes studies based in settings with a track record of successful recruitment.

- v. *Ethical, legal and social implications of the research proposed have been considered.*
- vi. *Reasonable costs.* The HTA Programme includes 'value for money' in its assessment. The resources requested should be reasonable to answer the specific research question.

## 5. General guidance

### Public involvement

The HTA Programme recognises the increasing active involvement of members of the public in research and would like to support research projects appropriately. The HTA Programme encourages applicants to consider *how* the scientific quality, feasibility or practicality of their proposal *might* be improved by involving members of the public. Research teams wishing to involve members of the public should include in their application:

- The aims of active involvement in this project; a description of the members of the public (to be) involved.
- A description of the methods of involvement.
- An appropriate budget.

Applications that involve members of the public will not for that reason alone, be favoured over proposals which do not, but it is hoped that the involvement of members of the public will improve the quality of the application.

**INVOLVE** ([www.invo.org.uk](http://www.invo.org.uk)) is a key organisation for promoting public involvement in research, in order to improve the way that research is prioritised, commissioned, undertaken, communicated and used. Researchers should use the INVOLVE website for further details on involving the public in research.

### Governance and regulation

Applicants are asked to consult the following documents and follow them as appropriate:

- Medical Research Council's Good Clinical Practice guidelines: <https://www.mrc.ac.uk/research/policies-and-guidance-for-researchers/good-research-practice/>. To be used when planning how studies, particularly RCTs, will be supervised. Further advice specific to each topic will be given by the HTA Programme at stage 2 proposal and contract stages.
- Department of Health's Research Governance Framework for Health and Social Care [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4108962](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962).
- Department of Health/Medical Research Council Clinical Tool Kit <http://www.ct-toolkit.ac.uk/>.

Note that trials or studies involving medicinal products must comply with *The Medicines for Human Use (Clinical Trials) Regulations 2006* and the amendment to the regulations. In these cases, the DH expects the employing institution of the chief investigator to be nominated as the sponsor. Other institutions may wish to take on this responsibility or agree co-sponsorship with the employing institution. The DH is prepared to accept the nomination of multiple sponsors. Applicants who are asked to submit a stage 2 proposal will need to obtain confirmation of a sponsor(s) to complete their application. The DH reserves the right to withdraw from funding the project if they are not satisfied with the arrangements put in place to conduct the trial. The MHRA ([info@mhra.gsi.gov.uk](mailto:info@mhra.gsi.gov.uk), <http://www.mhra.gov.uk>) can provide guidance as to whether your trial would be covered by the regulations.

### **Timescale**

There are no fixed limits on the duration of projects or funding, and proposals should be tailored to fully address the problem. However, applicants should balance the pressing need within the NHS for the information with the need to follow up participants for long enough to measure important outcomes.

### **Making an application**

- To access the form please go to: [www.nets.nihr.ac.uk/funding/hta-researcher-led](http://www.nets.nihr.ac.uk/funding/hta-researcher-led). Before completing your form you should read the guidance notes which can be found on this page. A number of other helpful documents are available on this page to support your application.
- Applications received after **1pm on Wednesday 15<sup>th</sup> May 2019** will not be considered in this assessment round and will be placed into the next cycle for consideration at a later date.

### **Further questions**

If you have any questions which have not been covered in these guidance notes, please visit the website or contact us on [htacet@nihr.ac.uk](mailto:htacet@nihr.ac.uk)