



National Institute for Health Research
Health Technology Assessment Programme



IMPORTANT INFORMATION AND GUIDANCE NOTES FOR APPLICANTS

HTA STANDARD CALL FOR PROPOSALS

There are two types of HTA grant application - OUTLINE proposal and FULL proposal.

This document contains information and guidance to applicants submitting an HTA Standard call OUTLINE proposal only. This may be either Evidence Synthesis or Primary Research.

Please check the Commissioning Brief you are applying for carefully to ensure you are filling in the correct form.

The NIHR Health Technology Assessment programme is funded by the NIHR, with contributions from the CSO in Scotland and NISCHR in Wales.

Data Protection

We have an obligation to keep data secure and to use it appropriately. To fulfil our obligations under law and as a result of our contract with the Department of Health, we adopt various procedures to use and protect data. This will impact on how we deal with you and your joint applicants.

The Department of Health, National Institute for Health Research (DH NIHR) is the Data Controller under the Data Protection Act 1998 ('the Act'). Applicants for funding should be aware that information contained in this application might be shared with other DH NIHR bodies for the purposes of statistical analysis and other DH NIHR management purposes, including targeted communications with selected groups of researchers. Applicants may be assured that DH NIHR is committed to protecting privacy and to processing all personal information in a manner that meets the requirements of the Act.

Data Security - data about you

Personal information will be held on a database in the NETSCC password-protected network that is available only to NETSCC staff. Your details and those of your joint applicants will be retained by NETSCC on behalf of the Department of Health in order to facilitate the running of the HTA programme. If your application is successful at any stage of our process your name, and the details of the sponsoring organisation, will appear on the NETSCC website. In addition, once funding has been agreed and the contract signed, your details will appear in other literature as a grant holder and will be passed to the Department of Health (DH) for inclusion in their publicly available databases of research projects. Your name and those of your joint applicants will be added to our mailing list. This means that you will be sent updates on all the programmes. We may also send you separate literature about the HTA programme and related events in medical/health research. If you have any questions, or if you would prefer not to receive routine and/or general communications, please contact us at: hta@hta.ac.uk

Completing your electronic application form - useful information

Please note that the HTA Standard Call work stream will only accept and consider the outline application form and flow diagram at this stage. If applicants do submit any other documents, these will be removed and will not be considered in the assessment process.

To submit an outline proposal, you must complete all the pages of the up to date electronic application form for the current closing date and provide a flow diagram illustrating the study design and flow of participants (as a .pdf file) if applicable. Please note that previous application forms will not be accepted.

On-screen help is provided by the 'Assistant' (in the form of a ? on the form), and you should refer to this for guidance on specific questions as you complete your application form.

Applicants should be aware that there are character limits set for each text box within the application form; this is to ensure that the form can print out correctly and limits depend on the amount of text inserted into each box. If applicants are cutting and pasting text into the application form and exceed the character limit, an error message will appear. This states 'There is too much text to fit on printed form. It has been changed to indicate where the limit has been reached'. A symbol '<---->' will appear within the body of text inserted to indicate the character limit for the text box. The text can be removed and placed into a word processing document to determine the character limit for the box to help applicants adjust there text to fit the required word limit.

Space restrictions

Applicants should be aware that there are character limits set for each text box within the application form; this is to ensure that the form can print out correctly and limits depend on the amount of text inserted into each box. If applicants are cutting and pasting text into the application form and exceed the character limit, an error message will appear. This states 'There is too much text to fit on printed form. It has been changed to indicate where the limit has been reached'. A symbol '<---->' will appear within the body of text inserted to indicate the character limit for the text box. The text can be removed and placed into a word processing document to determine the character limit for the box to help applicants adjust there text to fit the required word limit.

Before you begin

It is advisable to save your form soon after you begin. To do this, click save and follow the instructions, making sure that you take note of your Save ID number.

It is important that you read these guidance notes fully before starting to complete the application form to ensure that you provide the correct information.

Saving your form

It is advisable to save your form soon after you begin. To do this, click the **Save** button, making sure that you take note of your **Save ID**, located in the top right hand corner of the screen throughout your application. This is the ID number for your application and will be sent to you via email, to the email address that you provide when you first save the form. The email will include a direct URL link to access your form.

Giving others access to the form

If you send a colleague the Save ID for the form they can access and make changes to your form, however only one person can access the form at any one time.

Exiting your form correctly

Should you wish to exit and return to the form at any time, the Save ID will be required to re-access the form.

Please note that you must click the 'EXIT' button on the screen before closing the window that contains the application rather than closing down your internet browser. This will ensure that you are not temporarily locked out of your form.

Locked form

If you are locked out of the form an on-screen notice will let you know how many minutes remain before the form is unlocked.

If a colleague is currently using the form you will need to wait until they have exited the form, as only one person can access it at any one time.

If you are sure that no-one else is using the form, but are still locked out, then please try the following before calling the programme for assistance:

- Wait for the lock-out time to expire
- Re-boot your computer completely, as sometimes a hidden copy of the form is created in the background
- Instead of clicking on the weblink in your letter or email, copy the link and paste it into a new internet browser window

URL links

You may wish to upload URL links to your application or refer to URL links in a body of your text. You are advised not to use any URL shortening service such as '*tiny.cc*' when completing your application. These types of shortening services are associated with hacking and spamming (as it promotes the sending of links that are unclear where they are pointing). Using such URL links may result in your application not reaching us despite receiving confirmation that your application has been submitted successfully.

Printing the form

Please note that the print layout for the form differs from the version you will see online.

Applications Involving Evidence Synthesis

Applicants undertaking systematic reviews should note the commitment of NIHR to publication in the PROSPERO database. PROSPERO was developed by the NIHR's Centre for Reviews and Dissemination (CRD), and is the first online facility to register systematic reviews for research about health and social care from all around the world. Access is completely free and open to the public. PROSPERO registration is a condition of NIHR funding for systematic reviews.

It is accepted that not all systematic reviews commissioned by the HTA programme will fall in to the scope of the CRD register. The immediate focus is on reviews of the effects of interventions and strategies to prevent, diagnose, treat, and monitor health conditions for which there is a health related outcome. A review should also only be registered once it is in receipt of confirmed funding, and not before.

The timing of registration should be at the point when the protocol is complete/stable but before screening studies for eligibility has begun. It is at this point where intentional, or inadvertent, bias could come in to play i.e. manipulating the inclusion criteria to capture those studies that show a particular desired result.

Researchers are required, once registered on PROSPERO, to keep their protocol up to date, this includes mirroring any protocol amendments, updating status when completed (or abandoned) and adding publication details when published.

Registration should take place on the PROSPERO website, and can be accessed at <http://www.crd.york.ac.uk/prospero/>.

SECTION A: Lead Applicant

This is for you to complete your contact details.

SECTION B: Project Details

Strategic HA: Please select the Strategic health Authority where the lead applicant's organisation is located. If outside the UK, select "unspecified", followed by the country where their organisation is located (e.g. unspecified - Italy).

Country if not UK: Eligibility is limited to those administrations that contribute to the relevant NIHR funding scheme unless there is insufficient capacity/capability in those administrations to meet our needs. In practice this means that commissioned research will be limited to England for all programmes, and to Scotland, Wales and Northern Ireland for the programmes to which they are contributing. However, if there is insufficient capacity in these locations to meet our needs, we will consider commissioning research from a wider geographical area in order to meet our needs. This applies to both primary research and evidence synthesis.

Start Date: You should provide your proposed project start date. Please note that successful projects are expected to start within a reasonable time following a decision to fund (usually about six months). Please also be aware that if your project requires ethics/Medicines for Human use approval we are unable to release payments until these approvals have been gained. Your intended start date should allow time for obtaining these approvals and submitting appropriate documents to the HTA programme prior to the official start of the project. (It is worth noting that the start date we are referring to is the HTA formal start date for when we start releasing money and the main bulk of the research begins. We acknowledge that the project team will have actually started working on the project prior to this date, but the formal start date is when our clock starts ticking.)

Research Grant & Research Grant inc. NHS costs: Please enter total amount estimated at this stage. Applicants from Higher Education Institutions should enter the research grant figure as 80% of the Full Economic Cost. Applicants from other organisations (such as NHS Trusts) should enter 100% of the research cost.

Applicants should note that it is in their interests to undertake a thorough, realistic and accurate costing. Costs should not be underestimated and the HTA programme expects that costs identified should not differ between outline and full proposal stage. The Board will pay close scrutiny to such increases and applicants must provide a clear and full justification for any differences.

Although there is no limit to the amount of money you can ask for on one proposal, applicants should be aware that they will have to demonstrate value for money to the NHS.

Objectives: Please summarise the key objectives.

Summary of Project: Basic information on the headings required is provided on the form, however more detailed guidance concerning content follows;

- *Design:* Give a brief statement on the type of study design to be used
- *Setting:* State the health service setting(s) in which the study will occur (e.g. general practice, hospital outpatients, ambulance service users).
- *Strategy for reviewing literature (PR or Modelling):* Explain the criteria applied to assess the quality and relevance of studies identified by the search strategy. Provide an explanation of how these will be decided if these are not yet known.
- *Target population:* Define the population from which the study sample receives the health technology concerned (or the control intervention where appropriate) e.g. women over 60, people with learning disability, people with advanced cancer.
- *Health technologies being assessed:* Give a clear definition of the health technology to be assessed. The purpose of HTA is to assess the value of a health technology compared to best alternatives or where none exists, against no intervention. Where there are established alternative technologies, these should also be defined carefully. Where the technology is

subject to rapid change, details of how this will be dealt with in the project should be included.

- *Measurement of costs and outcomes:* Details should include justification of the use of outcome measures where a legitimate choice exists between alternatives. If the study includes a health economic component, state from what perspective costs and benefits will be considered, and (briefly) how these will be collected.
 - **Where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise. Please see The COMET Initiative website at www.comet-initiative.org to identify whether Core Outcomes have been established.**
- *Sample size:* State the required sample size, giving details of the estimated effect size, power and/or precision employed in the calculation.
- *Project timetables including recruitment rate:* Indicate the anticipated duration of the study, paying particular attention to the expected recruitment rate and a justification for your estimate. Outline the main stages of the proposed project and the expected duration of each.
- *Flow Diagram:* Please note that a Flow Diagram should accompany your application.
- *Expertise in team:* The team should be multidisciplinary and include relevant expertise in the clinical area concerned, in performing systematic reviews, and (where appropriate) others e.g. operational research, health economics, service user.

Clinical Trials Unit: The HTA programme encourages applicants to involve a CTU (where appropriate). Some CTUs in the UK receive support funding from the NIHR and we are keen to gather data on their activity. If you are using a CTU please provide all the information requested. The CTU will be aware of this requirement and able to supply this for your use.

Planned or active related research grants: The HTA Commissioning Board would welcome information on your or your teams wider research activity. We are particularly keen to hear about how your previous or current work will fit with this application.

UK Clinical Research Networks: The HTA programme expects, where appropriate, that applicants will work with the relevant research network(s). Please state which network(s) you intend to work with and indicate how far you have progressed this.

Working with the research networks: We are keen to learn about the benefits you have identified as a result of network collaboration. Please provide as much detail as you can.

Summary for the non-Expert: The summary for the non-Expert should be suitable for a service user and enable them to understand the research proposed. Explain specialised technical terms and acronyms and avoid jargon. More detail on writing for public consumption is available from the Plain English Campaign. A free guide, designed specifically for the Health Sector, can be found at <http://www.plainenglish.co.uk/medicalguide.pdf>.

SECTION C1: Details of Joint Applicants.

Do not include collaborators (individuals who will contribute to the research but do not have responsibility for its management) in this section. You will have the opportunity to include them at the full proposal stage. Please note that at the outline stage we limit the number of joint applicants to eight. This can be increased at full proposal stage if required.

SECTION I: 'History of Proposed Research'

Please answer questions 1 to 4 as fully as possible.

Q1: Please note that the HTA programme does not accept applications that are currently pending with other research funding organisations (unless under shared funding arrangements). If this applies to your application form, please contact the HTA programme.

Q2: If you are proposing a study which requires joint or shared funding, it is in your interests to provide a clear explanation of the arrangements for this. This should include details as to full access to all data relating to the proposed study, and consideration of any conflicts of interest that may arise from the funding arrangements.

Q4: Conflicts of Interest: declare any potential conflicts of interest that you or your joint applicants may have, including any facts that, should they come to light at a future date, would embarrass either the programme or the individual who withheld the fact (e.g. if a member of the team holds a patent or has a financial interest within the HTA area). Where the commercial sector may be involved with the application or the study, please state clearly the relationship to the ownership of data, access to data, and membership of project oversight groups

FLOW DIAGRAM

For primary research and for other types of study where appropriate, please create a flow diagram (as a .pdf file) illustrating the study design and the flow of participants for submission with your application form. The HTA Commissioning Board values the inclusion of such a diagram to explain the design of your proposed study. Applicants should describe complex interventions and controls as accurately and fully as possible within their diagram. If proposing a RCT, we advise you refer to the CONSORT statement and website for guidance (<http://www.consort-statement.org>).

SUBMITTING YOUR APPLICATION

The HTA programme requires you to submit your application form and flow diagram .pdf in time to reach our offices before the stated deadline in order to process your application. Please note that we cannot grant any time extensions beyond this deadline.

The deadline for this call is 13:00 on the 9th February 2012.

Please ensure that before you submit your application, you have completed the necessary fields and saved a version of your form.

If you need help

You can contact the team at the HTA Programme using the telephone numbers provided on the application form and giving the identification number of the form (click on the telephone icon in the top right-hand corner of the screen). This will enable the team to see your form while they are speaking to you, but not to make changes.

If, after carefully reading all the instructions, you still have difficulties completing your application. Please visit the HTA programme website (<http://www.hta.ac.uk>.) which contains a list of Frequently Asked Questions and Answers. If your particular query or problem is not addressed, please telephone 023 8059 5621 and leave a message or contact htacmsng@southampton.ac.uk. A member of the team will get back to you as soon as they are able. Please be aware that while every effort is made to answer queries, if the query is made very near the closing date and time, the HTA Programme may not be able to provide a considered response.