



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 FULL proposal.**

Please note: This form is to be used for applicants responding to Evidence Synthesis briefs only unless otherwise stated.

Primary Research applicants should only use this form if their proposal has been short-listed by the HTA Commissioning Board, and you have been invited to submit a Full Proposal form.

**Full Proposal:** A full proposal consists of two parts;

- 1. Electronic Application Form (Part I):** Please complete all the relevant sections of the electronic application form.
- 2. Detailed Project Description (Part II):** Please prepare a detailed project description of your proposed project (as a Microsoft Word document).

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

***Please note that animal studies are not appropriate to the HTA programme***

#### **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](mailto:hta@hta.ac.uk)

## **Completing your electronic application form - useful information**

To submit a Full proposal, you must complete all the pages of the up to date electronic application form for the current closing date and provide a detailed project description. Please note that previous application forms will not be accepted.

Please ensure that you read the Commissioning brief thoroughly before starting your application particularly if you are responding to an advert for an Evidence Synthesis topic. If you are unsure about any aspect then please contact the team at [htacmsg@soton.ac.uk](mailto:htacmsg@soton.ac.uk).

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.

### **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 their 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.**

### **To submit a proposal**

In order to submit a full proposal to the programme you must:

- complete all mandatory fields of the electronic application form
- provide a detailed project description of up to 20 pages, including a flow chart (further guidance relating to the detailed project description is available from page 13).

### **Where to find the link to the form**

If you have already submitted an outline proposal, the link to the full proposal form will be in the letter inviting you to complete a full proposal. Please use this link at all times. Applications submitted on the incorrect form may be rejected.

### **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 registration in the PROSPERO database. PROSPERO was developed by the NIHR's Centre for Reviews and Dissemination (CRD), and is the first international online facility to prospectively register systematic reviews for research about health and social care. Access is free of charge 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 major 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/>.

Due to the limited capacity of the board and peer reviewers, the HTA Commissioning work stream is unable to present more than three evidence synthesis proposals in a single topic area at any one board. As such, if four or more proposals are received in any one topic area there will be a pre-board shortlisting process, allowing a maximum of three to progress. Any unsuccessful applicants will be notified and the decision ratified at the board meeting.

## **Completing the form**

### **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:**

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 (Primary Research (PR) & Evidence Synthesis (ES)):* Give a brief statement on the type of study design to be used (e.g. PR: controlled trial; ES: systematic review).
- *Setting (PR):* State the health service setting(s) in which the study will occur (e.g. general practice, hospital outpatients, ambulance service users).
- *Search strategy (ES):* Provide details of the body of existing evidence that will be covered and access arrangements (e.g. use of databases, hand-searching, communication with authors).

- *Review strategy (ES) and 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 (PR)*: 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 (PR)*: 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 (PR)*: 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.
- *Sample size (PR)*: State the required sample size, giving details of the estimated effect size, power and/or precision employed in the calculation.
- *Project timetables (ES) including recruitment rate (PR)*: 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 (PR)*: Please note that a Flow Diagram (as described on page 13) 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.
- *Expected output of research (ES)*: Outline how report conclusions will be presented: synthesis type (qualitative / quantitative), guidelines for practice and recommendations for further research.

**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.

**You will also be required to supply documented evidence, in the form of a letter from the CTU, providing details of how they have agreed to support your project.**

You do not need to complete these questions if you are not proposing to undertake a clinical trial.

**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 (PR only):** 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 (PR only):** 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.**

You must complete personal details of everyone involved and state their contribution towards the proposed project (e.g. data collection, coordination and project management, analysis, methodological input, service user input). The form allows for you to include a maximum of 30 joint applicants.

Do not include collaborators (individuals who will contribute to the proposal but do not have responsibility for its management) in this section. Collaborators should be included under 'Expertise' in section 5 of Part II of your detailed project description.

## **SECTION D: '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 using the icon at the top of any of the pages.

**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.

**Q3:** We would like to know more about the knowledge you may generate through this project. The knowledge and know-how generated can be described as Intellectual Property. Intellectual Property (IP) includes both traditional IP (patents, trademarks and registered designs etc) and non-traditional IP (software and codified knowledge such as written procedures, guidelines etc). In the healthcare context, non-traditional IP will include new service delivery designs, toolkits, checklists, questionnaires and so on, all of which have the capacity to improve patient care and deliver cost savings to the NHS. In answering the questions below, it might help you to consider if your project will generate any of the following research outputs:

- New or improved checklist or questionnaire
- New medical patient data
- New or improved software tool
- New comprehensive toolkit for patient care
- New database design
- New medical device or pharmaceutical drug

Each of these research outputs constitute the development of new or foreground IP.

### **QUESTIONS:**

1. Please provide details of any background IP – the IP available at the start of your research project - which is being used in delivery of this project. Background IP may have been developed through earlier research projects which may or may not have benefitted from NIHR funding. Have you reached agreement to use the background IP? If so, please provide a copy of these agreements.
2. Will any Foreground IP be generated during the research project?
3. Have you taken any advice from your organisation (eg technology transfer office) in terms of IP matters?
4. Has any third party approached the project (or has the project team offered to a third party) to use the research outputs generated from this project? If so, are there any licencing/copyright agreements in place? If so, please provide a copy of these agreements.
5. If any product or material is being trialled (ie medical device, toolkit, questionnaire) please provide details of the availability of these products or materials to the project team once the research project has ended.
6. How will any research outputs be managed, protected and exploited, either through adoption in the healthcare service or through commercial exploitation?
7. What are the market opportunities both in the UK and worldwide and, if any are identified, how will these be managed?

8. What impact will this have on patients, staff and health services?

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.

## **FINANCIAL INFORMATION**

The cost details required in this section are those that relate strictly to the R&D costs you wish the HTA programme to support. These are all the research costs which your institution will incur solely through undertaking this piece of research.

### **Section G1: Details of posts and salaries**

Please list all members of staff working on the project. Those named as principal and co-applicants earlier in the application form will automatically be inserted under 'Principal and Co-applicants'. Other staff will need to be listed.

You should state the full time annual costs of members of staff at the start of the project.

Full staff costs should be included and should not be reduced to take into account the percentage of time or the duration of time which the person will spend on the project – this operation will be done in G2.

For members of staff which your institution chooses to cost on the basis of average bands rather than actual salary, please state which band you are using and what the full annual cost is.

### **Section G2: Annual costs of posts listed under G1**

Those named as principal and co-applicants earlier in the application form will automatically be inserted under 'Principal and Co-applicants'. Other staff should be listed, as in G1.

You should now allocate the individual staff member costs to each year of the project, allowing for increments and inflation. Please note the '% full time on project column' and the years 1-5 cost columns are independent and the % figure is not used to calculate the staff costs.

You should allow for inflation at your institution's usual rate when calculating salary costs. Use current rates of pay, and build in any known annual increments (again at current rates). If your project is subsequently selected for funding then, once it is underway, you will NOT be able to claim for pay awards retrospectively.

For the years 1-5 columns, the amount the applicants enter should be the cost of the individual to the project, taking into account that the person may not be full time. For example, if the person costs £20,000 and is expected to work 50% of the time on the project, in the percentage column put 50, then £10,000 in year 1, £10,000 plus inflation and any increment in year 2, £10,000 plus inflation and any increments in year 3, etc. Alternatively, if someone is going to work full-time on the project, but only for the last 6 months, you would enter 100 in the % column and 6 in number of months then the cost of their work in the year which is the last one of the project. If the project lasts for several months and someone's involvement varies over the course of the project, it may be easier to make a separate line entry each time it changes.

It is important to double check that the %, total months and yearly costs information are consistent with the 'Current Annual costs' information in G1 (G1 should show the full current staff costs independent of % etc, whereas the yearly costs in G2 depend on % etc).

Please take care to check whether staff are employed by a Higher Education Institution (HEI) or non-HEI organisation (as this will have an effect on the funding provided – HEI funding is calculated at 80% of costs, and non-HEI funding is calculated at 100%). All Non-HEI staff should be marked by clicking the Non-HEI cost circle in the far right column, against the relevant row.

If there are more than 12 co-applicants you will have created an additional electronic application form. You need to enter the salary costs of the additional co-applicants (Sections G1.1 and G2.1) in this form. Once the staff costs in G2.1 have been fully defined, copy the figures in the rows labelled the "Applicant - HEI costs" and "Applicant - non-HEI Costs" to the relevant rows of table G2.1 in the main form. This ensures the costs of all co-applicants involved in the project are included in the total cost of the project calculated by the main form.

### **G3: Travel and Subsistence**

If conferences or international travel are included, a statement naming the conference or purpose of travel and demonstrating the benefit to the project must also be included. Applicants are encouraged to promote and present their findings and travel and subsistence costs relating to this should be included here. Please note that the HTA programme will fund a maximum of two people to attend one international conference, or one person to attend two international conferences.

You will need to include the travel and subsistence costs of your Trial Steering Committee and Data Monitoring & Ethics Committee if applicable.

Costs of a Monitoring meeting at NETSCC, HTA for primary research projects, should be included. Please note that the HTA programme will fund a maximum of three people to attend. These meetings do not apply to evidence synthesis projects.

**Journeys cost:** Enter the total cost of transport for all journeys for destination/purpose. If travel is by car transport, apply your institution's mileage rates (however this should not exceed the DH maximum rate, currently 30p per mile).

**Subsistence:** Subsistence covers accommodation (if necessary) and meals associated with the travel.

### **G4: Equipment**

Costs of computers are normally restricted to a maximum of £750 each, so a statement of justification must be included for any purchase above this limit.

Equipment costs over £50,000 will normally be funded at 100%. If you are an HEI then please contact us if your equipment exceeds £50,000, as the form will automatically reduce it to 80% and a manual adjustment will therefore need to be made.

If your organisation is an 'eligible body' under HM Customs & Excise Notice 701/30 (VAT: Education and Vocational Training), e.g. you are a university or NHS Trust, the cost of any equipment should include any VAT you have to pay on purchase.

### **G5: Consumables**

Please itemise and describe the requirements fully (e.g. postage, stationery, photocopying).

### **G6: Other Direct Costs**

Itemise and describe fully anything which does not fit into the previous categories. Please note that in HEIs, recruitment of staff, and general training (e.g. in common IT packages) are costs which should be covered by the indirect costs element of the grant being sought. Training specific to this trial, e.g. in how to deliver a specific intervention, should be itemised and fully described here.

External consultancy costs, including service user involvement can also be claimed here. A guide to involvement and payment for support by service users is available via web link at

<http://www.hta.ac.uk/funding/troubleshooting/index.html#hta86>

For consultancy specify the hourly rate and the number of hours. Please note that consultants must not be employed by the applicant's institution, if they are, any costs should be entered in section G1 and G2.

You can claim here for initial preparation costs of a Cochrane review, if the Commissioning Brief specifically encourages applicants to consider producing and maintaining a Cochrane systematic review from HTA commissioned systematic reviews concerned with evaluation of interventions for prevention, treatment or rehabilitation.

Additional costs (e.g. the charges levied by MHRA) associated with obtaining a Clinical Trial Authorisation should be included here if your trial falls under the remit of 'The Medicines for Human Use (Clinical Trials) Regulations 2004' Anticipated costs (e.g. the costs of an inspection if the MHRA decide to visit your trial) should not be included. The HTA programme is committed to supporting costs that occur as a result of the clinical trials regulations and will honour costs as and when they occur but will not support costs that may not happen. If you are unsure as to whether your trial is covered by the regulations you should see the MHRA website

(<http://www.mhra.gov.uk/index.htm>) which contains the latest information and a helpful FAQ page. Any costs associated with publication or presentation of findings (other than those related to travel and subsistence or consumables) should be included here.

Any large costs (i.e. greater than £25k) should be further detailed with a breakdown of constituent parts or a timescale profile of the costs.

### **H: Indirect Costs**

These costs are calculated on the basis of TRAC methodology and only apply to HEI. Applicants from other types of institutions should leave this section blank.

#### **H1: Estates Charges**

This number is based on the number of full-time equivalent research staff working on the project, using the estates charges set by your institution.

The HTA programme reserves the right to examine the full breakdown of the calculation of your institution's estates charges.

Where staff from more than one HEI is working on the project there may be different estates charges for each one. Please list each of these on separate lines.

#### **H2: Indirect Costs Charges**

This number is based on the number of full-time equivalent research staff working on the project, using the indirect costs charges set by your institution.

The HTA programme reserves the right to examine the full breakdown of the calculation of your institution's indirect costs charges.

Where staff from more than one university is working on the project there may be different indirect costs charges for each one. Please list each of these on separate lines.

### **S: Summary of Cost of Project**

The figures in this section are completed automatically.

NIHR Programmes are currently funding HEIs at a maximum of 80% of full economic cost (except for equipment over £50,000: 100%)

There are no estates charges or indirect costs for non-HEI institutions, therefore NHS R&D will fund a maximum of 100% of directly incurred and directly allocated (non-estates) costs.

Please note that whilst these percentages will be used to calculate the maximum grant payable, the HTA programme reserves the right to award a grant for less than this maximum where this is appropriate.

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## **APPENDIX A:**

### **NHS Support Costs and Treatment Costs (inc. Excess Treatment Costs)**

The NHS costs associated with your application should be entered in this section.

Much health and health services R&D is associated with patient care services. The R&D cannot proceed unless that patient care service is also being provided. A distinction is drawn between the costs of the R&D itself (the Research Costs) - which are always paid for by the funder of the research - and the associated patient care costs (NHS Support and Treatment Costs). With regard to R&D funded directly by DH (which includes all work commissioned by the HTA programme), the NHS is obliged to support the research through normal patient care commissioning arrangements - including any Excess Treatment Costs.

Appendix A of the electronic form requires an estimation of the patient care costs associated with the research. An explanation of why these costs are being incurred and the basis on which the estimations have been made should be included in your Detailed Project Description (see section 7: 'Justification of the support requested').

**NHS Support Costs:** These are the additional patient care costs associated with the research, which would end once the R&D activity in question had stopped, even if the patient care service involved continued to be provided. These might cover items such as extra patient tests, extra in-patient days and extra nursing attention.

**Treatment Costs:** These are the patient care costs which would continue to be incurred if the patient care service in question continued to be provided after the R&D activity had stopped. Where patient care is being provided which differs from the normal, standard, treatment for that condition (either an experimental treatment or a service in a different location from where it would normally be given), the difference between the total Treatment Costs and the costs of the "usual standard care" (if any) constitutes Excess Treatment Cost, but is nonetheless part of the Treatment Cost, not an NHS Support or Research Cost.

Applicants must note that Treatment Costs are the responsibility of Trusts and PCTs, and they will be expected to meet these costs should the research be funded (except in very exceptional circumstances). Further information on these costs can be found in the DH document Non-commercial, externally funded R&D in the NHS HSG (97)32.

Please note you should take into account any cost savings due to release of any usual standard care resources when calculating the total treatment costs involved in the R&D.

For further information please refer to the DH document 'Attributing revenue costs of externally-funded non-commercial research in the NHS' for guidance on completing this section (web link provided at <http://www.hta.ac.uk/funding/troubleshooting/index.html#hta82>).

If you have any queries regarding NHS costs, please email Sue Wight, Support Costs Manager at NETSCC at [s.f.wight@soton.ac.uk](mailto:s.f.wight@soton.ac.uk).

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## APPENDIX B:

### Department of Health Monitoring Information

This information is required for monitoring purposes by the DH. The majority of the boxes offer a choice from a drop down menu or simply require applicants to tick boxes relevant to them. However, please note that this section must be completed.

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## DETAILED PROJECT DESCRIPTION

### **Applicants submitting a Full Proposal must also include a Detailed Project Description.**

This should be a maximum of 20 pages, using a font size no smaller than 10 (Times New Roman).

Applicants should note that any extra pages will be removed upon receipt and therefore not assessed. If applicants wish to add additional information, this should be in the way of hyperlinks in the text which can be downloaded by assessors. The HTA Programme does not guarantee that these will be taken into account. Please note that additional pages will not be circulated to assessors by the HTA Programme

### **A Detailed Project Description should contain the following sections and information:**

**1. Project title:** This should be the same as that given in your application form (Section B: Project Details). PR applicants should also quote the HTA project number given at the outline stage.

**2. How the project has changed since the outline proposal was submitted (PR only):** A concise summary of how your proposed project has changed (e.g. in the light of new research) since your outline proposal was submitted.

**3. Planned investigation:** Include the following subheadings as appropriate:

**Research objectives** - these need to be measurable and time-bound for project monitoring purposes.

**Existing research** - summarise existing research on this topic, with particular emphasis on secondary research, and set out the implications of this for the proposed project.

**Research methods** - The type of research required is usually listed in the commissioning brief. However, there may be practical or ethical reasons why the required research method (e.g. RCT) may not be possible. Applicants proposing research methods other than those stated in the commissioning brief should fully explain and justify their decision.

Reference should be made to established research techniques and any adaptations of these for the purposes of the research proposed should be fully explained and substantiated.

In the case of literature-based work, valid and reliable methods should be proposed for identifying and selecting relevant material, assessing quality and synthesizing results.

Where policy implications are considered, applicants should place emphasis upon assessing the likely effects of a range of policy options (open to decision-makers) rather than solely providing a judgement on a single strategy.

If proposing a randomised trial, describe explicitly how participants will be allocated to trial groups, and describe methods to protect against other sources of bias.

State if any pilot study has been carried out using this design and if yes, findings must be provided. Also please state any implications resulting for the proposed research.

**Planned Interventions (PR only)** - include both experimental and control interventions. Are there likely to be any problems with compliance and if so, please provide an estimation of the likely loss-to-follow-up anticipated?

**Planned inclusion/exclusion criteria** – a full detailed list must be included.

**Ethical arrangements** - Outline the ethical issues, and arrangements for handling them. Are you using patient information from an existing database? If so, have the patients given their consent for their data to be included in that database for research purposes? If not, is the database exempt under s60 of the Health and Social Care Act 2001? Please note: if your application is successful, funding will not be released until all approval documents have been submitted to the HTA programme.

**For Primary Research only** - give further details under the following subheadings as appropriate:

- Risks and anticipated benefits for trial participants and society, including how benefits justify risks.
- Informing potential trial participants of possible benefits and known risks.
- Obtaining informed consent from participants whenever possible or proposed action where fully informed consent is not possible (e.g. emergency settings).
- Proposed time period for retention of relevant trial documentation.
- Proposed action to comply with 'The Medicines for Human Use (Clinical Trials) Regulations 2004'.

**Proposed sample size** - specify the number of patients and centres (including both control and treatment groups), and recruitment rates. A justification for the assumptions underlying power calculations used must be provided. A full, clear justification is required for any patient recruitment planned outside the U.K.

**Statistical analysis** – clearly state the purpose of any statistical analysis, and do not simply name a statistical test or software package. Please state the proposed type and frequency of analyses.

**Proposed outcome measures** - include both primary and secondary measures. The endpoints of interest will in most cases include disease-specific measures, health-related quality of life and costs (directly and indirectly related to patient management). A period of follow up should be considered and undertaken which is sufficient to ensure that a wider range of effects are identified other than those which are evident immediately after treatment.

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](http://www.comet-initiative.org) to identify whether Core Outcomes have been established.

**Research Governance (for PR only)** - all primary research proposals must have a nominated sponsor. The DH expects the employing institution of the lead applicant to undertake this role. 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 full proposal will need to obtain confirmation of a sponsor(s) to complete their application. The DH reserve the right to withdraw from funding the project if they are not satisfied with the arrangements put in place.

The application form includes a section where the lead applicant's employer needs to confirm they are prepared to take on sponsorship of this study. For further discussion – please see the FAQ page (<http://www.hta.ac.uk/funding/troubleshooting/index.html>).

The Clinical Trials Toolkit website (<http://www.ct-toolkit.ac.uk/>) is a useful resource containing information about trial regulation and governance requirements. .

The RGF and 'The Medicines for Human Use (Clinical Trials) Regulations 2004' both require that arrangements for the management of trials involve an element of expert advice that is entirely independent from the lead investigator and their host institution(s). The HTA programme expects that all funded trials have a trial steering committee (TSC), including an independent chair and at least two other independent members and a Patient and Public Involvement representative where appropriate, along with the lead investigator. Observers from the HTA programme should be invited to all TSC meetings although they usually will not attend. The trial would be expected to either propose a separate Data Monitoring and Ethics Committee (DMC), or to justify why such a committee is not required. Where a DMC is established it should be independent of the applicants and of the TSC, while reporting to the TSC and (via the TSC) to the HTA programme. Detailed arrangements may need to vary according to the nature of the study and the host institution(s) involved. The HTA programme is keen that the arrangements for each proposed trial are proportionate to the type, size and duration of the study involved. Proposed arrangements for independent supervision should therefore be detailed and justified in this application, particularly if a case is being made to justify why a TSC and/or a DMC is not required. We do not require a proposed TSC/DMC membership lists at this stage, but an indication of members who are likely to be proposed (including overseas members) should be included.

For further guidance please see Appendix 3 of the MRC Guidelines on Good Clinical Practice in Clinical Trials which can be found at -

<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416>

**4. Project timetable and milestones:** Provide a detailed project timetable including milestones to represent specific steps towards achieving the stated research objectives. Milestones should include a defined start and end date, be measurable, concise and realistic as they will be used for project monitoring purposes. Although the precise number of milestones will depend on the size and nature of the project, it is expected that between 3 and 10 milestones should be set for each project year. If your project requires ethics/Medicines for Human use approval, allow time for obtaining these approvals and submitting appropriate documents to the HTA programme prior to the official start date (see section B above). Time for production of the draft report and a draft paper suitable for publication in a peer-reviewed journal should also be included. Please note that failure to produce these documents will result in the final payment being withheld.

If your application is successful, you will be required to submit progress reports against which relevant milestones will be checked. Where appropriate, these progress reports will be based on the project timetable and milestones, but will occur at approximately six month intervals. If you are late producing progress reports and a single draft final report of the expected standard for the HTA programme, we may withhold payments, in accordance with our retention policy.

**For Primary Research:**

*Additional milestones must include:* patient recruitment and expected recruitment rates; follow-up; closing the database and analysis of the data. Other milestones could include: recruiting staff, establishing premises, purchasing equipment, publishing protocols, ethics approval, organisation recruitment, literature searches, pilot programmes, interviews, data capture, data cleaning, and report writing.

*NB - Ethics and 'The Medicines for Human Use (Clinical Trials) Regulations 2004':* please note that if your project requires ethics approval and / or a Clinical Trials Authorisation, funding will not

be released until all required approval documents have been submitted to the HTA programme.

The Project Lead/Budget Holder may consider that the requirements for project management, control and reporting necessitate the appointment of an appropriate Project Manager/Coordinator. Experience of other projects sponsored by the HTA Programme has shown that a good Project Manager can facilitate the delivery of a project on time and within budget. If so the costs attributable to this person should form part of the proposal to be considered. An example job description of a Project Manager is available via <http://www.hta.ac.uk/investigators/governance.shtml>.

**5. Expertise:** Outline the particular contribution each member of the team will make towards the project and the particular contribution that collaborators are intending to make. In addition, give details of supervision arrangements for junior staff involved. The HTA programme expects teams proposing randomised controlled trials to include input from an accredited clinical trials unit, or one with equivalent experience.

**6. Service Users:** The HTA programme recognises the increasing active involvement of service users in research and would like to support research projects appropriately. Applicants are encouraged to consider whether the scientific quality, feasibility or practicality of a proposal could be improved with service user involvement. Research teams wishing to involve service users should outline their plans here stating: the aims of active involvement in this project; a description of the service users to be involved; a description of the methods of involvement. Applications that involve service users will not be favoured over proposals that do not, but it is hoped that the involvement will improve the quality of the application. INVOLVE (formerly Consumers in NHS Research) has issued guidance for researchers on public involvement in research and the paying of service users actively involved in research. These are available via [www.hta.ac.uk/PPIguidance/index.shtml](http://www.hta.ac.uk/PPIguidance/index.shtml).

**7. Justification of support required:** Outline staff numbers and grades, timescales, equipment purchases etc that you are requesting the HTA programme to fund. If you propose to purchase expensive medical equipment, justify fully why you are not proposing to lease it, since this is the DH preferred option. You must also provide an explanation and justification of the NHS Support Costs and Excess Treatment Costs associated with this proposal within this section, including an explanation of the basis on which these NHS costs have been estimated, if applicable. High quality health technology assessment is essential to improving health care. However, the conduct of such work involves activities that entail the burning of fossil fuels thereby releasing carbon dioxide and other greenhouse gases (GHG) into the atmosphere. These gases are changing the global climate with serious implications for human health and for ecosystems. For this reason, it is essential that all sectors of the economy, including the health research sector, take action to reduce their GHG emissions. The HTA programme is committed to reducing the GHG associated with its activities and urges applicants to consider carefully this important consideration when undertaking HTA funded research. Further information about how to reduce GHG emissions is available from: [www.carbontrust.co.uk](http://www.carbontrust.co.uk)

**8. Flow diagram (primary research only):** Please supply a flow diagram illustrating the study design and the flow of participants, for submission with your application form. The HTA programme boards value 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>).

Your flow diagram will be reviewed by the Designated Board Members prior to board, and projected to the whole board during their discussions. **Please therefore supply versions in both Powerpoint and PDF for these purposes.**

**9. References:** Use the Vancouver format  
(Author(s). Title. Journal. Year; Volume: Start page - End page).

Finally, when you have completed your Detailed Project Description:

- Create a header containing your allocated project reference if known.
- Create a footer showing page numbers.
- Create a .pdf version of your document

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**In addition, where appropriate please attach a letter of support from the Clinical Trials Unit which is involved in your application.**

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## **SUBMITTING YOUR APPLICATION**

You must submit your application form, with the attached detailed project description and flow diagram (in both Powerpoint and PDF), by the stated deadline. We cannot grant any time extensions and the deadline will be strictly observed. You should therefore plan your application carefully. We will not enter into negotiations for extensions.

Full proposals must be submitted electronically **and** as hard copies.

- Submit your application electronically, using the Submit button on the last page of the web form.
- Two paper copies of your proposal, one of which must contain all appropriate original signatures should be sent to us at the address below. Please note that the signed paper copies should be received by the office no later than a maximum of 1 week after the deadline below. The paper copies **must** be identical to the electronic application, as no further changes can be made after the deadline.

**The HTA Commissioning Team, NETSCC  
Alpha House, Enterprise Road,  
Chilworth Science Park,  
Chilworth, Southampton SO16 7NS**

**For Evidence Synthesis full applications the deadline is 13:00 on the 12<sup>th</sup> January 2012.**

**Please refer to your decision letter for deadline details if submitting a Primary Full or shortlisted Evidence Synthesis outline application.**

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](mailto: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.*