GUIDANCE NOTES FOR APPLICANTS COMPLETING OUTLINE PROPOSALS

MIS on-line NIHR Standard Application Form (SAF)

These guidance notes apply to:
Themed Calls

About these guidance notes

This document contains information and guidance to applicants submitting an OUTLINE proposal.

Applications for funding are made online through the NETSCC Management Information System (NETSCC MIS). You must register or log-in to the NETSCC MIS to complete and submit your application.

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. You may also find it helpful to read our FAQs www.nets.nihr.ac.uk/faqs

We have endeavoured to cover all necessary information relating to the application form through these resources. Incorrectly completed applications may be rejected.
PART 1: Background information

1. Introduction
   1.1 Data Protection
   1.2 Data security
   1.3 NIHR Carbon Reduction Guidelines
   1.4 Requirements for Systematic Reviews to be registered with PROSPERO.
   1.5 Applications involving tissue collection and biobanks

2. Getting Started And Using the Form
   2.1 Starting an application
   2.2 To access an application
   2.3 To submit an application
   2.4 Saving your form and system time-out
   2.5 Browsers that best support the NETSCC MIS
   2.6 Spell-checking
   2.7 Space restrictions when entering text
   2.8 Giving others access to the form
   2.9 Leaving the application task
   2.10 Technical support
   2.11 Space restrictions
   2.12 Use of non-standard characters

PART 2 Guidance for completing your application form

3. Research Details
4. Contact information
5. Lead applicant details
6. Curriculum Vitae (CV) section
7. Research CV
   7.1 Recent Relevant Publications
   7.2 Volume Reference
   7.3 Research Grants Held
8. Co-applicants
9. Patient and Public Involvement
10. History of application
   10.1 Previous submission
   10.2 Applications Submitted to NETS Programmes
   10.3 Other Funders / Applications in Progress
11. Case for support
   11.1 Scientific Abstract
   11.2 Summary in Plain English
12. Research Plan
13. Background and Rationale
   13.1 What is the problem being addressed?
   13.2 Why is this research important in terms of benefit to patients and the NHS?
   13.3 Evidence – why is the research needed now?
   13.4 Aims and Objectives
14. Changes from first stage
15. Dissemination and outputs
16. Relevant Expertise
16.1 Strengths of Research Team - contribution of each member 20
16.2 Declarable interests 20

17. **Justification of costs** 20
17.1 Guidance on costing for Outline Application Form 21
17.2 Information on Different Types of Organisations 21
17.3 Direct Costs 22
   i) Posts and Salaries Summary.
   ii) Travel, Subsistence and Conference fees.
   iii) Equipment.
   iv) Consumables.
   v) Patient and Public Involvement.
   vi) Other Direct Costs.
   vii) Patent and Legal.
17.4 Indirect costs/ Overheads 23
17.5 Commercial/Other Partner Organisation Indirect Costs 23
   i) Indirect Costs
17.6 NHS Support and Treatment Costs 24
   (incl. Excess Treatment Costs/Savings)
      i) NHS Support Costs
      ii) NHS Treatment Costs
17.7 Further information 24

18. **Intellectual Property** 25

19. **Wider context** 27
   19.1 Network Involvement 27
   19.2 Involvement of Clinical Trials Units 27
   19.3 Involvement with other partners 28
   19.4 Other Sources of Funding 28

20. **DH Monitoring** 28
   20.1 UKCRC Health Categories 29
   20.2 UKCRC Research activity Codes 29

21. **Research Design Service (RDS) Involvement** 29

22. **Suggested Referees** 29

23. **Uploads** 30
   23.1 Flow Diagram 30
   23.2 References 30
   23.3 Letter of support from Clinical Trials Unit 30

24. **Acknowledgement** 30
   24.1 Agreement to the Terms and Conditions 30

25. **Review and Submit** 30
   25.1 Un-submitted applications 31

26. **Assistance/ Contacting us** 31

27. **Useful links** 32
PART 1: Background information

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.

Anyone who considers that they can carry out high-quality health-related research is likely to be eligible. If you have any concerns regarding your eligibility to apply we advise that you contact us before completing an application. The HTA programme welcome applications which are within the programmes' remits from all sectors. Applicants from non-clinical or non-academic sectors are strongly advised to consider collaborating with the relevant sectors or organisations to demonstrate they have the full breadth of expertise required to carry out their proposed research within their applications to the HTA programme. Applicants should always check individual call specification documents for any additional eligibility requirements. Applicants, and their employing organisations, should be aware that to host research the organisation concerned must be capable of fulfilling the role of research sponsor as set out in the Research Governance Framework for Health & Care.

The NIHR Health Technology Assessment 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 programme operates three funding streams; Commissioned calls for research where important questions for the NHS have been agreed by our prioritisation panels, Clinical Evaluation and Trials (CET) which is our researcher-led funding stream and also welcomes applications that may span other NETSCC Programmes, and annual / bi-annual Themed Calls.

1.1 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’). Under the Data Protection Act, we have a legal duty to protect any information we collect from you. You should be aware that information given to us might be shared with other DH NIHR bodies for the purposes of statistical analysis and other DH NIHR research management purposes. NETSCC also reserves the right to share, in confidence, details of your application with other approved research funding organisations outside NIHR in order to coordinate research activity in the UK.

Information collected from you will not be passed to any third party outside the NIHR except specifically as detailed above without your consent except where we are under a statutory obligation or entitled to do so by law.

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.
1.2 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 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

1.3 NIHR Carbon Reduction Guidelines

Researchers applying for NIHR funding are asked to consider the carbon footprint of their research and take steps to reduce carbon emissions where appropriate. Advice on how to do this can be obtained from the NIHR Carbon Reduction Guidelines: www.nets.nihr.ac.uk/resources-and-support/nihr-initiatives.

1.4 Requirements for systematic reviews to be registered with PROSPERO

Applicants undertaking systematic reviews should note the commitment of NIHR to publish 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.

1.6 Applications involving tissue collection and bio-banks

UK Biobank is a major national health resource with the aim of improving the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses. As such, applicants are encouraged to consider whether Biobank may be able to provide suitable data for their study, rather than request funding for unnecessary new data collection. We do not want to discourage establishment of new collections of participants and their data where this is necessary to address the research questions under consideration, our aim is to avoid applications for funding to set up Biobank-like cohorts where the use of Biobank would prevent wasteful duplication of Biobank-like activities.

UK Biobank has recruited 500,000 people aged between 40-69 years in 2006-2010 from across the country to take part in this project. They have undergone measures, provided blood, urine and saliva samples for future analysis as well as detailed information about themselves. The health of members of this large cohort will be followed over the coming years and the participants have consented to be approached about health research. http://www.ukbiobank.ac.uk/

Please note: Some of the NIHR programmes, including the HTA Programme, are unlikely to fund work which focuses on collection of physiological, biochemical or other information unless there is a clearly defined way in which this will be used for the benefit of patients (either directly or in terms of improving outcomes of other patients). For these reasons we generally do not fund bio-banks or disease registers. If you would like to include this as an element of your research proposal, please contact us.
2. Getting started and using the form

Applications for funding are made online through the NETSCC Management Information System (NETSCC MIS).  [https://netscc-mis.nihr.ac.uk/](https://netscc-mis.nihr.ac.uk/)

You must register or log-in to the NETSCC MIS to complete and submit your application.

2.1 Electronic Application form - Learning Guide

To assist you with completing the application form an in-form learning guide can be accessed by clicking on *'For help and guidance click here.'* which is located at the top of each page of the application form, under the ‘Instructions’ heading. The learning guide aims to explain each section and provide guidance as to what information is required.

There is also an ‘FAQ’ section available to the left hand side of the application form screen.

2.2 To Access the Application form

For Themed calls follow the link: [www.nets.nihr.ac.uk/funding/hta-themed](http://www.nets.nihr.ac.uk/funding/hta-themed)

To apply for a specific call, click on the relevant ‘Apply Now’ button where you will be taken directly to the NETSCC MIS log in screen. You will need to either register (one off process) or log-in using your registered email address (your user ID) and password. Once logged in you will able to apply directly for the call and will be presented with additional information such as the specification document to aid your submission.

You will then be directed to the confirmation page for the specific call. Clicking Cancel will return you to your MIS ‘home page’. If this is the correct call, click on the ‘Apply’ button and this will start the application process. Applying for a funding opportunity creates a task on your home page titled either ‘Full Application’ or ‘Outline Application’. This task will be available on your home page for you to complete until 1:00pm on the closing date, as indicated on the research call and on your task.

This task will be available for you to complete until the closing date as indicated on the research call and on your task-list. The ‘Full or Outline Application’ task can be accessed at any time until you either submit the application (using the Submit button in the application process which will appear once all the validation is complete) or the call closes.

The NETSCC MIS can always be accessed directly at [https://netscc-mis.nihr.ac.uk](https://netscc-mis.nihr.ac.uk) for you to go to your homepage where all your applications will be listed.

See the screenshot example below:
Clicking on the **Outline Application** link takes you to the application’s main page where you can complete your application information (clicking on this link will not submit an incomplete application).

This task will be available for you to complete until **1pm on the closing date** as indicated on the research call and on your My Tasks folder.

Seven days prior to the closing date you will receive an email reminder that you have an open application (i.e. not submitted).

### 2.3 To submit an application

In order to submit an outline application to the programme you must:

- Complete all mandatory fields as indicated with a red asterisk *. The final review and submit page of the application provides a final check of the completed mandatory fields as well as providing reminders about optional entries.
- Submit a flow diagram (single-side of A4), as a separate PDF for submission with your application form. This should illustrate the study design and the flow of participants.
- Applicants should also describe complex interventions and controls as accurately and fully as possible within their diagram. If proposing an RCT, we advise you refer to the CONSORT statement and website for guidance ([www.consort-statement.org](http://www.consort-statement.org)). Alternatively, you may find the EQUATOR Network website useful ([www.equator-network.org](http://www.equator-network.org)).
- Submit a letter of support from your CTU, if applicable to the type of research you are conducting.

### 2.4 Saving your form and system time-out

As you work through the application form, you are asked to save each page. This will save all the information you have entered so far. You can save the form at any point and leave the application prior to submission. The save button is always located at the bottom of each page of the application form. Large text areas on the form also have their own save button beside them. The application task will remain on your home page until complete and submitted or the deadline for the application has passed.

**It is important to remember to ‘Save’ each section as you go through the form before navigating away from the page.**

There is a security time out set on the MIS so that after 60 minutes of inactivity, the user will be logged out of the MIS. It is advisable therefore to save your work at regular intervals using the save button on any page. The NETSCC MIS will give you a warning that you are due to be timed out 10 minutes before this happens. If this message is displayed, you should close the pop-up screen and save the task that you are carrying out.
There is a left hand navigation menu in the application form so that you can select specific parts of the form to complete, however you should always ensure that you save any information entered on your page before using this left hand menu.

2.5 Browsers that best support the NETSCC MIS

The NETSCC MIS will operate successfully across a wide range of browsers and operating systems. However, we recommend that you use the following:

- Windows users - Internet Explorer (versions 7 and 8), Firefox and Chrome
- Apple users - Safari
- Linux - Opera

2.6 Spell-checking

The system does not have a spell-checker. We would advise you to complete large amounts of text in Word first and then cut and paste them into the relevant screens in the NETSCC MIS. If you paste content that is longer than the character limit it will be cut off, so please check the content after you have pasted it.

Spell checking and text box entry resizing is available in the MIS for users using Chrome, Firefox, Safari and Opera web browsers. **This functionality is provided by the browser not the MIS application.**

2.7 Giving others access to the form

- **Co-applicants:** Access to your application is through your user login to the NETSCC MIS. This should not be shared. The outline application does not require co-applicants to complete this form. If you want to share your form with your co-applicants, please create a PDF of the form and send it to them. Options to create a PDF are available on the Home page and the Review and Submit page.
- **Signatories:** You are not required to have signatories for outline applications.

Please note: A Word version of the application form is available through the HTA funding opportunities webpage.

This document can be used to share information with your co-applicants but will not be accepted as an application form.

2.8 Leaving the application task

You can leave your application task at any time. As long as you have saved any new information you have entered for the application, you can navigate to your home page or log out of the NETSCC MIS system.

2.9 Printing your form

Please note that the form does not print out in the same order that it is filled in online. The printing order for the outline form can be found as a Word document in the ‘Support Documentation for Applicants’ section of the Programme’s funding opportunities web page

2.10 Technical Support

If you encounter any problems with the NETSCC MIS system, you should call the programme funding support team either via email or by phone. The contact numbers can be found on the home page of the NETSCC web on this link: [www.nets.nihr.ac.uk/mis/contacts](http://www.nets.nihr.ac.uk/mis/contacts)
2.11 Space restrictions when entering text

You should be aware that there are character limits set for each text box within the application form. For larger text areas these are indicated with ‘Limit’ and ‘Remaining’ at the bottom of the text entry box. Carriage returns and spaces are counted as characters. The character count will be slightly less than that of an MS Word character count. Please note that the system does not provide a spell checker but certain browsers do support spell checking functionality.

The form counts all blank space as a part of the content of each box, so if you are short of space it will help if you delete extra carriage returns and place any bulleted lists into paragraph format.

2.12 Use of non-standard characters

You are advised not to use any non-standard characters in your text; in particular, you may experience a technical difficulty that affects the use of these characters ‘<’ ‘>’ ‘≥’ and ‘≤’. The system will currently strip these characters out of the content of the text without warning. If you need to use these symbols, then please replace them with text. It is advisable that you should either type text directly into the form or ensure these characters are not included in any text that you copy and paste from other documents.

You may wish to include 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).
PART 2: Guidance for completing your electronic application form

3. Research Details

Whether you are applying to an advertised Commissioning Brief or a Specification Document for a researcher-led call, please ensure that you read the relevant document thoroughly before starting your application.

If you are a themed call applicant and have a query about whether your research idea is within the HTA Programme’s remit or have a question about the Specification Document, please e-mail your question to htatcall@southampton.ac.uk

3.1 Host Organisation

Please give details of the organisation that will be the host or contractor if the project is funded.

3.2 Research Title
(Limit: 300 characters)

The project title should clearly and concisely state the proposed research. Please spell out any abbreviations.

3.3 Application type

Please select the appropriate research type. If your proposed project includes any element of primary research, please select ‘Primary Research’. If you are carrying out new analysis of existing data, please select ‘Evidence Synthesis’ or ‘Secondary Research’. Choose the closest match to your research. If uncertain it can be adjusted later.

3.4 Proposed Start Date

Please note this should be from 1st of the month regardless of if this is a working day or not. Please be realistic about your possible start date taking account of the necessary contracting and recruitment time and any ethics approval you may need prior to starting your project.

Shortlisted outline proposals that are invited to go forward as full proposals will usually be considered at the following Board Meeting and given 8 weeks to complete the full application form.

3.5 Research Duration (months)

Please ensure you include sufficient time to complete all aspects of the research including the final report.

3.6 End Date

This field will automatically populate once you have saved the research duration information.

3.7 Total Research Costs Requested and Total NHS Support & Treatment costs (savings)

For guidance on how to complete the financial costs of your application, please see the financial guidance.
4. Contact information

Please complete your contact details and ensure each section has information identified as primary.

Organisation Affiliations
Please select the appropriate affiliation provided in the drop-down box.

Address
Please provide a postal address

Web Address
Please give your personal university/NHS webpage if you have one.

5. Lead applicant details

Please note that the following questions which appear in this section are all mandatory and will need to be completed prior to submission of your application:

Specify role in research
Please describe the role you will undertake as lead on this project.

%FTE (Full Time Equivalent) Commitment
This refers to the percentage (to 1 decimal place) of your time that you will be committing to this project.

Do you currently hold an NIHR award?
Please enter any other awards you currently hold.

Date of commencement
If you currently hold an NIHR award please provide the date that the award commenced.

Is this a full time post?
Please indicate your WTE at your host institution.

Current Grade:
Please list your job title, e.g. Professor, Reader, Consultant etc.

Current Research Commitments
Please list the research projects that you are currently involved in, the percentage of time you are involved and the end date of the projects Please specify other research activity if relevant.

Provide an approximate breakdown (%) of how your current appointment is divided between the following activities
Please indicate the relative percentage of your time committed to each of the activities.

Administrative Contact Details
Even when indicating ‘Yes’ to this question, you may wish to name an alternative contact here. Suggested alternative contacts could include PA/project administrative staff.
6. Curriculum Vitae (CV) section

6.1 Degrees and Professional Qualifications

Please add details and approximate dates achieved of qualifications held. You must add each qualification individually.

6.2 Present and Previous positions held

Please add details and approximate dates of previous positions held. You must add each post individually.

6.3 Patient/Service User or Carer Applicants

This section is only relevant if the Lead Applicant is a Service User or Carer.

Are you a member of the public, patient / service user or carer?

Please note that this question is mandatory and will need to be completed (select Yes or No) prior to submission of your application:

If yes, please tell us about your knowledge, skills and experience that are relevant to this application. You are not required to provide a CV.

(Limit: 1000 characters)

We recognise and value the varied perspectives that members of the public, patients and carers bring to a project as applicants. In this section, please provide a summary of any relevant knowledge, skills and experience that you will draw upon to contribute to this project.

This could include information about:

- Previous or present work (paid or unpaid) with any relevant organisations;
- Links with any relevant groups, committees, networks or organisations;
- Experience of particular health conditions, treatments, use of services - or as a member of a particular community;
- Knowledge and experience of research including previous research undertaken;
- Knowledge and experience of PPI including previous involvement activities;
- Skills from any other roles that are transferable;
- Relevant qualifications, training and learning.

7. Research CV

7.1 Recent relevant publications

(Limit 10,000 characters)

Please enter a maximum of 6 relevant recent publications here in citation format, including the name of the journal, title, and list of authors. Please use DOI reference numbers if needed.

If you have updated your publications/grants in your profile you will be able to access the list by clicking ‘view all publications held’ and copy the information across to this section.

7.2 View your publication outputs

Outputs produced from work involving NETSCC will in time be listed in any new applications which can be accessed by ‘view your publication outputs’ and it will be up to the author to determine their relevance to that application. This should reduce the time taken for you to complete this section.

7.3 Research Grants Held

(Limit: 10,000 characters)

This should include research grants held (as a named applicant) currently or in the last three years. If no grants are held please enter N/A (as this is a mandatory field).
8. Co-applicants

8.1 Adding co-applicants

You must declare whether co-applicants will be involved in this application or not.

Please add details of all co-applicants individually. The number of co-applicants is calculated automatically. Do not include collaborators, who should be included in the ‘Relevant Expertise’ section of the on-line application form. Co-applicants are those individuals with responsibility for the day to day management and delivery of the project. Collaborators normally provide specific expertise on particular aspects of the project. Please note that co-applicants are considered part of the project team and are expected to share responsibility for its successful delivery.

Each co-applicant must be added individually using the ‘add’ button. The details for each co-applicant must be completed exactly paying particular attention to the email address. The lead applicant should ensure that this is the exact email address the co-applicant uses to access the MIS system. An incorrect address will prevent the co-applicant from being added to the full application form.

Please complete all mandatory fields for each co-applicant. The system will automatically calculate the total number of co-applicants in your application.

The co-applicants listed will not be contacted by the MIS system at this point. However, this information will automatically be pulled through to the full application form should the application be shortlisted. From here the system will use the information provided to contact the co-applicant and arrange for their agreement to participate in the research.

9. Patient and Public Involvement (PPI)

The NIHR expects the active involvement of patients and the public in the research it supports. NIHR recognise that the nature and extent of active patient and public involvement is likely to vary depending on the context of each study or award. The term involvement refers to an active partnership between patients, members of the public and researchers in the research process. This can include, for example, involvement in the choice of research topics, assisting in the design, advising on the research project or in carrying out the research.

The INVOLVE website (see below) provides a detailed definition of ‘patient and public involvement in research’ as well as further information on involvement in research, listing resources and advice available. In this section it is important that you describe in as much detail as possible how patients and the public have been involved in the development of the proposal as well as plans for involvement in the proposed research. Please note that this section does not refer to the recruitment of patients or members of the public as participants in the research.


Further information and resources can be found at the INVOLVE website http://www.invo.org.uk

The NIHR Research Design Service http://www.ccf.nihr.ac.uk/Pages/RDSMap.aspx can provide advice on, and support in, developing your application including the involvement of patients and the public in your research.
9.1 Were patients and the public actively involved in identifying the research topic or prioritising the research questions?

Were patients and the public actively involved in preparing this application?

(Limit: 1200 characters)

If you have ticked the YES box to either or both of these questions describe the ways in which you have involved patients and the public. Where appropriate, provide names of individuals and/or groups and outline the activities they have been involved in and how this involvement has, or has not, influenced or changed this research proposal.

If you have ticked the NO box to either or both of these questions you must explain why you have not actively involved patients and the public.

9.2 Please indicate the ways in which patients and the public will be actively involved in the proposed research

Tick all boxes that apply.

9.3 If active involvement is planned, please give more details, including how it will benefit the research, the reasons for taking this approach and arrangements for training and support.

(Limit: 1200 characters)

Please describe the way in which patients and the public will be involved.

Where appropriate, provide names of individuals and/or groups and outline the activities they will be involved in. In addition, what plans are there for providing training and support?

If you have ticked ‘no plans for involvement’, you must explain why you do not plan to actively involve patients and the public in your proposed research.

10. History of application

10.1 Previous submission

Please select ‘Yes’ or ‘No’ from the drop down box to indicate whether this or a similar application has previously been submitted to this or any other funding body?

We will not accept research proposals that are currently being considered by other funding bodies.

Please note that none of the NETSCC programmes will accept applications that are currently pending with other research funding organisations (unless under shared funding arrangements).

Please answer all questions as fully as possible. We are keen to know if the application has been submitted elsewhere and you must be as open about this as possible. This includes, but is not limited to, 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 research area).

Failure to disclose accurately or fully will be considered by the programme as academic misconduct and as such treated seriously. If you provide incorrect or out of date information, do not declare in full, or fail to disclose any relevant information, your application may be rejected without further consideration. You should also include in this section information on whether this or a similar application has been submitted to any programme previously, or to any other funder including other NIHR programmes. You should name, and provide dates and outcomes of these. Please indicate whether you hold or have ever held an NIHR programme contract which has been terminated prior to completion, extended in time or in terms of funding. Indicate which of the NETSCC funding streams you are applying to. (e.g. HS&DR, HTA commissioning, CET, etc.)
10.2 Applications Submitted to NETS Programmes

Any previous application submissions as a lead or co-applicant to NETS programmes will be listed on this page, please select ‘Yes’ or ‘No’ for each application submission to indicate whether it is relevant to this application. Where ‘Yes’ is selected click the ‘Edit’ button and complete the information to indicate how your current research application differs from this previous application, if unsuccessful, please indicate why. Occasionally the list will need to be re-sorted by NETSCC ID to identify all relevant applications.

IMPORTANT NOTE - NETSCC RESUBMISSION POLICY:

A previously unsuccessful application cannot be resubmitted to the HTA Programme or any other NETS programme within one year of the original decision letter, unless the Board has specifically informed the applicant that this is acceptable. For researcher led work streams resubmissions will be accepted if applicants can demonstrate it has been changed significantly and is essentially a new proposal.

N.B. A maximum of 10 previously submitted applications will be listed on this page, if more than 10 previous applications have been submitted click ‘Show All’ to the left of the page to view the complete list.

10.3 Other Funders / Applications in Progress

Where a proposal like this, or with similar content, has been submitted to this organisation or elsewhere and is not listed; please click the ‘Add’ button and complete the necessary information.

11. Case for Support

11.1 Scientific Abstract

(Limit: 3500 characters)

Please provide an expert summary of the project plan of investigation plus any additional points required to support statements made in the above sections, and include any key references required to justify the points made (e.g. in the use of particular outcome measures or methods of analysis).

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: (Primary Research only) 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 (Secondary 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.
- Inclusion/Exclusion Criteria. Please provide a detailed explanation of the inclusion/exclusion criteria.
- 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: Not all HTA studies require full economic evaluations. When considering inclusion of a cost effectiveness analysis, applicants should carefully
describe what this will add to the study. Where an economic component is proposed, applicants should endeavour to use the simplest approach, or fully justify where more complex methodologies are needed

- 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.
- 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.

11.2 Summary (in Plain English)
(Limit: 3500 characters)

Please note that this summary should be easily understood by a wider audience and is intended to help non-experts in your subject area understand what your project involves and decide whether it is the best one to answer the question posed in the commissioning brief/specification document. There should be sufficient detail to inform, for example, a service user or methodological referee who is unlikely to be conversant with the specialised vocabulary of your specific discipline. Explain specialised technical terms and acronyms and avoid discipline-specific jargon. Further information on writing for public consumption is available from the Plain English Campaign. They provide a free downloadable guide, designed specifically for the Health Sector, at: http://www.plainenglish.co.uk/free-guides.html.

12. Research Plan

This section contains a flexible number of fields as determined by the needs of the specific NETS Programme to which you are applying.

Your application form will indicate which have been selected by your Programme and which of these are mandatory (Required – Yes/No). If required click on the ‘Add’ button to the right of the screen and complete the text box as necessary.

For HTA applications the following three fields are available to be completed.

Care Pathways in comparative or randomised trials
(Limit 2000 characters)

Please explain the patient care pathways in each of the trial arms, including the control arm.

Difference between current and planned care pathways
(Limit 1500 characters)

What is the current standard patient care pathway and how does this differ from the trial arms.

Other Information
(Limit: 4000 characters)

Please use this to add any additional information you would like those evaluating your proposal to consider which could not be entered in the Case for Support section.
13. Background and Rationale
This section should include a brief literature review and how you expect to add to the body of knowledge with reference to current NHS policy and practice.

13.1 What is the problem being addressed?
(Limit: 2000 characters)

For researcher-led applications this section is used in the first stage of proposal assessment and is therefore the most important part of your application in terms of demonstrating competitiveness against others received. It allows you to demonstrate why your chosen research area is needed by the NHS and how it fits in with the programme’s remit www.nets.nihr.ac.uk/programmes/hta/remit.

For all researcher-led proposals, this section must include the following:

1. Please explain how your proposed research is within the remit of the HTA Programme. You should include a clear explanation of the main (single) research question phrased in PICO terms (Population; Intervention; Comparator; Outcome). Give a brief explanation of how or in what ways the design constitutes a clinical trial or evaluation study. You are welcome to highlight any other aspects of the design that you would like to bring particular attention to, in order to explain how it is within remit. Please remember that HTA research looks at patients or people seeking healthcare; studies using healthy volunteers and animals are not within the remit of the programme.

2. Please provide a clear explanation of the health problems to be addressed, the impact on patients and healthcare, an explanation of the scientific principles of the proposed research and an overview of the potential economic benefits (you are not required to include health economics analysis within your research). Please explain why this trial is needed now.

13.2 Why is this research important in terms of improving the health of the public and/or to patients and the NHS?
(Limit: 3500 characters)

For researcher-led applications, this section must include the following:

Please justify the clinical importance of your proposed study and outline the anticipated value or contribution the study will provide to clinical practice. Classification of need for research is set out below:

- Health need: These will be expected benefits in terms of substantial health gain with the ultimate aim of improving patient health or care. This covers the potential for preventing avoidable mortality and morbidity, improving quality of life and considerations of disease prevention and should be justified in terms of burden of disease;
- Sustained interest and intent: Evidence that the issue or area is one in which there will be sustained interest in the future, such that the results of research once commissioned and undertaken will remain highly relevant and important to the needs of the NHS in the future;
- Capacity to generate new knowledge: Please explain how the proposed research will contribute to development of the research area;
- Scientific knowledge: Please explain how the study will make a substantial advance in scientific understanding and knowledge and the potential substantial health gain.

13.3 Please provide evidence explaining why this research is needed now (how does the existing literature support this proposal)?
(Limit: 2000 characters)

It is a requirement of NIHR and the HTA Programme that all primary research is informed by a review of the existing literature.
In addition to searching Europe PubMedCentral (PMC), applicants should check the list of existing research funded by the NIHR and not limit their search to the programme to which the current application is being submitted.

We will only fund primary research* where the proposed research is informed by a review of the existing evidence.

*Primary Research defined as: Original research conducted to collect new data to answer a research problem. Source: Health Technology Assessment Programme A-Z of useful terms. www.nets.nihr.ac.uk/glossary

For researcher-led applications, please describe the existing evidence base for this research and demonstrate why this means your research is important now, both in terms of time and relevance.

Where no such systematic review exists it is expected that the applicants will undertake an appropriate review of the currently available evidence (using a predetermined and described methodology that systematically identifies, critically appraises and then synthesises the available evidence and then present a summary of the findings of this in their proposal. You should give reference to any relevant systematic reviews and discuss the need for your study in light of these. References should be provided in the Vancouver format (Author(s). Title. Journal. Year; Volume: Start page - End page). All applicants must also include reference to relevant on-going studies, e.g. from trial registries.

13.4 Aims and Objectives
(Limit: 3000 characters)

Please summarise the key aims and objectives of your project and provide a concise statement of the proposed research.

14. Changes from First Stage

14.1 How has this changed from the first stage application?
(Limit: 3500 characters)

This question will not be applicable for the majority of applicants completing an outline form. If this is the case please enter ‘not applicable’ in the box.

If you are re-submitting an outline application, please detail how you have incorporated the Board feedback and any additional changes.

15. Dissemination and outputs

15.1 Please describe your plans for disseminating the findings of this research
(Limit: 2500 characters)

Explain how the findings from the proposed research will be shared with, or disseminated to, others and how this will maximise the potential impact of the proposed research referencing your response to the ‘Expected output of research/Impact section’. Describe who are the likely beneficiaries of the research, when are they likely to benefit and in what ways.

We require that all NIHR funded research will be reported fully and made publicly available when the research has been completed. It is expected that research funded by the HTA programme will publish a full and complete account of that research in the NIHR HTA Journal. This will ensure that this research is reported fully, and is publicly available with the abstract and full report freely available via the NIHR Journals Library website and the abstract freely available via Europe PubMed Central.
We expect that all researchers who have a contract with the NIHR to undertake research shall ensure that the outcome of the research is prepared as a research paper for publication in a suitable peer-reviewed journal. We would also encourage all researchers to disseminate their research findings to the broader public as well as to the research participants when the study has completed.

Planning for article processing charges in Open Access journals

During the course of your project and throughout review and publishing phase you may choose to submit an article based on your research to an Open Access publication. Depending on the publication you may be subject to an article processing charge (APC). APC rates vary but are usually within the range of £300 and £3000. Open Access publications usually list their APC rates on their websites. Where possible you should include an estimate for any APC in your funding application. This should be entered in to other direct costs on the application form.

NIHR expects that APCs will be covered by the funding award.  
http://www.nihr.ac.uk/research/Pages/Research_Open_Access_Policy_Statement.aspx

15.2 Expected Output of Research / Impact  
(Limit: 2500 characters)

Use this section to provide more information about the research outputs and the impact you anticipate these outputs may have. We acknowledge that defining impact can be challenging and paths to impact are complex with many steps beyond your control. We therefore define impact broadly as the contribution, effect on, or benefit that excellent research makes to knowledge, health, the NHS, health services, society or the economy. We wish to understand the ways in which the proposed research may change activity, attitudes, awareness, behaviour, capacity, opportunity, performance, decision-making, practice or processes. Impact can also result from new understanding that benefits individuals, population, organisations, communities, constituencies or the nation.

16. Relevant Expertise

16.1 Strengths of Research Team - Contribution of Each Member  
(Limit: 2000 characters)

Outline the particular contribution each member of the team will make towards the project. The team should be multidisciplinary and include all relevant expertise to enable delivery of the proposed research. The HTA Programme strongly recommends teams proposing randomised controlled trials include input from an accredited clinical trials unit or one with equivalent experience.

16.2 Please declare any conflicts or potential conflicts of interest that you or your co-applicants may have in undertaking this research, including any relevant, non-personal & commercial interest that could be perceived as a conflict of interest.  
(Limit: 2000 characters)

Please declare any conflicts or 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, could lead to a perception of bias or embarrass either the programme, NIHR 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 research area). Include any relevant personal, non-personal and commercial interest that could be perceived as a conflict of interest, examples include (this list is not all encompassing), secondary employment, consultancy, financial or commercial gain (pensions, shareholdings, directorships, voting rights), honoria, etc. In a case of commercial sector involvement with the application or the study, please state clearly the relationship to ownership of data, access to data, and membership of project oversight groups. If in doubt you should err on the side of disclosure.
17. Justification of costs

If you are subsequently invited to submit a full application, the finance section will require a detailed breakdown of these costs associated with undertaking the research as described in the application. At the outline application stage this level of detail is not required, however the following guidance is provided to assist you with calculating your costs at the outline stage.

You should indicate here how this research will potentially benefit the NHS. For example, where appropriate, describe the likely cost savings or benefits in terms of numbers of patients treated, treatment times etc.

Note that some proposals will have included full cost benefit analysis as part of the design; for others, a broad indication of likely benefits is all that is required. You should describe the value for money of the research itself.

Please provide a breakdown of the NHS costs associated with undertaking the research and provide justification for the resources required. If there are no NHS Support or Excess Treatment Costs associated with the research you must explain why you think this is the case.

17.1 Guidance on costing for Outline Application Form

In this outline application you should fully justify what the major costs are and how they have been allocated, in the text boxes provided.

If you are unsure of how to attribute the costs between research and NHS support and treatment costs, please refer to the following guidance on ‘Attributing the costs of health & social care Research & Development (AcoRD)’: https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

You should also indicate in the text boxes how this research will potentially improve the health of the public and reduce inequalities in health.

Note that some proposals will have included full cost benefit analysis as part of the design; for others, a broad indication of likely benefits is all that is required. You should describe the value for money of the research itself – the strength of the research team and contribution of each member, ways of recruiting the sample, of administering interventions etc.

If you are subsequently invited to submit a full application, the finance section should provide a breakdown of costs associated with undertaking the research as described in the proposal. At the outline stage this level of detail is not required, however the following is guidance on how you should calculate your costs.

General Information

- These costs will be used to assess value for money.
- It is in the best interest to undertake a thorough, realistic and accurate costing. The Committee/Panel will pay close attention to any material increase in costs between outline and full application stages. You must provide a clear and full justification for all costs including NHS costs. You must also ensure that you include all costs including those required to secure good research management.
- Costs must be provided at current prices. An adjustment for inflation will be made annually thereafter at rates set by the Department of Health. Whilst allowances for incremental increases should be included on the form, nationally or locally agreed pay increases should be excluded.
- Years should be calculated starting from the anticipated start date of the proposed research. For example, if your research is expected to start on 01 June 2020 then its second year starts 01 June 2021.
• Further itemisation of costs and methods of calculation may be requested to support the application at a later date.

• NHS Support Costs are funded via Clinical Research Networks. Researchers should contact their local NHS R&D Department initially and, if they are unable to help directly or if there is no local NHS R&D Department, contact the local Comprehensive Local Research Network (CLRN) Senior Manager. Further details about CLRN contacts is available at www.crncc.nihr.ac.uk/about_us/ccrn

17.2 Information on Different Types of Organisations

Higher Education Institutions (HEIs)
• Higher Education Institutions (HEIs) should determine the Full Economic Cost (FEC) of their research using the Transparent Approach to Costing (TRAC) methodology. For HEIs, up to 80% of FEC will be paid, provided that TRAC methodology has been used. Applicants from HEIs should enter 80% FEC when entering the total costs requested.

NHS Organisations
• For applications where the contractor is an NHS organisation, up to 100% of direct costs will be paid.

Commercial Organisations
• If you are a commercial organisation/consultancy, please include direct costs and commercial indirect costs (if appropriate). Indirect costs should be included in proportion to the amount of research staff effort requested on the funding application form. Up to 100% of costs will be paid.

Other Partner Organisations
• If you are an ‘other partner’ organisation (e.g. charity or NGO), please include direct costs and other partner organisations indirect costs. Indirect costs should be included in proportion to the amount of research staff effort requested on the funding application form. Up to 100% of costs will be paid.

17.3 Direct Costs

These are costs that are specific to the research, which will be charged as the amount actually spent and can be supported by an audit record. They should comprise:

I) Posts and Salaries Summary.
Please include all members of staff working on the research. Use current rates of pay, and build in any known annual increments (again at current rates). Staff employed by a Higher Education Institution (HEI) are funded at 80% of cost and staff employed by NHS, commercial or other partner organisation at up to 100% of cost.

You may include ‘Shared Staff Costs’ which are costs of an institution’s research resources which can be charged to the research on the basis of estimated use, rather than actual costs. These may include: applicants’ costs, unless directly incurred or non-chargeable, IT technicians, laboratory staff, and costs of pooled staff efforts.

II) Travel, Subsistence and Conference fees.
Include journey costs, subsistence and conference fees. Where applicable, you will need to include the travel and subsistence costs of your Project Advisory Group, Steering Committee and/or Data Monitoring & Ethics Committee. Travel and subsistence costs relating to dissemination should also be included here, as should costs relating to overseas travel.

Journey Costs
The total cost of transport for all journeys for destination/purpose. If travel is by car, apply your institution’s mileage rates (however this should not exceed HMRC approved mileage allowance payments, which is 45p per mile for the first 10,000 miles and 25p thereafter).
Travel by the most economic means possible is encouraged. NIHR programmes do not usually fund first class travel.

**Subsistence**
Subsistence covers accommodation (if necessary) and meals associated with the travel, excluding any alcoholic beverages.

**Conference Fees**
Where national or international conference fees are included, a statement naming the conference or purpose of travel and the benefit to the research must also be made; failure to adequately justify your attendance at a conference will mean the programme will not fund this cost.

For research of up to five years, the programme will usually fund up to a maximum of two international conference attendances. For research beyond five years, the programme will usually fund up to a maximum of two international conference attendances per five year or part of five year research period.

**III) Equipment.**
Essential items of equipment plus maintenance and related costs not included as part of estates should be included. These can be lease or purchase costs. The purchase cost of pieces of equipment, valued up to £5,000 excluding VAT, will be considered.

Pieces of equipment costing more than £5,000 to purchase will usually need to be leased.

**IV) Consumables.**
Include non-reusable items specific to the research. These items should be research specific, not just general office costs which should be covered by indirect costs.

**V) Patient and Public Involvement.**
Please include costs associated with Patient and Public Involvement. These are likely to include out of pocket expenses, payment for time and any relevant training and support costs.

**VI) Other Direct Costs.**
These are costs, not identified elsewhere, that are specifically attributed to the research. For example, external consultancy costs, specialist publications, open access publications, computer licensing, recruitment and advertising costs. Please note that for organisations claiming indirect/overhead costs, costs such as recruitment of staff, and general training (e.g. in common IT packages) are costs that should be covered by the indirect costs element of the award being sought and should not be included within Direct costs.

If external consultancy costs or any other large costs are included they must be fully justified.

**VII) Patent and Legal.**
The NIHR will consider supporting reasonable patent and legal costs arising from the research during the period of the award only. The NIHR will not support retrospective patent costs incurred by the applicant prior to NIHR funding and will not be liable for any costs post-completion of the research.

**VIII) Sub-Contracts.** These costs can be claimed for organisations outside of England who are providing these services, but suitable justification is required.

**17.4 Indirect costs/ Overheads**

HEI Indirect Costs
Total HEI indirect costs must be fully justified. HEIs are permitted to claim estate and other indirect costs. These costs are calculated on the basis of TRAC methodology. Proposals from other types of institutions/organisations should leave this section blank.

HEI indirect costs are based on the number of full-time equivalent research staff working on the research and the indirect/estates charges set by an institution.

The applicant(s) should consult their HEI Finance Departments for the appropriate amounts to include.

**17.5 Commercial/Other Partner Organisation Indirect Costs**

Commercial/Other Partner Organisations can claim indirect costs which are the costs of resources used by the research that are shared by other activities. Please seek advice from your finance department about the appropriate costs.

Total Commercial/Other Partner Organisation indirect costs must be fully justified.

Indirect costs will be charged in proportion to the amount of research staff effort requested on the award. Commercial/Other Partner Organisations should calculate them, using their own cost rates. They comprise:

- General office and basic laboratory consumables;
- Premises costs;
- Library services/learning resources;
- Typing/secretarial;
- Finance, personnel, public relations and departmental services;
- Usage costs of major research facilities;
- Central and distributed computing;
- Charge out rates for shared equipment;
- Cost of capital employed.

**17.6 NHS Support and Treatment Costs (incl. Excess Treatment Costs/Savings)**

The application form includes a section that asks researchers to provide an estimate of the patient care costs associated with the research (if applicable). An explanation of why these costs are being incurred and the basis on which the estimations have been made should be fully detailed under the relevant ‘Justification of Costs’ section.

The Committee/Panel will take NHS Support and Treatment Costs into account when considering the value for money of the research. It is important that you consider these costs and discuss them with the NHS organisation(s) involved in order to avoid any delay in commencing the research.

Please be aware that the research award does NOT include NHS Support and/or Treatment Costs. NHS Support Costs will be funded via the Comprehensive Research Networks. NHS Treatment Costs, including any Excess Treatment Costs/Savings, will be met by the NHS through normal patient care commissioning arrangements.

If there are no NHS Support or Excess Treatment Costs associated with the research you must explain why you think this is the case.

**I) NHS Support Costs**

These are the additional patient care costs associated with the research, which would end once the R&D activity in question has stopped, even if the patient care service involved continues to be provided. These might cover items such as extra patient tests, extra in-patient days and extra nursing attention. Researchers should contact their local NHS R&D Department initially and, if they are
unable to help directly or if there is no local NHS R&D Department, contact the local Comprehensive Local Research Network (CLRN) Senior Manager for advice on NHS Support Costs. Further details about CLRN contacts are available at http://www.crncc.nihr.ac.uk/about_us.

II) NHS Treatment Costs

These are the patient care costs that would continue to be incurred if the patient care service in question continued to be provided after the R&D activity has stopped. In determining NHS Treatment costs you must assume that the patient care service being assessed will continue even though there may be no plans for it to do so. 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/Saving, but is nonetheless part of the Treatment Cost, not an NHS Support or Research Cost. These costs should be determined in conjunction with your NHS trust partner(s) and their commissioners.

17.7 For further information, please see:

18. Intellectual Property (IP)

At the outline stage of your application, we understand that you are in the early stages of developing your research project. We therefore ask that you answer the questions to the best of your ability. You will have the opportunity to provide a more developed response to these questions at full proposal stage.

It is essential that any Intellectual Property (IP) which may arise from NIHR-funded research is recognised, captured and utilised in the most appropriate way, to ensure that the potential benefits of the research are realised effectively for patients and the taxpayer. The funding for health research is now over £1billion per annum as confirmed in the most recent spending review (http://www.nihr.ac.uk/about/Pages/About_Spending_Review.aspx). This level of investment is unlikely to be sustainable unless tangible benefits for patients are realised.

The NIHR takes a broad definition of IP which might include research outputs such as new or improved software, training materials; manuals; checklists, scales, protocols, questionnaires, toolkits, guidelines or similar; service innovations or new service delivery models; research tools, such as data analysis techniques, assays, cell lines, antibodies; biomarkers, materials; as well as patentable inventions such as a new/improved medicinal products, diagnostic test or medical device. Such new developments of IP are known as ‘foreground IP’. In addition, the proposed research is likely to build on IP generated previously by others or yourselves as applicants. This is known as ‘background IP’. IP may be protected via a number of methods including Copyright, trademarks or Patents. Taking this into account we can assume that much of the research funded by NIHR is likely to generate or modify IP.

This section of the application form asks you to consider the background IP on which this application is based, and the nature of any foreground IP likely to be generated.

18.1 What relevant IP (patents, design right, copyright etc.) is held by the applicants and how does it relate to this application?
(Limit: 3000 characters)

In this section you, need to tell us about what IP you, your co-applicants, collaborators and sub-contractors hold in relation to this application. If relevant IP is held by another individual, institution or
company you need to tell us about it in your response to the question here. Where appropriate, please provide detailed information relating to third party licence requirements etc.

We request this information to ensure that the NIHR understands your starting IP position. We place this information in context with any new IP you may generate during your research, and also with reference to third parties’ rights which may be found during due diligence searches. This knowledge will help to delineate the IP ‘rights’ and who might own them.

You or your institution may hold the relevant background IP. The term ‘background IP’ refers to 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 you may or may not have been involved; and may or may not have benefitted from NIHR funding. If the research you propose will use background IP you will need to ensure you have reached agreement to use the background IP. This may require licences, collaboration agreements and/or sub-contracts. If so, you will need to tell us about these arrangements in your application and provide a copy of these agreements if you are successful in obtaining funding for your proposed research.

An important part of this process is ensuring that any relevant background IP has been identified before the research starts. It may be that you or your institution holds the background IP or alternatively, it may be held by another individual, institution or company. Even if your institution owns it others may have rights. The ‘freedom to operate’ with background IP not just in the research but in how that research may translate into patient benefit is important.

18.2 Has a freedom to operate search been conducted? If yes, please provide details of all relevant IP and how it relates to the application and details of who carried out the freedom to operate search
(Limit: 1500 characters)

A ‘freedom to operate search’ is taken to mean undertaking a series of activities to determine if the background IP (including any interventions) you are proposing to use or develop as part of the research can be used/developed without infringing on valid intellectual property rights of others. Such activities may be undertaken by you or a third party on your behalf. In the context of research funding this is important as it could be that the intellectual property rights of others may either prevent your proposed work from going ahead, prevent you from maximising the benefits from your research, or prevent you from using any foreground IP generated by your study. It is worth noting that IP rights are specific to different countries or regions (jurisdictions), and any freedom to operate search and analysis needs to consider this aspect as many health interventions cross jurisdictional boundaries.

You need to tell us if you have, or have not, conducted a freedom to operate search in relation to this application. If you have already, or you plan to undertake a search, then please indicate briefly the procedure you have used/plan to use. If you have conducted a search you need to tell us and what you have found from your searches, even if you have found nothing. If you have not undertaken a search it is very likely that your study draws upon existing background IP and therefore a search would be helpful in preparing for your study. If you need further advice regarding this issue you should contact your Technology Transfer Office (TTO).

18.3 Will any IP be produced or improved during the proposed research? If yes, please describe what IP will be produced or improved?
(Limit: 3000 characters)

We anticipate that most NIHR will develop new, or improve existing IP (e.g. by modifying or enhancing an existing intervention, developing data analysis techniques, developing new software etc.). In this section we would like you to detail the potential areas for IP development. Where appropriate, please link this back to any background IP that you have previously mentioned. Indicate why you think the new IP is novel over what is already known/in existence. We understand that at this stage your ideas may be tentative. If funded, you will be given the opportunity to tell us more as
your project develops. Please note IP produced may, or may not have a commercial use but we would anticipate projects will produce IP that has patient or wider public health benefit.

18.4 Please describe how any new IP generated through the proposed research will be recognised, captured, managed and utilised, either through dissemination and adoption in the healthcare service or through commercial exploitation. Please give details on who will lead on dissemination and/or exploitation.

(Limit: 3000 characters)

All recipients of NIHR funding have a responsibility upon them to realise the potential benefits from funded research activities. In this section, please indicate the plans for benefit realisation (such as adoption for patient benefit and/or commercial exploitation) of IP or research outputs. Explain how you plan to recognise, identify and log your research outputs (IP assets), and how you plan for these to be used and/or disseminated to users. If successful in securing funding for your proposed research you will need to report creation of research outputs to NIHR and how they are being used/disseminated/adopted via regular reporting. If you already have commercial partners in place (or in view) you should tell us about this here.

In your application, it is important to demonstrate that you have plans and competent staff in place to manage any new (or existing) IP. NIHR funding requires benefit realisation from all resulting IP of value, this is not restricted to Patents and Design Right/Registered Design, but includes Copyright and know how encapsulated in software, checklists, scales, protocols, questionnaires, toolkits, guidelines, standard operating procedures or similar that have a market within the healthcare service or public health arena. You should consider how the knowledge and IP generated could be adopted in the NHS and beyond. In some circumstances this may best be achieved through the application of commercial exploitation models, in other circumstances other approaches may be more appropriate.

If you consider a commercial model is applicable then you should seek advice from your TTO (or equivalent). Ensure you identify the relevant TTO in this section of the application form, including if possible a named individual and contact details. Advice from a TTO or equivalent should be sought even where a research output is to be made available free of charge to ensure the IP generated is appropriately protected. If there are likely to be costs associated with the effective development and exploitation of IP these should be included in your application and an explanation of the required costs provided here.

18.5 What are the key current and future barriers to utilising the IP/innovation through adoption in the healthcare service or through commercial exploitation, e.g. potential regulatory hurdles?

(Limit: 3000 characters)

Are there any current barriers (e.g. approvals required) or potential barriers to the IP generated by the proposed research being utilised? Please indicate where and when any regulatory hurdles may arise. Provide an indication of timing and any delays that may occur and whether this is something you or a commercial partner will manage.

19. Wider context

Please note that studies that do not require participant (or surrogate decision-maker) consent do not contribute to NIHR Clinical Research Network Activity-Based Funding through accrual metrics, but are still eligible for NIHR Clinical Research Network support. Please demonstrate in your application how you will ensure that sufficient NHS service support will be available to secure successful delivery of your study.
19.1 Network Involvement
(Limit: 400 characters)

Where appropriate, you are expected to work with the relevant NIHR Clinical Research Network(s) and other relevant bodies. 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 in all sections.

Involvement of Clinical Trials Units

If your proposal is for a clinical trial, there are questions here about whether you are using a clinical trials unit (CTU). The CTU will be aware of this requirement and able to supply this for your use. You do not need to complete these questions if you are not proposing to undertake a clinical trial.

19.2 Is a Clinical Trials Unit involved with this research proposal?
(Limit: 1500 characters)

Please select ‘yes’ or ‘no’ from the drop down menu and complete the relevant fields.

Please name and explain the involvement of the CTU at all stages of your research, including design and follow up, should the trial be funded.

A list of UKCRC CTU ID numbers can be accessed via http://www.ukcrc-ctu.org.uk/.

Clinical Trials Units are regarded as an important component of any trial application and can advise and participate throughout the process from initial idea development through to project delivery and reporting. However, they may not be essential for all types of studies. If you feel this is the case, please justify the reasons on your application.

NETSCC CTU Support Funding www.nets.nihr.ac.uk/programmes/ctu provides information on the units receiving funding from the NIHR to collaborate on research applications to NIHR programmes and funded projects.

In addition UKCRC CTU (http://www.ukcrc-ctu.org.uk) provides information and searchable information resource on all registered units in the UK.

A letter of confirmation from the CTU Director is now required for outline proposals where you have indicated their involvement. If your CTU is supporting a number of studies to HTA calls, they can submit a single letter of support listing all of them, rather than prepare individual letters. The supporting letter can be added in the ‘Uploads’ section.

Clinical Trials Toolkit

Researchers designing or undertaking clinical trials are encouraged to consult the Clinical Trials Toolkit (www.ct-toolkit.ac.uk). This NIHR resource is an innovative website designed to help researchers navigate through the complex landscape of setting up and managing clinical trials in line with regulatory requirements. Although primarily aimed at those involved in publicly funded Clinical Trials of Investigational Medicinal Products (CTIMPs), the Toolkit will also benefit researchers and R&D staff working on trials in other areas, who will find useful information and guidance of relevance to the wider trials environment.

19.3 Involvement with other NIHR organisations
(Limit: 1500 characters)

Please use the drop down menu to identify any other organisation which will partner this research.
If applicable please describe their role in the research.

**19.4 Other Sources of Funding**  
_(Limit: 2000 characters)_

Will this application be supported by any other funding body? Please indicate ‘yes’ or ‘no’ from the drop down menu.

If you are proposing a study which requires joint or shared funding, it is in your interest 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 which may arise from the funding arrangements. Please also explain if any organisation is providing benefits in kind or free/discounted products.

**20. Department of Health (DH) Monitoring**

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 you to tick boxes relevant to them. Please note it is mandatory to complete this section. If necessary please refer to the user’s guide on the UKCRC website.  

http://www.ukcrc.org/home/

**20.1 UKCRC Health Categories**

Please tick all health categories that apply to your research.

**20.2 UKCRC Research activity Codes**

Research Activity Codes classify types of research activity. This dimension of the HRCS has 48 codes divided into eight overarching code groups which encompass all aspects of health related research activity ranging from basic to applied research. The Research Activity Codes are modelled on the structure of the Common Scientific Outline, a cancer research specific classification system developed by the International Cancer Research Partners.  

http://www.hrcsonline.net/rac

**21. Research Design Service (RDS) Involvement**

Applicants are recommended to seek advice from suitable methodological support services, at an appropriate stage in the development of their research idea and application. It is advisable to make contact at an early stage as possible to allow sufficient time for discussion and a considered response.

The NIHR Research Design Service can advise on appropriate NIHR programme choice, and developing and designing high quality research grant applications  

www.nihr.ac.uk/research/Pages/ResearchDesignService.aspx

**21.1 Advice on Non-standard methodologies**

The Methodology Advisory Service for Trials (MAST), offered by the Network of Hubs for Trials Methodology Research  

http://www.methodologyhubs.mrc.ac.uk/methodology_advisory_service.aspx, is a resource for resolving non-standard methodological issues. Referrals to MAST, should ideally be made through Clinical Trials Units (CTUs)  

http://www.ukcrc.org/infrastructure/networks/ukcrn/
22. Suggested Referees

Applicants must complete this section with suggestions of at least two potential referees. You will also be given the option to identify referees that you do not want approached, or who would have a potential conflict of interest. Please note that NETSCC reserves the right to approach any relevant referee.

If your outline application is shortlisted by an HTA Funding Board, it will be subject to external review by at least two clinical experts. You should provide details of two to three clinical experts who will be able to provide an independent assessment of your proposal. Please note that the referees must not be from your host institution, or those of your joint applicants. In addition you should not have recently (within the last five years) collaborated with any of the nominated referees. It is permissible to nominate overseas experts.

Nominated referees who are acceptable to the HTA Programme will be approached shortly after the submission deadline. If they are willing to assist, they will be supplied with a copy of your proposal, an assessment form and guidance notes, and will be given a 2-3 week period to complete their review.

23. Uploads

It is important to upload one document at a time and save it before adding another, otherwise earlier documents will be over-written.

There is a maximum upload limit of 2Mb per document. You will not be able to proceed with the upload if your document exceeds this size limit. If this is the case you should reduce the file size as much as possible before trying again.

23.1 Flow Diagram

Please supply a flow diagram illustrating the study design and the flow of participants. The flowchart should be in a PDF format and not PowerPoint. Applicants should also describe complex interventions and controls as accurately and fully as possible within their diagram. If proposing an RCT, we advise you refer to the CONSORT statement and website for guidance, (http://www.consort-statement.org). Alternatively, you may find the EQUATOR Network website useful (www.equator-network.org). The file should be uploaded to the ‘Flowchart’ section of the Uploads tab and submitted along with your application form. Please bear in mind the flowchart will be projected on a large screen to the board at the meeting, so please ensure it is clear, and that any text is concise.

23.2 References

List all references cited in the full project description, using either the Vancouver or Harvard referencing conventions. References should be uploaded as a separate document Please DO NOT include them in the same document as your flow diagram.
23.3 **Letter of support from Clinical Trials Unit (‘Supporting Letter’ on application form)**

Please note that where you have indicated engagement with a Clinical Trials Unit, we now require a letter of support from your unit at outline stage and this must be uploaded with your application. If your CTU is supporting a number of studies to HTA calls, they can submit a single letter of support listing all of them, rather than prepare individual letters.

Please do not attach any additional information as it will not be considered in your application when reviewed by the board.

**24. Acknowledgement**

**24.1 Agreement to the Terms and Conditions**

Please tick the check box to indicate that you have read and understood the terms on which you have been nominated as Chief Investigator for this proposal along with the associated documentation and accept this role. Ticking this box constitutes an electronic signature of the Lead Applicant with regard to this application.

**No original (wet or ink) signatures are required for this application.**

**25. Review and Submit**

Please ensure that before you submit your application, you have completed the required fields and saved a version of your form. You must submit your application form, with the attached detailed project description, flow diagram, references and supporting letter from your Clinical Trials Unit where applicable, by the stated deadline **before 1pm**. 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.

**The HTA programme no longer requires paper copies.**

Submit your application using the Submit button on the last page of the web form. Please note that the Submit button will not appear unless all necessary sections have been completed. Warning signs (¡) may appear to indicate that you may have omitted some information but this sign indicates the information is not mandatory and you can submit without it.

<table>
<thead>
<tr>
<th>✓</th>
<th>Complete</th>
<th>The section/form has been filled out correctly</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>Incomplete</td>
<td>Mandatory information has not been provided and the task cannot be submitted until this has been completed</td>
</tr>
<tr>
<td>¡</td>
<td>Attention</td>
<td>This section has not been completed but is not mandatory</td>
</tr>
</tbody>
</table>

We strongly advise applicants at this point to check that all sections are completed and the correct documents have been uploaded into the system as they cannot be altered once submitted.

Once all sections have been completed and show as green ticks a submit button will appear in the top left hand corner of the page and the form can be submitted to the HTA.

You will then receive an automated confirmation email from the HTA.

**25.1 Un-submitted applications**
Seven days prior to a funding opportunity application submission deadline you will receive an automatic email reminder. If you no longer wish to submit your application you do not need to do anything. However, you will not receive another reminder for this application submission.

Although you will still be able to view the application in a PDF format, you are strongly advised to keep a copy of the content of your application on a local hard drive/local copy of the form, from which you can copy and paste into an application form when you are ready to submit an application in time for a close date.

**26. Assistance/Contacting us**

Any questions, queries or requests for clarification in relation to the call you are applying to should be to one of the following e-mail addresses with the reference number and title for the call for proposals as the email header. Please be aware that while every effort will be made to respond to enquiries in a timely fashion, it is advisable to send queries in as far in advance of the call closing date as possible to ensure we can respond whilst still leaving you enough time to complete your application.

Commissioned calls for research (advertised briefs):
- [htacommissioning@southampton.ac.uk](mailto:htacommissioning@southampton.ac.uk) / 023 8059 5621 (24 hr. answerphone)

Clinical Evaluation and Trials / Researcher-led
- [htacet@southampton.ac.uk](mailto:htacet@southampton.ac.uk) / 023 8059 6974 (24 hr. answerphone)

**27. Useful links**

You may find the following presentations helpful when preparing your application.

- Professor Tom Walley, Director of NIHR Evaluations Trials and Studies - ‘[top tips for applying to the NIHR for funding](#)’ – from the NIHR workshop on surgery research, May 2012
- Professor Dion Morton, Professor of Surgery, School of Cancer Sciences, University of Birmingham - ‘[top tips for applying to the NIHR for funding](#)’ – from the NIHR workshop on surgery research, May 2012
- Mr Matt Costa, Senior Lecturer at Warwick Medical School and Consultant Orthopaedic Surgeon at The University Hospitals Coventry and Warwickshire – ‘[views on working with the NIHR and tips for applying to the NIHR for funding](#)’ – from the NIHR workshop on surgery research, May 2012