

V1.28 March 2017

GUIDANCE NOTES FOR COMPLETING FULL PROPOSALS

MIS on-line NIHR Standard Application Form (SAF)

These guidance notes apply to:

Commissioned calls (advertised research briefs)

Researcher-led calls (Clinical Evaluation and Trials)

Text which only applies to certain calls is highlighted in the colours above.

About these guidance notes

This document contains information and guidance to applicants submitting a **FULL** proposal and is applicable for primary research and evidence synthesis applications.

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.

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

Extract from the HTA programme's scope (www.nihr.ac.uk/funding-and-support/funding-for-research-studies/funding-programmes/health-technology-assessment/):

The NIHR HTA Programme supports research that is immediately useful to patients, clinical practice, and policy or decision makers.

HTA research is undertaken when evidence exists to show that a technology can be effective. The purpose of an HTA study is to establish the clinical and cost-effectiveness for the NHS in comparison with the current best alternative(s). A study may also investigate uncertainty around a technology's place in the existing care pathway.

"Technologies" in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), based at the University of Southampton, manages evaluation research programmes and activities for the NIHR

Health Technology Assessment Programme
National Institute for Health Research
Evaluation, Trials and Studies Coordinating Centre
University of Southampton, Alpha House
Enterprise Road, Southampton, SO16 7NS

tel: +44(0)23 8059
5586

fax: +44(0)23 8059
5639

email: hta.funding@nihr.ac.uk

www.nihr.ac.uk/funding-and-support/funding-for-research-studies/funding-programmes/health-technology-assessment/

<u>Contents</u>	<u>Page</u>
PART 1: Background information	
1 Introduction	5
1.1 Data Protection	5
1.2 Data security – about you	6
1.3 NIHR Carbon Reduction Guidelines	6
1.4 Requirement for systematic reviews to be registered with PROSPERO	6
1.5 Applications involving tissue collection and bio-banks	6
1.6 HRA – Information for participants at the end of a study	7
2. Getting started and using the form	7
2.1 Electronic Application form – Learning Guide	7
2.2 To access the application form	7
2.3 To submit an application	8
2.4 Saving your form and system time-out	9
2.5 Browsers that best support the NETSCC MIS	9
2.6 Spell-checking	9
2.7 Giving others access to the form	9
2.8 Leaving the application task	11
2.9 Printing your form	11
2.10 Technical support	11
2.11 Space restrictions when entering text	11
2.12 Use of non-standard characters	11
2.13 URL links	11
PART 2: Guidance for completing your application form	12
3. Research Details	12
3.1 Host organisation	12
3.2 Research title	12
3.3 Research type	12
3.4 Proposed start date	12
3.5 Research duration	12
3.6 End date	12
3.7 Total costs requested	12
3.8 Total NHS Support & Treatment costs (savings)	12
3.9 I have read the NIHR Carbon Reduction Guidelines	13
4. Contact info	13
5. Lead Applicant details	13
5.1 Specify role in research	13
5.2 %FTE (Full Time Equivalent) Commitment	13
5.3 Do you currently hold an NHR award?	13
5.4 Date of commencement	13
5.5 Is this a full-time post?	13
5.6 Current Grade	13
5.7 Current Research Commitments	14
5.8 Provide an approximate breakdown (%) of how your current appointment is divided between the following activities	14
5.9 Do you require or currently hold a working permit or visa?	14
5.10 Are you on a fixed term contract?	14
5.11 Administrative Contact Details	14

6.	CV Section	14
	6.1 Degrees and Professional Qualifications	14
	6.2 Present and Previous Positions Held	14
	6.3 Patient/Service User or Carer Applicants	14
7.	Research CV	15
	7.1 Recent relevant publications	15
	7.2 View your publication outputs	15
	7.3 Research Grants Held	15
8.	Research Team	15
	8.1 Co-Applicants	15
	8.2 Other supporting roles	16
	8.3 Electronic signatures	17
	8.4 Signatory statements	19
9.	Patient and Public Involvement (PPI)	19
	9.1 Were patients and the public actively involved in identifying the research topic or prioritising the research questions?	19
	9.2 Were patients and the public actively involved in preparing this application?	19
	9.3 Please indicate the ways in which patients and the public will be actively involved in the proposed research	19
10.	History of application	20
	10.1 Previous submissions	20
	10.2 Applications Submitted to NETS Programmes	20
	10.3 Other Funders / Applications in Progress	20
11.	Case for support	21
	11.1 Scientific Abstract	21
	11.2 Summary in Plain English	22
12.	Research Plan	23
13	Background and Rationale	23
	13.1 What is the problem being addressed?	23
	13.2 Why this research is important in terms of benefit to patients and the NHS	24
	13.3 Providing evidence explaining why this research is needed now	24
	13.4 Aims and Objectives	25
14	Changes from First Stage	25
	14.1 How has the proposal changed from the first stage application	25
15	Dissemination and Outputs	26
	15.1 Plans for disseminating the findings of this research	26
	15.2 Expected Output of research / Impact	26
16	Relevant Expertise	26
	16.1 Strengths of Research Team - contribution of each member	26
	16.2 Declarable interests	27
17	Detailed Budget	27
	17.1 General Information	27
	17.2 Information on different types of organisation	28
	17.3 Direct Costs	28
	17.4 Indirect Costs/overheads	31
	17.5 NHS Support and Treatment Costs	32
	17.6 Summary of Costs	33

18	Justification of costs	33
18.1	Please explain how the research provides value for money	33
18.2	Please explain how the research costs requested have been calculated and justify how they have been allocated	33
18.3	Please explain how the NHS Support and Treatment costs requested have been calculated and justify how they have been allocated	33
19	Management and Governance	34
19.1	Research timetable	34
19.2	Research management arrangements	34
19.3	Prior work to this proposal	34
19.4	Success Criteria and barriers to proposed work	34
19.5	Does the proposed research programme raise ethical issues?	34
19.6	Please detail how and when you intend to get ethical review completed	34
20	Intellectual Property	35
20.1	What relevant IP is held by the applicants and how does it relate to this application?	35
20.2	Has a freedom to operate search been conducted?	36
20.3	Will any IP be produced or improved during the proposed research?	36
20.4	Please describe how any new IP generated through the proposed research will be recognised, captured, managed and utilised	36
20.5	Current and future barriers to utilising the IP/ innovation through adoption in the healthcare service or through commercial exploitation	37
21	Wider Context	37
21.1	Network Involvement	37
21.2	Involvement of Clinical Trials Units (CTUs)	38
21.3	Involvement with other partners	38
21.4	Other sources of funding	38
22	Department of Health (DH) Monitoring	39
23	Research Design Service (RDS) Involvement	39
23.1	Advice on Non-standard methodologies	39
24	Suggested referees	40
25	Uploads / supporting documentation	40
25.1	Detailed project description	41
25.2	Flow diagram	44
25.3	References	44
25.4	Letter of support from Clinical Trials Unit	44
26	Acknowledgements / Agreement to Terms and Conditions	44
27	Review and Submit Application	44
27.1	Submission checklist	45
27.2	Unsubmitted applications	45
28	Assistance / Contact us	46
29	Useful links	46

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' remit 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, or commissioning brief, 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, Health Care and Research Wales and the HSC R&D Division, Public Health Agency in Northern Ireland. Researchers from Northern Ireland and Scotland for certain NICE related calls, as indicated in the commissioning brief, should contact NETSCC Commissioning Team to discuss their eligibility to apply.

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 NIHR Themed Calls.

The programme obtains topic suggestions from a wide range of sources and on occasion proposals may be submitted to the researcher-led (CET) streams which are on a similar topic area as one in development via our commissioned stream. Please note that **commissioning briefs take priority over applications to researcher led funding calls**. If an Expression of Interest (EoI) is submitted on a similar topic to a commissioning brief or any proposed research areas for HTA commissioned calls, it will not be considered and either:

- once the commissioning brief is advertised, the applicant can tailor their application to the commissioning brief and submit it in response to this

or,

- if a decision is made not to advertise a commissioning brief, applicants can apply through the researcher-led work stream in the usual way.

1.1 Data Protection

We have an obligation to keep data secure and to use it appropriately. To fulfil our obligations under the 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.funding@nihr.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.nihr.ac.uk/research-and-impact/research-priorities/

1.4 Requirements for systematic reviews to be registered with PROSPERO

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

1.5 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 the establishment of new cohorts 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. 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.

1.6 Health Research Authority (HRA) – Information for participants at the end of a study

The Health Research Authority provides guidance which sets out how and what information must be supplied to participants, and their legal representatives, consultees, close relatives or close friends (where applicable), at the end of a study. Information about the background to the guidance and an explanation of the points below is available at:

www.hra.nhs.uk/documents/2015/08/hra-guidance-end-study-pis-v4-1_20-august-2015.pdf

- What type of research does this guidance apply to?
- How does this information sheet fit in with other previously supplied participant information sheets (PIS)?
- When should the end of study information be given to participants?
- Does the end of study information sheet require review by a Research Ethics Committee (REC)?
- Guidance for the design and content of information sheets at the end of a study.

2. Getting started and using the form

Applications for funding are made online through the NETSCC Management Information System (NETSCC MIS). 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 various support documents are available here www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/nihr-evaluation-trials-and-studies-coordinating-centre/management-information-system/

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 Commissioned and researcher led calls follow the link:

www.nihr.ac.uk/funding-and-support/current-funding-opportunities/

To apply for a specific call, click on the relevant 'Click here to apply' 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 be able to apply directly for the call or commissioning brief and will be presented with additional relevant information such as the commissioning brief 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 '**Full 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.

If you have already submitted a first stage proposal and we have informed you via email that you should now complete a full application, you should log-in and will be taken to your NETSCC MIS home page where there will be a task called '**Full Application**'. This task will guide you through the full application. The NETSCC MIS can always be accessed directly at netscc-mis.nihr.ac.uk for you to go to your homepage where all your applications and incomplete tasks will be listed.

See the screenshot example below:



The screenshot shows a web application interface with a navigation bar at the top containing 'My Tasks', 'My Projects', 'Profile', and 'Apply For Funding'. Below the navigation bar are two buttons: 'Apply for Funding' and 'View All My Tasks'. A section titled 'My Tasks' contains a table with the following data:

System Reference Number	NETSCC ID	Chief Investigator	Task (Asc)
113577	13/56/02	Test, HTA	Full Application

The 'Full Application' link in the 'Task (Asc)' column is circled in red.

Clicking on the **Full Application** link takes you to the Full Application 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 task. For shortlisted applicants, this information will also appear in your outcome letter.

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 a **full proposal** 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 mandatory fields as well as providing reminders about optional entries.
- Provide a detailed project description (further guidance relating to the detailed project description is available in a later section of these guidance notes). This and other required supplementary documents can be uploaded with your electronic form.
- Submit a flow diagram (single-side of A4), as a separate PDF for submission with your application form (Primary Research only). 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). Alternatively, you may find the EQUATOR Network website useful (www.equator-network.org) or the recently published ACCEPT paper (Charlesworth et al. BMC Medical Research Methodology 2013, 13:78 www.biomedcentral.com/1471-2288/13/78).
- 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 form 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 one of the following:

- Windows users - Internet Explorer (versions 7 onwards). Firefox and Google 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

For full applications, the Lead Applicant can nominate someone in an administrative role to fill in some of the form, as well as a finance person to complete the relevant sections. This can be activated via the '**Administrative Contact Details**' section at the bottom of the 'Lead Applicant' tab in the application form. These people will be sent a user name and password.

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.

Co-applicants

Guidance for how co-applicants complete their sections can be found at: www.nihr.ac.uk/about-us/documents/NETSCC/MIS/MIS-brief-for-Co-Applicants.pdf

Access to your application is through your NETSCC MIS user login. **This should not be shared.** The full application is designed as a collaborative submission. As the lead applicant, you can nominate co-applicants to provide their CV information and collaborate on sections of the application. You select the type of access they have to the application. As a result of the nomination, your co-applicants will be invited via email to login to the MIS, accept their role and complete their application tasks.

It is essential to ensure you accurately complete the co-applicant contact details, specifically, their email address as this will be how the MIS will notify them of their role in the application and submission. **Please note that all the co-applicants need to complete their part of the application before you can submit. Currently, out of office replies will be returned to an unmonitored inbox and we advise the lead applicant to ensure the co-applicant is available to complete their sections.** There is a page in the application that shows you who have yet to complete their part of the application form. It is *your* responsibility to remind your colleagues to complete their application tasks and you should make sure that you allow time for them to do this before the closing date for the call.

Signatories

Instead of requiring wet ink signatures (for roles such as Sponsor, Department Head, Financial Director, NHS facilities Manager etc.) on a paper copy of the application form, you will be asked to provide contact information (including a valid individual's email address.) about the required signatories for the full application so that they can complete their approvals electronically. This process replaces the need for 'wet ink' signatures with an electronic version.

This is now a **two stage process** and requires signatories to first complete an '**agree to participate**' task prior to submission, followed by a '**confirmation**' task immediately after submission of the application.

In the first stage, you will be able to '**Notify**' the signatories and invite them via email to register/login to the MIS and accept their role.

Following submission the lead applicant will notify each signatory using the MIS, they will then acknowledge that they have seen and support your completed submitted application in time for the deadline by submitting the '**Provide full application signatures**' task. They will be able to see a PDF copy of your completed application via the system.

The HTA Programme acknowledges that it may not be possible for you to obtain confirmation from your Signatories immediately after submission, however; it remains your responsibility to obtain these electronic approvals within two weeks of the submission deadline. You can check that your signatories have completed the approval process on your MIS task page.

Once all signatories have completed their task you should take a screen shot of the completed page and email it to the relevant funding team. For contact details see '[contact us](#)' below.

Further information about these requirements can be found in the '**Other supporting roles**' and '**Electronic signatures**' sections of this document.

It is essential to ensure you accurately complete the signatory contact details, specifically their email address, as this is how they will be registered into the MIS and notified of their role in the submission.

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.

2.9 Printing your form

Please note that the form does not print out in the same order that it is filled in. The printing order for the full form can be found as a Word document in the 'Support Documentation for Applicants' section of the Programme's web page. This is intended to help you work offline and will not be accepted as a submission.

2.10 Technical Support

If you encounter any problems with the NETSCC MIS system, you should contact the programme funding support team either via email or by phone.

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. 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.

2.13 URL links

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 researcher-led call, please ensure that you read the relevant documentation thoroughly before starting your application.

If you are unsure about any aspect of a commissioning brief please contact the team at htacommissioning@nihr.ac.uk

If you are a researcher-led 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 htacet@nihr.ac.uk

3.1 Host Organisation

Please give details of the organisation that will be the host or contractor if the project is funded using the selection from the drop down menu. If your host institution is not shown you should contact the relevant team above to add your institution. This can take 24 hours to take effect so please leave plenty of time for any requests.

3.2 Research Title

(Limit: 300 characters)

The project title should clearly and concisely state the proposed research. Any abbreviations should be spelt out. The project title used here should be the same as the title used on your first stage proposal if you are completing this as part of a two-stage application.

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'. If you are submitting an application to a one-stage evidence synthesis call, select 'Evidence Synthesis'. If you are not sure which category to select, please choose the closest match to your project as this can be adjusted later.

3.4 Proposed Start Date

Please note that projects are expected to start within **eight months** of issue of the funding outcome letter. Start dates must be on the 1st of the month, regardless of whether this is a working day or not. It is important to be realistic about your proposed start date, taking account of the time required for contracting and any other activities that need to be undertaken before the contract start date.

3.5 Research Duration (months)

Please ensure you include sufficient time to complete all aspects of the research including applications for regulatory approvals (where required) and writing of 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 3.8 Total NHS Support & Treatment costs (savings)

For guidance on how to complete the financial costs of your application, please see the [financial guidance](#)

3.9 I have read the NIHR Carbon Reduction Guidelines

Please read the information here www.nihr.ac.uk/research-and-impact/research-priorities/ and tick the box.

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

If you are proposing a Clinical Trial of an Investigational Medicinal Product (CTIMP) – the Chief Investigator must be an authorised health professional as defined in the [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(SI 2004/1031\)](#) . This means a person registered in the UK as a doctor, dentist, nurse or pharmacist. Further information on the requirements for a CTIMP can be accessed via the [Clinical Trials Toolkit](#).

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:

5.1. Specify role in research

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

5.2. %FTE (Full Time Equivalent) Commitment

This refers to the percentage (to one decimal place) of your time that you will be committing to this project.

5.3. Do you currently hold an NIHR award?

Please enter any other awards you currently hold.

5.4. Date of commencement

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

5.5. Is this a full-time post?

Please indicate your WTE at your host institution.

5.6. Current Grade:

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

5.7. 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.

5.8. 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.

- Service/ Clinical
- Research
- Teaching
- Other – Please complete the text box as appropriate

5.9. Do you require or currently hold a working permit or visa?

Please indicate 'yes' or 'no'

5.10. Are you on a fixed-term contract?

Please indicate 'yes' or 'no'

5.11. 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 patient and public involvement 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 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 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 3 years. If no grants are held please enter N/A (as this is a mandatory field).

8. Research Team

You must complete personal details for everyone involved and state their contribution towards the proposed project (e.g. data collection, coordination and project management, analysis, methodological input, PPI input).

8.1 Co-Applicants

Please add details of all co-applicants. 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 and under 'Expertise' in your detailed project description. 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.

Including co-applicants in your application

For applicants who have completed a first stage application:

The list of co-applicants will have been brought forward from your first stage application automatically. You should ensure that their details are correct and the list reflects all of those involved in the full application. An incorrect address will prevent the co-applicant from being added to the full application form. Please note that a co-applicant, once added and saved, cannot be edited. If a mistake has been made, please delete the co-applicant using the DELETE button and ADD a new entry.

If your application includes co-applicants, you will not be able to complete and submit your application **until** the co-applicant has provided the information that we require from them. It is *your* responsibility to ensure completion of the tasks by the co-applicants in good time for the submission.

Once you have completed the details for each co-applicant you have to select the option '**notify**' on the Co-Applicants Instructions page. This will then prompt an email to be sent to each co-applicant for them to approve involvement with your project.

Important note: This is a two-stage process.

Stage 1: Agree to participate

If a co-applicant agrees to participate, they must tick to say they have read the NIHR carbon guidelines and press '**submit**', then a pop-up window will be displayed which asks them to undertake the second 'collaborate' task. The pop up will say '*Are you sure you wish to submit?*' If you press OK, a further task will be found on their My Tasks page which states 'Collaborate on Full Application'. They will at this point be able to access the full application form and depending on access permissions are able to edit various sections.

Stage 2: Agree to collaborate

They should work through the tasks on the left-hand menu providing:

- Contact Info,
- CV (**CVs need to be kept to a maximum of one side of A4.**)
- Publications and Grants information (listed on the left-hand pane).

Please make sure that you:

- Allow sufficient time for your co-applicants to complete their sections of the online form **before** the application deadline. This includes a task for the co-applicant to agree or decline participation in the application task. If the applicant agrees, they will automatically have two tasks appear in their homepage. The task '**Agree to Collaborate**' enables the co-applicant to update their CV details. The other 'Full Application' task allows the co-applicant to amend any details in the form. It is the responsibility of the lead applicant to ensure that the co-applicants complete all the tasks generated.
- Enter co-applicants details accurately as we will use these to contact them (the **exact email address is essential** to ensure they receive the automatic communication as part of the application process). **It is advisable to contact your co-applicants in advance to ensure you enter the e-mail address they are registered with on our MIS, and that this is spelt correctly.**
- If you are including **PPI** representatives as co-applicants you should list their affiliated organisation as **Patient Representative**
- If you observe incorrect details of a co-applicant you will be able to '**resubmit**' the task back to the co-applicants to correct OR you can delete them from the list and re-add them with the correct information. The system does not allow the lead applicant to edit the co-applicant's details.

Your application must be submitted, including the co-applicant's sections by the closing date and time for the call. These details can be found in your outcome letter and submission is due before 1pm on the designated date.

Please note that any out of offices or undeliverable messages will only be received to an unmonitored email account so please ensure your co-applicants are available to complete their tasks.

8.2 Other supporting roles

As a minimum the following supporting roles are required to be added to a full proposal application:

- **Administrative Authority or Finance Officer**
- **Head of Department or Senior Manager Sponsor**
- **Sponsor**
- **NHS Costs Nominated Signatory** - if NHS treatment costs are included in the application then we will need confirmation from the lead site where patients are to be recruited (note further assurance will be sought in relation to NHS costs at other sites) that they will fund all costs

attributed under this category. Applicants need to be sure they leave sufficient time when planning their work up of an application, to have discussions with all the recruitment sites to ensure that finances have been correctly calculated. It is important to be aware of the following differing requirements in relation to the Devolved Nations and NHS England:

If the NHS treatment costs are to be covered by Specialised Commissioning, the signatory has to be from the appropriate member of the NHSE Specialised Commissioning team. As above, sufficient time should be allowed for discussions with NHSE Specialised Commissioning to ensure that finances have been correctly calculated and the individual at Specialised Commissioning can sign the form. Please note that NHSE Specialised Commissioning will not be reviewing the fact of the research but the appropriateness of the costings. For further guidance on NHSE costs please refer to the NHSE guidance www.england.nhs.uk/ourwork/research/etc/

- **Representative of the R&D Function of the Devolved Country** - if a project is originating or has recruitment sites in Scotland, Wales or Northern Ireland we will require evidence of support with regards to NHS costs. The nominated signatory for this section should be an authorised person on behalf of the Public Health Agency in Northern Ireland, the NHS Health Scotland or Health and Care Research in Wales. By signing the form, the signatory is agreeing that the excess treatment costs and support costs stated in this application appear reasonable and will be met if this research is funded.

In addition other listed supporting roles should be added as necessary. **At the time of adding the necessary supporting roles required to approve your application, you are advised to inform the Trust R&D office of the site most likely to be the lead site for your proposed research. The aim is to help speed up the permissions process should your application be successful. Please note this will not apply to all proposals.**

Electronic signatures

Each person nominated to a supporting role will be required to tick a checkbox indicating that they have read and understood the terms on which they have been nominated for this proposal and accept this role. Ticking this box constitutes an electronic signature of the supporting role with regard to this full proposal application.

Once the application form is completed and prior to submission the Lead Applicant is also required to tick a check box to indicate that they 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 (see acknowledgement section on page 43).

No original signatures are required for this application.

8.3 Electronic signatures

Once the application form is completed and prior to submission, the Lead Applicant is also required to tick a check box to indicate that they 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 (see the Acknowledgement section).

Each person nominated to a supporting role will be required to tick a checkbox indicating that they have read and understood the terms on which they have been nominated for this proposal and accept this role. This is the first stage of a two-stage process and requires signatories' completion to submit the task. A valid individual's or generic email address is required.

Types of signatory and definitions

- **Sponsor** - All research projects must have a nominated sponsor responsible for the management and conduct of the project. For full details of sponsor definitions and responsibilities please refer to the Department of Health's

www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition

- **Head of Department** - The person who signs this should be the person who is responsible for the department where the bulk of the research will take place.
- **Administrative Authority or Finance Office** – This person is expected to confirm that the staff grades and salaries quoted are correct and in accordance with the normal practice of your institution.

The preceding signatories are mandatory

- **NHS costs nominated signatory** – This person is expected to be agreeing to the NHS costs being funded by their organisation for patients recruited to this trial within the sites covered by their organisation, further assurance will be sought in relation to NHS costs at other sites.

This signatory is mandatory if NHS costs are being sought

- **Representative of the R&D Function of the Devolved Country** - For research projects originating in Scotland, Wales or Northern Ireland, you will need to provide evidence of support with regards to NHS support and treatment costs.

This signatory is mandatory if NHS costs are being sought from outside England

- **NHS Facilities and Staff Nominated Signatory** - this person is expected to be able to agree to the use of NHS facilities and staff for this work.

- **Partner Organisations Facilities & Staff Nominated Signatory** – This person should be able to agree to the use of the Partner Organisation facilities and staff for this work.

The final two signatories are not mandatory and may not be necessary for all applications.

A full list of definitions of all members of the study team can be found here: www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/nihr-evaluation-trials-and-studies-coordinating-centre/management-information-system/terms-and-conditions.htm

Once the electronic form is submitted by the lead applicant, a separate task will be generated for the lead applicant to notify signatories to review their relevant sections in the application and confirm they accept the application's content. This replaces the need for wet or ink signatures on the paper copy. Submitting this task constitutes an electronic signature of the supporting role with regard to this full proposal application.

It is the Lead Applicant's responsibility to ensure these 'signatures' have been completed within two weeks of submission, after which time the form will close. The Lead Applicant can monitor these acceptances via the 'Research Team' tab. Once all signatories are completed the lead applicant should email a screen shot of the completed page to the relevant funding team. [Contact](#) details below.

No original or 'wet ink' signatures are required for this application.

8.4 Signatory statements

Please ensure that the required signatories (above) are aware of the statements of responsibility that they are agreeing to by making an electronic signature. The statements can be found by clicking on the following link: www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/nihr-evaluation-trials-and-studies-coordinating-centre/management-information-system/terms-and-conditions.htm

9. Patient and Public Involvement (PPI)

The NIHR expects the active involvement of patients and the public in the research it supports, including research undertaken as part of an individual training award. 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.

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 application 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.

Further information and resources can be found on the INVOLVE website www.invo.org.uk/. This includes a detailed [definition](#) of patient and public involvement in research, [briefing notes for researchers](#) on how to involve patients and the public and an [involvement cost calculator](#) and budgeting guide. The NIHR [Research Design Service](#) provide advice on developing research applications including involving patients and the public and the [James Lind Alliance](#) has a step-by-step guide on involvement in research identification and priority setting.

9.1 Were patients and the public actively involved in identifying the research topic or prioritising the research questions? *Yes/No*

9.2 Were patients and the public actively involved in preparing this application? *Yes/No*

- **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, outline the activities they have been involved in and how this involvement has, or has not, influenced or changed this research application.
(Limit: 1200 characters)
- **If you have ticked the NO box to either or both of these questions** please explain why patient and public involvement was not thought necessary.
(Limit: 1200 characters)

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

Tick all boxes that apply.

9.4 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?

9.5 If there are no plans for active involvement, please explain why it is not thought necessary
(Limit: 1200 characters)

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

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).

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.

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.

Please answer all questions as fully as possible. We are keen to know if the proposal 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.

10.2 Applications Submitted to NETS programmes

Any previous application submissions to NETS programmes in the preceding three years 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 proposal 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. You may find the list of previous submissions changes between Expression of Interest and Full application as they fall outside of the date range.

IMPORTANT NOTE - NETSCC RESUBMISSION POLICY:

A previously unsuccessful application cannot be resubmitted to the HTA programme or any of the other NETS programmes 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. The list will only include applications submitted to NETSCC in the previous three years only. Should a relevant application (regardless of funder) not be listed in this section it can be manually added in the 'Other Funders' section at the base of the page.

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 requested information.

11. Case for support

11.1 Scientific Abstract

(Limit: 3500 characters)

These headings in this section should be used to provide a summary of your proposed research.

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.
- **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.
 - The programme is interested in taking advantage of the growing utility of routine data (such as HES, GP records etc.), and would like investigators, where appropriate, to ask study participants to consent to long-term follow-up (e.g. beyond the outcomes to be collected in the funded trial) using routinely collected data, and appropriate linkage to allow this data to be best used.
- **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)

The importance of a plain English summary

A plain English summary is a clear explanation of your research.

Many reviewers use this summary to inform their review of your funding application. They include clinicians and researchers who do not have specialist knowledge of your field as well as members of the public. If your application for funding is successful, the summary will be used on National Institute for Health Research (NIHR) and other websites.

A good quality plain English summary providing an easy to read overview of your whole study will help:

- Those carrying out the review (reviewers and board and panel members) to have a better understanding of your research proposal
- Inform others about your research such as members of the public, health professionals, policy makers and the media
- The research funders to publicise the research that they fund.

If we feel that your plain English summary is neither clear nor of a good quality then you may be required to amend your summary prior to final funding approval.

It is helpful to involve patients / carers / members of the public in developing a plain English summary.

When writing your summary consider including the following information where appropriate:

- Aim(s) of the research
- Background to the research
- Design and methods used
- Patient and public involvement
- Dissemination.

The plain English summary is not the same as a scientific abstract - please do not cut and paste this or other sections of your application form to create the plain English summary.

Further guidance on writing in plain English is available online at NIHR Make it Clear www.involve.nihr.ac.uk/makeitclear.

For further support and advice on writing a plain English summary, please contact your local Research Design Service www.rds.nihr.ac.uk

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 of these are relevant (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 primary research applications the following three fields are available to be completed. For HTA Evidence Synthesis applications only the 'Other' field is available. Other programmes may have different requirements

12.1 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.

12.2 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.

12.3 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 applicants responding to advertised calls (commissioned calls), please describe here how your proposal is relevant to the research question and meets the requirements as set out in the commissioning brief.

Applicants are encouraged to follow the brief where possible. The brief outlines the methods expected by the programme, but in exceptional circumstances the board may consider alternative designs if well justified. Deviations will be accepted, but they must stick to the spirit of the brief, be clearly explained and justified with supporting evidence. Applicants do this at their own risk and it is the team's responsibility to demonstrate sufficient numbers of patients are available for any alternative design proposed.

For **Evidence Synthesis** applications ONLY to researcher-led calls: As you are completing a one-stage application process, 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

The research question should usually identify the intervention to be evaluated, the comparator, main outcome and the relevant population.

For all researcher-led / Clinical Evaluation and Trials proposals, this section must include the following:

- I. 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.
- II. 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 the research important in terms of improving the health of the public and/or to patients and the NHS?

(Limit: 3500 characters)

For applicants responding to advertised (commissioned) calls, please describe how your research addresses the specification set out in the commissioning brief.

For researcher-led/Clinical Evaluation and Trials applications, this section must include the following: It is essential that you identify the NHS needs your research meets or contributes to. Please outline the anticipated value or contribution the study will provide. Classification of need for research is set out below:

- **Health need:** There will be benefits in terms of improving health for patients and carers. This covers the potential for preventing avoidable mortality and morbidity, improving quality of life and considerations of disease prevention. For example, research in this area is likely to identify new ways of working that enhance opportunities for health promotion or quality and safety of care. Benefits may also arise from improving the acceptability and effectiveness of care, cost effectiveness to the NHS, better targeting of services or equity of access to care.
- **Expressed need:** The existence of an expressed need for the research in the NHS management community, and evidence that it is, or will be, highly relevant and important to the needs of the NHS.
- **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:** The existence of uncertainty or “knowledge gaps” which cannot be addressed by the existing body of research in this area and that require new research.
- **Organisational focus consistent with the HTA mission:** The focus of the expressed research need is consistent with the wider mission of the HTA Programme and its primary orientation towards the organisation and delivery of healthcare.
- **Generalisable findings and prospects for change:** Research in this area is likely to produce findings of value to the NHS management community, which NHS organisations are likely to be able to use in their decision making in ways that bring about change and improvement.
- **Building on existing work:** Research contributes to building a coherent body of knowledge in the area, and may build on previous research commissioned by the HTA Programme. This information is to be used to describe rather than justify the need. This process will have been assessed at the first stage, if this full proposal is part of a two-stage application process.
- **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.nihr.ac.uk/glossary

Where the request for research to address a specific research question is via a commissioning brief advertised through a commissioned call, the review of the existing evidence will have already been undertaken by the NIHR HTA Programme to inform the commissioning brief. Applications in response to commissioned calls will need to address the commissioning brief requirements specific to the NIHR HTA Programme.

For researcher-led/ Clinical Evaluation and Trials 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 published 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.

The proposed standard for what constitutes a satisfactory review of the existing evidence to inform new primary research is as follows:

- I. Citing a relevant Cochrane Review (or)
- II. If no Cochrane Review exists then citing another systematic review that is published in a peer reviewed journal (or)
- III. If no published systematic review is identified then the research applicants should present the findings of a systematic review that they have undertaken for the purposes of the application, where the definition of systematic review for audit purposes is taken from the HTA Monograph series as “when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.”

Importantly, if the applicants undertake and present the findings of their own review of the existing evidence undertaken systematically then they have to provide sufficient details of the methodologies employed to allow the review to be replicated.

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)

If you are submitting a one-stage full proposal please ignore this question as it is not applicable to you. If this is the case please enter ‘not applicable’ in the box.

If you have previously submitted an HTA Expression of Interest (EoI) please detail how the feedback from the first stage has been addressed in the full proposal and state any changes e.g. to aims and objectives or your methodology, and whether these have influenced estimates of costs and/or the duration of the project. The project title should remain the same as it was at the first stage. Please describe and explain any additional changes that have been made to this proposal since the first stage, e.g. in the light of new research.

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 into other direct costs on the application form. NIHR expects that APCs will be covered by the funding award. www.nihr.ac.uk/funding-and-support/funding-for-research-studies/how-to-apply/support-for-study-teams/publishing-your-research/nihr-open-access-policy.htm

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)

Please provide a clear account of the team assembled and the skills and expertise each member will provide, in particular, please note the contribution of the Lead Applicant. Where appropriate, it needs to draw on the expertise and knowledge of managers, researchers, clinicians and those trained in methodologies such as health economics, medical statistics, study design and patients and the public. In addition, please give details of supervision arrangements for junior staff involved.

The HTA Programme strongly recommends that teams proposing randomised controlled trials include input from an accredited clinical trials unit or one with equivalent experience. Applicants are also

expected to engage a qualified Trial Manager for appropriate projects. A commitment to team working must be shown and applicants may wish to consider a collaborative approach between several institutions.

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), honoraria, 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. Detailed Budget

The finance section should provide a breakdown of costs associated with undertaking the research as described in the proposal.

For guidance on costs for public involvement you may find useful information at -

www.invo.org.uk/posttypepublication/national-institute-for-health-research-payment-rates-for-public-involvement/

17.1 General Information

- The information entered in this section should provide an analysis of the total funds requested to undertake the research proposed and should be based on current prices. These costs will be used to assess value for money.
- It is in the best interest to undertake a thorough, realistic and accurate costing. Where an EoI/‘stage 1’ application has been produced and this is the full/ ‘stage 2’ application, the Committee/Panel will pay close attention to any material increase in costs. 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.
- Payments will be made to the contracted organisation only and the contracted organisation will be responsible for passing on any money due to their partner organisation(s).
- Appropriate sub-contracts must be put in place for any element of the research which is to be paid to another organisation.

- 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.nihr.ac.uk/funding-and-support/study-support-service/study-support-service-contacts/
- All applications are expected to have appropriate NHS, HEI, commercial and other partner organisation input into the finance section of the application form.

Costs for un-named co-applicants

If you need to provide costs for more than one unnamed individual it is important to name them as 'TBA 1', 'TBA 2' etc. not just 'TBA', otherwise their costs will not appear in the PDF version of the form.

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.**
- **NHS bodies and other providers of NHS services in England**
For applications where the contractor is an NHS body or provider of NHS services in England, up to 100% of direct costs will be paid.
- **Commercial Organisations**
If you are a commercial organisation/consultancy, please fill in direct costs and commercial indirect costs. Indirect costs should be charged 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 fill in direct costs and other partner organisations indirect costs. Indirect costs should be charged 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. This section presents an overview of salary costs for the applicant(s) contributing to the research, including normal salary increments broken down individually.

Please include all members of staff working on the research by clicking 'add a new staff member' or editing a current one. You should include pay grades, scale points and increment dates. If there are any applicant(s) whose costs are not being claimed you will need to state the applicant's name and, explain briefly why costs are not being claimed and the resources being used to cover their contribution.

II. Apply to years. This section specifies the annual costs of each applicant contributing to the research. You should now allocate the individual staff member costs to each year of the research, allowing for increments. Use current rates of pay, and build in any known annual increments (again at current rates). You will not be able to claim for pay awards retrospectively, once your research is underway.

Please note the '%fte and the 'Total Salary' columns are independent and the % figure is not used to calculate the net staff costs.

In the Total Salary column, enter the cost of the individual to the research. **For example:**

- If an individual's total annual salary costs are £20,000 and they are expected to work 50% of the time on the research, in the '% FTE column enter 50, then £10,000 in the Year 1 Total Salary column, £10,000 plus any increment in Year 2 Total Salary column, £10,000 plus any increments in Year 3 Total Salary column, etc.
- If an individual is going to work full-time on the research, which lasts 4 years, but only for the last 6 months, enter 100 in the '% FTE column and 6 in ' Number of months in year' column, and the cost of their work in the Year 4 Total Salary column.
- If the research lasts for several years and an individual's involvement varies over the course, it may be necessary to explain fully in the justification of costs section the % FTE and months per year for an individual staff member.

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

Please ensure that you check the 'Type of Cost' box which describes the employing organisation for a member of staff, as this impacts on the level of funding provided. 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.

Please note that this section also includes 'Shared Staff Costs' which is located under directly allocated costs in some other funders' applications. These 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. HEI indirect costs cannot be claimed on these shared costs.

III. Travel, Subsistence and Conference fees. This section includes 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**
Enter 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 years or part of five year research period.

IV. Equipment. Essential items of equipment plus maintenance and related costs not included as part of estates should be input in this section. 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. Where applicants are leasing equipment with a purchase price of more than £5,000, a comparison of leasing versus purchasing costs must be provided in the 'Justification of Costs' section.

Items of equipment valued at £250 or more must be itemised separately; however grouping same type equipment is permitted. Costs of computers are normally restricted to a maximum of £650 each excluding VAT and a statement of justification must be included, in the relevant 'Justification of Costs' section for any purchase above this limit.

Equipment must exclude VAT, but if your organisation is unable to reclaim/recover the VAT on a piece of equipment, you should check the box 'VAT cannot be reclaimed'. You will need to seek expert advice from the organisation purchasing the equipment regarding its VAT status. If you check the 'VAT cannot be reclaimed' column, VAT at 20% will automatically be calculated into the overall cost of that item.

V. Consumables. This section includes non-reusable items specific to the research. Please itemise and describe the requirements fully (e.g. postage, stationery, photocopying). These items should be research specific, not just general office costs which should be covered by indirect costs.

VI. Patient and Public Involvement. Please itemise and describe fully the 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. **Guidance for making payments to members of the public actively involved in NHS, public health and social care research (2010) can be found here:**

www.invo.org.uk/posttypepublication/budgeting-for-involvement/

www.invo.org.uk/posttypepublication/national-institute-for-health-research-payment-rates-for-public-involvement/

www.invo.org.uk/posttypepublication/what-you-need-to-know-about-payment/

VII. Other Direct Costs. These are costs, not identified elsewhere, that are specifically attributed to the research. For example, costs associated with the use of research facilities, 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 appear in this section.

Any costs associated with publication, presentation or dissemination of findings (except related travel and subsistence or consumables costs) should be itemised and included here. Any large costs should be further detailed with a breakdown of constituent parts or a timescale profile of the costs. Meetings to share best practice, training events and events to disseminate research findings must be run at the lowest possible cost with minimal catering. 'Conferences' which are described as such are not eligible for funding.

If external consultancy costs are included in this section they must be fully justified in the 'Justification of Costs' section. Please specify the hourly rate and the number of hours and note that consultants must not be people who are already employed by the applicant's institution. If they are, any costs should be entered as direct costs in the 'Details of Posts and Salaries' and 'Annual Costs of Posts' sections.

VIII. Patent and Legal. The NIHR will consider supporting reasonable costs requested to protect any Intellectual Property which arises from the research project. Any costs will be supported during the period of the research only. Supported costs include, but are not limited to, legal advice, patent and Freedom to Operate searches, patent submission costs and third-party licensing fees. The NIHR will not support any costs incurred prior to or following the research project, including patent maintenance costs. All requests should be fully itemised and justified.

IX. Sub-Contracts. A sub-contract is regarded as an external specialist service which cannot be provided by the organisation leading the project or its collaborators. Services include consultancy, design services, or the development and provision of specialist equipment. These costs can be requested for organisations providing these services outside of England, 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. Please note HEI indirect costs cannot be claimed on shared staff costs. Where staff from more than one HEI are working on the research there may be different indirect/estates charges for each one. Please list each institution on a separate line.

The applicant(s) should consult their HEI Finance Departments for the appropriate figures to include in the estate charges and other indirect cost sections

- **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 cost for this section.

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

- **Indirect Costs**

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

17.5 NHS Support and Treatment costs (incl. Excess Treatment Costs/Savings)

(Limit: 2500 characters)

The finance section 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.

A representative of the NHS organisation - incurring any NHS Support and Treatment Costs - must sign off the application. The 'Declarations and Signatures' page is intended to ensure that the aforementioned organisation is satisfied that all NHS Support and Treatment Costs in the application are correct and is prepared to meet these costs.

Note for applications involving centres in Northern Ireland:

For research projects originating in Northern Ireland (NI), or likely to recruit mainly in NI, the HTA programme will need you to provide evidence that the Public Health Agency in Northern Ireland are aware of and approve your Service Support costs before we can approve any funding. For proposals originating outside NI but using NI as one of many recruitment areas, you will need to contact the Public Health Agency in Northern Ireland after any funding approval, and they will take the final decision as to whether they will support recruitment there.

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 www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/crn/

II. NHS Treatment Costs

Please read the following guidance on the funding of excess treatment costs prior to completing your application www.england.nhs.uk/ourwork/research/etc/

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.

Please note if the patient care intervention under investigation is **in addition to** usual care there is no need to complete the 'Usual Treatment Costs' section, however, this will need to be justified in the relevant 'Justification of Costs' section. If the patient care intervention under investigation either wholly or partially replaces usual care, the 'Usual Treatment Costs' section must be completed.

17.6 Summary of Costs

- NIHR programmes currently fund HEIs at a maximum of 80% of full economic cost, NHS bodies and other providers of NHS services in England at 100% and commercial/other partner organisations at 100%.
- Please note that whilst these percentages will be used to calculate the maximum grant payable, the programme reserves the right to award a grant for less than this maximum where it is considered appropriate.

18. Justification of costs

All figures quoted in this section should be shown at 100% FEC

18.1 Please explain how the research provides value for money

(Limit: 2500 characters)

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. You should also 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.

18.2 Please explain how the research costs requested have been calculated and justify how they have been allocated

(Limit: 2500 characters)

Please provide a breakdown of research costs associated with undertaking the research and provide justification for the resources requested. This should include the following costs: staff costs, travel, subsistence and conference fees, equipment (including lease versus purchase costs), consumables, patient and public involvement and any other direct costs.

18.3 Please explain how the NHS Support and Treatment costs requested have been calculated and justify how they have been allocated

(Limit: 2500 characters)

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.

For further information, please see:

Attributing the costs of health & social care Research & Development (AcoRD)

www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

19. Management and Governance

19.1 Research Timetable

(Limit: 2000 characters)

Please provide a concise summary here of the project plan of investigation, preferably in the form of a monthly project timetable showing the scheduling of all key stages in the project, their expected durations, and the timing of key milestones throughout the project including the production of outputs.

This timetable will be an important aspect of the monitoring framework during the life of the project.

19.2 Research Management Arrangements

(Limit: 2000 characters)

All project proposals should include details of how the project will be managed. For projects involving a number of institutions or component parts, effective project management is essential to ensure the work is completed within the planned timeframe.

You should set out how joint applicants in different institutions will communicate and monitor progress of the project. The project team is encouraged to appoint a dedicated (but not necessarily full-time) project manager who can assist with the day-to-day management of the project, a role which should be appropriately costed where necessary.

All primary research projects are expected to establish a Project Advisory Group (or similar) which ideally should have an independent Chair. Costs incurred by this group should be included in the budget as appropriate.

19.3 Has any work relevant to this proposal already commenced?

If yes, please give details of any relevant work that has already commenced in the preparation of this research proposal. *(Limit: 2000 characters)*

19.4 Success Criteria and barriers to proposed work

(Limit: 2000 characters)

Please set out the measurements of success you intend to use, the risks to the proposed research and how you intend to mitigate against them.

19.5 Does the proposed research programme raise ethical issues?

If yes, outline the ethical issues, and arrangements for handling them. Consider when the project requires approval by an ethics committee. *(Limit: 1600 characters)*

19.6 Please detail how and when you intend to get ethical review completed

(Limit: 1600 characters)

If there is development work that is essential before you intend to apply for ethics approval, state this and make the timescales clear in your plan of investigation and project timetable.

The funding board will consider this in detail and consider whether to offer staged funding. If you are using patient information from an existing database, you should check whether the patients have given their consent for their data to be included in that database for research purposes, or if not whether the database is exempt under Section 60 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 programme.

19.7 If ethics approval is NOT required, then justify

(Limit: 1600 characters)

20. Intellectual Property (IP)

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 £1 billion per annum as confirmed in the most recent spending review. 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 tests or medical devices. 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.

20.1 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 subcontractors 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 with; 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.

20.2 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.

20.3 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.

20.4 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 Technology Transfer Office (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.

20.5 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.

21. 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.

Where appropriate, you are expected to work with the relevant NIHR Clinical Research Network(s). 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.

21.1 In your proposed research, do you intend to link to NIHR Networks? If yes, please state which networks
(Limit: 400 characters)

21.2 Please describe the benefits identified from working with networks
(Limit: 1500 characters)

21.3 Please indicate other organisations that you may have contacted in the course of preparing this application
(Limit: 1000 characters)

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.

21.4 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.

Clinical Trials Units are regarded as an important component of many trial applications 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.

NIHR CTU Support Funding (www.nihr.ac.uk/funding-and-support/funding-to-support-research/funding-to-support-research-in-the-nhs/ctu-support-funding.htm) provides information on units receiving funding from the NIHR to collaborate on research applications to NIHR programmes and funded projects.

In addition UKCRC CTU Network (www.ukcrc-ctu.org.uk) provides a searchable information resource on all registered units and CTU ID numbers in the UK and lists key interest areas and contact information.

A letter of confirmation from the CTU Director is required for a full proposal submission to be complete 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.

Involvement with other NIHR organisations

21.5 What, if any, other NIHR organisations will partner this research?

(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.

Other Sources of Funding

21.6 Will this application be supported by any other funding body?

(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 have selected yes you will need to click 'add' and supply further details relating to other funding sources.

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 a demonstration that full access to all data relating to the proposed study will be achieved, and clarity about where responsibility will lie contractually in terms of publication, copyright, and research governance issues. Please also explain if any organisation is providing benefits in kind or free/discounted products. These matters should have been briefly referred to during the first stage, with a detailed description of the co-working arrangements now provided at the full proposal stage.

22. 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 www.ukcrc.org/home/

22.1 UKCRC Health Categories

Please tick all health categories that apply to your research.

22.2 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. www.hrcsonline.net/rac

Please tick all codes that apply to your research.

23. 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 a 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.rds.nihr.ac.uk/

23.1 Advice on Non-standard methodologies

The Methodology Advisory Service for Trials (MAST), offered by the Network of Hubs for Trials Methodology Research 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) www.ukcrc.org/research-infrastructure/clinical-trials-units/

24. Suggested Referees

Applicants may 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 to be approached, or who would have a potential conflict of interest. Please note that NETSCC reserves the right to approach any relevant referee.

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 week period to complete their review.

25. 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.

Guidance on how to reduce file size can be found at:

<http://www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/nihr-evaluation-trials-and-studies-coordinating-centre/management-information-system/>

PLEASE NOTE: we will only accept the following uploads. Any additional documents **will not** be considered by the board during its review

25.1 Detailed project description

It is mandatory to submit a detailed project description, which is a fuller account of the proposed project than can be provided in the space allowed in the Case for Support section of the application form. Whilst we are trying to keep duplication to a minimum, we do accept there is a level of duplication between the two sections, Case for Support and Upload of detailed project description. The applicant should provide concise and succinct information to the questions within Case for Support, which will be held within our database for future reference. Detailed information should be included in the upload of the detailed project information. This must be uploaded before the application form is submitted. Additional, non-requested documents that are attached (please note that not all documents on the drop-down menu will be mandatory e.g. flowchart for ES proposal) will be accessed at the assessors' discretion. Applicants should assume that any documents linked here (other than those requested e.g. detailed project description and flow chart) will not be treated as part of the application form.

Format

Your detailed project description should:

- not exceed 20 A4 pages
- have a font size no smaller than *10cpi Times New Roman*
- have a header containing your allocated project reference number
- have a footer showing your page numbers
- be converted to a **.PDF** version before uploading it

Broadly, the detailed project description should follow the format set out in the application form, as follows:

Full title of project:

This section should clearly state what the proposed research is and any abbreviations should be defined.

Response to board feedback points:

Please describe here the steps you have taken to respond to the board's feedback. Please address each point provided.

Summary of Research:

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).

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.

Evidence explaining why this research is needed now:

Indicate the necessity for the research, both in terms of time and relevance.

Aims and objectives:

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

Research Plan:

Outline the design of your research including the methods you plan to use; the target organisations, staff groups/professions, patient care group or disease area to be studied and brief details of the team involved in undertaking the research. Please ensure your fieldwork and methods are clearly connected to the aims and objectives and research questions you outlined earlier.

The programme is interested in taking advantage of the growing utility of routine data (such as HES, GP records etc.), and would like investigators, where appropriate, to ask study participants to consent to long term follow-up (e.g. beyond the outcomes to be collected in the funded trial) using routinely collected data, and appropriate linkage to allow this data to be best used.

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.

Design and theoretical/conceptual framework:

Please provide a brief statement on the type of study design to be used, and the theoretical framing, concepts and models to be used.

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.

Setting/context:

Please describe the health service setting or context, in which the study will take place (such as the organisation or service type).

Search strategy (in the case of projects involving evidence synthesis):

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, etc.).

Sampling:

Please describe for all projects your approach and rationale for sampling or selecting research sites and subjects. For quantitative studies, if appropriate, state the required sample size, giving details of the estimated effect, size, power and/or precision employed in the calculation where applicable. You should also provide estimations of recruitment and retention rates

Data collection:

Please describe the data you plan to collect. Depending upon your study design and methodology, you may need to explain what data collection instruments or measures you plan to use and whether you will be using instruments already developed and tested elsewhere or instruments which you develop as part of this project. For example, where cost or outcome data is to be collected, you need to make clear and justify your approach to defining and measuring the costs or outcomes in question. You should make clear the link between the data collected and the research questions outlined earlier.

Data analysis:

Please describe how you plan to analyse the data you have collected. Depending upon your study design and methodology, you may need to explain what quantitative statistical methods you plan to employ, your methods for qualitative data analysis, and your approach to combining data from multiple methods or sources.

Dissemination and projected outputs:

Please describe the main knowledge products or outputs from your research and how they will be presented, disseminated and used. State how you plan to promote knowledge mobilisation so that the findings from the research impact on the management of health services and to improving practice and service delivery in the NHS.

Plan of investigation and timetable:

Please provide a concise summary here of the project plan of investigation, preferably in the form of a monthly project timetable showing the scheduling of all key stages in the project, their expected durations, and the timing of key milestones throughout the project including the production of outputs.

Please ensure your timings (e.g. time allowed for securing ethics/governance approval, for undertaking data collection and analysis, and for reporting and writing up) are realistic.

This timetable will be an important aspect of the monitoring framework during the life of the project.

If your application is successful, you will be required to submit progress reports, usually every six months. Where appropriate, these progress reports will be based on the project timetable and milestones. If you are late producing progress reports or a single draft final report of the expected standard for the programme, we may withhold payments, in accordance with our retention policy.

Applicants should note that the HTA Programme monitors the degree to which requested timetables are met and that having a proven track record in delivering on time may be a consideration when deciding future awards.

Project management

All project proposals should include details of how the project will be managed. For projects involving a number of institutions or component parts, **effective project management is essential** to ensure the work is completed within the planned timeframe. You should set out how joint applicants in different institutions will communicate and monitor progress of the project.

Approval by ethics committees

Outline the ethical issues and arrangements for handling them. Consider when the project requires approval by an ethics committee. If there is development work that is **essential** before you intend to apply for ethics approval, state this and make the timescales clear in your plan of investigation and project timetable. The funding board will consider this in detail and consider whether to offer staged funding. If you are using patient information from an existing database, you should check whether the patients have given their consent for their data to be included in that database for research purposes, or if not whether the database is exempt under Section 60 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 programme.

Researchers may find the [SPIRIT 2013 statement](#) a useful resource when preparing their protocol for ethics and other approvals. In particular, we would recommend maintaining an amendment history within the body of the protocol.

Patient and Public Involvement

NIHR expects involvement of patients, carers or the wider public in the research it supports. You are encouraged to consider whether the scientific quality, feasibility or practicality of a proposal can be improved with Patient and Public Involvement.

Research teams wishing to involve service users should outline their plans stating:

- the aims of active involvement in this project
- a description of the patients, carers or members of the public to be involved
- a description of the methods of involvement

Applications not involving PPI must **clearly justify** this. 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 from www.invo.org.uk

Expertise and justification of support required

Outline the particular contribution each member of the team will make to the project and the particular contribution that collaborators are intended to make. In addition, please give details of supervision arrangements for junior staff involved.

You should outline staff numbers and grades, timescales, equipment purchases, etc. that you are requesting funding for. If you propose to purchase expensive medical or other equipment, justify fully why you are not proposing to lease it since this is the DH preferred option.

If applicable you must also provide an explanation and justification of the NHS Support Costs and Excess Treatment Costs associated with this proposal including, if applicable, an explanation of the basis on which these NHS costs have been estimated.

25.2 Flow chart

Please attach 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: www.consort-statement.org. Alternatively, you may find the EQUATOR Network website useful (www.equator-network.org) or the recently published ACCEPT paper (Charlesworth et al. BMC Medical Research Methodology 2013, 13:78 www.biomedcentral.com/1471-2288/13/78). The file should be uploaded to the 'flow chart' 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.

25.3 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.

25.4 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 no longer require a letter of support from your unit at first stage. 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.

26. Acknowledgement

26.1 Agreement to the Terms and Conditions

Please tick the checkbox to indicate that you have read and understood the terms of 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 full proposal application.

A list of terms and conditions can be found here: www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/nihr-evaluation-trials-and-studies-coordinating-centre/management-information-system/terms-and-conditions.htm

No original (wet or ink) signatures are required for this application. Signatories are required to sign electronically after the lead applicant has submitted the application.

27. 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 will not enter into negotiations for extensions and the deadline will be strictly observed. You should, therefore, plan your application carefully. Full proposals can only be submitted electronically.

The HTA programme no longer requires paper copies of submissions.

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.

✓	Complete	The section/form has been filled out correctly
X	Incomplete	Mandatory information has not been provided and the task cannot be submitted until this has been completed
⚠	Attention	This section has not been completed but is not mandatory for submission

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 (or as a yellow advisory exclamation mark) 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. If you do not receive an email please contact us immediately as there may be an issue with your submission.

Following successful submission of the application, the Lead Applicant will receive some further tasks from the system to notify the Signatories that they are now required to review the completed PDF and confirm their acceptance of the costs. It is the Lead Applicant's responsibility to ensure these 'e-signatures' have been completed within two weeks of submission, after which time the form will close.

Failure to provide the e-signatures may result in the form being withdrawn as an incomplete submission.

The Lead Applicant can monitor these acceptances via the 'Research Team' tab. Once completed please email a screen shot showing the completed screen to the relevant funding team, for details see ['contact us'](#) below.

27.1 Submission checklist

1. Electronic form completed with no sections showing red crosses.
2. Co-applicants have all completed both parts of the two stage process:
 - I. Accept task
 - II. Agree to collaborate and complete relevant sections of their CV. Co-applicants may find it easier to complete this section in their personal profile thus allowing the information to be pulled through to this and subsequent applications.

Further guidance for how co-applicants complete their sections can be found here:
www.nihr.ac.uk/about-us/documents/NETSCC/MIS/MIS-brief-for-Co-Applicants.pdf

3. Uploads are all attached in one of the accepted formats (.doc, .docx, .mpp, .pdf, .xls, .xlsx)
 - Detailed project description (upload to 'Detailed Project Description' section)
 - Flow diagram (upload to 'Flowchart' section).
 - References can be attached as a separate document in the 'References' upload section
 - Letter of support from Clinical Trials Unit (if required) uploaded under 'Supporting Letter'
 - Any other documents requested by the board from the first stage (where applicable) uploaded separately under Supporting Letter.
 - A cover letter, if desired (upload to cover letter).

Evidence Synthesis projects are not required to upload flow charts.

Additional, not requested uploads will not be considered by the board.

Once all sections are complete, the Submit button will become active near the top of the screen. The NETSCC MIS will send you an email acknowledging receipt of your application.

Post-submission checklist

1. Lead applicant notifies all Signatories to review the completed form within two weeks.
2. Lead applicant monitors for Signatories acceptances noting that the form will close down two weeks after the submission date.

27.2 Unsubmitted 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.

If you are completing a researcher-led (CET) full application (i.e. **not** in response to an advertised Commissioning Brief) and will be unable to complete the application form before the submission deadline date, please inform us.

If you do not contact us within 7 days of receiving the automatic email reminder, your application will be closed but not submitted and you will no longer be able to edit or submit it after the call close date.

Although you will still be able to view the application in a PDF format under the 'View all my tasks' tab in your homepage, 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.

28. 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@nihr.ac.uk / 023 8059 5621 (24 h answerphone)

Clinical Evaluation and Trials / Researcher-led

htacet@nihr.ac.uk / 023 8059 6974 (24 h answerphone)

29. Useful links

You may find the following presentations and links 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 ([click here](#))
- 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 ([click here](#))
- 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 – [click here](#)
- www.nihr.ac.uk/05-development/useful-links.htm