Health Services and Delivery Research Programme

NHS National Institute for Health Research

GUIDANCE NOTES FOR APPLICANTS:

OUTLINE APPLICATIONS

(MIS on-line NIHR Standard Application Form (SAF))

Version September 2015

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Introduction

The Health Services and Delivery Research (HS&DR) programme is part of the National Institute for Health Research (NIHR).

The National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR) programme aims to produce rigorous and relevant evidence on the quality, access and organisation of health services, including costs and outcomes. The programme will enhance the strategic focus on research that matters to the NHS including research on implementation and a range of knowledge mobilisation initiatives. It is keen to support ambitious evaluative research to improve health services.

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

Anyone who considers that they can carry out high-quality 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. NETS programmes (with the exception of the EME programme researcher-led workstream) welcome applications which are within the programmes' remit from all sectors. Applicants are strongly advised to consider establishing partnerships with other relevant sectors or organisations to demonstrate they have the full breadth of expertise to carry out their proposed research in their applications to NETS programmes. Applicants should always check individual call specification documents for any additional eligibility requirements.

The programme operates two funding streams; researcher-led and commissioned. Researchers in England, Wales and Northern Ireland are eligible to apply for funding from either workstream under this programme. Researchers in Scotland may apply to the researcher-led workstream but are not eligible to respond to the commissioned workstream and should contact the CSO (tom.barlow@scotland.gsi.gov.uk) to discuss funding opportunities for healthcare delivery-type research.

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.

Further information regarding the assessment process, criteria and application requirements are available on the HS&DR website, www.nets.nihr.ac.uk/hsdr

Data Protection

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

The Department of Health, National Institute for Health Research (DH NIHR) is the Data Controller under the Data Protection Act 1998 ('the Act'). Under the Data Protection Act, we have a legal duty to protect any information we collect from you. You should be aware that information given to us might be shared with other DH NIHR bodies for the purposes of statistical analysis and other DH NIHR research management purposes. NETSCC also reserves the right to share, in confidence, details of your application with other approved research funding organisations outside NIHR in order to coordinate research activity in the UK.

Information collected from you will not be passed to any third party outside the NIHR except specifically as detailed above without your consent except where we are under a statutory obligation or entitled to do so by law. Applicants may be assured that DH NIHR is committed to protecting privacy and to processing all personal information in a manner that meets the requirements of the Act.

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 HS&DR 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 HS&DR website (www.nets.nihr.ac.uk/hsdr). 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 HS&DR 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: hsdrinfo@soton.ac.uk.

About these guidance notes

This document contains information and guidance to applicants submitting an **OUTLINE** application. 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. Please note that the application form cannot be submitted until you have completed all the mandatory fields. You are strongly advised to leave sufficient time to submit your application prior to the deadline.

Please also ensure that you have read these guidance notes fully and referred to the HS&DR programme website and FAQs before contacting us with any queries. We have endeavoured to cover all necessary information relating to the application form through these resources. Incorrectly completed applications may be rejected.

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 eligible systematic reviews. Link to PROSPERO website: http://www.crd.york.ac.uk/prospero/.

UK Biobank

UK Biobank is a major national health resource, and a registered charity in its own right, with the aim of improving the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses – including cancer, heart diseases, stroke, diabetes, arthritis, osteoporosis, eye disorders, depression and forms of dementia. UK Biobank recruited 500,000 people aged between 40-69 years in 2006-2010 from across the country to take part in this project. They have undergone measures, provided blood, urine and saliva

samples for future analysis as well as detailed information about themselves. The health of members of this large cohort will be followed over the coming years and the participants have consented to be approached about health research. http://www.ukbiobank.ac.uk/

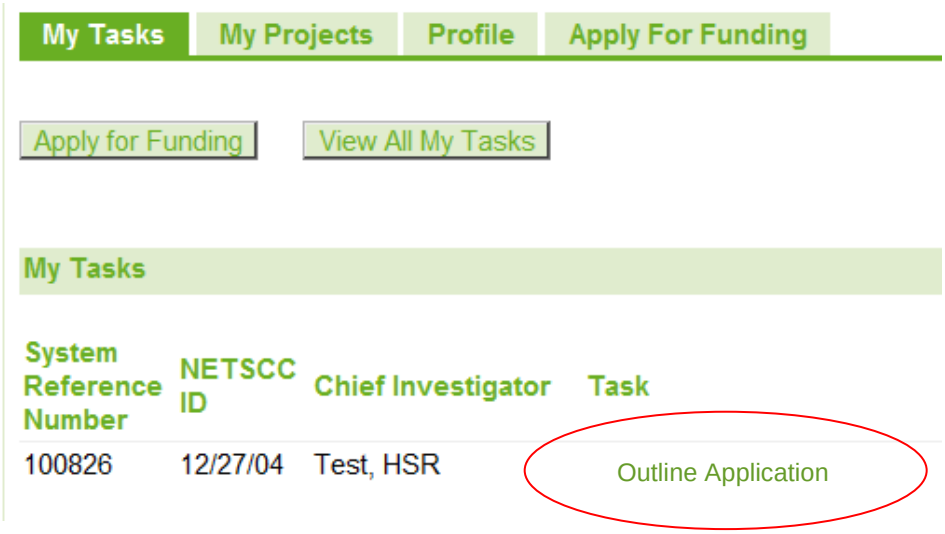
Applicants are encouraged to consider whether Biobank may be able to provide suitable data for their study. We do not want to discourage establishment of new collections of participants and their data where this is necessary to address the research questions under consideration, our aim is to avoid applications for funding to set up Biobank-like cohorts where the use of Biobank would prevent wasteful duplication of Biobank-like activities.

Guidance for using this electronic application form

To Access the Application form

Use the 'Apply Now' button on the funding opportunity page on the NETSCC website to access the online application form. This also provides call specific supplementary information. This will direct you to the NETSCC MIS login page. If you already have a username (email address) and password, enter these details or, if you have not yet registered, complete the short registration process. You will then be directed to the confirmation page for the specific call. If this is the correct call, click on the Apply button and this will start the application process. Clicking Cancel will return you to your 'home page'. Applying for a funding opportunity creates a task called 'Outline Application'. This task will be available for you to complete until the closing date as indicated on the research call and on your tasklist. The 'Outline Application' task can be accessed at any time until you either submit the application (using the Submit button in the application process which will appear once all the validation is complete) or the call closes.

See the screenshot example below:



Clicking on the Outline Application link takes you to the Submit Application main page where you can complete your application information.

This task will be available for you to complete until the closing date as indicated on the research call and on your task.

Seven days prior to the closing date you will receive an email reminder that you have an open application (i.e. not submitted). Additional guidance will be available on most screens as you progress through your application.

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

To submit an application

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

- Complete all mandatory fields. 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.
- Submit a flow diagram (single-side of A4), as a separate .pdf file, for submission with your application form. This should illustrate the study design and the flow of participants. Applicants should also describe complex interventions and controls as accurately and fully as possible within their diagram. If proposing an RCT, we advise you refer to the CONSORT statement and website for guidance (www.consort-statement.org).

Alternatively, you may find the EQUATOR Network website useful (www.equator-network.org). The .pdf file must be submitted along with your application form.

Saving your form

As you work through the application, you are asked to save each page. This will save all the information you have submitted 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. 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 it times you out. If this message is displayed, you should close the pop-up.

There is a left hand navigation menu in the application so you can select specific parts of the form to complete, however you should always ensure that you save any information entered on your page before using this left hand menu.

Giving others access to the form

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

Leaving the application task

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

Technical Support

If you encounter any problems with the NETSCC MIS system, you should call the programme funding support team either via email or by phone. The contact numbers can be found on the NETSCC website on this link: www.nets.nihr.ac.uk/mis/contacts

Electronic Application form - Learning Guide

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

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. Please note that the system does not provide a spell checker. Carriage returns and spaces are counted as characters. The character count will be slightly less than that of a Microsoft 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.

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 words (i.e. less than or greater than, or less than or equal to or greater than or equal to). You will not be able to submit the form if you have either of these symbols or any other non-alphabetical or non-numerical characters in your text. For these reasons it is advisable that you 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.

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. This type of shortening service is associated with hacking and spamming (as it promotes the sending of links that are unclear where they are pointing).

Final PDF version of the application form

Applicants should be aware that the final pdf version of the application form will be ordered differently to the completed on-line application, to assist the reviewing committees when making shortlisting/funding recommendations.

Technical support documents including how to spell check, resize text boxes and use Mac/iPads can be found on the NETSCC website at http://www.nets.nihr.ac.uk/mis/mis-technical-support **and are also listed below:**

Supporting web pages when using the NETSCC MIS

How to use spell checking in the NETSCC MIS (pdf, 203.92 KB)

How to reduce the size of files before uploading them (pdf, 514.48 KB)

How to resize text boxes in the NETSCC MIS (pdf, 246.33 KB)

General technical advice for using the NETSCC MIS (pdf, 1020.86 KB)

Reviewing Board Papers using an iPad (pdf, 270.02 KB)

Accessing the NETSCC MIS using an iPad (pdf, 398.84 KB)

Accessing the NETSCC MIS using a Mac (pdf, 513.45 KB)

Role specific documents

These documents outline the requirements of different roles.
External Reviewers (pdf, 801.94 KB)

Board Members (pdf, 628.52 KB)

Co-applicants and Supporting Roles (pdf, 771.48 KB)

Chief Investigators (pdf, 530.56 KB)

Consultant/Scientific Advisors (pdf, 666.25 KB)

Editors (pdf, 1038.02 KB)

Guidance for completing your electronic application form

Research Details

Host Organisation: Please give details of the organisation who will be the contractor if the project is funded.

Research Title *(Limit: 300 characters)*
The project title should clearly and concisely state the proposed research. Any abbreviations should be spelled out.

Research 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 'Secondary Research'. If you are not sure which category to select, please choose the closest match to your project as this can be adjusted later.

Proposed Start Date
Please note this should be from 1st of the month regardless of whether this is a working day or not. Please note that successful projects are expected to start within eight months of notification of intention to fund.

Research Duration (months)
Please ensure you include sufficient time to complete all aspects of the research including the final report.

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

Total Research Costs Requested
Please enter the total amount of research costs requested (not including NHS Support & Treatment costs).

Total NHS Support & Treatment costs
Please enter the total amount of NHS support and treatment costs associated with this proposal.

For guidance on financial costs of your application, please see the financial guidance section.

I have read the NIHR Carbon Reduction Guidelines
Please click on the check box to indicate that you have read the NIHR Carbon reduction guidelines (available via a link in the 'Instructions' section at the top of the page).

Contact Information

Please complete your contact details

Lead Applicant Details

Specify role in research: Please explain in addition to your role as Lead Applicant, the role that you will be undertaking in the research, e.g. co-ordination and project management, analysis, methodological input etc. *(Limit: 200 characters)*

%FTE Commitment: This refers to the percentage of your time that you will commit to this project.

Do you currently hold an NIHR award: Yes/No Selection

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

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

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

Administrative Contact Details: Where possible an alternative contact address for the lead applicant should be given. Please note that all correspondence will be sent to the lead applicant and the information in this section will only be used if the lead applicant is unavailable. *(Limit: 600 characters)*

Curriculum Vitae (CV) Section

Patient/Service User or Carer Applicants:

Are you a patient / service user or carer? This section is only relevant if the Lead Applicant is a Service User or Carer. *(Limit: 1000 characters)*

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

Research CV

Recent Relevant Publications
Volume Reference
Please provide details of a MAXIMUM of 6 of your most recent publications relevant to this application (using Vancouver or Harvard citation format)… listed one after another with a blank line between each one.

Please use DOI reference numbers if needed.

Research Grants Held
This should include research grants held (as a named applicant) CURRENTLY or IN THE LAST 3 YEARS – please include who the grant is with and the amount of each grant. If no grants are held please enter N/A (as this is a mandatory field).

Co-Applicants

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. 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.

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.

The INVOLVE website(http://www.invo.org.uk/) provides a detailed definition of 'patient and public involvement in research' as well as further information on involvement in research, listing resources and advice available. In this section it is important that you describe in as much detail as possible how patients and the public have been involved in the development of the 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.

Budgeting for public involvement in your research study
A guide (produced by INVOLVE and the Mental Health Research Network) for practical advice on budgeting for actively involving the public in research studies can be viewed at http://www.nihr.ac.uk/news/Lists/News/DispForm.aspx?ID=1626

'Putting it into Practice' database http://www.invo.org.uk/resource-centre/putting-it-into-practice-database and INVOLVE's Exploring Impact report http://www.invo.org.uk/posttypepublication/exploring-impact-public-involvement-in-nhs-public-health-and-social-care-research Further information and resources can be found at the INVOLVE website http://www.invo.org.uk

The NIHR Research Design Service http://www.ccf.nihr.ac.uk/Pages/RDSMap.aspx can provide advice on, and support in, developing your application including the involvement of patients and the public in your research.

Were patients and the public actively involved in identifying the research topic or prioritising the research questions?

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

Please indicate the ways in which patients and the public will be actively involved in the proposed research.
For each box that you ticked, 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? *(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. *(Limit: 1200 characters)*

History of Application

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.

Applications Submitted to NETS Programmes
Any previous application submissions to NETS programmes will be listed on this page (if submitted via the NETSCC MIS i.e. since Apr 2012), please select 'Yes' or 'No' for each application submission to indicate whether it is relevant to this application. Where 'Yes' is selected click the 'Edit' button and complete the information to indicate how your current research application differs from this previous application. If unsuccessful, please indicate why.
A maximum of seven applications will be displayed on this page. In order to view more than this, please double click on the 'NETSCC ID' to sort into ascending (Asc) order, and repeat to see the descending (Desc) order - this should display all submitted applications.

NETSCC resubmission policy
A previously unsuccessful application cannot be resubmitted to the HS&DR programme or any other NETS programme within one year of the original decision, unless applicants can demonstrate it has been changed significantly and therefore essentially a new proposal.

Other Funders / Applications in Progress
Where this application or a similar one has been submitted to a NETS programme or elsewhere (and is not listed) please click the 'Add' button and complete the necessary information (as above).

Please note the HS&DR programme will not accept research proposals that are currently being considered by other funding organisations (unless under shared funding arrangements).

Please answer all questions as fully as possible. We are keen to know if the application has been submitted elsewhere and you must be as open about this as possible. This includes, but is not limited to, any facts that, should they come to light at a future date, would embarrass either the programme or the individual who withheld the fact (e.g. if a member of the team holds a patent or has a financial interest within the research area).

Failure to disclose accurately or fully will be considered by the programme as academic misconduct and as such treated seriously. You should also include in this section information on whether this or a similar application has been submitted to any programme previously, or to any other funder including other NIHR programmes. You should name, and provide dates

and outcomes of these. Please indicate whether you hold or have ever held an NIHR programme contract which has been terminated prior to completion, extended in time or in terms of funding. Indicate which of the NETSCC funding streams you are applying to.

Case for Support

Scientific Abstract *(Limit: 3500 characters)*
Please provide a summary of your proposed research, including the research questions, main aims, outcomes and analysis proposed. You should also provide a summary of the main benefits and potential impact you expect the research to deliver to the NHS.

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 it is felt that your plain English summary is not clear and 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.

Content
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 (where applicable). www.nihr.ac.uk/research/Pages/ResearchDesignService.aspx

Research Plan

Please note: Where there is a 'Yes' in the required text column you should provide a response where relevant to your proposal. If not relevant, please enter 'N/A'. You can enter each response by selecting 'Add'.

- **Design - Provide research plan for Design** *(Limit: 4000 characters)* Please provide a clear summary of the type of study design to be used (e.g. PR: controlled trial; ES: systematic review).

- **Care Pathways in comparative or randomised trials** *(Limit: 2000 characters)* – Where applicable please explain the care pathways in each of the trial arms, including the control arm. Where your proposal is for a non-RCT study (and where appropriate) please explain the different care pathways that are included in the study.

- **Difference between current and planned care pathways** *(Limit: 1500 characters)* - What is the current standard care pathway and how does this differ from the trial arms. For non-RCT studies please explain the current standard care pathway and how this differs from any others included in the study.

Background & Rationale

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

This section must include the following information:

- Please explain how your proposed research is within the remit of the HS&DR programme. You should include a clear explanation of the main (single) research question, and how it addresses the key aim of the programme to produce rigorous and relevant evidence on the quality, access and organisation of health services.
- Please provide a clear explanation of the health problem to be addressed, the impact on patients and healthcare, and how this research would fill a demonstrable evidence gap.

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

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 HS&DR mission: The focus of the expressed research need is consistent with the wider mission of the HS&DR 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 HS&DR programme. This information is to be used to describe rather than justify the need. This process will have been assessed at outline stage if this full proposal is part of a two-stage application process.

Please provide evidence explaining why this research is needed now (how does the existing literature support this proposal?) (Limit: 2000 characters)
Please explain why this research is needed now, both in terms of time and relevance. We will only fund primary research where the proposed research is informed by a review of the existing evidence. In addition to search EuropePMC, 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.

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 funding NIHR Programme to inform the commissioning brief. Applications in response to commissioned calls will need to address the commissioning brief requirements specific to the NIHR Programme.

For researcher-led or researcher-initiated proposals that are not in response to a specific commissioning brief as part of a commissioned call, if these include primary research then they should include reference to the existing evidence and explain how this evidence has informed the proposed research. Where a systematic review already exists that summarises the available evidence this should be referenced, as well as including reference to any relevant literature published subsequent to that systematic review. Where no such systematic review exists it is expected that the applicants will undertake an appropriate review of the currently available and relevant evidence (using as appropriate 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. All applicants must also include reference to relevant on-going studies, e.g. from trial registries.

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.

Changes from First Stage

How has this changed from the first stage application *(Limit: 3500 characters)*
This question will not be relevant for most outline applications. If this is the first time you have submitted this proposal to the HS&DR programme, please enter **N/A**.

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

Dissemination & Output

Please describe your plans for disseminating the findings of this research
(Limit: 2500 characters)
Please describe the main knowledge products or outputs from your research and how they will be presented, disseminated and used. 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.

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.

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 HS&DR programme will publish a full and complete account of that research in the NIHR HS&DR 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.

Relevant Expertise

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

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

Declarable interests *(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 & 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.

Justification of Costs

Please explain how the research provides value for money *(limit 2500 characters)*

Please explain how the research costs requested have been calculated and justify how they have been allocated (limit 2500 characters)

Please explain how the NHS Support and Treatment costs requested have been calculated and justify how they have been allocated *(limit 2500 characters).*

Guidance on costing for Outline Application Form

In this outline application you should fully justify what the major costs are and how they have been allocated, in the text boxes provided. If you are unsure of how to attribute the costs between research and NHS support and treatment costs, please refer to the following guidance on 'Attributing the costs of health & social care Research & Development (AcoRD)' http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_133882

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

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

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

GENERAL INFORMATION

- These costs will be used to assess value for money.
- It is in the best interest to undertake a thorough, realistic and accurate costing. The Committee/Panel will pay close attention to any material increase in costs between outline and full application stages. You must provide a clear and full justification for all costs including NHS costs. You must also ensure that you include all costs including those required to secure good research management.
- Costs must be provided at current prices. An adjustment for inflation will be made annually thereafter at rates set by the Department of Health. Whilst allowances for incremental increases should be included on the form, nationally or locally agreed pay increases should be excluded.
- Years should be calculated starting from the anticipated start date of the proposed research. For example, if your research is expected to start on 01 June 2020 then its second year starts 01 June 2021.
- Further itemisation of costs and methods of calculation may be requested to support the application at a later date.
- NHS Support Costs are funded via Clinical Research Networks. Researchers should contact their local NHS R&D Department initially and, if they are unable to help directly or if there is no local NHS R&D Department, contact the local Comprehensive Local Research Network (CLRN) Senior Manager. Further details about CLRN contacts is available at www.crncc.nihr.ac.uk/about.us/ccrn.

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, <u>up to 80%</u> 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 include direct costs and commercial indirect costs (if appropriate). 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 include 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.

DIRECT COSTS

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

I) Posts and Salaries Summary.

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

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

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

Journey Costs
The total cost of transport for all journeys for destination/purpose. If travel is by car, apply your institution's mileage rates (however this should not exceed HMRC approved mileage allowance payments, which is 45p per mile for the first 10,000 miles and 25p thereafter).

Travel by the most economic means possible is encouraged. NIHR programmes do not usually fund first class travel.

Subsistence

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

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

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

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

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

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

V) Patient and Public Involvement. Please include costs associated with Patient and Public Involvement. These are likely to include out of pocket expenses, payment for time and any relevant training and support costs. **Guidance for making payments to members of the public actively involved in NHS, public health and social care research (2010) can be found at the following address:**
http://www.invo.org.uk/posttypepublication/payment-for-involvement/
http://www.invo.org.uk/posttypepublication/national-institute-for-health-research-payment-rates-for-public-involvement/

Budgeting for public involvement in your research study
A guide (produced by INVOLVE and the Mental Health Research Network) for practical advice on budgeting for actively involving the public in research studies can be viewed at http://www.nihr.ac.uk/news/Lists/News/DispForm.aspx?ID=1626

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

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

Dissemination of your research
Planning for article processing charges in Open Access journals
During the course of your project and throughout review and publishing phase you may choose to submit an article based on your research to an Open Access publication. Depending on the publication you may be subject to an article processing charge (APC). APC rates vary but are usually within the range of £300 and £3000. Open Access publications usually list their APC rates on their websites.

Where possible you should include an estimate for any APC in your funding application. This should be entered in to other direct costs on the application form.

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

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

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

INDIRECT COSTS/OVERHEADS

HEI Indirect Costs

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

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

The applicant(s) should consult their HEI Finance Departments for the appropriate 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 will be charged in proportion to the amount of research staff effort requested on the award. Commercial/Other Partner Organisations should calculate them, using their own cost rates.

They comprise:

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

NHS SUPPORT AND TREATMENT COSTS (incl. Excess Treatment Costs/Savings)

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.

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.

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 bodies or providers of NHS services involved in order to avoid any delay in commencing the research and the estimated values for these in are input. It should be noted that applicants are expected to have contacted the appropriate NHS organisation(s) regarding the NHS support and treatment costs that will be required if their research is funded. If the costs are felt to be material, a letter of support may be asked for from the NHS organisation(s) concerned.

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

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

II) NHS Treatment Costs
These are the patient care costs that would continue to be incurred if the patient care service in question continued to be provided after the R&D activity has stopped. In determining NHS Treatment costs you **must** assume that the patient care service being assessed will continue even though there may be no plans for it to do so. Where patient care is being provided which differs from the normal, standard, treatment for that condition (either an experimental treatment or a service in a different location from where it would normally be given), the difference between the total Treatment Costs and the costs of the “usual standard care" (if any) constitutes Excess Treatment Cost/Saving, but is nonetheless part of the Treatment Cost, not an NHS Support or Research Cost. These costs should be determined in conjunction with your NHS body or provider of NHS services and their commissioners.

For further information, please see:

Attributing the costs of health and social care research and development (AcoRD)
https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

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 £1billion per annum as confirmed in the most recent spending review (http://www.nihr.ac.uk/about/Pages/About_Spending_Review.aspx). This level of investment is unlikely to be sustainable unless tangible benefits for patients are realised.

The NIHR takes a broad definition of IP which might include: 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 or equipment and devices; as well as patentable inventions such as a new therapeutic product, diagnostic test or medical device. Such new developments of IP are known as 'foreground IP'. In addition, the proposed research is likely to build on IP generated previously by others or yourselves as applicants. This is known as 'background IP'. IP may be protected via a number of methods including Copyright, trademarks or Patents. Taking this into account we can assume that much of the research funded by NIHR is likely to generate or modify (IP).

This section of the application form asks you to consider the background IP on which this application is based, and the nature of any foreground IP likely to be generated. **At the outline stage of your application we understand that you are in the early stages of developing your research project. We therefore ask that you answer the questions to the best of your ability. You will have the opportunity to provide a more developed response to these questions at full proposal stage.**

What relevant IP (patents, design right, copyright etc.) is held by the applicants and how does it relate to this application? *(Limit: 3000 characters)*
In this section you, need to tell us about what IP you, your co-applicants, collaborators and sub-contractors hold in relation to this application. If relevant IP is held by another individual, institution or company you need to tell us about it in your response to the question here. Where appropriate, please provide detailed information relating to third party licence requirements etc.

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

You or your institution may hold the relevant background IP. The term 'background IP' refers to the IP available at the start of your research project - which is being used in delivery of this project. Background IP may have been developed through earlier research projects which you may or may not have been involved; and may or may not have benefitted from NIHR funding. If the research you propose will use background IP you will need to ensure you have reached agreement to use the background IP. This may require licences, collaboration agreements and/or sub-contracts. If so, you will need to tell us about these arrangements in your application and provide a copy of these agreements if you are successful in obtaining funding for your proposed research.

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

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)*
You need to tell us if you have or have not conducted an IP search in relation to this application. If you have, or you plan to, then please indicate briefly the procedure you used to search for existing IP and what you have found from your searches, even if you have found nothing.

If no search has been conducted, please set out the rationale. *(Limit: 1500 characters)*

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 projects 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.

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 (adoption for patient benefit and/or commercial exploitation) of IP or research outputs. 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 as this may best be achieved through the application of commercial exploitation models.

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.

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.

Wider Context

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

Clinical Trials Units (CTU) Participation

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.

Is a Clinical Trials Unit involved with this research proposal? *(Limit: 1500 characters)*
If you are proposing to involve a clinical trials unit, a letter of confirmation of CTU involvement from the CTU Director is required if your outline application is shortlisted to go forward as a full application.

If applicable, please describe how you have worked with a Clinical Trials Unit in developing your application and what support they will provide if funding is approved. *(Limit: 1500 characters)*

If a Clinical Trials Unit is not be used, please explain why and who/what will be involved instead, if applicable to this application. *(Limit 1500 characters)*

If you are looking for a CTU to collaborate with in your application, then the following sources can provide more help:

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

The UKCRC CTU Network (http://www.ukcrc-ctu.org.uk) provides a searchable information resource on all registered units in the UK, and lists key interest areas and contact information.

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

Other Sources of Funding

Will this application be supported by any other funding body? *(Limit: 2000 characters)*
If you are proposing a study which requires joint or shared funding, it is in your interest to provide a clear explanation of the arrangements for this. This should include details as to full access to all data relating to the proposed study, and consideration of any conflicts of interest which may arise from the funding arrangements. Please also explain if any organisation is providing benefits in kind or free/discounted products.

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.

UKCRC Health Categories
Research Activity Codes classify types of research activity. This dimension of the HRCS has 48 codes divided into eight overarching code groups which encompass all aspects of health

related research activity ranging from basic to applied research. The Research Activity Codes are modelled on the structure of the Common Scientific Outline, a cancer research specific classification system developed by the International Cancer Research Partners. http://www.hrcsonline.net/rac

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 (http://www.ccf.nihr.ac.uk/pages/rdsmap.aspx).

Suggested Referees

Applicants must complete this section with suggestions of at least two potential referees and you are welcome to add more. In order to submit the form you must have at least two potential referees.

If your outline application is shortlisted and you submit a full proposal, this will be subject to external review by relevant experts, including academic, NHS and public reviewers. You should provide details of two to three relevant experts who would be able to provide an independent assessment of your application. Please note that the referees may 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 experts overseas.

Nominated referees who are acceptable to the HS&DR programme may be approached shortly after the submission of a full proposal, if shortlisted. If they are willing to assist, they will be supplied with a copy of your application, an assessment form and guidance notes, and will be given a 2-3 week period to complete their review.

Uploads

ATTACHMENT1: FLOW DIAGRAM
Finally, please create a flow diagram (single-side of A4), as a separate PDF file, for submission with your application form. This should illustrate the study design and the flow of participants. Applicants should also describe complex interventions and controls as accurately and fully as possible within their diagram. If proposing an RCT, we advise you refer to the CONSORT statement and website for guidance, (http://www.consort-statement.org). Alternatively, you may find the EQUATOR Network website useful (www.equator-network.org). The PDF file should be submitted along with your application form.

ATTACHMENT2: REFERENCES
If you wish, you may supply one A4 page listing references used throughout your proposal.

Please do not attach any additional information as it will not be included in your application.

ACKNOWLEGEMENT

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 http://www.nihr.ac.uk/files/NIHR_Carbon_Reduction_Guidelines.pdf.

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

No original signatures are required for this application.

Review and Submit Application

You will not be able to submit your application until all required validations are complete. Please review the validation status of each item to determine the outstanding requirements and correct accordingly. Validated or completed requirements are marked with a green checkmark (✓). Items marked for attention in yellow with an exclamation mark - (!) - are not mandatory for submission. Once all requirements are validated (the checklist should not have any red **X** against any items), the Submit button will be displayed and you can submit the task.

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 and flow diagram, by the stated deadline. We cannot grant any time extensions and the deadline will be strictly observed. You should therefore plan your application carefully. We will not enter into negotiations for extensions. 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, also, warning signs may appear to indicate that you may have omitted some information (although not mandatory).

Un-submitted applications

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

If you do not contact us within seven days of receiving the automatic email reminder, your application will be closed but not submitted and will no longer be editable after the call close date.

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

The HS&DR Commissioning Team, NETSCC
NETSCC, Health Services and Delivery Research
Alpha House
University of Southampton Science Park
Southampton
SO16 7NS

Assistance

If, after carefully reading all the instructions, you still have difficulties completing your application, please visit the HS&DR programme website (www.nets.nihr.ac.uk/hsdr) which contains a list of Frequently Asked Questions and Answers. If your particular query or problem is not addressed, please send an email to hsdrinfo@southampton.ac.uk. Please be aware that while every effort is made to answer queries, if the query is made very near the closing date, the HS&DR programme may not be able to provide a considered response. When emailing us please include details of the call which you are responding to, and the name of the lead applicant.