

APPLICATION FORM GUIDANCE NOTES FOR APPLICANTS SUBMITTING STAGE 2 APPLICATIONS

(On-line NIHR Stage 2 Standard Application Form (SAF))

Version: January 2018

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This guidance should be used by applicants who have either:

1) been shortlisted at Stage 1 and asked to submit a Stage 2 application.

Or:

2) by those applying for a specific call where a single stage, straight to Stage 2 application has been requested as part of the call. Typically for an Evidence Synthesis or fast-track proposal.

*For shortlisted applicants, the fields indicated with an asterisk will be automatically populated in the Stage 2 form with content input to the Stage 1 form. This content is editable and should be updated in line with any changes made to the application following feedback from the board at Stage 1.

NIHR Research Standard Application Form (SAF)

Stage 2 Application Form & Guidance

1. Application Summary Information

Host Organisation

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

Please note that we expect the Chief Investigator's host organisation (substantive employer) to act as the contractor.

Please also bear in mind that:

- Thought must be given to the most appropriate institution to act as the contractor as part of the application process, as changes are unlikely to be agreed once a funding decision has been made.
- The contractor is expected to respond to annual financial reconciliation exercises, provide the final financial reconciliation statement for the project and to provide ad hoc requests for financial information during the lifetime of the project. In the unlikely event that a request is made for the contractor to differ from the CI's host institution, the suggested contractor must be able to fulfil these expectations and to do so in the usual timeframes.
- In the same way, the contractor is expected to respond to any queries relating to Intellectual Property, commercialisation and benefit realisation.

If you have any queries, please contact nets-finance@nihr.ac.uk before submitting your application.

Research Title

The project title should state clearly and concisely the proposed research. Any abbreviations should be spelled out in full. You may like to present this in a PICOST format (Population, Intervention, Comparator, Outcome/s, Setting and Timing).

Research Type

Select the appropriate research type. If your proposed project includes any element of primary research (collection of data), please select 'Primary Research'. If you are carrying out new analysis of existing data, select 'Secondary Research'. If you are not sure which category to select, choose the closest match to your project as this can be adjusted later.

Proposed Start Date

Note this should be from 1st of the month regardless of whether this is a working day or not. Please be realistic about your possible start date taking account of the necessary contracting, and staff recruitment prior to starting your project, on average this will take 3-4 months from receipt of final board funding recommendation.

Research Duration (months)

Ensure you include sufficient time to complete all aspects of the research including applications for regulatory approvals (where required) and the final report.

End Date

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

Total (Stage 2) Research Costs

Automatically populated from detailed budget section.

Total (Stage 2) NHS Support & Treatment costs or external (not NHS) intervention costs

Automatically populated from detailed budget section.

Administrative Contact Details

Do you wish us to contact you, the lead applicant, regarding this application? If no, provide administrative contact details (name, post held, department, organisation, contact details and access rights)

2. CV - Lead and Co-applicants

Complete your name, contact details and other requested information

Please note: **You are required to obtain a free unique ORCID ID number and update your [MIS user profile](#) with this before you can submit your application. By clicking the link 'View ORCID record' you will be taken to the ORCID website where you will need to register or sign in. Once logged in to ORCID and following acceptance of T&Cs, you will be returned to the MIS and the profile field for your ORCID number will automatically be populated. You will only have to do this once. For a Stage 2 application this is a mandatory requirement.**

PPI co-applicants

If your proposal includes PPI co-applicants, we are interested in their knowledge, skills and experience that are relevant to this application. They are not required to provide a full CV (i.e. N/A may be appropriate for Publication Record and Research Grants held).

We recognise and value the varied perspectives that members of the public, patients and carers bring to a project as applicants. In this section, PPI co-applicants should provide a summary of any relevant knowledge, skills and experience that they 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

3. Research Background - Lead and Co-applicants

Publication record

Provide details of a MAXIMUM of 6 of your most recent / relevant publications (in the last 10 years) 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 5 YEARS – as well as any additional previous grants, relevant to this application. Please include the name of the funder and the amount of each grant. If no grants are held please enter N/A (as this is a mandatory field).

History of Application - Has this application been previously submitted to this or any other funding body?

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. For more information about resubmission of a research/trainee funding application, or joint funding please contact the appropriate NIHR research funding programme.

Applications Submitted to other NIHR programmes

Where this application or a similar one has been submitted to this or another NIHR programme or elsewhere please click the 'Add' button and complete the necessary information.

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 treated accordingly. 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.

4. The Research Team

Specify your (lead applicant) role in this research

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.

%FTE

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

Co-Applicants

Add details of all co-applicants and their specific role in the project. The number of co-applicants is calculated automatically. Do not include collaborators, who should be mentioned (if necessary) in the Detailed Research Plan section/upload of the on-line application form.

Co-applicants are those individuals with responsibility for the day to day management and delivery of the project. Co-applicants are considered part of the project team and are expected to share responsibility for its successful delivery and outputs. Collaborators normally provide specific expertise on particular aspects of the project but do not share in the responsibility for the delivery of the project.

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

Your application must be submitted, including the co-applicant's section by the closing date and time for the call. Please note that any out of offices or undeliverable messages from the co-applicant's

mailbox will be received by an unmonitored email account at NETSCC.

5. Other supporting roles – signatories (electronic)

Other supporting roles This is a stage 2 application submission requirement but will not appear on Board/committee member version of the application form

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

1. Administrative Authority or Finance Officer

2. Head of Department or Senior Manager Sponsor

If you, the lead applicant, are also signing as Head of Department you should not complete this signatory task until you are ready to submit your application form. Once the lead applicant completes the Head of Department signatory task, various fields within the application form will become non-editable.

3. Sponsor

4. 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.

Where your application falls under Specialised Commissioning it is important you discuss your NHS Treatment costs with NHS England to ensure you are using the correct tariff information to accurately calculate the costs. If your application is recommended for funding further discussions with NHS England may be undertaken to assure that the costs have been calculated correctly. A representative of the NHS body or provider of NHS services - incurring any NHS Support and Treatment Costs - must sign off the application. 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.**

5. Representative of the R&D Function of the Devolved Country - For research projects originating in Scotland, Wales or Northern Ireland, we will require evidence of support with regards to NHS support and treatment costs (where applicable). 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 the R&D office in the lead NHS organisation in Wales. By signing the form, the signatory is agreeing that the excess treatment costs and support costs stated in this application appear reasonable.

Electronic signatures

Each person nominated to a supporting role will be required to tick a check box 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).

No original signatures are required for this application.

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: <https://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>

6. Scientific Abstract

Scientific Abstract *(limit 3,500 characters)*

The scientific abstract should be a clear and concise scientific summary of the Detailed Research Plan / Methods, with a word limit of 500 words (one side of A4 maximum).

The following is a list of potential elements / headings that might be included depending on the design of the proposed research, the setting and programme being applied to, and whether it is for primary research or secondary research. It will be for researchers to decide the appropriate elements to be included in the scientific abstract and could include elements outside this list. Applicants may find the guidance on the EQUATOR Network website (www.equator-network.org) useful.

- Research question
- Background
- Aims and objectives
- Methods
- Timelines for delivery
- Anticipated impact and dissemination

7. Plain English Summary

The importance of a plain English summary *(limit 3,500 characters)*

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 it 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

8. Changes from First stage

Changes from first stage (limit 3,500 characters)

Please list the feedback received at first stage and under separate headings indicate what has changed as a result.

Please describe and explain any additional changes that have been made to this proposal since the stage 1 application e.g. in the light of new research.

Please note, If you are submitting a one step, straight to Stage 2 proposal please ignore this question as it is not applicable to you. If this is the case please enter 'not applicable' in the box.

9. PPI

Please describe how patients and the public have been involved in developing this proposal (limit 3,500 characters)

You should describe who has been involved and why this is appropriate, what role(s) they have they played and what influence or change has happened as result of their involvement.

Please describe the ways in which patients and the public will be actively involved throughout the proposed research, including any training and support provided (limit 3,500 characters)

INVOLVE has developed guidance both on how patients and public can be involved <http://www.invo.org.uk/posttypepublication/involve-briefing-notes-for-researchers/> and the processes, procedures and values necessary to support this involvement www.invo.org.uk.

Patients and public can be involved in every stage of a research project, from developing a proposal through to dissemination and evaluation.

In your description you will need to say who will be involved and why.

Explain why your approach to public and patient involvement is appropriate for this proposal.

Describe how you will support and enable patient and public involvement in your research (e.g.: payments, training).

In rare cases where proposals do NOT involve patients and the public, clear justification must be provided. (limit 3,500 characters)

Complete / justify as necessary.

10. Detailed Budget

Justification of costs

- 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 and subsistence, dissemination costs, equipment (including lease versus purchase costs), consumables, patient and public involvement (PPI) and any other direct costs. For help with estimating PPI costs please see the INVOLVE cost calculator available at <http://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/involvement-cost-calculator/>.

- When justifying staff costs you should also provide the % amount of time input of each member of staff and link this to the specific area/work package of the proposed study where this input will be taking place.
- You should indicate here how this research will potentially benefit the NHS and/ or public health. For example, where appropriate, describe the likely cost savings or benefits in terms of numbers of patients treated, treatment times etc.
- You should describe the value for money of the conduct of the proposed research.
- 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.
- Please provide a breakdown of any non-NHS intervention costs and provide justification for the resources required. Non-NHS intervention costs should include costs incurred in delivering the intervention which would continue to be incurred after the trial, should the intervention become standard care. Please note that NIHR have no provision to cover non-NHS intervention costs, and it is the responsibility of the applicant to secure these costs if they are needed.

Detailed Budget Breakdown

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

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 outline/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 Clinical Research Network Senior Manager for advice on NHS Support Costs. Further details about LCRN contacts is available at <https://www.nihr.ac.uk/nihr-in-your-area/local-clinical-research-networks.htm>.

- All applications are expected to have appropriate NHS, HEI, commercial and other partner organisation input into the finance section of the application form.
- Please note that whilst the applicable 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.

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.

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.

Other Partner 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.
- 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.

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 and associated on-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. If there are any applicant(s) whose costs are not being claimed you should still include their details within this section, but don't include any actual costs. Where applicants are already in receipt of NIHR funding for any part of their salaries (e.g. NIHR Fellowships), these should not be additionally charged to the project. Where applicants are already receiving salaries funded by NIHR, these should be declared in the application.

The Apprenticeship Levy can be included in the salary costs from 1st April 2017 where relevant.

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 'Total Salary' column figures need to be calculated using the current annual costs, %FTE and number of months. 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: IT technicians, laboratory staff, and costs of pooled staff efforts. HEI indirect costs cannot be claimed on these shared costs.

III) Travel, Subsistence and Dissemination costs. This section includes journey costs, subsistence and dissemination costs, including conference fees and open access publication costs. 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.

Dissemination costs

Conferences

Where national or international conference costs 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.

Open Access Costs

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, since NIHR expects that APCs will be covered by the funding award.

Other Dissemination Costs

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.

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.

INVOLVE have produced a number of useful payment-related resources which can be found at the following link:

<http://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/>

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, 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.

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.

Indirect Costs/Overheads

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 Bodies or other providers of NHS services indirect costs

NHS Indirect Costs cannot be claimed through NIHR/DH programme funding. NHS Bodies or other providers of NHS services have been allocated NIHR Research Capability Funding (RCF) to contribute to the cost of hosting NIHR/DH-supported research. For more information please click on the link below:

<https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/research-capability-funding.htm>

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.

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.

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.

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 body or provider of NHS services - 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.

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 Clinical Research Network Senior

Manager for advice on NHS Support Costs. Further details about LCRN contacts is available at <https://www.nihr.ac.uk/nihr-in-your-area/local-clinical-research-networks.htm>.

II) NHS Treatment Costs

Please read the following guidance on the funding of excess treatment costs prior to completing your application <https://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 body or provider of NHS services 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.

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>

11. Management and Governance

Is Clinical Trials Authorisation required?

Yes / No

Does your project require ethics approval?

Yes / No

If yes, has ethics approval already been obtained?

Yes / No

12. Suggested Referees This information is to assist the programme secretariat function and will not appear to reviewers of the application form

Applicants should attempt to complete this section with suggestions of two (where possible) and a maximum of three potential referees

Applicants may complete this section with suggestions of at least two potential referees. Those suggested should not be closely affiliated with members of the project team or the intervention. They should also not be within the same institution of any of the applicants on the project team.

Please indicate who you would not like to be approached as referees (maximum of three).

If there are any experts in the field who you feel are particularly conflicted on this application and should not be approached please provide details in this section or otherwise leave it blank. Please note that NETSCC reserves the right to approach any relevant referees.

14. Uploads

ATTACHMENT 1: Detailed Research Plan - It is mandatory to upload and submit a Detailed Research Plan (DRP), which is a full account of the proposed project.

Format

- Use Arial font size 11
- Not exceed 20 A4 pages
- Margin widths should be no less than 2cm
- Have a header containing your allocated project reference number if known
- Have a footer showing your page numbers
- Be converted to a .PDF version before uploading it

Broadly, the detailed research plan should follow the following structure:

Headings / guidance

- **Full title of project**

This section should clearly state what the proposed research is and any abbreviations should be defined. You may like to present this in a PICOST format (Population, Intervention, Comparator, Outcome/s, Setting and Timing).

- **Background and Scientific Rationale**

This section should include a brief literature review and how you expect to add to the body of knowledge with reference to current policy and practice. The necessity for the research both in terms of time and relevance should be explained.

- **Research Questions**

Please provide the precise research questions your project will seek to answer. You may like to present this in a PICOST format (Population, Intervention, Comparator, Outcome/s, Setting and Timing).

- **Research Plan / Methods**

Outline the design of your research ensuring your methods and fieldwork are clearly connected to the aims and objectives and research questions you outlined earlier.

- *Search strategy (in the case of projects involving evidence synthesis):* Provide details of preliminary searches, the body of existing evidence that will be covered, access arrangements (e.g. use of databases, hand-searching, communication with authors, etc.) and the search and review strategy. The databases you wish to use need to be specified and the team's ability to access them commented on.
- *Strategy for reviewing literature (in the case of projects involving evidence synthesis):* Explain the criteria to be applied to assess the quality and relevance of studies identified by the search strategy. Provide an explanation of how these will be decided if they are not yet known. Describe your methods for combining, aggregating or synthesising research findings and different forms of evidence.
- *Design and theoretical/conceptual framework:* please provide a clear summary of the study design, including all of its components (e.g. primary and secondary outcomes, process and economic evaluations) and relevant time points for baseline and follow-up data collection for each component. Reference should be made to established research techniques and any adaptations of these for the purposes of the research proposed should be fully explained and justified. Where randomisation of participants is proposed please describe and justify the

chosen method of randomisation.

- *Control/comparator group:* please state what appropriate comparator will be used in an evaluation and how they will be selected. Changes to control conditions or 'treatment as usual' during the conduct of the trial should be documented.
- *Progression criteria:* All applications to the PHR programme which propose to carry out feasibility and/or pilot studies should include clear and challenging criteria to judge whether progression to the definitive study is justified. There are no fixed universally applicable thresholds for progression criteria but they should aim to address whether the uncertainties that were set out to be resolved in the preliminary studies have been determined.

Q: Did you resolve the uncertainties you set out to resolve? Examples of progression criteria could include (but not limited to*):

- *Did you recruit people / centres within a reasonable timespan and to the numbers anticipated?*
- *Could you deliver the intervention with reasonable fidelity?*
- *Could you assess the outcome measures?*
- *Was the intervention sufficiently acceptable and feasible to implement?*
- *Do you have commitment to fund the intervention for the duration of the study?*
- *Is the underlying question still the same/has the context changed?*
- *Do you have reasonable estimates of effect size and variability to inform a sample size calculation?*
- *Have you established whether there is contamination between the arms of a cluster study and any strategies to mitigate this?*
- *Does the initial evaluation suggest that the intervention could be effective?*
- *Has the study led to refinement of the logic model?*

**Please note that the criteria listed above should be used as a guide only and do not represent a comprehensive list of all the progression criteria that should be included within an application.*

- *Planned intervention:* you should include details of the planned intervention(s) and components, and their frequency and intensity, theoretical basis, specific techniques used, modes of delivery, and who will deliver the intervention. You may like to refer to the [TIDIER](#) guidance on reporting interventions. A logic model (or similar) should be provided as an additional upload to help explain the underlying context, theory and mechanisms of the intervention being evaluated.
- *Setting/context:* Please describe the setting or context in which the study will take place and intervention be delivered.
- *Study population:* which population(s) will be the target for the intervention and the subject of the research? How will the population(s) be recruited and retained?
- *Sampling:* please justify the proposed sampling frame and sample size for each element of the study. A justification for the assumptions underlying the sample size calculations must be provided. Please provide the source or some sensitivity analysis around assumed values.
- *Outcome measures:* please state and justify the primary and secondary outcome measures. Validated surrogate markers are acceptable where appropriate. Details should include justification of the use of outcome measures where a legitimate choice exists between alternatives, the proposed duration of the intervention and frequency and duration of follow up.
- *Methods for data collection:* for each outcome, process or economic measure proposed, please state the method of data collection, including qualitative methods where appropriate.

- *Data & Statistical analysis:* please provide details of how each study data set will be analysed. Clearly state the purpose of any statistical analysis. The proposed type and frequency of analyses must be stated including the selection of participants to be included in the analyses. Describe any planned interim and sub-group analyses, sensitivity analysis and how missing data will be handled.
- *Health economic evaluation:* to inform affordability and return on investment a health economic evaluation should be included in your study. If you do not intend to include a health economic evaluation, justification for why this is not appropriate should be provided.
- *Assessment and follow up:* A period of follow up should be considered and undertaken which is sufficient to ensure that a wider range of effects are identified other than those which are evident immediately after the intervention. Please provide details of how / when outcomes will be assessed including:
- *Assessment of efficacy/effectiveness:* Please describe the methods and timing for assessing, recording, and analysing of efficacy/effectiveness parameters.
- *Assessment of unanticipated outcomes:* Please describe the:
 - Methods and timing for assessing, recording, and analyzing parameters of harm.
 - Procedures for eliciting reports of and for recording and reporting adverse events and other harms.
 - The type and duration of the follow-up of subjects after adverse events.
- *Scalability and translation:* A summary of any issues regarding the scalability and translation of the intervention into wider contexts if proven to be effective should be provided. This could be reflected in the study logic model. Applicants may like to consider following consulting published frameworks for scalability or intervention contextualisation (examples include; [WHO](#), [PHRP](#), [CICI Framework](#).)
- *Socioeconomic position and inequalities:* A summary of how your proposal will take into account the socioeconomic position of the research participants and potential participants should be included, as well as a description of how the research will attempt to address inequalities. Please detail if and how the study will measure the distributional impacts of the intervention (You may like to refer to [PROGRESS-Plus characteristics](#)).

Dissemination, Outputs and anticipated Impact

The purpose of this section is for the applicant to describe the planned outputs of the research, how these will be communicated and to whom, and how the research may lead to short and longer term impacts. NIHR understands that the impact of any research may take time to be realised and will likely involve other funders, institutions and sustained efforts in practice. NIHR also recognises it may be difficult to provide definitive answers or guarantees on longer term impacts. However, applicants are invited below to consider various aspects of pathways and how the likelihood of impact can be maximised. This includes considering what outputs are produced, how these can best be communicated to key stakeholders, what efforts and investment are likely to be needed beyond the project, what barriers are likely to be encountered and what impacts the research is seeking to achieve.

What do you intend to produce from your research?

Please provide brief details of each anticipated output. NB the term 'outputs' refers to *any* tangible product of the research, not just academic publications. Outputs can include but are not limited to: Conference presentation or other workshop events; Publications (academic or otherwise); Guidelines (clinical, service or otherwise); Other copyright (e.g. questionnaires, training aids, toolkits, manuals, software, etc); New or improved design of devices or instrumentation; New or improved diagnostic; Outcome data that could be used to support a CE mark, market authorisation or equivalent; Trial data that could be used to shape or influence a healthcare market or government; Potential new public health

intervention.

How will you inform and engage patients, NHS and the wider population about your work?

Describe who you need to communicate with within this research, and your plans for engaging relevant audiences. For impact, it is unlikely that simply making outputs available will be sufficient. Please consider, and outline the active approach you will take to engaging key parties, or identify the process you will use to identify them and formulate an engagement plan.

How will your outputs enter our health and care system or society as a whole?

Describe the process by which the research will enter the healthcare or public health environment, including how your outputs will be acknowledged, selected and introduced for use in the health and care service or wider society. Where possible consider how the work will be able to be adopted and implemented longer term. Please describe the proposed route to market (commercial or non-commercial) for your outputs. Describe who is needed to take it forward and the relationship you currently (or propose to) have with these parties. If your outputs are likely to be commercially exploitable, please include details on how you plan to develop this.

What further funding or support will be required if this research is successful (e.g. from NIHR, other Government departments, local government, charity or industry)?

Consider what investment or support may be needed at the end of this project to maximise impact. Not all projects will require this but if so, plans should be linked to the responses in points 2 and 3 above.

What are the possible barriers for further research, development, adoption and implementation?

Describe the difficulties that may be faced in generating impact from your research. These may be difficulties you will face yourself, or challenges faced by those in the implementing context (e.g. clinicians).

- Will the proposed research use data, technology, materials or other inventions that are subject to any form of intellectual property protection (e.g. copyright, design rights, patents) or rights owned by another organisation(s)? If yes, provide brief details including how such third party IP will be accessed (e.g. collaboration agreement, drug supply agreement).
- What are the key current and future barriers to uptake of any likely output or innovation directly in health and care services, through commercial exploitation or other means, e.g. potential regulatory hurdles?
- What are the challenges for getting your research implemented in terms of acceptability, accessibility and feasibility? How will you address these?

What do you think the impact of your research will be and for whom?

Describe the impacts you aim to achieve as a direct result of the project and those which are anticipated longer term. Please consider how any smaller, more immediate effects may mature over time into larger scale or more significant effects, and the steps by which this may be achieved. As far as possible, indicate anticipated timescales for these benefits and a quantitative estimate of their scale. Impacts may include, but are not restricted to - patient benefit; healthcare staff benefits; changes in NHS service (including efficiency savings); changes to public health services, change to public health policy or policies in other sectors, commercial return (which could contribute to economic growth); public wellbeing.

Project / research 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.

Project management and governance

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.

It is expected that all primary studies have a study steering committee (SSC). Please state in this section if you are going to have an SSC or, if not, you must explain your reasons for not doing so. Please note that if an SSC is not proposed, that decision will be reviewed by referees and the Research Funding Board and it is possible the programme may require that an SSC is established.

Depending on the study design and questions being asked a separate Data Management Executive Committee (DMEC) may be required. Applicants should indicate if they require a DMEC. Where a DMEC is established it should be independent of the applicants and of the Study Steering Committee (SSC), while reporting to the SSC and (via the SSC) to the Programme. Detailed arrangements may need to vary according to the nature of the study and the host institution(s) involved. The Programme is keen that the arrangements for each proposed study are proportionate to the type, size and duration of the study involved. We do not require proposed SSC/DMEC membership lists at this stage, but an indication of members who are likely to be proposed (including overseas members) should be included.

Ethics / Regulatory Approvals

Outline any ethical and/or other regulatory issues, and arrangements for handling them. The Programme expects applicants to follow ethical guidelines appropriate to the study and setting proposed. We will scrutinise ethics arrangements as part of the assessment of applications. Applicants must either comply with the [Economic and Social Research Council's \(ESRC\) research ethics framework](#) or obtain approval via the [National Research Ethics Service](#).

(Note that work outlined in your application/protocol must adhere to the [UK Policy Framework for Health and Social Care Research](#)).

Patient and Public Involvement

Note that your description of how patients and the public have been involved in developing this proposal, and how they will be involved in the proposed research, should be captured in the three specific Patient and Public Involvement (PPI) questions asked elsewhere in the application form. Although you are encouraged to include information about PPI activities within the Detailed Research Plan upload, there is no requirement to repeat or duplicate the responses to the three specific PPI questions. In rare cases where proposals do not involve patients or the public, clear justification must be provided, in response to the third PPI question.

INVOLVE has issued guidance for researchers about involving patients and the public in research, as well as about payment and support, including the Briefing Notes for Researchers and the Payment resource centre:

<http://www.invo.org.uk/posttypepublication/involve-briefing-notes-for-researchers/>

<http://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/>

Project / research expertise

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.

Please also provide details of collaborators and how they have aided the development of the proposal. Letters of support from collaborators should be provided as uploads. Where appropriate this should include a letter from the provider of the intervention costs.

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

Success criteria and barriers to proposed work

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.

ATTACHMENT 2: CTU support letter (if required / appropriate to the study)

If appropriate to the study, please supply and upload a CTU letter of support.

ATTACHMENT 3: Flow Diagram

In order to submit a Stage 2 application to the programme you must upload a diagram (single-side of A4), as a separate .PDF file, for submission with your application form. This diagram will be projected at the board meeting to provide board members with a visual summary of the study proposed.

The diagram should illustrate the study design and the flow of participants (if appropriate). If the project consists of more than one work package, consider a diagram that conveys the sequence and timing of research packages as well as how the work packages are linked.

Please ensure diagrams are large and clear enough for them to be projected as a slide at the board meeting.

If proposing an RCT, we advise you refer to the [CONSORT statement](#) and website for guidance. If you are proposing a [pilot or feasibility trial](#) please refer to the consort extension for pilot and feasibility trials. Alternatively, you may also find the [EQUATOR Network](#) website useful.

ATTACHMENT 4: Logic Model

Where appropriate please supply a logic model or equivalent

ATTACHMENT 5: References (maximum 3 pages of A4)

List all references cited in the full project description, using the Vancouver referencing conventions.

ATTACHMENT 6: Letters of support

Please upload any letters of support from study collaborators or partners. Where applicable a letter from the provider of the intervention costs for the purposes of the study should be provided.

ATTACHMENT 7: Papers in press

Supporting research papers not yet published or publically available should be provided.

15. Acknowledge, review and submit

Conflict checks

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. The [ICMJE criteria](#) for conflict management can be used as a guide. If

in doubt, you should err on the side of disclosure.

Agreement to terms and conditions

I have read and understood the terms on which I have been nominated as Chief Investigator for this proposal along with the associated documentation and accept this role.

A list of terms and conditions can be found here: [Terms and Conditions](#)

Checklist of information to include when submitting a NIHR stage 2 research application

Applicants should click the check boxes to indicate that they have included the necessary information prior to submitting their application.

- Appropriate and relevant involvement of patients and the public www.involve.nihr.ac.uk
- A good quality Plain English Summary www.involve.nihr.ac.uk/makeitclear
- A clear description of team member roles and contribution
- A clear scientific abstract
- A clear description of the changes from first stage (if applicable)
- A flow diagram (where appropriate) illustrating the study design / flow of participants (document upload)
- A full and accurate detailed budget breakdown
- A clear justification of costs / value for money
- References (maximum 3 pages of A4 - document upload)
- A clear Detailed Research Plan outlining the study design, methods, dissemination etc. (document upload)
- A CTU letter of support if required (document upload)
- Logic model or equivalent (document upload)
- Letters of support (document upload)
- Papers in press (document upload)
- The support and agreement from the necessary supporting roles / signatories