



MRC

Medical
Research
Council



NHS

National Institute for
Health Research

Efficacy and Mechanism Evaluation Programme

APPLICATION FORM GUIDANCE NOTES FOR APPLICANTS SUBMITTING STAGE 2 APPLICATIONS

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

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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 Systematic Review topic.

*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 Funding Committee 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 CI'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.

Research Type

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, 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.

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 (Stage2) 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 (limit 10,000 characters)

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 (limit 10,000 characters)

This should include research grants held (as a named applicant) CURRENTLY or IN THE LAST 5 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).

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. Research Team

Specify your (lead applicant) role in this research (*Limit: 200 characters*)

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 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. Collaborators normally provide specific expertise on particular aspects of the project but who 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 submission requirement only and will not be visible to reviewers of the application form

As a minimum the following (mandatory) supporting roles are required to be added to a stage 2 proposal application:

1. Administrative Authority or Finance Officer

2. Head of Department or Senior Manager - Please note, 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 task has been completed, and as a named signatory, various fields within the application form will become non-editable.

3. Sponsor

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.**

4. 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 stage 2 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 character limit of 3500 (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 evidence synthesis. 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 of Research

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 funding committee 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 Design Service (where applicable). www.nihr.ac.uk/research/Pages/ResearchDesignService.aspx

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 (limit 8,000 characters)

- Please provide a breakdown of research costs associated with undertaking the research and provide justification for the resources requested. This should include the following costs: staff costs, travel 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/involve-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 a stage 1 application has been produced and this is the stage 2 application, the Committee 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 individuals to attend one international conference, or one individual to attend two international conferences. 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 verses 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 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. Please note that as part of the work to address the issues surrounding the way in which Excess Treatment Costs are funded, new arrangements are now being implemented as part of a pilot. To underpin the new arrangements, a cost attribution tool has been created by the Health Research Authority (HRA) in partnership with charity funders and research sponsors. This tool provides a standardised approach across England, ensuring that the attribution of study activities complies with the Department of Health and Social Care Guidance on Attributing the Costs of Health and Social Care Research and Development (AcoRD). As part of their funding applications, researchers are required to complete this new tool, known as a Schedule of Events Cost Attribution Tool (SoECAT) for clinical research, which has been developed from the current HRA Schedule of Events. This tool is designed to capture the different costs associated with clinical research and attribute them accordingly. The totals for excess treatment costs and NHS support costs calculated by using the SoECAT can be entered directly into the application form.

Researchers and/ or their study teams and Research Sponsor/ Lead NHS Provider (e.g. R&D office/ Clinical Trial Unit) are supported by AcoRD Specialists in the Local CRN to verify the accuracy of the SoECAT. For more information please see the NIHR CRN Routemap available at:

<https://www.nihr.ac.uk/funding-and-support/study-support-service/resources/supporting-research-in-the-nhs.htm>

Under the new arrangements, sign off via the LCRN AcoRD Specialist is required to confirm the study attribution complies with the Department of Health and Social Care AcoRD guidance. This early attribution support will underpin the excess treatment cost management process by providing formal sign off, supporting the role of the research sponsor and lead R&D office or Clinical Trial Unit. Completion of the Schedule of Events Cost Attribution Tool will be required for studies eligible for the NIHR portfolio and the support this provides, which will include access to excess treatment cost payments under the new arrangements. This ETC value, alongside recruitment activity in the NIHR Central Portfolio Management System, will then be utilised to inform the payments to NHS providers.

A completed Schedule of Events Cost Attribution Tool (SoECAT) is now required to be uploaded and submitted as part of the application submission for all applications. The SoECAT must be signed off by an AcoRD Specialist even where there are no excess treatment costs.

More information can be found here:

[Download the supporting guidance for researchers, study teams and sponsors to complete the SoECAT](#)

[Download a preview of the Schedule of Events Cost Attribution Tool \(SoECAT\)](#)

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. Uploads

Any additional, not requested, documents will not be considered by the funding committee during its review. However, there may be other requested documents e.g. cover letter, collaborative documents, dictated by the specification of the call, and these are listed under Attachment 5: Additional EME Documents at the end of this section.

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. The DRP must also include the Gantt chart described below in Section 7, and may contain relevant diagrams and charts within the 20 A4 pages.

Format

Your detailed research plan should:

- Use Arial font size 11
- Not exceed 20 A4 pages
- 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
- Include a Gantt chart

Each recommended section of the Detailed Research Plan is not specifically word count limited, which provides applicants with the opportunity to use the 20 pages to provide elaboration in specific sections as required. Broadly, the Detailed Research Plan uploaded document for an intervention trial should follow the following format. For studies of diagnostic or prognostic tests, please modify these headings as appropriate.

1. Full title of project

2. Summary of Research (abstract)

The scientific abstract should be a clear and concise scientific summary of the Detailed Research Plan / Methods. Applicants may wish to refer back to/or duplicate Section 6 of this form, and have the opportunity to expand the information if needed.

The following is a list of potential headings that might be included depending on the design of the proposed research. It will be for researchers to decide the appropriate elements to be included in this summary and could include elements outside this list.

- Research question
- Background
- Aims and objectives
- Methods, including justification of study design
- Timelines for delivery
- Anticipated impact and dissemination

3. Background and Rationale

Provide a clear explanation of the health problem to be addressed, the impact on patients and / or public as well as health and care services, and how this research would fill a demonstrable evidence gap.

Please briefly explain:

- a. Why is this research needed now?
 - i. Describe the unmet health need to be addressed
 - ii. Provide the size of the incident or prevalent patient population in the UK
 - iii. Provide context of your proposed research in terms of current practice.
 - iv. If relevant, describe any time-limited opportunities.
- b. What is the knowledge gap this research will address?
 - i. Explain how you identified and reviewed all the directly relevant literature.
 - ii. Give details of other recent or on-going relevant trials or research, both nationally and internationally, and critique their relevance to this study.
 - iii. Explain why your proposed research would lead to an improvement in the care of the patient population.
- c. Describe the evidence that provides proof-of-concept in man for your research. Please ensure you include references on proof of concept in your bibliography. If you need more information about what proof of concept is required, please see: <https://www.nihr.ac.uk/funding-and-support/documents/funding-for-research-studies/research-programmes/EME/how-does-eme-define-proof-of-concept.pdf>

4. Aims and objectives

Please summarise the aim of the research and research questions / objectives.

Please provide:

- a. The aim(s) – broad and general statement(s) of intent addressing the overall purpose of your proposed research.
- b. The hypothesis should be stated for a clinical study. When a mechanistic component is included the hypothesis that is being tested should also be clearly stated.
- c. Research objectives should be listed. They need to provide a focused indication of what you will do to achieve the aim(s). It may be helpful to divide these, where appropriate, into clinical and mechanistic objectives.

Mechanistic components to studies are strongly encouraged. These must test a clear hypothesis and contain an indication of how the tests / measurements will confirm or refute this hypothesis. For examples of EME funded studies with mechanistic components, please see: <https://www.nihr.ac.uk/funding-and-support/documents/funding-for-research-studies/research-programmes/EME/how-does-eme-define-mechanistic-studies.pdf>.

- d. For clinical trials, include a single sentence describing the study including the primary outcome measure.
- e. The deliverables from the project.

5. Research Plan / Methods

Research design: Reference should be made to established research techniques. Any adaptations of these for the proposed research should be fully explained and justified. If you are proposing a randomised trial, describe explicitly how participants will be allocated to trial groups, and describe any other methods to protect against bias. State if any pilot study has been carried out using this design and if so, findings must be provided. Also describe any "stopping rules" for parts of, or the entire study.

Study population: Please provide a detailed list of the planned inclusion / exclusion and withdrawal criteria.

Planned interventions: Include both experimental and control interventions. If there are likely to be any problems with compliance or follow up please provide an estimation of the likely loss of analysable data. Clearly justify why this drug / intervention has been chosen over alternatives, and provide a referenced justification for the dosing regimen / treatment schedule.

Proposed outcome measures: Detail both the primary and secondary outcome measures. Again it can be helpful to divide into clinical and mechanistic component where relevant. Validated surrogate markers are acceptable only if evidence in support of the surrogate-to-final end point outcome relationship can be provided.

Assessment and follow up: Please provide details of how/when outcomes/safety will be measured and assessed including:

Assessment of efficacy: Describe the methods and timing for assessing, recording, and analysing of efficacy outcomes.

Proposed sample size: Justifications for the assumptions underlying the sample size calculations must be provided. These should be in sufficient detail to allow replication by the reviewers. Where mechanistic components are included, rigorous power calculations are also expected.

Recruitment Strategy: Specify the number of patients and centres and recruitment rates indicating the total patient numbers available from which the trial patient population may be drawn. Detail of the contemporary incidence or prevalence rates for the condition (whichever is relevant) should be given as well as how you have identified these rates, and descriptions of any other trials recruiting the same group of patients. A full clear justification is required for any patient recruitment planned outside of the UK. Explain how you will recruit and the critical factors that will lead to the optimisation of recruitment.

Statistical analysis: Clearly state the purpose of any statistical analysis, and do not simply name a statistical test or software package. 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.

Value for money: Provide an explanation of how the project offers value for money.

6. 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 below and how the likelihood of impact can be maximised. This includes considering what outputs are produced, how these can be best connected to the healthcare environment, 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 medical devices or instrumentation; New or improved diagnostic; Trial 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 drug or healthcare 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. **Link to NIHR Dissemination guidance:** [How to disseminate your research: Getting your message heard - and used.](#)

- **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 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, 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 which 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 the health and care service, 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); commercial return (which could contribute to economic growth); public wellbeing.

7. Project / research timetable

Project timetable - Provide a detailed project timetable with key deliverables and milestone indicated that assess specific interim achievements which are crucial to fulfilling the stated research objectives. A Gantt diagram must be included as a visual summary of the overall project.

Applications to this call may include a series of linked stages (usually 2 to 3) with progression to the next stage dependent on the outcome of the previous stage(s). In addition to the main clinical

evaluation, typical stages include.

- Feasibility stage(s)
 - Used to estimate important parameters required to finalise design of the next stage of the study or main clinical evaluation, to further develop an intervention or key component of the treatment pathway or to help select the intervention used later in the study.
- Pilot stage(s)
 - Used to test processes used for the main clinical evaluation when there is a high risk of failure to deliver. Trial/Study processes are typically piloted in initial sites with clear targets set to be reviewed at a specific point early in recruitment as part of an ad hoc monitoring milestone.

Researchers who wish to submit a staged programme of work must make the progression criteria clear, outline what the stages are and how success would be assessed. These need to be identified as **decision points** and clearly shown. These should be based on verifiable achievements, both concise and realistic, as they will be used for project monitoring purposes. These time points should appear on the overall project timeline and Gantt.

The precise type and number of **decision points** will depend on the size and nature of the project. Recruitment targets will be continuously monitored by EME and should not be listed as **decision points** except in studies with a feasibility or pilot stage.

Following review of your application the programme may identify one or more of the decision points listed as **contractual Stop/Go** decision points. These are typically between project stages where there could be good reasons, other than failure to deliver, for a programme of work not to continue to the next stage. (i.e. even if the research progressed according to the agreed schedule, there would still be a requirement to review results of the previous stage to determine whether the next stage should be funded).

In such cases a **contractual Stop/Go** decision point is inserted into the DH contract, payment schedules are aligned with costs agreed for the preceding stage with payments over and above this figure held until approval from the programme is granted.

NIHR EME Monitoring: Your progress will be regularly monitored, comparing your submitted progress reports against your planned deliverables and milestones checked. These progress reports will be based on the project timetable and milestones, and will occur at approximately six month intervals. If you are late producing progress reports and a single draft final report of the expected standard for the EME Programme, we reserve the right to withhold payments as per the contract. Applicants should note that the EME Programme monitors the degree to which requested timetables are met, and that having a proven track record in delivering on time may be a consideration when deciding future awards.

If your project requires ethics/regulatory approval, you should allow time for obtaining these approvals and submitting appropriate documents to the EME Programme. Time for the recruitment of staff, the production of the draft report and a draft paper suitable for publication in a peer-reviewed journal should also be included.

8. Project management

Please demonstrate how you have addressed any “deliverability” issues for your project, including:

- Ensuring sample size is realistic and achievable
- Appropriate recruitment strategy
- Consideration of subject attrition

- Ensuring sufficient resource, expertise and facilities at each site
- Potentially competing studies for recruitment

Please note that it is important that you are aware of your institution's procurement policies so that if successful, your research can begin within your projected timeframe.

9. Ethics / Regulatory Approvals

Outline any ethical and/or other regulatory issues, and arrangements for handling them. Consider when the project requires approval by an ethics committee and/or any other regulatory body. If there is development work that is **essential** before you intend to apply for ethics and/or other regulatory approvals, state this and make the timescales clear in your plan of investigation and project timetable. The Funding Committee will consider this in detail and consider whether to offer staged funding.

Guidance on the application process for ethical and other approvals can be found on the [HRA website](#). Please note that if your study is led from England and involves the NHS in England you should apply for [HRA approval](#).

If you are using patient information from an existing database, you should check whether the patients have given their consent for their data to be included in that database for research purposes, or if not whether the database is exempt under Section 251 of the NHS Act 2006. Where exemptions are not already in place, approval to use confidential patient information without consent must be requested from the HRA who make decisions with advice from the [Confidentiality Advisory Group \(CAG\)](#)

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

Researchers may find the [SPIRIT 2013 statement](#) a useful resource when preparing their protocol for ethics and other approvals.

10. 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 this Detailed Research Plan 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/>

11. Project / research expertise

Outline the particular contribution each member of the team will make towards the project and the particular contribution that collaborators are intending to make. In addition, give details of supervision arrangements for junior staff involved, and details of arrangements to retain critical staff or co-applicants who do not have a contract of employment that spans the project period. The EME Programme recommends teams proposing randomised controlled trials to include input from an accredited clinical trials unit, or organisations with equivalent experience.

If commercial partners are involved in the study, a detailed description of the contributions and expectations from all parties must be included.

12. 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.

Please explain any barriers to completion of the study that are not covered elsewhere in this form, and your plans to overcome/avoid them. Describe the deliverables that would indicate a successful project completion.

Attachment 2: CTU support letter (required if your research is a Clinical Trial)

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.

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.

If proposing an RCT, we advise you refer to the CONSORT statement and website for guidance (www.consort-statement.org). 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 (www.equator-network.org).

Attachment 4: References (maximum 3 pages of A4)

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

Attachment 5: Additional EME attachments

- List of Abbreviations: required
- Supporting Letter (Tech Transfer Office): required
- If your study involves a collaborator they must supply a letter of support. You may also submit supporting letters from others if relevant.
- You may include relevant in-press publications. Please provide details of when these were submitted and to which journal.

13. 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. 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 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)
- The support and agreement from the necessary supporting roles / signatories
- A completed and approved SoECAT