NHS
National Institute for
Health Research

APPLICATION FORM GUIDANCE NOTES FOR APPLICANTS SUBMITTING STAGE 1 APPLICATIONS

(On-line NIHR Stage 1 Standard Application Form (SAF))

Version: June 2018

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NIHR Research Standard Application Form (SAF)

Stage 1 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.

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.

Estimated Research Costs

Enter the total amount of research costs requested (not including NHS Support & Treatment costs).

Estimated NHS Support & Treatment costs or external (not NHS) intervention costs

Enter the total amount of NHS support and treatment costs associated with this proposal.

Estimated non-NHS intervention costs

These are similar to excess treatment costs but they mainly apply to Public Health Research. We are unable to fund the intervention costs of non-NHS interventions. It is mandatory that letters of support from funders are included in Stage 2 applications.

2. Lead Applicant CV

Complete your name, contact details and other requested information.

3. Lead Applicant Research Background

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, 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 Research Plan section of the on-line application form.

Co-applicants are those individuals with responsibility for the day to day management and delivery of the project. 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.

5. 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. To support the assessment of applications to this commissioning brief please ensure the importance of the research is clearly justified in the Plain English Summary of Research and sections 1-4 of the Research Plan.

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 from 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.

For further support and advice on writing a plain English summary, please contact your local Research Design Service (where applicable).

6. Research Plan

(Limit: 20,000 characters)

Using all of the headings (in the order presented) and guidance below, please use this section to clearly explain your proposed research. **As this is the main part of your application which will be considered by the reviewing committee you should ensure that the information is accurate, succinct and clearly laid out**. The overall amount of information that you can provide at this stage is limited to 3 - 5 pages (dependent on the type/complexity/scale of study proposed).

The NIHR expects appropriate and relevant involvement of patients and the public and other key stakeholders in the research it supports. It is essential to set out your plans to involve patients and the public in the Stage 1 application. Your patient and public involvement plans will be assessed by the funding panel/board including patient and public members.

Information and resources to assist you can be found on the INVOLVE website (a detailed definition of patient and public involvement in research, briefing notes for researchers on how to involve patients and the public , and an involvement cost calculator and budgeting guide)

In the Research Plan section, it is important that you identify all stakeholders who are relevant to your research proposal. For each stakeholder group you need to be clear about how they benefit from your proposed research and, where appropriate, how they have been involved in the development of the application, as well as the plans for their involvement in the proposed research.

6.1 What is the problem being addressed?

Provide a clear explanation of the health problem to be addressed, the impact on patients as well as health and care services, and how this research would fill a demonstrable evidence gap.
www.involve.nihr.ac.uk/makeitclear

6.2 Why is this research important in terms of improving the health and/or wellbeing of the public and/or to patients and health and care services?

It is essential that you clearly identify the health and care need your research meets or contributes to. Please outline the anticipated value or contribution the study will provide

Please treat this section as a single field and use it to describe how your proposal meets the specification set out in the call brief. If you wish to propose a study that does not meet one or more of the requirements set out in the brief, please use this section to explain the reasons for your approach.

Please justify the clinical importance of your proposed study and outline the anticipated value or contribution the study will provide.

6.3 Review of existing evidence - How does the existing literature support this proposal?

Explain why this research is needed now, both in terms of time and relevance. We will only fund primary research where the proposed research is informed by a review of the existing evidence.

Please describe the existing evidence base for this research and demonstrate why this means your research is important now, both in terms of time and relevance.

Where a relevant published systematic review (or reviews) exists they should be presented.

Where no such published systematic review exists it is expected that the applicants will undertake an appropriate review of the currently available evidence (using a predetermined and described methodology that systematically identifies, critically appraises and then synthesises the available evidence) and then present a summary of the findings of this in their proposal. You should give reference to any relevant systematic reviews and discuss the need for your study in light of these. References should be provided in the Vancouver or Harvard

format (Author(s). Title. Journal. Year; Volume: Start page - End page). All applicants must also include reference to relevant on-going studies, e.g. from trial registries.

If the study proposed builds on previous work funded by the NIHR then the results of the previous study must be made available to the board before an application will be considered. Please either provide a link to published results or a draft report with your application.

6.4 What is the research question / aims and objectives?

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

6.5 Project Plan

Provide an expert summary of the project plan of investigation plus any additional points required to support statements made in the previous sections, and include any key references required to justify them.

- **Design**: Give a brief statement on the type of study design to be used.
- **Setting**: (Primary Research only) State the health service setting(s) in which the study will occur (e.g. general practice, hospital outpatients, ambulance service users).
- **Strategy for reviewing literature (Secondary research or Modelling):** If appropriate, explain the criteria applied to assess the quality and relevance of studies identified by the search strategy. Provide an explanation of how these will be decided if these are not yet known.
- **Target population**: If appropriate, clearly define which population(s) will be targeted for the study from which the study sample receives the health technology concerned (or the control intervention where appropriate) e.g. women over 60, people with learning disability, people with advanced cancer.
- **Inclusion/Exclusion Criteria**: Please provide an explanation of the inclusion/exclusion criteria.
- **Health technologies being assessed**: Give a clear definition of the health technology to be assessed. The purpose of programmes is to assess the value of a health technology compared to best alternatives or where none exists, against no intervention. Where there are established alternative technologies, these should also be defined. Where the technology is subject to rapid change, details of how this will be dealt with in the project should be included.
- **Measurement of costs and outcomes**: Not all studies require full economic evaluations. When considering inclusion of a cost effectiveness analysis, applicants should carefully describe what this would add to the study. Where an economic component is appropriate, applicants should endeavour to use the simplest approach, or fully justify where more complex methodologies are needed. Details should include justification of the use of outcome measures where a legitimate choice exists between alternatives. If the study includes a health economic component, state from what perspective costs and benefits will be considered, and (briefly) how these will be collected.
- **Sample size**: Where appropriate, state the required sample size, giving details of the estimated effect size, power and/or precision employed in the calculation. Information must be provided so the Board can replicate the calculation and understand the assumptions made.
- **Project timetables**: Indicate the anticipated duration of the study, paying particular attention to the expected recruitment rate if appropriate and a justification for your estimate. Outline the main stages of the proposed project including regulatory steps, team recruitment, study set up, and the expected duration of each.
- **Expertise in team**: The team should be multidisciplinary and include relevant expertise in the clinical area concerned. Particular care should be used to describe how you have and will involve patients and the public in your research.
- **CTU involvement**: It is advisable that studies involving a clinical trial have engaged with an accredited Clinical Trials Unit noting a letter of CTU support will be required with all stage 2 applications involving a clinical trial.

6.6 Intellectual property and commercialisation

The definition of Intellectual Property (IP) includes copyright (such as new software, checklists, scales, protocols, questionnaires, toolkits, guidelines or similar) and research tools (such as data analysis techniques, assays, cell lines, biomarkers, materials or equipment and devices) patents, trademarks and designs.

a. Please provide details of any existing or potential future intellectual property and ownership, including patents or patent applications that are relevant to the project.
b. If commercial partners are involved in the study, a detailed description of the contributions and expectations from all parties must be included.

7. Uploads

Any additional, not requested, documents will not be considered by the board during its review. However, there may be other requested documents e.g. cover letter, collaborative documents, dictated by the specification of the call.

Attachment 1: Flow Diagram

In order to submit a Stage 1 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.

Please ensure diagrams are large and clear enough for them to be projected as a slide at the board meeting to provide board members with a visual summary of the study proposed.

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 2: References

One single-side A4 page, listing references used throughout your proposal is also a mandatory PDF upload.

Please use either the Vancouver or Harvard referencing conventions.

Attachment 3: Logic model or equivalent

Where appropriate please supply a logic model or equivalent

8. 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

(Note that terms and conditions statement to include expectation/responsibility for applicant keep host institution/interested parties informed).

Checklist of information to include when submitting a NIHR stage 1 research application

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

- ☐ A good quality Plain English Summary
- ☐ A clear explanation of the problem being addressed
- ☐ A clear demonstration of the need and importance of the research
- ☐ A review of existing literature (primary research)
- ☐ A clear research question / aim(s) and objectives
- ☐ A clear project plan summarising the study design and methods
- ☐ A clear description of team member roles and contribution
- ☐ Appropriate and relevant involvement of patients and the public www.involve.nihr.ac.uk
- ☐ A clear, appropriate and relevant plan for dissemination
- ☐ A flow diagram illustrating the study design / flow of participants (document upload)
- ☐ A single A4 page of references (document upload)