NIHR | 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: March 2019

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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 or external (not NHS) intervention associated with this proposal.

Estimated non-NHS intervention costs

Non-NHS intervention costs include costs incurred in delivering the intervention which would continue to be incurred after the trial, should the intervention become standard care. The figure that should be entered here is the difference between the cost of the intervention and the cost of current 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. Where applicable a letter from the provider of the intervention costs for the purposes of the study should be supplied.

These are similar to excess treatment costs but they mainly apply to Public Health Research. They are unlikely to be applicable to HTA unless the intervention is being delivered outside the NHS (e.g. in school or by a local authority etc).

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. Lead Applicant CV

Complete your name, contact details and other requested information.

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.

Lead Applicant's %FTE Commitment

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

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 – as well as any additional previous grants, relevant to this application. 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 – Joint Lead Applicant / Co-Applicants

Joint Lead Applicant

Where appropriate and justified it is acceptable for the application to be led by joint Lead Applicants.

NOTE: For application / contracting purposes the joint lead applicant will be regarded as a co-applicant.

Please click the 'Add' button and select the Joint Lead Applicant Role drop down option and enter their dates (if applicable)

Justification for Joint Lead Applicant (Limit: 1500 characters)

Justification should be given to demonstrate why more than one person would be required to lead this research and how this brings added value to the application.

Relevant expertise and experience of Joint Lead Applicant (Limit: 1500 characters)

Please summarise the proposed Joint Lead Applicant's relevant expertise and track record in applied health research, in terms of skills and experience, previous publications, grant funding and impact on health service provsion.

Joint Lead Applicant / Co-Applicants / Co-Applicants - PPI

Add details of all co-applicants (including Joint Lead Applicant if appropriate) 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.

Please note that once you enter a co-applicants details they will receive an automated email informing them that this information has been added into our Management Information System (MIS) in conjunction with your application. Therefore, we would expect for you to have consulted with co-applicants before adding their details into the MIS.

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.

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 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.
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.rds.nihr.ac.uk

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 committee 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.

For Commissioned calls only:

Much of this information will be provided in the Commissioning Brief and you should only provide any relevant additional information not already captured in the commissioning brief

For Researcher-Led calls only:

Please explain how your chosen research is in the remit of the HTA programme www.nihr.ac.uk/hta and a clear explanation of the impact on patients and the NHS.

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.

For Commissioned calls only:

Please treat this section as a single field and use it to describe how your proposal meets the specification set out in the commissioning 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.

For Researcher-Led calls only:

This section is used in the first stage of proposal assessment and is therefore the most important part of your application in terms of demonstrating competitiveness against others received. It allows you to demonstrate why your chosen research area is needed by the NHS.

Please justify the clinical importance of your proposed study and outline the anticipated value or contribution the study will provide to clinical practice and how it could be implemented across the wider NHS. Classification of need for research is set out below:

- **Health need**: These will be expected benefits in terms of substantial health gain with the ultimate aim of improving patient health or care. This covers the potential for preventing avoidable mortality and morbidity, improving quality of life and considerations of disease prevention and should be justified in terms of burden of disease;
- **Sustained interest and intent**: Evidence that the issue or area is one in which there will be sustained interest in the future, such that the results of research if commissioned and undertaken will remain highly relevant and important to the needs of the NHS in the future;
- **Capacity to generate new knowledge**: Please explain how the proposed research will contribute to development of the research area;
- **Scientific knowledge**: Please explain how the study will make a substantial advance in scientific understanding and knowledge and the potential substantial health gain.

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.

For Commissioned calls only:

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

For Researcher-Led applications only:

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 funding committee before an application will be considered. Please either provide a link to published results or a draft report with your application.

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

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

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

All proposals recommended for funding which involve a clinical trial will be double-checked for potential overlaps using WHO trials (http://apps.who.int/trialsearch/) before the communication of any funding decision. Consequently, a funding recommendation may not be taken forward if a major overlap is identified at this stage. It is therefore important that applicants highlight any potential overlaps prior to consideration by the funding committee.

Applicants should then explain how they expect that the research proposed will add to the body of knowledge with reference to current NHS policy and practice.

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.

You should include a clear explanation of the main (single) research question phrased in PICO terms where applicable to your study type:

Population: NHS target population i.e. real patients

Intervention: A technology that is or could be used now in the NHS

Comparator: Usually next best treatment, but could be placebo

Outcome: Patient centred, leading to effectiveness and cost-effectiveness

Give a brief explanation of how or in what ways the design constitutes a clinical trial or evaluation study. You are welcome to highlight any other aspects of the design that you would like to bring particular attention to, in order to explain how it is within remit or meets the commissioning brief. Please remember that HTA research looks at patients or people seeking healthcare; studies using healthy volunteers and animals are not within the remit of the programme.

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 (e.g. in the use of particular outcome measures or methods of analysis).

- **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):** 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**: Clearly define the population from which the study sample receives the health technology concerned (or the control intervention where appropriate) e.g. women over 60, people with learning disability, people with advanced cancer.
- **Inclusion/Exclusion Criteria**: Please provide 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 HTA is to assess the value of a health technology compared to best alternatives or where none exists, against no intervention. Where there are established alternative technologies, these should also be defined. Where the technology is subject to rapid change, details of how this will be dealt with in the project should be included.
- **Measurement of costs and outcomes**: Not all HTA studies require full economic evaluations. When considering inclusion of a cost effectiveness analysis, applicants should carefully describe what this will add to the study. Where an economic component is proposed, applicants should endeavour to use the simplest approach, or fully justify where more complex methodologies are needed. Details should include justification of the use of outcome measures where a legitimate choice exists between alternatives. If the study includes a health economic component, state from what perspective costs and benefits will be considered, and (briefly) how these will be collected.
  - Where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise. Please see The COMET Initiative website at www.comet-initiative.org to identify whether Core Outcomes have been established.
- **Longer-term follow up**: In some instances a commissioning brief may ask researchers to consider obtaining consent from participants to allow future to allow future follow up through efficient means (such as routine data) as part of a separately funded study.
  This is because it may be useful, after the main study is completed, to undertake longer-term follow up, either because of what is currently known about the possible long term effects of the intervention, or because subsequent research suggests long term follow up of this cohort would be useful. Researchers should therefore consider building in provision for a mechanism to facilitate longer term follow up beyond the life of the main study, including obtaining consent for this from participants at study entry.
- **Sample size**: 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 funding committee can replicate the calculation and understand the assumptions made.

- **Difference between current and planned care pathways**: Please define the current standard patient care pathway and how this differs from the trial arms.
- **Project timetables including recruitment rate**: Indicate the anticipated duration of the study, paying particular attention to the expected recruitment rate and a justification for your estimate. Outline the main stages of the proposed project including regulatory steps, team recruitment, patient recruitment, and the expected duration of each.
- **Expertise in team**: The team should be multidisciplinary and include relevant expertise in the clinical area concerned, in performing systematic reviews, and (where appropriate) others e.g. operational research, health economics. 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.
- **Dissemination:** Our key concern is to ensure that projects funded by the HTA programme are designed from the outset to produce useful, timely and relevant research findings, which are then used and actually make a difference. Please describe the main outputs from your research and how they will be presented, disseminated and used. Explain how the findings from the proposed research will be shared with, or disseminated to others and how this will maximise the potential impact of the proposed research. Describe who are the likely beneficiaries of the research, when are they likely to benefit and in what way. **Link to NIHR Dissemination guidance**: How to disseminate your research: Getting your message heard - and used.
- **Studies within a trial**: The HTA Programme is running a pilot enabling HTA applicants to embed studies that evaluate approaches to support trial delivery success within HTA main trials (SWATs) in their applications. Many trials take longer than planned, either struggling to recruit, or retain participants, or going over budget. The NIHR are interested in working with researchers to evaluate interventions to make trials more efficient. Applicants may apply for up to £10,000 funding to evaluate alternative ways of managing trials and to complete these SWATs as part of their main study. Any SWATs proposed should represent a minor element of a larger trial which must not undermine delivery of the main trial. Some examples of SWATs are provided on the Northern Ireland Hub for Trials Methodology Research Webpages. Applicants are also encouraged to review the work of Trial Forge (https://www.trialforge.org)
  SWATS may not all be powered to provide meaningful outcomes but will be useful for meta-analysis and applicants should consider using protocols published on the Northern Ireland MRC Trials Hub for Methodology Research SWAT registry.
  Applicants who wish to include a SWAT in their study should indicate that they intend to do so in their first stage application (there is no need to provide a detailed description of the SWAT at this stage).

7. 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.

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 funding committee meeting to provide funding committee 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 (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 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.

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

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 www.involve.nihr.ac.uk/makeitclear
- ☐ 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) using either the Vancouver or Harvard referencing conventions