

APPLICATION FORM GUIDANCE NOTES
FOR APPLICANTS
SUBMITTING
STAGE 1 APPLICATIONS

NIHR Research Standard Application Form (SAF)

Stage 1 Application Form

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.

2. Lead Applicant CV

Complete your name, contact details and other requested information.

3. Lead Applicant Research Background

Publication record

Provide details of a MAXIMUM of 6 of your most recent / relevant publications (in the last 10 years) relevant to this application (using Vancouver or Harvard citation format) listed one after another with a blank line between each one. Please use DOI reference numbers if needed.

Research Grants Held

This should include research grants held (as a named applicant) CURRENTLY or IN THE LAST 5 YEARS – as well as any additional previous grants, relevant to this application. Please include 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).

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 see 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. Indicate which of the NIHR funding streams you are applying to.

4. The Research Team

Specify your (lead applicant) role in this research

Explain in addition to your role as Lead Applicant, the role that you will be undertaking in the research, e.g. co-ordination and project management, analysis, methodological input etc.

%FTE

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

Co-Applicants

Add details of all co-applicants and their specific role in the project. The number of co-applicants is calculated automatically. Do not include collaborators, who should be mentioned (if necessary) in the 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

A plain English summary is a clear explanation of your research.

Many reviewers use this summary to inform their review of your funding application. They include clinicians and researchers who do not have specialist knowledge of your field as well as members of the public. If your application for funding is successful, the summary will be used on National Institute for Health Research (NIHR) and other websites.

A good quality plain English summary providing an easy to read overview of your whole study will help:

- those carrying out the review (reviewers and board and panel members) to have a better understanding of your research proposal
- inform others about your research such as members of the public, health professionals, policy makers and the media
- the research funders to publicise the research that they fund.

If it is felt that your plain English summary is not clear and of a good quality then you may be required to amend it prior to final funding approval.

It is helpful to involve patients / carers / members of the public in developing a plain English summary.

Content

When writing your summary consider including the following information where appropriate:

- aim(s) of the research
- background to the research
- design and methods used
- patient and public involvement
- dissemination.

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

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 PHR [Programme Advisory Board \(PAB\)](#) assess all proposals based on public health importance. The PAB make their assessment based on the Plain English Summary of Research, sections 1-4 of the Research Plan, as well as section 5.2, the planned intervention. Other sections of the SAF are not shared with the PAB.

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 this 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.

1. What is the problem being addressed?

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 explain how your proposed research is within the remit of the PHR programme and how it will generate evidence to inform the delivery of non-NHS public health interventions.

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.

In your response, please refer to the criteria set out below:

1. *Health need:* Please identify the anticipated benefits in terms of improving the health of the population and reducing inequalities in health. This may cover the potential to promote or protect health, or to prevent ill health, reducing avoidable mortality or morbidity, or improving quality of life. Benefits may also arise from improving the acceptability, effectiveness, and cost effectiveness of interventions, with better targeting and equity of access to services.
2. *Expressed need:* Please state how the research or evidence generated will be relevant and important to the need to improve public health.
3. *Sustained interest and intent:* Please provide evidence that the issue or area is one in which there will be sustained interest in the future, such that the results of research once commissioned and undertaken will remain relevant and important to public health in the future.
4. *Capacity to generate new knowledge:* Please identify the existence of uncertainty or “knowledge gaps” which cannot be addressed by the existing body of research in this area and that require new research.
5. *Generalisability and transferability of findings and prospects for change:* The PHR Programme wants to ensure that the findings of the research it funds benefit as many people as possible. PHR will, therefore, be looking for evidence and an explanation

as to how findings can be used and translated for implementation in routine policy or practice and will be generalisable beyond the participant group/location for your study.

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. Proposals that include primary research should reference the existing evidence, including within the PHR portfolio and those of other funders, and explain how this evidence has informed the proposed research. Where a systematic review already exists that summarises the available evidence this should be referenced, as well as including reference to any relevant literature published subsequent to that systematic review. Where no such systematic review exists, it is expected that the applicants will undertake an appropriate review of the currently available and relevant evidence (using as appropriate a predetermined and described methodology that systematically identifies, critically appraises and then synthesises the available evidence) and then present a summary of the findings of this in their proposal.

4. What is the research question / aims and objectives?

Please summarise the research question / key aims and objectives.

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

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

1. **Research Design: *Primary Research*:** please provide a clear summary of the study design, including all of its components (e.g. primary and secondary outcomes, process and economic evaluations) and relevant time points for baseline and follow-up data collection for each component. Reference should be made to established research techniques and any adaptations of these for the purposes of the research proposed should be fully explained and justified. Where an RCT is being proposed please describe and justify the chosen method of randomisation. **Evidence Synthesis:** if you are proposing a systematic review and/or an evidence synthesis, details regarding the size of the available literature base should be provided, along with details of the search and review strategy.
2. **Planned intervention:** you should include details of the planned intervention(s) and components, and their frequency and intensity, theoretical basis, specific techniques used, modes of delivery, and who will deliver the intervention. You may like to refer to the TiDIER guidance on reporting interventions (Template for Intervention Description and Replication (TiDieR), <http://www.bmj.com/content/348/bmj.g1687>).
3. **Control/comparator group:** please state what appropriate comparator(s) will be used in an evaluation and how it will be selected.
4. **Study population:** which population(s) will be the target for the intervention and the subject of the research? How will the population(s) be recruited and retained?
5. **Setting:** where will the research be undertaken and the intervention delivered?
6. **Outcome measures:** please state and justify the primary and secondary outcome measures.

7. **Methods for data collection:** for each outcome, process or economic measure proposed, please state the method of data collection, including qualitative methods where appropriate.
8. **Sample size:** please justify the proposed sample size for each element of the study. Justifying the values used in the calculation by giving their source or some sensitivity around assumed values.
9. **Data & Statistical analysis:** please provide details of how each study data set will be analysed. Clearly state the purpose of any statistical analysis. The proposed type and frequency of analyses must be stated including the selection of participants to be included in the analyses. Describe any planned interim and sub-group analyses, sensitivity analysis and how missing data will be handled.
10. **Health economic evaluation:** to inform affordability and return on investment a health economic evaluation should be included in your study. If you do not intend to include a health economic evaluation, justification for why this is not appropriate should be provided.
11. **Research Governance and Ethical approval:** please indicate what research governance issues will need to be addressed in your research and state how ethical approval will be sought and obtained. Applicants must either comply with the research ethics framework formulated by the Economic and Social Research Council (ESRC) or obtain approval via the National Research Ethics Service (NRES).
12. **Project timescale and milestones:** please provide a clear indication of the study timescale and dates by which key milestones should be achieved.
13. **Study management:** please state how and by whom the study will be managed, referring to the roles of specific applicants as appropriate.
14. **Public involvement:** the NIHR expects the active involvement of patients and the public and other key stakeholders in the research it supports. In this section it is important that you describe how patients and the public, as well as relevant stakeholders (including evidence users), have been involved in the development of the application as well as plans for involvement in the proposed research. For more guidance, please our website; <http://www.nets.nihr.ac.uk/ppi/resources-for-researchers>.
15. **Dissemination, knowledge exchange and impact:** Explain how the findings from the proposed research will be disseminated to key stakeholders and end users and what other methods will be used to maximise the potential impact of the proposed research. Describe who the likely beneficiaries of the research are, when are they likely to benefit and in what ways. Applicants should clearly state the public health utility of their project outcomes and the mechanisms by which they will inform future public health policy and practice. Details about the potential impact and scalability of interventions, if shown to be effective, should be provided. This includes how health economic evaluation will inform affordability and return on investment where appropriate.
We acknowledge that defining impact can be challenging and pathways to impact are complex with many steps beyond your control. We therefore define impact broadly as the contribution, effect on, or benefit that excellent research makes to knowledge, people, health and care, the NHS, health and care services, society, the economy and policy. We wish to understand the ways in which the proposed research will change activity, attitudes, awareness, behaviour, capacity, opportunity, performance, decision-making, practice or processes. Impact can also result from new understanding that benefits individuals, population, organisations, communities, constituencies or the nation.
Link to NIHR Dissemination guidance: [How to disseminate your research: Getting your message heard - and used](#).
16. We require that all NIHR funded research will be reported fully and made publicly available when the research has been completed. It is expected that research funded by the NIHR PHR Programme will publish a full and complete account of that research in the NIHR PHR Journal. This will ensure that this research is reported fully, and is publicly available with the abstract and full report freely available via the NIHR Journals Library website and the abstract freely available via Europe PubMed Central.
We expect that all researchers who have a contract with the NIHR to undertake research shall ensure that the outcome of the research is prepared as one or more research papers for publication in suitable peer-reviewed journals.

17. Further guidance

All applications to the PHR programme that propose to carry out **feasibility and/or pilot studies** should include clear criteria to judge whether progression to the definitive study is justified. If a definitive trial is being proposed details of any prior feasibility and/or pilot work should be included as an upload. How the progression criteria of the feasibility and/or pilot study have been met should also be detailed. There are no set **progression criteria** to use but they should aim to address whether the uncertainties that were set out to be resolved in the preliminary studies have been determined. Examples of progression criteria could include (but not limited to):

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

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

18. **Collaborators:** Collaborators normally provide specific expertise on particular aspects of the project. Please detail who your collaborators are and how they have aided the development of the proposal. Where possible letters of support from collaborators should be added as an upload.

7. Uploads

ATTACHMENT 1: FLOW DIAGRAM

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

You should also upload a logic model (single-side of A4), as a separate PDF file, to support the application. The logic model should describe the theory of change underpinning the intervention. You may find it useful to refer to the Nesta Guidance when developing your logic model:

<https://www.nesta.org.uk/toolkit/theory-change/>

PHR are unable to fund intervention costs, it is important that letters of support from funders are included as uploads. These will be mandatory within the stage 2 application.

ATTACHMENT 2: REFERENCES

Upload a list of references used throughout your proposal, using either the Vancouver or Harvard referencing conventions (maximum 1 side of A4).

ATTACHMENT 3: CTU support letter (if required / appropriate to the study)

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

ATTACHMENT 4: Logic model or equivalent

Where appropriate please supply a logic model or equivalent

ATTACHMENT 5: Letters of support

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

ATTACHMENT 6: Papers in press

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

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.

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.

(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 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)
- A logic model (document upload)
- Letters of support (document upload)
- Papers in press (document upload)
- CTU letter of support (if appropriate) (document upload)