Research for Patient Benefit Programme - Guidance for Stage 1 applications

This document provides guidance on completing a Stage 1 application for the <u>NIHR Research for Patient Benefit (RfPB) Programme (/explore-nihr/funding-programmes/research-for-patient-benefit.htm)</u>. Please see also the <u>supporting information for Stage 1 and Stage 2 applicants (/documents/research-for-patient-benefit-supporting-information-for-stage-1-and-stage-2-applicants/20442).</u>

We supply a word document version of the online Stage 1 application form to help researchers prepare their proposal ahead of submission. This is to be used as a guide and to assist with completion of the online application form only. Please do not try to use this as an application form. You must apply using the online form in the Research Management System (RMS) (https://ccfrms.nihr.ac.uk/Login.aspx), available when calls are open.

Download a word version template of the Stage 1 online Standard Application Form:

(/media/21786/download/)

NIHR-Template-Application-Form-stage-1.docx

DOCX

Last updated: 13 September 2024

Download document (51.27 KB)

Recent changes to NIHR Stage 1 application form and guidance notes

As part of NIHR response to the Government's call for <u>further reduction in bureaucracy (/news/nihr-responds-to-the-governments-call-for-further-reduction-in-bureaucracy-with-new-measures/25633) in August</u>

2020 the Stage 1 application was reduced in scope. The changes include:

- Section 2: the lead applicant's research background and details of the history of the application are no longer required at this stage.
- Section 3: less information is requested at this stage about the joint lead applicant.
- Section 5: the 'Research plan' has been limited to 3000 words, that is 3-4 pages
- Section 10 and specifically the pre-submission checklist for applicants has been removed.

In May 2020, the application guidance notes were 'refreshed' to include important NIHR changes and updates that applicants still need to take note of and reflect in their stage 1 applications. The changes/updates include the following:

- More explicit guidance for applicants on NIHR's expectations with regard to patient and public involvement
- New guidance for applicants on Equality, Diversity and Inclusion for study participants (research following patient need and clusters of morbidity)
- New guidance information about the provision of applicants equality and diversity monitoring information, in the <u>Supporting information for Stage 1 and Stage 2 applicants</u>
 (/documents/research-for-patient-benefit-supporting-information-for-stage-1-and-stage-2-applicants/20442)
- A broadening of the guidance wording to ensure appropriateness for social care research

Section 1: Application Summary Information

Host Organisation

Provide details of the organisation who will be the contractor if the programme is funded.

Research Title

The programme title should state clearly and concisely the proposed research. Any abbreviations should be spelled out in full. The title should also reflect the study research design.

Research Type

Select the appropriate research type. If your proposed programme includes any element of primary research, please select 'Primary Research'. If you are carrying out a 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 the 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 entered the start date and research duration information.

Estimated Research Costs

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

PLEASE NOTE: Applicants should no longer include open access costs as part of their stage 1 estimated application Research Costs.

From the 1st of June 2022 all eligible awards contracts issued across NIHR Programmes, NIHR Personal Awards and NIHR Global Health Research Portfolio will have an Open Access Envelope allocated to them on top of the award value, which is ring-fenced for open access costs of peer reviewed research articles that arise directly from the research funded by the award in question.

Further information can be found by reading the Open Access Funding Guidance (/documents/nihr-open-access-publications-funding-guidance/30210).

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.

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. (Limit: 200 words)

Agreement to terms and conditions

As lead applicant, please tick the box to confirm that the information entered into the application form is correct and that you take responsibility for overall management and delivery of the research.

Section 2: Lead Applicant CV

Complete your name, contact details and other requested information.

Section 3: 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. coordination and project management, analysis, methodological input etc. (Limit: 100 words)

%FTE Commitment

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

Joint Lead Applicant

Where appropriate and justified it is acceptable for the application to be led by joint Lead Applicants. Where this applies, please complete your name, contact details and other requested information.

NOTE: Early career researchers leading applications to RfPB are encouraged to apply as Lead Applicant, with a more senior colleague fulfilling the role of mentor and Joint Lead Applicant.

Justification for Joint Lead Applicant and role in this research

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. Please also provide a brief

overview of their role in the proposed research. (Limit: 150 words)

NOTE: Clearly describe how the Joint Lead Applicant will provide mentorship and guidance for the early career researcher fulfilling the role of Lead Applicant. 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 provision.

%FTE Commitment

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

NOTE: For application/contracting purposes, the joint lead applicant will be counted as a coapplicant.

Co-Applicants

Add details of all co-applicants and their specific role in the programme. Do not include collaborators, who should be mentioned (if necessary) in the Research Plan section of the form.

We encourage the inclusion of public co-applicants, where appropriate. Please include a clear description of their role and the reasons why a public co-applicant is joining the team. For further information please access the <u>'Public Co-Applicants in Research' guidance</u> (https://www.learningforinvolvement.org.uk/content/resource/public-co-applicants-in-research-guidance-on-roles-and-responsibilities/?). (Limit: 25 words)

Co-applicants are those individuals with responsibility for the day to day management and delivery of the project and can include patients, carers and service users. Co-applicants, including public co-applicants, are considered part of the project team and are expected to share responsibility for its successful delivery. In contrast, collaborators normally provide specific expertise on particular aspects of the project but do not share in the responsibility for the delivery of the project.

PPI Lead

There should be a named person with appropriate skills and experience who is responsible for leading the PPI element within the project. This role should be adequately costed and resourced research team member who is able to manage the PPI plans and related activities. More information and examples of the activities a PPI lead might undertake can be found in our guidance on the NIHR website (/documents/definition-and-role-of-the-designated-ppi-patient-and-public-involvement-lead-in-a-research-team/23441).

Section 4: Plain English Summary of Research

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, other practitioners 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 the 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 committee members) to have a better understanding of your research proposal
- 2. inform others about your research such as members of the public, health professionals, policy makers and the media
- 3. 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 / service users / practitioners and members of the public in developing a plain English summary. (Limit: 450 words).

Content

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

- 1. aim(s) of the research
- 2. background to the research
- 3. design and methods used
- 4. patient and public involvement
- 5. 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. (/documents/plain-english-summaries/27363)

For further support and advice on writing a plain English summary, please contact the NIHR Research Support Service (/node/48001) (where applicable).

Section 5: Research Plan

Using all of the headings in the order presented below, please use this section to clearly explain your proposed research. Schematics, tables, illustrations, graphs, and other types of graphics can be embedded to clarify the research plan but they should not clutter the central narrative. Images do not count towards the overall word count but inclusion of them to overcome word limits is not permitted. Images may only be included within the 'Research Plan.' Images included in other sections will be removed from the application and not seen by reviewers.

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, clearly laid out and provides sufficient methodological detail. The overall amount of information that you can provide at this stage is limited to 3 - 4 pages (dependent on the type/complexity/scale of study proposed). (Limit: 3,000 words).

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

A list of PPI resources for applicants to NIHR research programmes (https://www.nihr.ac.uk/research-funding/application-support/working-with-people-and-communities) is available on the NIHR website, including: Briefing notes for researchers on how to involve patients/service users, carers and the public (https://www.nihr.ac.uk/briefing-notes-researchers-public-involvement-nhs-health-and-social-care-research), including definition of involvement engagement and participation (/get-involved); and Payments Guidance for researchers and professionals with information on budgeting for involvement (https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392)

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.

What is the problem being addressed?

Provide a clear explanation of the health problem to be addressed, the impact on patients/service users, carers, practitioners as well as health and care services, and how this research would fill a demonstrable evidence gap, addressing patient/service user and carer needs and DHSC priorities (at national or local levels).

Explain how your proposed research is within the remit of the RfPB programme and how it addresses the key aim of the programme to produce research findings that will have practical application for the benefit of patients, service users, carers, the public or populations, and the NHS or social care sector in the relatively near future.

Applicants are reminded that the application will be reviewed by assessors who may not have a detailed understanding of the particular clinical, public health or social care area that your application relates to. It is vitally important that you clearly tell the story of why this research is important, and how it will make a stepped change to practice and/or outcomes. The committee is looking for novel approaches. Research which, in the committee's view, represents only an incremental development on current practice, or is unlikely to have general application / uptake is unlikely to be supported. Research which improves efficiency and effectiveness (rather than increasing workload in an already stretched NHS) is welcomed.

Please indicate under this question if you are responding to any <u>current NIHR themed call</u> (https://www.nihr.ac.uk/research-funding/themed-calls) or <u>ongoing research priorities</u> (https://www.nihr.ac.uk/research-funding/themed-calls#two:~:text=the%20first%20instance.-, Our%20highlight%20notices,-We%20also%20publish).

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 that your research aims to address. Please outline the anticipated value or contribution the study will provide.

Briefly describe:

- 1. the importance of the proposed research and its relevance to the priorities and needs of the NHS (including a statement of the significance of the research area, e.g. burden of disease). If you are responding to a themed call or highlight notice, please explain how your proposed research addresses the key themes of the call or notice.
- 2. the anticipated outputs, outcomes and impact of the proposed research on the health of patients/service users, carers and/or the public, highlighting the trajectory to patient benefit and

quantifying the potential benefits, where possible

3. the anticipated timescale for the benefits resulting from the proposed research to be realised.

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.

Briefly describe:

- the need for research in this area, drawing particularly from systematic reviews (including NHS
 context and relevant literature), and the rationale for the particular lines of research you plan to
 pursue.
- 2. past and current research that justifies the proposed research and shows that it will add distinct value to what is already known, or in progress
- 3. work undertaken previously by the research team which has led to the proposed programme (e.g. describe any pilot or feasibility data).

Applicants should be aware of ongoing research in this area and comment on any other research which might be deemed to overlap with the contents of the proposal. Applicants are advised to use both PubMed Central and Europe PubMed Central for recent material on the relevant topic area(s).

Any applications that include primary research should include reference to the existing evidence 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, along with 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 summarise this in their proposal. All applicants must also include reference to relevant ongoing studies, e.g. from trial registries such as the International Standard Randomised Controlled Trial Number (ISRCTN) registry, ClinicalTrials.gov and the European Union Clinical Trials Register.

For further information please read about our <u>Adding Value in Research model</u> (https://www.nihr.ac.uk/adding-value-research-appropriate-research-design-conduct-and-analysis), aimed

at ensuring that our research answers the most important questions and is appropriately designed, efficiently delivered, unbiased, published in full, appropriately disseminated, and usable.

What is the research question/aims and objectives

This section should be used to indicate the overarching aims/objectives of the research, outlining the key question(s) which the work will address and, where appropriate, the main hypothesis

Project Plan

NOTE: Applicants should aim to reserve a significant proportion of the word limit for the project plan to ensure methodological approaches are fully specified.

Applicants are reminded that NIHR strategy encourages research which follows patient/service user, carer need. Researchers should clearly articulate how their research meets this objective, and how this contributes to the scientific rigour of their research study. Studies should recruit participants from geographical areas where patient/service user, carer need is greatest, including for example the rural and semi-rural areas where many older people live, and represent areas of diverse socioeconomic and ethnic diversity.

Equality, inclusion and diversity should also be properly considered when planning and describing the research, and evidenced in the application.

Guidance for applicants on Equality, Diversity and Inclusion for study participants

Every person eligible to take part in research should be offered the same opportunity of taking part in that research regardless of:

- Geographical location
- Age
- Disability
- Gender reassignment
- Marriage and civil partnership
- Pregnancy and maternity
- Ethnicity for example:
 - The Centre for Ethnic Health Research toolkit for increasing participation of BAME groups
 in health and care research (https://ethnichealthresearch.org.uk/research/resources-2/increasing-diversity-in-research/)

- The <u>INCLUDE Ethnicity Framework (https://www.trialforge.org/trial-diversity/include/)</u>, which aims to improve trial delivery for under-served groups
- Religion or belief
- Sex
- Sexual orientation
- Socioeconomic status
- Access to health or social care

All NIHR applications are expected to include information about how this data will be collected. In addition, applicants should demonstrate how these factors have been considered and addressed in their proposal, including steps taken to ensure the research sample is representative of the population the study is targeted at. Applicants need to explain who they are planning to recruit to ensure inclusivity of study participants and justify and explain any exclusions, for example by completing an Equality Impact Assessment. Costs associated with inclusivity, which may include, but are not limited to justified translation of research participant material into other relevant languages, would be expected and where appropriate should be included in the detailed budget section under 'Other Direct Costs' if shortlisted. Additionally, applicants should demonstrate that all potential recruiting locations have been considered and the research is deliverable to those areas.

Please see the NIHR INCLUDE Guidance for more information about how to include under-served groups effectively:

• NIHR INCLUDE Guidance (General) (https://www.nihr.ac.uk/improving-inclusion-under-served-groups-clinical-research-guidance-include-project)

Helpful links:

• NIHR promoting equality, diversity, and inclusion in research (/about-us/who-we-are/research-inclusion)

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).

Research plan/methods

Describe the proposed research plan and how it will achieve the project's aims/objectives. If there are multiple work streams, provide brief descriptions of each one and detail how they will be integrated into a coherent programme of work. Specify the methodological approaches proposed in sufficient detail to allow them to be assessed (justification for sample sizes, inclusion and exclusion criteria, recruitment strategy, nature of follow up, techniques of data collection, choice of analysis and why etc.).

Team

Briefly describe why the team is well qualified to do the work. If submitting with a joint lead applicant, justify why more than one person is needed to lead the proposal. The team should be multidisciplinary and include relevant expertise in the clinical, public health or social area concerned, e.g. operational research, PPI lead, public voice with lived experience, health economics (if appropriate) etc.

There should be a named person with appropriate skills and experience who is responsible for leading the PPI element within the project. This role should be an adequately costed and resourced research team member who is able to manage the PPI plans and related activities. More information and examples of the activities a PPI lead might undertake can be found in our guidance on the NIHR website. (https://www.nihr.ac.uk/role-patient-and-public-involvement-ppi-lead)

Please also list and explain the role of key collaborators involved in the research, as well as any patient and public leads (not previously listed as co-applicants). Collaboration with other stakeholders such as Clinical Trials Units should also be described.

Timetable

Briefly detail the timetable for the proposed research, including key milestones and deliverables.

PPI (Patient/service user, carer and public involvement)

The NIHR expects appropriate and well-designed involvement of patients/service users, carers and the public and other key stakeholders in the research it supports. In the Stage 1 application, it is essential to show your plans for involving patients/service users, carers and the public at each appropriate stage of the research project life cycle. For example, sitting on oversight committees, being a member of the research team involved in activities such as recruitment, data collection, analysis, producing study materials and sharing findings. Your PPI plans will be assessed by the funding committee which includes patient and public members. In the rare circumstances where PPI is not appropriate, a clear justification must be provided.

You should also outline how PPI has informed the development of the project so far. For example, the involvement of patients/service users, carers or the public in shaping the research question and

study design. These activities could include the development of feasible, relevant and acceptable recruitment plans, data collection tools, information materials, outcome measures, follow-up, intervention design and delivery.

For a Stage 2 application, you will be asked how the PPI will be managed, reported and evaluated; whilst it is not necessary to provide the detail in Stage 1, early consideration should be given to these aspects.

More resources to support the design of your PPI are available in our guidance on the NIHR website (https://www.nihr.ac.uk/research-funding/application-support/working-with-people-and-communities). Your initial application will be assessed by a public committee member who will consider this aspect of your proposal.

Provide information on the potential impact that the project might have. We acknowledge that defining impact can be challenging and paths 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 or the economy. 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.

Dissemination

Please describe the main knowledge products or 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 they are likely to benefit and in what ways, and describe how the knowledge will be translated into the real world. It is important to include details of how you will share the progress and findings of the study with study participants.

Further information and help can be found in our <u>guidance on how to disseminate your research</u> (https://www.nihr.ac.uk/how-disseminate-your-research).

For pilot or feasibility studies, clear progression criteria to the substantive study should be provided, including identification of the potential funder of the substantive study. Time should also be allocated to the development of the protocol for the substantive study should the proposed pilot or feasibility study be successful.

References should be provided as an attachment (see Section 6: Uploads).

Section 6: Uploads

Mandatory

One single-side A4 page, listing references used throughout your proposal.

Non-mandatory

If required, an additional supporting (single side of A4) document can be submitted with your application form (e.g., a flow diagram illustrating the study design and the flow of participants, gantt chart, diagrams, pictures etc.). If submitting a flow diagram, 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 (https://www.consort-spirit.org/) for guidance. Alternatively, you may find the EQUATOR Network website (https://www.equatornetwork.org/) useful. The PDF file should be submitted along with your application form.

Section 7: Administrative Contact Details

Please provide the details of an administrative lead as a secondary point of contact for any queries relating to the application, should it be supported.

NOTE: This person does not need to be a co-applicant.

Section 8: Research and Development Office Contact Details

Please provide the contact details and job title of a person in the R&D office so that we are able to notify them of the Stage 2 outcome of this application including any associated feedback.

NOTE: Please note this person does not need to be included as a co-applicant

Section 9: 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

As lead applicant, please tick the box to confirm that the information entered into the application form is correct and that you take responsibility for overall management and delivery of the research.

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

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

Action	Checkbox
A good quality plain English summary (/documents/plain-english-summaries/27363)	-
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 (/research-funding/application-support)	-
A single A4 page of additional supporting documentation (document upload), if appropriate	-
A single A4 page of references (document upload), mandatory	-