National Institute for Health Research

Invention for Innovation (i4i)

Product Development Awards

Guidance for Stage 1 Applications

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.

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 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. Please note, i4i projects can be up to a maximum duration of 36 months.

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).

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.

Section 2: Lead Applicant CV

Complete your name, contact details and other requested information.

Section 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). Please use DOI reference numbers if needed.

Research Grants Held
Please select 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 stating 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). For more information about resubmission of a research/trainee funding application, or joint funding please contact the appropriate NIHR research funding programme.

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.

Section 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.

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.

Justification for Joint Lead Applicant
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
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.

Specify role in research
Please provide a brief overview of your role in the proposed research. You have the opportunity to elaborate upon this further in the **'Research Plan'** section.

%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 co-applicant.

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

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 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 do not share the responsibility for the delivery of the

project.

Section 5: 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 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:

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

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

a) aim(s) of the research
b) background to the research
c) design and methods used
d) patient and public involvement
e) dissemination

The plain English summary is not the same as a scientific abstract - please do not cut and paste this or other sections of your application form to create the plain English summary.

Further guidance on writing in plain English is available online at NIHR Make it clear http://www.invo.org.uk/makeitclear/.

For further support and advice on writing a plain English summary, please contact your local Research Design Service (where applicable).
http://www.nihr.ac.uk/about-us/how-we-are-managed/our-structure/research/research-design-service/

Section 6: 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 panel, 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 - 5 pages (dependent on the type/complexity/scale of study proposed). (Limit: 4000 words).

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 problem to be addressed, the impact on patients, the public and health and care services, and how this project would fill a demonstrable gap.

Describe the current unmet need both within the NHS and globally and how your proposed solution would meet these needs.

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. Outline the anticipated value or contribution the intervention will provide, making a clear health economic case and indicating the anticipated timescales for any proposed impacts to be realised.

Describe how the proposed solution may have an impact on patient benefit (such as reduced mortality or morbidity, improved quality of life, reduced misdiagnosis, improved patient outcomes and experiences) and/or on future health care provision and long-term outcomes, comparing it with the existing standard of care and any other competing solutions in development or on the market. Describe why your approach is superior and what its benefit would be over existing NHS practice.

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

Explain why this research is needed now, in terms of time, relevance and competing solutions. We will only fund research which is informed by a review of the existing evidence.

Describe the level of innovation of the proposed technology, clearly stating the current level of development of the proposed solution, including what technical and clinical validation (proof of concept) you have to date, and what challenges remain to be addressed and overcome.

4. What is the research question /aims and objectives

Please summarise the research question, key aims and objectives.

Projects in this programme will vary considerably in their design; however, it is expected that applicants will clearly describe:

- The problem to be addressed
- The technology to be developed, stating the current status of development
- The key aims for the project, including key measures of success, project deliverables and project milestones
- The proposed project exit point

5. Project Plan

Provide an expert summary of the project plan 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 research design and methodology).

The project plan should include the following:

- The individual work packages within your project and your project milestones (a Gantt chart may be

attached in the supporting information)
- A description of the main hurdles to be overcome technically, clinically and commercially
- The key risks to your project (including financial and IP risks) and the steps you will take to manage and mitigate these risks. Ensure that these risks are considered when defining milestones (the go/no go points for your project).
- An explanation of the role of key collaborators and sub-contractors involved in the research, as well as any patient and public leads (not previously listed as co-applicants). Sub-contractors provide external specialist services which cannot be provided by the organisation leading the project or its co-applicants or collaborators. Services include, for example, consultancy, design services, or the development and provision of specialist equipment. These costs can be requested for organisations providing these services in a territory that is outside England, but suitable justification is required.
- A description of how patients and the public, as well as other relevant stakeholders, including evidence users, have been involved in the development of the application, will actively be involved in the proposed research and how this involvement will benefit the project. Describe the reasons for the selected approach and any arrangements for training and support. If you are invited to submit a full application, your outline application will be assessed by a public panel member who will consider the patient and public involvement aspect of your proposal, and feedback will be provided for you to be considered in the full application.

6. Intellectual Property & Commercialisation

The definition of Intellectual Property (IP) includes patents, trademarks, designs, 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).

- Provide details of any existing IP and ownership arrangements, including patents or patent applications that are relevant to the project.
- Indicate the procedure you used to evaluate your freedom to operate (FTO) position.
    - Please describe any FTO searches conducted to date and details of who carried them out.
    - Please list all related IP not owned by any of the applicants, including details relating to third party IP licensing requirements.
    - If no search has been conducted to evaluate FTO, please explain your rationale.
- Provide details of any IP which will be produced or improved during the proposed research by any of the partners.
- Provide details of how any new IP generated through the proposed research will be recognised, captured, managed and utilised, providing information on who will lead on dissemination and/or commercial exploitation.
- Describe any competitive technologies that exist on the market or are currently in development and how your proposed technology is different.
- Describe how long (in years) it will take from the project start date until the technology/solution is patient-ready, assuming that all necessary follow-on funding and commercial resources become available after the i4i project is successfully concluded.
- Explain how you will ensure that your technology is adopted in the healthcare service. Please outline your intended strategy including the current and future barriers which may hinder the adoption of this technology and how these will be overcome.
- Please outline the proposed route to market for your technology. Ensure that any regulatory hurdles arising are clearly indicated and how these may impact on the success of the technology. You should also indicate whether the project team or a third party (i.e. commercial partner) will be responsible for overcoming these hurdles.

Section 7: 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 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.

Section 8: 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 9: 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 outcome of this application including any associated feedback. In the event of this project being recommended for funding, we would also need to communicate with this person with regard to contract negotiations and general management of the project throughout its duration.

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

Section 10: 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 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
http://www.invo.org.uk/ ☐

A single A4 page of references (document upload), mandatory ☐