National Institute for Health Research

Invention for Innovation (i4i)

Guidance for Stage 2 Applications

Section 1: Application Summary Information

Host Organisation
Provide details of the organisation who will be the contractor if the project is funded.

If you have any queries, please contact i4i@nihr.ac.uk before submitting your application.

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 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.

End Date
This field will automatically populate once you have entered the start date and research duration information.

Total (Stage 2) Research Costs
This will be automatically pulled through from the budget section.

Total (Stage2) 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: CV - Lead and Co-applicants

Complete your name, contact details and other requested information.

Co-applicants who are patients, service users or carers are not obliged to complete a standard CV but are required to provide a summary of any knowledge, skills and experience relevant to their role in the application in a separate text box. This appears when 'yes' to indicate if co-applicants are a member of the public.

We recognise and value the varied perspectives that patients / service users and carers bring to a project as applicants. In this section, please provide a summary of any relevant knowledge, skills and experience that you will draw upon to contribute to this project.

This could include information about:

- Previous or present work (paid or unpaid) with any relevant organisations
- Links with any relevant groups, committees, networks or organisations
- Experience of particular health conditions, treatments, use of services - or as a member of a particular community
- Knowledge and experience of research including previous research undertaken
- Knowledge and experience of patient and public involvement including previous involvement activities
- Skills from any other roles that are transferable
- Relevant qualifications, training and learning.

The bullet point list above is not exhaustive. Please include anything else that is relevant to the application.

Section 3: Research Background - Lead and Co-applicants

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, edit 'Manage My Details' to ensure that your record of research grants held (as a named applicant) is complete and up to date – please 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?

To be completed by the lead applicant only.

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.

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 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.

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 Detailed Research Plan section of the 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.

Allow sufficient time for your co-applicants to complete their sections of the online form **before** the application deadline.

Section 5: Other supporting roles – signatories (electronic)

Other supporting roles
The following supporting roles from the host organisation must be added to the application:

i) Director of Finance
ii) Head of Department or Senior Manager

If the host organisation, e.g. an SME, does not have these supporting roles, these fields should be completed with the details of the person fulfilling these functions.

Electronic signatures

On assigning these contacts an email will be sent to each of them by the system. They will be required to tick a check box indicating that they have read and understood the terms on which they have been nominated for this proposal and accept this role. Ticking this box constitutes an electronic signature of the supporting role for the full application.

At the time of adding the necessary supporting roles required to approve your application you are advised to inform the R&D office of the site most likely to be the lead site for your proposed research. The aim is to help

speed up the permissions process should your application be successful. Please note this will not apply to all proposals.

The Lead Applicant will also be required to tick a checkbox to indicate that they have read and understood the terms on which he/she has been nominated as Chief Investigator for this proposal and accept this role (see page 22).

Once everyone has approved the application you will be able to proceed to submit.

No original or 'wet ink' signatures are required for this application

Section 6: Scientific Abstract

The scientific abstract should be a clear and concise scientific summary of the Detailed Research Plan / Methods.

The following is a list of potential elements / headings that might be included depending on the design of the proposed research, the setting and programme being applied to, and whether it is for primary research or evidence synthesis. It will be for researchers to decide the appropriate elements to be included in the scientific abstract and could include elements outside this list. Applicants may find the guidance on the EQUATOR Network website (www.equator-network.org) useful.

Research question
Background
Aims and objectives
Methods
Timelines for delivery
Anticipated impact and dissemination

Section 7: 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:

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.
Content

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 8: Changes from First Stage

Please list the feedback received at first stage and under separate headings indicate what has changed as a result.

Please describe and explain any additional changes that have been made to this proposal since the stage 1 application e.g. in the light of new research.

Section 9: Detailed Research Plan

Using all of the headings (in the order presented) and guidance below, 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 adequate detail. This section should not exceed 10 pages in Arial Font 11**.**

1. Background and Rationale

Briefly describe the background and rationale of the proposed research, addressing the following areas:
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.
Explain how your proposed research is within the remit of the i4i 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 and the NHS in the relatively near future.

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, making a clear health economic case and indicating the anticipated timescales for any proposed impacts to be realised.

Briefly describe:
a) 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)
b) The anticipated outputs, outcomes and impact of the proposed research on the health of patients and/or the public, highlighting the innovation and/or development aspects and quantifying the potential benefits, where possible
c) The anticipated timescale for the benefits to the NHS 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:
a) 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.
b) 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.
c) Work undertaken previously by the research team which has led to the proposed project (e.g., describe any pilot or feasibility data).
d) 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.

NOTE: We will only fund primary research where the proposed research is informed by a review of the existing evidence.
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. In particular, applicants are advised to use both PubMed Central and Europe PubMed Central for recent material on the topic area they are applying for. 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, 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 summarise this in their proposal. All applicants must also include reference to relevant on-going studies, e.g. from trial registries.
Further information can be found at:
https://www.nihr.ac.uk/about-us/our-purpose/principles/adding-value-in-research.htm

2. Aims and objectives

This section should be used to indicate the overarching aims/objectives of the research. It is expected that applicants will clearly describe:

- The key question(s) which the work will address and, where appropriate, the main hypothesis;
- 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.

3. Research plan/Methods

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 success criteria, outcome measures or research design and methodology).

The project plan should include the following:

- The individual work packages within your project, including deliverables and milestones (a Gantt chart must be attached in the supporting information). Work packages may focus on, for example, technical, clinical or commercial aspects of the project.
- A description of the main hurdles to be overcome technically, clinically and commercially.
- The key risks to your project (including technical, 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). You may upload a risk register as one of your documents.

This section should also clearly describe your IP and commercialisation strategy, with details of the following:

- Any existing IP and ownership arrangements, including patents or patent applications that are relevant to the project.
- The procedure you used to evaluate your freedom to operate (FTO) position.
  - Describe any FTO searches conducted to date and details of who carried them out.
  - 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, explain your rationale.
- Any IP which will be produced or improved during the proposed research by any of the partners.
- 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.
- Any competitive technologies that exist on the market or are currently in development and how your proposed technology is different.

4. Dissemination, outputs and anticipated impact

The purpose of this section is for the applicant to describe the planned outputs of the research, how these will be communicated and to whom, and how the research may lead to short and longer-term impacts. NIHR

understands that the impact of any research may take time to be realised and will likely involve other funders, institutions and sustained efforts in practice. NIHR also recognises it may be difficult to provide definitive answers or guarantees on longer term impacts. However, applicants are invited below to consider various aspects of pathways below and how the likelihood of impact can be maximised. This includes considering what outputs are produced, how these can be best connected to the healthcare environment, what efforts and investment are likely to be needed beyond the project, what barriers are likely to be encountered and what impacts the research is seeking to achieve.

i. WHAT DO YOU INTEND TO PRODUCE FROM YOUR RESEARCH?

Please provide brief details of each anticipated output. NB the term 'outputs' refers to *any* tangible product of the research, not just academic publications. Outputs can include but are not limited to: conference presentation or other workshop events; publications (academic or otherwise); guidelines (clinical, service or otherwise); other copyright (e.g. questionnaires, training aids, toolkits, manuals, software, etc.); new or improved design of medical devices or instrumentation; new or improved diagnostic; trial data that could be used to support a CE mark, market authorisation or equivalent; trial data that could be used to shape or influence a healthcare market or government; potential new drug or healthcare intervention.

ii. HOW WILL YOU INFORM AND ENGAGE PATIENTS, NHS AND THE WIDER POPULATION ABOUT YOUR WORK?

Describe who you need to communicate with within this research, and your plans for engaging relevant audiences. For impact, it is unlikely that simply making outputs available will be sufficient. Please consider, and outline the active approach you will take to engaging key parties, or identify the process you will use to identify them and formulate an engagement plan.

iii. HOW WILL YOUR OUTPUTS ENTER OUR HEALTH AND CARE SYSTEM OR SOCIETY AS A WHOLE?

Describe the process by which the research will enter the healthcare environment, including how your outputs will be acknowledged, selected and introduced for use in the health and care service or wider society. Where possible consider how the work will be able to be adopted and implemented longer term. Please describe the proposed route to market (commercial or non-commercial) for your outputs. Describe who is needed to take it forward and the relationship you currently (or propose to) have with these parties. If your outputs are likely to be commercially exploitable, please include details on how you plan to develop this.

iv. WHAT FURTHER FUNDING OR SUPPORT WILL BE REQUIRED IF THIS RESEARCH IS SUCCESSFUL (e.g. from NIHR, other Government departments, charity or industry)?

Consider what investment or support may be needed at the end of this project to maximise impact. Not all projects will require this but if so, plans should be linked to the responses in questions 2 and 3 above.

v. WHAT ARE THE POSSIBLE BARRIERS FOR FURTHER RESEARCH, DEVELOPMENT, ADOPTION AND IMPLEMENTATION?

Describe the difficulties which may be faced in generating impact from your research. These may be difficulties you will face yourself, or challenges faced by those in the implementing context (e.g., clinicians)

a) Will the proposed research use data, technology, materials or other inventions that are subject to any form of intellectual property protection (e.g. copyright, design rights, patents) or rights owned by another organisation(s)? If yes, provide brief details including how such third party IP will be accessed (e.g. collaboration agreement, drug supply agreement).

b) What are the key current and future barriers to uptake of any likely output or innovation directly in the health and care service, through commercial exploitation or other means, e.g.

potential regulatory hurdles?

c) What are the challenges for getting your research implemented in terms of acceptability, accessibility and feasibility? How will you address these?

vi. WHAT DO YOU THINK THE IMPACT OF YOUR RESEARCH WILL BE AND FOR WHOM?

Describe the impacts you aim to achieve as a direct result of the project and those which are anticipated longer term. Please consider how any smaller, more immediate effects may mature over time into larger scale or more significant effects, and the steps by which this may be achieved. As far as possible, indicate anticipated timescales for these benefits and a quantitative estimate of their scale. Impacts may include, but are not restricted to - patient benefit; healthcare staff benefits; changes in NHS service (including efficiency savings); commercial return (which could contribute to economic growth); public wellbeing.

5. Project/Research timetable

Describe the progression of the research plan, including the timetable, key milestones and, deliverables of each work package/work stream.

6. Project management

Explain the practical arrangements for managing the project. This should include specification of the roles and responsibilities of the individual team members who will undertake the proposed research, the management structure (i.e., reporting lines), the project manager (where applicable), frequency of meetings, financial management etc., and highlight the role of any Advisory or Reference Groups associated with the research.

7. Ethics / Regulatory approvals

Outline any ethical issues associated with this research and the arrangements for handling them. If there are no plans to obtain ethical review, this must be clearly justified. Note that work outlined in your application/protocol must adhere to the UK Framework for Health and Social Care Research (https://www.hra.nhs.uk/documents/1068/uk-policy-framework-health-social-care-research.pdf).

8. Patient and Public Involvement

Note that your description of how patients and the public have been involved in developing this proposal, and how they will be involved in the proposed research, should be captured in the three specific Patient and Public Involvement (PPI) questions asked elsewhere in the application form. Although you are encouraged to include information about PPI activities within the Detailed Research Plan section, there is no requirement to repeat or duplicate the responses to the three specific PPI questions. In rare cases where proposals do not involve patients or the public, clear justification must be provided, in response to the third PPI question.

INVOLVE has issued guidance for researchers about involving patients and the public in research, as well as about payment and support, including the Briefing Notes for Researchers and the Payment resource centre: http://www.invo.org.uk/posttypepublication/involve-briefing-notes-for-researchers/

http://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/

9. Project/Research expertise

Explain why the group is well qualified to do this research, describing the track record of the research team in health research, including publication outputs, grant income and impact on health research.

Explain how the applicants work together (or propose to work together if they have not done so previously), and identify other major collaborations important for the research. State clearly the particular contribution that

each of the applicants will make towards the project and provide 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.

Describe the existing research support (e.g. funding from other sources) available to the research team, which is relevant to this proposal. Clearly delineate the proposed project from other related research, funded from another source.

(If, for any reason, salary costs of members of the team are not going to be sought via this application, it should be made clear how their contribution will be supported in the 'Detailed Budget' section).

10. Success criteria and barriers to proposed work

Pease set out the measurements of success you intend to use and also the key risks to delivering this research and what contingencies you will put in place to reduce or eliminate each risk or its impact.

NOTE: A risk is defined as any factor which may delay, disrupt or prevent the full achievement of a research objective. Typical areas of risk for a research application might include staffing, resource constraints, technical constraints, data access, timing, management and operational issues (please note that this list is not exhaustive).

Upload a Gantt chart

It is mandatory to attach a Gantt chart indicating a schedule for the completion of work, including the timing of key milestones and deliverables.

Section 10: Patient and Public Involvement

Please describe how patients and the public have been involved in developing this proposal.

You should describe who has been involved and why this is appropriate, what role(s) they have they played and what influence or change has happened as result of their involvement

Please describe the ways in which patients and the public will be actively involved in the proposed research, including any training and support provided.

INVOLVE has developed guidance both on how patients and public can be involved http://www.invo.org.uk/posttypepublication/involve-briefing-notes-for-researchers/ and the processes, procedures and values necessary to support this involvement www.invo.org.uk. Patients and public can be involved in every stage of a research project, from developing a proposal through to dissemination and evaluation.

In your description, you will need to say who will be involved and why.

Explain why your approach to public and patient involvement is appropriate for this proposal. Describe how you will support and enable patient and public involvement in your research (e.g.: payments, training)

In rare cases where proposals do NOT involve patients and the public, clear justification must be provided.
Complete/justify as necessary.

Section 11: Detailed Budget

Justification of costs

Provide a breakdown of research costs associated with undertaking the research and provide justification for the resources requested, including the following:

i) staff costs,
ii) travel, subsistence and conference fees
iii) dissemination costs
iv) equipment (including lease versus purchase costs)
v) consumables,
vi) patient and public involvement
vii) any other direct costs

For help with estimating PPI costs please see the INVOLVE cost calculator available at http://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/involvement-cost-calculator/

When justifying staff costs you should also provide the % amount of time input of each member of staff and link this to the specific area/work package of the proposed study where this input will be taking place.

You should indicate here how this research will potentially benefit the NHS and/ or public health. For example, where appropriate, describe the likely cost savings or benefits in terms of numbers of patients treated, treatment times etc.

You should describe the value for money of the conduct of the proposed research.

Also provide a breakdown of the NHS costs associated with undertaking the research and provide justification for the resources required. If there are no NHS Support or Excess Treatment Costs associated with the research you must explain why you think this is the case.

Provide a breakdown of any non-NHS intervention costs and provide justification for the resources required. Non-NHS intervention costs should include costs incurred in delivering the intervention which would continue to be incurred after the trial, should the intervention become standard care.

Detailed Budget Breakdown

The finance section should provide a breakdown of costs associated with undertaking the research as described in the proposal.

Programme specific information

There is no upper or lower set limit for the size of these awards, although typically projects range from £300k-1m in value. Applicants should request a budget appropriate for developing their innovative solution to the point at which it is either attractive to follow-on developers/investors or is ready for deployment. All funding requests will be scrutinised to ensure they are eligible within the appropriate guidelines (see core finance guidance).

NOTE: Letters of support from the NHS body or other provider of NHS services and appropriate Network should be provided as evidence to demonstrate that the NHS Costs requested will be met should the application be supported.

General information

The information entered in this section should provide an analysis of the total funds requested to undertake the research proposed and should be based on current prices. These costs will be used to assess value for money.

It is in your best interest to undertake a thorough, realistic and accurate costing. Where an outline/stage 1 application has been produced and this is the full stage (2) application, the committee/panel will pay close attention to any material increase in costs. You must provide a clear and full justification for all costs including NHS costs. You must also ensure that you include all costs including those required to secure good research management.

- Costs must be provided at current prices. An adjustment for inflation will be made annually thereafter at rates set by the Department of Health and Social Care. Whilst allowances for incremental increases should be included on the form, nationally or locally agreed pay increases should be excluded.
- Years should be calculated starting from the anticipated start date of the proposed research. For example, if your research is expected to start on 01 June 2020 then its second year starts 01 June 2021.
- Further itemisation of costs and methods of calculation may be requested to support the application at a later date.
- Payments will be made to the contracted organisation only and the contracted organisation will be responsible for passing on any money due to their partner organisation(s).
- Appropriate sub-contracts must be put in place for any element of the research which is to be paid to another organisation.
- NHS support costs are funded via Clinical Research Networks. Researchers should contact their local NHS R&D department initially and, if they are unable to help directly or if there is no local NHS R&D department, contact the Local Comprehensive Research Network (LCRN) senior manager for advice on NHS support costs. Further details about LCRN contacts are available at https://www.nihr.ac.uk/nihr-in-your-area/local-clinical-research-networks.htm.
- All applications are expected to have appropriate NHS, HEI, commercial and other partner organisation input into the finance section of the application form.

Please note that whilst the applicable percentages will be used to calculate the maximum grant payable, the programme reserves the right to award a grant for less than this maximum where it is considered appropriate.

Information on different types of organisations

Higher Education Institutions (HEIs)

Higher Education Institutions (HEIs) should determine the Full Economic Cost (FEC) of their research using the Transparent Approach to Costing (TRAC) methodology**. For HEIs, up to 80% of FEC will be paid, provided that TRAC methodology has been used.**

NHS bodies and other providers of NHS services in England

For applications where the contractor is an NHS body or provider of NHS services in England, up to 100% of direct costs will be paid.

Commercial/other partner organisations

If you are a commercial organisation/consultancy, please fill in direct costs and commercial indirect costs. Indirect costs should be charged in proportion to the amount of research staff effort requested on the funding application form. Up to 100% of costs will be paid.

If you are another partner organisation (e.g. charity or NGO), please fill in direct costs and other partner organisations indirect costs. Indirect costs should be charged in proportion to the amount of research staff effort requested on the funding application form. Up to 100% of costs will be paid.

Direct costs

These are costs that are specific to the research, which will be charged as the amount actually spent and can be supported by an audit record. They should comprise:

Details of posts and salaries (posts and salaries summary)

This section presents an overview of salary and associated on-costs for the applicant(s) contributing to the research, including normal salary increments broken down individually.

- Please include all members of staff working on the research by clicking ‘Add Staff Details’ or editing a current one.
- If there are any applicant(s) whose costs are not being claimed you should still include their details within this section, but don’t include any actual costs.
- Where applicants are already in receipt of NIHR funding for any part of their salaries (e.g. NIHR Fellowships), these should not be additionally charged to the project.
- Where applicants are already receiving salaries funded by NIHR, these should be declared in the application.

- The Apprenticeship Levy can be included in the salary costs from 1 April 2017 where relevant.

Salary costs (apply to years)

This section specifies the annual costs of each applicant contributing to the research. You should now allocate the individual staff member costs to each year of the research, allowing for increments. Use current rates of pay, and build in any known annual increments (again at current rates). You will not be able to claim for pay awards retrospectively, once your research is underway.

- Please note the 'Total' and 'Overall' column figures need to be calculated using the current annual costs, %FTE and number of months. If the research lasts for several years and an individual's involvement varies over the course, it may be necessary to explain fully in the justification of costs section the % FTE and months per year for an individual staff member.

- It is important to double check that the % FTE, total months and yearly costs information are consistent with the information presented in 'Details of Posts and Salaries' ('Details of Posts and Salaries' should show the full current staff costs independent of % FTE etc., whereas the yearly costs in 'Annual Costs of Posts' depend on % FTE etc.).

- Please ensure that you check the 'Type of Cost' box which describes the employing organisation for **a member of staff as this impacts on the level of funding provided. Staff employed by a Higher Education Institution (HEI) are funded at 80% of cost and staff employed by NHS, commercial or other partner organisation at up to 100% of cost.**

Please note that this section also includes 'Shared Staff Costs' which is located under directly allocated costs in some other funders' applications. These are costs of an institution's research resources which can be charged to the research on the basis of estimated use, rather than actual costs. These may include: IT technicians, laboratory staff, and costs of pooled staff efforts. HEI indirect costs cannot be claimed on these shared costs.

Travel, subsistence and conference dissemination costs.

This section includes journey costs, subsistence and conference fees. Where applicable, you will need to include the travel and subsistence costs of your project advisory group, steering committee and/or data monitoring & ethics committee. Travel and subsistence costs relating to dissemination should also be included here, as should costs relating to overseas travel.

Journey costs

Enter the total cost of transport for all journeys for destination/purpose. If travel is by car, apply your institution's mileage rates (however this should not exceed HMRC approved mileage allowance payments, which is 45p per mile for the first 10,000 miles and 25p thereafter).

Travel by the most economic means possible is encouraged. NIHR programmes do not usually fund first class travel.

Subsistence

Subsistence covers accommodation (if necessary) and meals associated with the travel, excluding any alcoholic beverages.

Conferences

Where national or international conference costs are included, a statement naming the conference or purpose of travel and the benefit to the research must also be made; failure to adequately justify your attendance at a conference will mean the programme will not fund this cost.

For research of up to five years, the programme will usually fund up to a maximum of two international conference attendances. For research beyond five years, the programme will usually fund up to a maximum of two international conference attendances per five year or part of five year research period.

Equipment

Essential items of equipment plus maintenance and related costs not included as part of estates should be input in this section. These can be lease or purchase costs.

- The purchase cost of pieces of equipment, valued up to £5,000 excluding VAT, will be considered.
- Pieces of equipment costing more than £5,000 to purchase will usually need to be leased. Where applicants are leasing equipment with a purchase price of more than £5,000, a comparison of leasing versus purchasing costs must be provided in the 'Justification of Costs' section.
- Items of equipment valued at £250 or more must be itemised separately; however grouping same type equipment is permitted.
- Costs of computers are normally restricted to a maximum of £650 each excluding VAT and a statement of justification must be included, in the relevant 'Justification of Costs' section for any purchase above this limit.
- Equipment must exclude VAT, but if your organisation is unable to reclaim/recover the VAT on a piece of equipment, you should check the box 'VAT cannot be reclaimed'.
- You will need to seek expert advice from the organisation purchasing the equipment regarding its VAT status. If you check the 'VAT cannot be reclaimed' column, VAT at 20% will automatically be calculated into the overall cost of that item.

Consumables

This section includes non-reusable items specific to the research. Please itemise and describe the requirements fully (e.g. postage, stationery, photocopying). These items should be research specific, not just general office costs which should be covered by indirect costs.

Patient and public involvement

Please itemise and describe fully the costs associated with patient and public involvement. These are likely to include out of pocket expenses, payment for time and any relevant training and support costs.

INVOLVE have produced a number of useful payment-related resources, including the 'Budgeting for Involvement' guide and the INVOLVE cost calculator, which can be found at the following link:

http://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/

Other direct costs

These are costs, not identified elsewhere, that are specifically attributed to the research. For example, open access costs, other dissemination costs, costs associated with the use of research facilities, external consultancy costs, computer licensing, recruitment and advertising costs.

Please note that for organisations claiming indirect/overhead costs, costs such as recruitment of staff, and general training (e.g. in common IT packages) are costs that should be covered by the indirect costs element of the award being sought and should not appear in this section.

If external consultancy costs are included in this section they must be fully justified in the 'Justification of Costs' section. Please specify the hourly rate and the number of hours and note that consultants must not be people who are already employed by the applicant's institution. If they are, any costs should be entered as direct costs in the 'Details of Posts and Salaries' and 'Annual Costs of Posts' sections.

Open access costs

During the course of your project and throughout the review and publishing phase, you may choose to submit an article based on your research to an open access publication. Depending on the publication, you may be subject to an Article Processing Charge (APC). APC rates vary but are usually within the range of £300 and £3000. Open access publications usually list their APC rates on their websites.

Where possible, you should include an estimate for any APC in your funding application, since NIHR expects that APCs will be covered by the funding award. https://www.nihr.ac.uk/about-us/our-purpose/principles/nihr-open-access-policy.htm

Other dissemination costs

Any large costs should be further detailed with a breakdown of constituent parts or a timescale profile of the costs. Meetings to share best practice, training events and events to disseminate research findings must be run at the lowest possible cost with minimal catering. 'Conferences' which are described as such are not eligible for funding.

Indirect costs/overheads

Indirect costs will be charged in proportion to the amount of research staff effort requested on the award.

They comprise:

- General office and basic laboratory consumables
- Premises costs
- Library services/learning resources
- Typing/secretarial
- Finance, personnel, public relations and departmental services

- Usage costs of major research facilities
- Central and distributed computing
- Charge out rates for shared equipment
- Cost of capital employed

NHS bodies or other providers of NHS services indirect costs

NHS indirect costs cannot be claimed through NIHR/DH programme funding. NHS bodies or other providers of NHS services have been allocated NIHR Research Capability Funding (RCF) to contribute to the cost of hosting NIHR/DH-supported research. For more information please click on the link below:

https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/research-capability-funding.htm

HEI indirect costs

Total HEI indirect costs must be fully justified. HEIs are permitted to claim estate and other indirect costs. These costs are calculated on the basis of TRAC methodology. Proposals from other types of institutions/organisations should leave this section blank.

- HEI indirect costs are based on the number of full-time equivalent research staff working on the research and the indirect/estates charges set by an institution.
- Where staff from more than one HEI are working on the research there may be different indirect/estates charges for each one. Please list each institution on a separate line.
- Please note HEI indirect costs cannot be claimed on shared staff costs.

The applicant(s) should consult their HEI finance departments for the appropriate figures to include in the estate charges and other indirect cost section.

Commercial/other partner organisation indirect costs

Commercial/other partner organisations can claim indirect costs which are the costs of resources used by the research that are shared by other activities. Please seek advice from your finance department about the appropriate cost for this section.

Total Commercial/other partner organisation indirect costs must be fully justified.

NHS support and treatment costs (incl. excess treatment costs/savings)

The finance section includes a section that asks researchers to provide an estimate of the patient care costs associated with the research (if applicable). An explanation of why these costs are being incurred and the basis on which the estimations have been made should be fully detailed under the relevant ‘Justification of Costs’ section.

The committee/panel will take NHS support and treatment costs into account when considering the value for money of the research. It is important that you consider these costs and discuss them with the NHS bodies or providers of NHS services involved in order to avoid any delay in commencing the research.

Please be aware that the research award does NOT include NHS support and/or treatment costs. NHS support costs will be funded via the Comprehensive Research Networks. NHS treatment costs, including any excess treatment costs/savings, will be met by the NHS through normal patient care commissioning arrangements.

A representative of the NHS body or provider of NHS services - incurring any NHS support and treatment costs - must sign off the application. The 'Other supporting roles – signatories (electronic)' page is intended to ensure that the aforementioned organisation is satisfied that all NHS support and treatment costs in the application are correct and is prepared to meet these costs.

NHS support costs

These are the additional patient care costs associated with the research, which would end once the R&D activity in question has stopped, even if the patient care service involved continues to be provided. These might cover items such as extra patient tests, extra in-patient days and extra nursing attention. Researchers should contact their local NHS R&D department initially and, if they are unable to help directly or if there is no local NHS R&D department, contact the Local Comprehensive Research Network (LCRN) senior manager for advice on NHS support costs. Further details about LCRN contacts are available at

https://www.nihr.ac.uk/nihr-in-your-area/local-clinical-research-networks.htm

NHS treatment costs

Please read the following guidance on the funding of excess treatment costs prior to completing your application https://www.england.nhs.uk/ourwork/research/etc/.

These are the patient care costs that would continue to be incurred if the patient care service in question continued to be provided after the R&D activity has stopped. In determining NHS treatment costs you **must** assume that the patient care service being assessed will continue even though there may be no plans for it to do so. Where patient care is being provided which differs from the normal, standard, treatment for that condition (either an experimental treatment or a service in a different location from where it would normally be given), the difference between the total treatment costs and the costs of the "usual standard care" (if any) constitutes excess treatment cost/saving, but is nonetheless part of the treatment cost, not an NHS support or research cost. These costs should be determined in conjunction with your NHS body or provider of NHS services and their commissioners.

Please note if the patient care intervention under investigation is **in addition to** usual care there is no need to complete the 'Usual Treatment Costs' section however this will need to be justified in the relevant 'Justification of Costs' section. If the patient care intervention under investigation either wholly or partially replaces usual care, the 'Usual Treatment Costs' section must be completed.

For further information, please see:

Attributing the costs of health and social care research and development (AcoRD).

https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-

research

HSG(97)32: Responsibilities for meeting patient care costs associated with research and development in the NHS

http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012392.pdf

Section 12: Management and Governance

Is Clinical Trials Authorisation required?
Yes / No

Does your project require ethics approval?
Yes / No

If yes, has ethics approval already been obtained?
Yes / No

Section 13: Suggested Referees

Provide suggestions of two (where possible) and a maximum of three potential referees. This information will not appear on the Selection Panel/Committee members' version of the application form.

Please indicate who you would not like to be approached as referees (maximum of three).

Section 14: Uploads

Mandatory:
A list of references cited in the application (maximum 3 pages A4).

If involving a CTU:
CTU letter of support.

The following file(s) are considered non-mandatory to submission; please number your files and attach:
Supporting documentation, including logic models, flow diagrams, pictures, charts, letters of support (including letters to confirm support for funding NHS Support and Treatment costs), papers in press etc. No more than five separate files are permitted, and the total file size should not exceed 5Mb. Total files sizes larger than this may not be considered as part of the submission. All supporting documentation must be uploaded with a clear and concise filename description, preceded by a numbered 'Appendix' reference.

Section 15: 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 16: 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.

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

Section 17: Acknowledge, review and submit

Conflict checks
Please declare any conflicts or potential conflicts of interest that you or your co-applicants may have, including any facts that, should they come to light at a future date, could lead to a perception of bias. Include any relevant personal, non-personal & commercial interest that could be perceived as a conflict of interest. Examples include (this list is not all encompassing) secondary employment, consultancy, financial or commercial gain (pensions, shareholdings, directorships, voting rights), honoraria, etc. In a case of commercial sector involvement with the application or the study, please state clearly the relationship to ownership of data, access to data, and membership of project oversight groups.

Agreement to terms and conditions
As lead applicant, please tick the box to confirm that the information given on this form is correct and that you will be actively engaged in this research and responsible for its overall management. In addition, you will accept responsibility for ensuring that the host institution and interested parties are kept informed.

Ticking this box constitutes an electronic signature of the lead applicant with regard to this application

Checklist of information to include when submitting a NIHR stage 2 research application
Applicants should click the checkboxes to indicate that they have included the necessary information prior to submitting their application.

Appropriate and relevant involvement of patients and the public http://www.invo.org.uk/ ▢

A good quality plain English summary www.involve.nihr.ac.uk/makeitclear ▢

A clear description of team member roles and contribution	▢
A clear scientific abstract	▢
A clear description of the changes from first stage	▢
A flow diagram illustrating the study design / flow of participants (document upload), if appropriate	▢
A full and accurate detailed budget breakdown	▢
A clear justification of costs / value for money	▢
References (document upload)	▢
A clear Detailed Research Plan outlining the study design, methods, dissemination etc.	▢
A CTU letter of support if required (document upload)	▢
The support and agreement from the necessary supporting roles / signatories	▢
Letters of support to meet NHS Support and Treatment Costs	▢