Research for Patient Benefit
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 rf pb@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.

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’ is selected 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, stating who the grant is with and the amount of each grant.

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.

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
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.

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

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, 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:
- Director of Finance
- Head of Department or Senior Manager

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.

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.

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:

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

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

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

Content

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

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

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/](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/](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 methodological detail.

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

Further guidance can be found in the Supporting Information for Applicants and on the RfPB website.

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 fits within the remit of the RfPB programme and how it addresses the key aim of the programme to support research which is concerned with the day-to-day practice of health service staff, and which has the potential to have an impact on the health or wellbeing of patients and users of the NHS.

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 and its likely trajectory into patient benefit.

Briefly describe:
● 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).
NOTE: 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 in this section.

- 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.
- The pathway and anticipated timescale to patient benefit.

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. The programme 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.
- 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.
- 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. 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. Applicants should also be aware of any current commissioned calls on related topics, such as through the NIHR Health Technology Assessment programme. For any similar or overlapping research identified, justification explaining the need for the proposed research should be included.

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 ongoing studies, e.g. from trial registries.

Further information can be found at:
https://www.nihr.ac.uk/about-us/who-we-are/our-policies/adding-value-in-research.htm

2. 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.

3. Research plan/Methods
Describe the proposed research plan, providing descriptions of individual work streams/work packages in turn and indicate how they integrate together to form a coherent body of work. In particular and where appropriate, specify the methodological approaches proposed in sufficient detail to allow them to be assessed (for example, study design, setting, target population, inclusion and exclusion criteria, measurements, sample size, nature of follow-up, economic evaluation, duration, and practical arrangements).

NOTE: The research plan for a feasibility study should also contain a brief outline of the substantive trial, along with a list of the key ‘uncertain’ parameters that are needed to design the trial. Please refer to the Guidance on Applying for Feasibility Studies for more information.

For full trials, collaboration with a Clinical Trials Unit is recommended where appropriate. A list of units with experience working with RfPB can be found by using the UKCRC CTU Network Resource Finder and choosing RfPB in the ‘Experience of Applying to Funding Bodies’ search field.

Researchers may find the SPIRIT 2013 (http://www.spirit-statement.org/) statement a useful resource when preparing their protocol.

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.

1. 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
2. **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.

3. **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.

4. **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.

5. **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?

6. **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 stream / work package.

NOTE: It is expected that when feasibility studies are proposed, time will be allocated to the development of the protocol for the substantive trial should the proposed feasibility study be successful.

6. **Project management**
Explain the practical arrangements for managing the research project. This should include specification of the management roles and responsibilities of the individual team members who will lead on the delivery of the proposed research, the management structure (i.e. reporting lines), the project manager (if applicable), and the financial and intellectual property management. Please also highlight the role of any steering, advisory or reference groups associated with the research.

7. **Ethics / Regulatory approvals**

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:
9. **Project/Research expertise**

Explain why the group is qualified to do this research, describing the track record of the research team in the relevant area, including publication outputs, grant income and impact on health service practice and policy. State clearly the particular contribution that each of the applicants will make towards the research and the particular contribution that any collaborators intend to make.

**NOTE:** 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**

Please set out the measurements of success you intend to use.

**NOTE:** It is expected that when feasibility studies are proposed, clear progression criteria to the substantive trial will be provided, including identification of the potential funder of the substantive trial. Please refer to the [Guidance on Applying for Feasibility Studies](http://www.invo.org.uk/posttypepublication/involve-briefing-notes-for-researchers/) for more information.

Please also identify the key risks to delivering this research and what contingencies you will put in place to reduce or eliminate each risk or its impact. 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 patient recruitment, 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 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/](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](http://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:
- staff costs
- travel, subsistence and conference fees
- dissemination costs
- equipment (including lease versus purchase costs)
- consumables
- patient and public involvement
- 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.

1. **Programme specific information**
The RfPB programme has a funding limit of £350,000. Any application for a feasibility study is expected to cost less than £250,000. Applications for more upstream research, and/or where the patient benefit may not be directly realised through the proposal, are expected to cost less than £150,000. Further information can be found in the RfPB Guidance on Funding Limits and in the Review of Tier 3 Funding, which includes a list of the types of applications which would be expected to cost less than £150,000.

2. **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. 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.

3. Information on different types of organisations

3.1. 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.

3.2. 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.

3.3. 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.

4. 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:

4.1. 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.

4.2. 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.

4.3. 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.

4.4. **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.

4.5. 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.

4.6. 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:

4.7. 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/who-we-are/our-policies/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.

5. **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

5.1. **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

5.2. **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 sections.

5.3. 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.

6. 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, can be accessed via the Lead LCRN managing the process on behalf of the local sites.

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.

Upload a Schedule of Events Cost Attribution Template (SoECAT) form
It is mandatory to attach a Schedule of Events Cost Attribution Template (SoECAT) form.

Please note that as part of the work to address the issues surrounding the way in which Excess Treatment Costs are funded, new arrangements are now being implemented as part of a pilot.

To underpin the new arrangements, a cost attribution tool has been created by the Health Research Authority (HRA) in partnership with charity funders and research sponsors. This tool provides a standardised approach across England, ensuring that the attribution of study activities complies with the Department of Health and Social Care Guidance on Attributing the Costs of Health and Social Care Research and Development (AcoRD). As part of their funding applications, researchers are required to complete this new tool, known as a Schedule of Events Cost Attribution Tool (SoECAT) for clinical research, which has been developed from the current HRA Schedule of Events. This tool is designed to capture the different costs associated with clinical research and attribute them accordingly. The totals for excess treatment costs and NHS support costs are calculated by using the SoECAT.
Therefore you are not required to add costs to the online application form under the ‘NHS Support Costs’ or ‘NHS Treatment Costs’ sections. However please still complete the question on whether the costs have been discussed and agreed with the Lead Network’. Researchers and/or their study teams and Research Sponsor/Lead NHS Provider (e.g. R&D office/Clinical Trials Unit) are supported by AcoRD Specialists in the Local CRN to verify the accuracy of the SoECAT. For more information please see the NIHR CRN Routemap available at https://www.nihr.ac.uk/funding-and-support/study-support-service/resources/supporting-research-in-the-nhs.htm

Under the new arrangements, sign off via the LCRN AcoRD Specialist is required to confirm the study attribution complies with the Department of Health and Social Care AcoRD guidance. This early attribution support will underpin the excess treatment cost management process by providing formal sign off, supporting the role of the research sponsor and lead R&D office or Clinical Trials Unit. Completion of the Schedule of Events Cost Attribution Template will be required for studies eligible for the NIHR portfolio and the support this provides, which will include access to excess treatment cost payments under the new arrangements. This ETC value, alongside recruitment activity in the NIHR Central Portfolio Management System, will then be utilised to inform the payments to NHS providers.

When considered necessary by the LCRN AcoRD specialist, a completed Schedule of Events Cost Attribution Tool (SoECAT) is now required to be uploaded and submitted as part of the application submission for all applications. When a completed SoECAT is not considered necessary by an AcoRD specialist, only the front page (study information tab) of the SoECAT needs to be uploaded and submitted as part of the application submission. The SoECAT must be authorised and signed off by an AcoRD Specialist even where there are no excess treatment costs.

The SoECAT form and more information can be found here: https://www.nihr.ac.uk/funding-and-support/study-support-service/resources/supporting-research-in-the-nhs.htm


6.1. 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

Please note: you are not required to add NHS Support Costs on the online form as these are now part of the new SoECAT form. However please still complete the
question on whether the costs have been discussed and agreed with the Lead Network’

6.2. 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.

Please note: you are not required to add NHS Treatment Costs on the online form as these are now part of the new SoECAT form. However please still complete the question on whether the costs have been discussed and agreed with the Lead Network’

For further information, please see:

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: Uploads
Mandatory:
● A list of references cited in the application (maximum 3 pages A4)
● A completed Schedule of Events Cost Attribution Tool (SoECAT)

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 protocols, questionnaires, 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 6Mb (this includes the SoECAT form and the Gantt Chart uploaded earlier in the form). 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 14: 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 15: 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 16: 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
- Completed Schedule of Events Cost Attribution Tool (SoECAT)