National Institute for Health Research

NIHR Research for Patient Benefit (RfPB) Programme
Guidance Information for Applicants

Appendix 8 – Guidance on using the Form **58**

1. Introduction

The Research for Patient Benefit (RfPB) Programme is a national, response-mode funding scheme that has been established in order to fund high quality research that will be directed at achieving benefit for users of the NHS in England. Applications will be considered by a Regional Advisory Panel and applications that relate to health service challenges, regionally or locally, will be particularly welcome. As a responsive (researcher-led) rather than a commissioning programme, RfPB does not seek to name specific topic areas and welcomes applications on a wide range of issues. Potential applicants are encouraged to visit the programme website (http://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/how-to-apply/research-programmes/research-for-patient-benefit/) for the most up-to-date information before submitting an application. There is also a regularly updated list of 'frequently asked questions' (FAQs) on the RfPB website to supplement this guidance.

2. Aims and Scope of the RfPB Programme

This programme is intended to support research which is related to the day-to-day practice of health service staff and is concerned with having an impact on the health or well-being of patients and users of the NHS. Funded research projects are likely to fall into the areas of health service research and public health research, although other areas are not excluded from the programme. The research projects might use quantitative or qualitative methods to:

- Study the provision and use of NHS services.
- Evaluate the effectiveness and cost effectiveness of interventions.
- Examine the resource utilisation of alternative means for healthcare delivery.
- Formally scrutinise innovations and developments.
- Consider the feasibility of research requiring major award applications to other funders (see further information in appendix 1).

Applications which have emerged from interaction with patients and the public, which relate to patient and service user experience, and which have been drawn up in association with a relevant group of service users will be particularly welcome (see further information in appendix 2). In all cases, however, potential trajectory to patient benefit will be a major selection criterion.

Systematic reviews may be funded as part of a larger research project or as stand-alone studies. For more details, see the frequently asked question in relation submission of systematic reviews http://www.nihr.ac.uk/funding/RfPB_faq.htm#13.

The programme will not fund:

- Laboratory-based research or basic science research, including research based on animal models.
- Infrastructure such as setting up or maintaining research units.
- Applications which are solely service developments unless they have wider generalisability. Note that the costs of any new service would not be funded by RfPB.
- Applications which are solely: audit, surveys, needs assessments, technology development (although these elements may be part of an integrated research study).

3. Background

RfPB is one of a series of programmes that fall under the scope of the National Institute for Health Research (NIHR). The Director of the RfPB Programme has oversight of the programme as a whole and sets the criteria for it. The programme is based around Regional Advisory Panels that are chaired by a senior academic/practitioner and their membership covers a wide range of disciplinary areas, including involvement from patients and/or members of the public. Details about RfPB Panel Chairs and the full Panel memberships in each of the regions are available on the website (http://www.nihr.ac.uk/funding/RfPB_regional-advisory-panels.htm). Applicants are strongly advised to familiarise themselves with the resources available on the website for the programme as well as for the NIHR as a whole.

4. Eligibility

Applications are made through an NHS body**[1]** and other providers of NHS services in England. If an application is successful, a contract will be placed with that organisation for delivery of the research and all funds for the research will be paid to the NHS organisation or other provider of NHS services. All NHS bodies are eligible provided they are capable of fulfilling the role of a research sponsor as set out in the Research Governance Framework for Health & Care.

It is recognised that where applications emerge from daily practice, considerable work may be needed to create a sound research design. We expect that all applications will have appropriate academic input and/or methodological advice (which can be accessed through the local Research Design Service (RDS); refer to section 8 for further information on the RDS). There may well also be a strong component of service user involvement.

Applications with appropriate collaborations in social care and third sector providers of health and social care are also encouraged.

[1] Under schedule 4 paragraph 138 (2) (c) of the Health and Social Care Act 2012, “NHS body” means: (a) the Board; (b) a Clinical Commissioning Group; (c) a Special Health Authority; (d) an NHS trust; and (e) an NHS Foundation Trust.

An application from an NHS body or provider of NHS services in England can include an academic partner organisation from outside England, provided a strong case is made that the chosen academic partner is best placed to provide the academic input to the planned research.

The RfPB Programme particularly encourages new investigators to apply for funding. The programme's policy is that the team of applicants will be evaluated in terms of their overall ability to deliver the proposed research. This means that a relatively new investigator can be the Lead Applicant/Principal Investigator if he/she is supported by a sufficient number of more experienced researchers, with appropriate commitment to the overall research project.

Applications up to the value of £350,000 and up to 36 months in duration will be accepted; however, please see appendix 3 for further guidance on the various funding levels applied within this limit, which relate to different types of research.

5. Programme Structure and Timetable

Applications will be considered by the appropriate RfPB Panel. They cannot be considered by more than one Panel, during any one competition. All applications are to be completed and submitted online through the NIHR Central Commissioning Facility (CCF) Research Management System (RMS) which the NIHR CCF uses to manage the application process. The NIHR CCF also acts as secretariat for the RfPB Panels and provides a point of contact for queries.

For general enquiries
call 0208 843 8057
or email rfpb@nihr.ac.uk
or visit
Research for Patient Benefit

Regional Advisory Panels meet three times per year.

Stage 1 application
A preliminary Stage 1 application has been introduced to provide guidance and advice on whether or not a full Stage 2 application would be welcomed by the RfPB Panel. The Stage 1 application will be judged on the research question – whether or not it is on a pathway to patient benefit – and the proposed methods. An estimate of overall costs is requested but no financial details are required at this stage. If the Stage 1 application is accepted by the Panel, applicants will receive feedback on any suggested changes that would strengthen the subsequent Stage 2 application.

Stage 2 application
Applicants of successful Stage 1 applications will be offered the opportunity of submitting a Stage 2 application within 6 weeks (to meet the deadline for the next RfPB Panel meeting) or

of deferring to the following Panel meeting. Bear in mind that the Stage 1 application will only be assessed for the proposed research question and methods; the full application will require satisfactory completion of other important aspects of the proposal such as choice of the research team, further detail on the public and patient involvement, intellectual property and financial details. The research design will also be reviewed at this stage, in light of any comments made during the review of the Stage 1 application.

Stage 2 applications will be sent out for external peer/public review before being assessed by a RfPB Panel. Rarely, if suitable peer reviewers cannot be identified for an application during the round to which it was submitted, the application may be entered into the following competition.

For additional guidance on these points, please see the FAQs on the website.

Please note: All submission deadlines are at 1pm.

	Competition 32	
	Stage 1	Stage 2 (if invited)
Applications open	07 December 2016	Mid June 2017
Submission deadline	22 March 2017	Late July 2017
Submission outcome	Mid June 2017	Late November 2017

Please note that future competition dates and times may be subject to change. To find the most up to date information regarding competition deadlines, check the RfPB Calls and competitions page on the website.

The RfPB Application Process:

- Stage 1 application submission
- Initial scrutiny (scope check)
- Panel assesses Stage 1 application
- Applicants informed of Panel decision and feedback
- Applicants prepare and submit Stage 2 application (if invited)
- Application sent for external peer and public review
- Panel assesses Stage 2 application
- Panel decision ratified and applicants notified

For further details of the process please check the Application process and apply page on the website.

6. Criteria for Funding

Applications will be judged on the quality of the research proposed, value for money and on their significance and potential benefit to the NHS and its patients.

Stage 1 application

Stage 1 provides an opportunity for applicants to get feedback on the suitability of their proposal and the chances of success following preparation of a full application. The Stage 1 application requires:

- The name and contact details of the principal investigator and list of proposed co-investigators.
- A plain English summary of the research.
- A brief background section together with research aims/questions.
- A description of the proposed methods.
- A brief overview of plans for patient and public involvement.

If the Stage 1 application meets the approval of the Panel, a full proposal, with appropriate suggestions for improvement, will be invited.

Stage 2 application

The Stage 2 application should:

- Contain a clear statement of objectives and a demonstration that the design of the research is appropriate to meet those objectives.
- Indicate that the team is fully aware of relevant literature as well as any ongoing studies on the topic, particularly those funded through the NIHR (see appendix 6).
- Make a case for potential improvements in health and/or health care arising from the study and include a discussion of potential impact.
- Provide a justification for the research design, methodologies, and techniques of data collection and analysis, demonstrating in as much detail as possible how the hypotheses or research questions will be addressed.
- Include full details on how patients and members of the public have been involved in the research design and would be involved in any subsequent study.
- Make reference to any anticipated difficulties of access to respondents and/or data and how these will be overcome.
- Show that current research governance frameworks and procedures for ethical approval have been followed.
- Give a full justification for the duration of the research and financial support requested, demonstrating that the objectives are achievable within the resources and timescales proposed, and justifying the time inputs of members of the research team (including for any patient and public involvement team members; see appendix 2).
- Indicate how dissemination of results will be handled and how action plans might follow.
- Be costed in line with the funding limit of £350,000 and have a maximum duration of 36 months (note guidance on funding limits in appendix 3, applying for feasibility studies in appendix 1 and for information resources in appendix 5).

The peer review process aims to include public, patient, healthcare and academic reviewers.

In line with the NIHR Policy on Open Access for its funded research, the RfPB programme anticipates that funded researchers seek to publish their research outputs in a peer-reviewed journal that is compliant with the policy on Open Access (for which appropriate costs can be requested). Outputs from the programme are likely to take the form both of academic publications and publications designed to reach a wide practitioner and/or patient/service user audience and to influence the ways in which health services are delivered.

Further information on how to complete an application for funding is available in appendix 7 and appendix 8.

7. Plain English Summary

The importance of a plain English summary

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

Many reviewers use this summary to inform their review of your funding application. They include clinicians and researchers who do not have specialist knowledge of your field as well as members of the public. If your application for funding is successful, the summary will be used on 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 we feel that your plain English summary is not clear and of a good quality then you may be required to amend your summary prior to final funding approval. It is helpful to involve patients/ carers/members of the public in developing a plain English summary.

Word length: 300 words maximum

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/.

For further support and advice on writing a plain English summary, please contact your local Research Design Service (where applicable).
http://www.rds.nihr.ac.uk/support-options/regional-centres/

8. The Role of Research Design Service (RDS)

Some applicants will have specialist advice available within their organisations but for others the most appropriate source of advice may be through the NIHR Research Design Service (RDS).

The RDS is funded by the NIHR to provide consultative advice on research methodology and protocol development and are located in ten regions across England. A complete list of regional RDS centres and contact information can be found on the website.

Making preliminary contact with an RDS about an idea for a research project that is still in the development stage can be helpful. Experience suggests that early approaches and a timetable that ensures RDS staff have a chance to see and comment on drafts of the full application maximises the chances of receiving high quality advice.

9. Confidentiality

Research applications are considered confidential by the NIHR CCF and all reasonable steps are taken to ensure that this confidentiality is not breached. In line with Department of Health policy, the CCF will be publishing summary minutes of NIHR programme funding Panel meetings. These changes are detailed in version 10 of the confidentiality guidance document and will apply to calls/competitions launched after its publication date. Please read the updated document to ensure that you are aware how we handle the information provided in application forms.

10. The R&D Contract

Once your application has been considered, the NIHR CCF will provide feedback to the Lead Applicant, along with the R&D contact at the host NHS body, as directed by the RfPB Panel.
Successful applicants will be given a contract by the Department of Health which will be managed by the NIHR CCF. The contract will be between the Department of Health and the host NHS body. The contract will contain a drop dead date. If the research has not commenced by this date, the recommendation for funding may be withdrawn.

The Department of Health reserves the right to negotiate the price it is prepared to pay for the work based on the cost of the application and its operating constraints. The Department of Health will expect the day-to-day running of your award (including employment of staff and purchase of equipment and consumables) to be handled by the contractor through a research leader. Payment will normally be made quarterly, in arrears.

All research funded by the Department of Health or through NIHR is subject to the standard R&D contract. **By submitting your application, you accept the terms and conditions of the standard contract and are agreeing to be bound by them in the event of an offer of funding.** If you wish to view a copy of the standard contract, click on the following link: standard contract.

11. NIHR Faculty

If an application is successful, the individuals named in the finance section (and who are either NHS or university employees), will become members of NIHR Faculty for as long as their salaries are supported by the RfPB Programme award. This is in recognition of their success in demonstrating that they are engaged in high quality research relevant to NIHR and/or NHS policy concerns.

NIHR Investigators, as members of NIHR Faculty, are expected, *via* the National Coordinating Centre through which their research activities are funded, to advise the Director of NIHR on research issues within their expertise. This may take the form of serving on review panels or carrying out peer review. We would not normally expect to require more than four peer reviews or serving on two review panels a year.

Please follow the link for further information on the NIHR Faculty.

12. Transparency Agenda

In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety to the general public. Further information on the transparency agenda is at: https://www.gov.uk/government/publications/procurement-and-contracting-transparency-requirements-guidance.

13. Complaints

As with any funding body, decisions will be based on the RfPB Panel's interpretation of information provided on the application form and advice provided by peer reviewers. It may also reflect the Panel's judgement on the relative priority of a particular application in the event of limited resources. Any complaint that the decision has not been reached in accordance with published RfPB guidance (including FAQs) or that there was some other irregularity in the decision making process should be referred to the NIHR CCF in the first instance.

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or email rfpb@nihr.ac.uk
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Research for Patient Benefit

14. Further Information

Applications involving bio-banks
UK Biobank is a major national health resource with the aim of improving the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses. As such, applicants are encouraged to consider whether Biobank may be able to provide suitable data for their study, rather than request funding for unnecessary new data collection. We do not want to discourage establishment of new collections of participants and their data where this is necessary to address the research questions under consideration, our aim is to avoid applications for funding to set up Biobank-like cohorts where the use of Biobank would prevent wasteful duplication of Biobank-like activities.

UK Biobank has recruited 500,000 people aged between 40-69 years in 2006-2010 from across the country to take part in this project. They have undergone measures, provided blood, urine and saliva samples for future analysis as well as detailed information about themselves. The health of members of this large cohort will be followed over the coming years and the participants have consented to be approached about health research. http://www.ukbiobank.ac.uk/

Overlaps with ongoing research

Applicants should be aware of ongoing research that relates to their research proposal and comment on any other research which might be deemed to overlap with the contents of the proposal. Applicants are advised to use both PubMed Central and Europe PubMed Central for recent material on the topic area they are applying for. Applicants should also be aware of any current commissioned calls on related topics, such as through the Health Technology Assessment programme. For any similar or overlapping research identified, justification explaining the need for the proposed research should be included.

International Standard Randomised Controlled Trial Number (ISRCTN)

All primary research studies need to be assigned an ISRCTN. You can view the ISRCTN website at: www.isrctn.org/. Please note that the remit of this database has been widened to include all primary research projects, even those that are not randomised controlled trials. There is no registration fee for NIHR funded trials.

Appendix 1 – Guidance on Applying for Feasibility Studies

Over half the current applications to RfPB are for feasibility studies towards full trials. These are sometimes not very well designed and applicants might like to consider the following:

- The programme welcomes randomised clinical trials, though it is recognised that squeezing the cost into the maximum available funding (of £350,000) can be challenging. Nevertheless in the past the programme has funded some interesting trials and continues to welcome proposals for full trials.

- NIHR has provided guidance across all programmes on the distinction between a pilot and feasibility study (Guidance). A pilot study is the full trial in miniature (and their data can often be incorporated into the data collected in the full trial). Pilot trials are therefore usually funded as part of the phased development of a full trial. In effect, they offer the researchers and funders a stopping point should the trial not prove viable. It is therefore unlikely that RfPB would fund a pilot trial as continuation would involve a separate application to another funder.

- Feasibility studies, on the other hand, attempt to derive more precise estimates of various parameters which will be required for a full trial. Guidance on what these parameters might be has been provided on the website and can be accessed here (Guidance). The design of a feasibility study involves listing those parameters (recruitment rates, retention rate, variability of primary endpoint, willingness to be randomised, etc) which are uncertain and describing the methods for improving their precision so that a full trial will have a better chance of being successfully funded. It should be noted that an underpowered 'exploratory trial' is not the same as a feasibility study and is unlikely to be funded through RfPB.

- The very nature of feasibility studies means that they are relatively high risk. On the one hand the end result may be to confirm that a full trial is not feasible and on the other hand, even if shown to be feasible, another funder may not be interested in supporting a full trial (because perhaps either the clinical question is not sufficiently important or there are ongoing trials in the area already in the portfolio). RfPB continues to discuss with other NIHR programmes how decisions to fund feasibility studies can be better integrated with opportunities for obtaining funding for the full trial and RfPB panels are asked to consider the likelihood of a feasibility study progressing to a full trial in their assessments.

- Given the nature and risks associated with feasibility studies it is expected that they will cost less than £250,000. Costs higher than this will need to be fully justified in terms of the number and levels of uncertainty of the parameters needed to make a viable proposal for a full trial.

- Phase II trials are occasionally submitted to RfPB. These usually involve fully powered randomised designs but involve a 'surrogate' endpoint rather than a clinically or patient significant one. Such trials are sometimes funded as they can provide an important step towards a full pragmatic trial. They are however that much further removed from patient benefit and are likely to be seen as having lower priority compared with a trial powered on a clinically important endpoint.

Appendix 2 – Patient and Public Involvement

Patient and Public Involvement in Research: Further information

INVOLVE describes 'patient and public involvement' as an active partnership between patients, members of the public and researchers in the research process. This can include, for example, involvement in the choice of research topics, assisting in the design, advising on the research project or in carrying out the research.

INVOLVE's definition of the term 'patients and public' includes: patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. Whilst all of us are actual, former or indeed potential users of health and social care services, there is an important distinction to be made between the perspectives of the public and the perspectives of people who have a professional role in health and social care services and research. (INVOLVE, 2012)

For a more detailed explanation of involvement, how it links to and differs from engagement and participation in research see what is public involvement in research?

Information on organisations providing useful resources, advice and support on patient and public involvement in research:

NIHR Research Design Service (RDS)
http://www.rds.nihr.ac.uk/support-options/regional-centres/
The RDS provides advice and support to researchers developing research proposals for submission to the NIHR and other national, peer-reviewed funding competitions for health and social care research. This includes resources, advice and support on patient and public involvement in the development of proposals.

INVOLVE
www.invo.org.uk
INVOLVE provide advice and a range of resources on patient and public involvement in research.
These include:

- A directory of research networks and organisations supporting involvement invoDIRECT.
- Resources which include briefing notes for researchers on what is public involvement and how to involve people in research; an involvement cost calculator to help with budgeting; searchable databases including an evidence library and many other resources.
- A website www.peopleinresearch.org providing information for patients and the public about current opportunities for getting involved in research. Researchers and funders can use People in Research to advertise and invite patients and the public to get involved in their research.

The James Lind Alliance (JLA)
www.jla.nihr.ac.uk
The JLA has a guidebook with step-by-step guidance on involving patients and clinicians in the identification and prioritisation of research topics and questions.

Appendix 3 – Guidance on Funding Limits

RfPB will fund research that presents a clear trajectory into patient benefit. The trajectory into patient benefit might occur over several years and when assessing applications RfPB will expect to see this trajectory clearly explained. RfPB panels will then consider the potential of the proposed study to achieve patient benefit in relation to the project's cost.

One of the reasons trials are so popular in clinical research is that, if properly designed and conducted, they will provide a clear answer to a clinical question. A feasibility study for a trial, however, would normally seem of less value than the trial itself as it is that many more years away from patient benefit and, if it shows the trial not to be feasible, carries a higher risk of not leading to patient benefit than the trial itself. In the same vein, a study searching for the side-effects of a drug or one inviting patients to suggest possible interventions for, say, obesity carries an even higher risk that little of value will emerge. RfPB panels will therefore balance the probability of achieving patient benefit against the cost of the proposal: if the proposed study is likely to require further research to achieve patient benefit or if it seems to have a lower probability of realising results that may be of patient benefit then a lower cost would be expected if it is to offer value-for-money and remain competitive.

Tier Guidance

As guidance for what the programme will fund, and its expected cost, we would encourage applications for a wide range of topics in which the cost reflects the probability of patient benefit. The tiers in the RfPB programme are defined as:

Tier 1

Research that has a clear and close trajectory to patient benefit. The programme has an upper limit of £350,000 (for up to 3 years) for research costs and any application needs to be within this limit.

Tier 2

The programme receives many applications for feasibility studies towards trials and these would normally be expected to cost less than £250,000 though in exceptional circumstances, well argued in the application itself, they could cost more.

Tier 3

The programme will also consider research that is on a pathway to patient benefit yet is further from it so long as it is appropriately costed. As a rule of thumb such research might be expected to cost less than £150,000.

Examples of studies that might fall within this category of 'higher risk' research include:

- Observational studies using clinical databases, which might provide preliminary estimates of an effect size that would be useful in the design of a clinical trial.
- Observational studies to establish for example the practicality and acceptability of changes to clinical practice, or the best means to ensure and measure adherence, prior to a formal evaluation.
- Developing and refining interventions.

- Developing new scales or outcome measures.
- Exploratory studies, e.g. using qualitative methods, that might provide insights into an intractable problem.
- Additional follow up of patients in a completed clinical trial.
- Post-market surveillance for unknown side-effects of a drug (Phase IV trials).
- A systematic review, especially where the number of relevant studies is likely to be limited.

In summary, it may be helpful for applicants if they work within three cost tiers for their research: £250,000 to 350,000 for research that might have fairly immediate patient benefit (such as a randomised controlled clinical trial), £150,000 to 250,000 for feasibility studies that assess the parameters needed for a full trial, and up to £150,000 for research, such as observational studies, that will generate results that may be useful for more downstream investigations or might carry higher risk of not carrying through into patient benefit. These are not fixed cost limits but indicative ranges. Costs will be accepted if they are clearly justified according to the challenges of doing the work and they show value-for-money in terms of the potential for realising patient benefit.

Appendix 4 – NIHR Guidance on Adding Value in Research

Adding Value in Research is the approach to maximising the potential impact of research through ensuring that our funded research:

- answers questions relevant to clinicians, patients and the public
- uses appropriate design and methods
- is delivered efficiently
- results in accessible full publication, and
- produces unbiased and usable reports.

Adding Value in Research is the positive response to the work of Sir Iain Chalmers and Professor Paul Glasziou in 2009[1]. We have used the stages in the research cycle from their framework to identify where we can add value in research.

Ensure that all primary research is informed by a review of the existing literature

NIHR will only fund primary research* where the proposed research is informed by a review of the existing evidence.

Where the request for research to address a specific research question is via a commissioning brief advertised through a commissioned call, the review of the existing evidence will have already been undertaken by the funding NIHR Programme to inform the commissioning brief. Applications in response to commissioned calls will need to address the commissioning brief requirements specific to the NIHR Programme.

For researcher-led or researcher-initiated proposals that are not in response to a specific commissioning brief as part of a commissioned call, if these include primary research then they 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 present a summary of the findings of this in their proposal. All applicants must also include reference to relevant ongoing studies, e.g. from trial registries.

**Primary Research defined as: Original research conducted to collect new data to answer a research problem. [Source: Health Technology Assessment Programme A-Z of useful terms. http://www.nets.nihr.ac.uk/glossary*

Ensure that all NIHR funded research is published

Current estimates suggest that 40-50% of research undertaken is never published.[1]

However, we expect that all NIHR funded research will be reported fully and publicly available when the research has been completed. The standard NIHR contract with researchers includes the following statement:
"17.7 The Contractor shall ensure that the outcome of the Research is prepared for publication in a suitable peer-reviewed journal"

We expect that all researchers who have a contract with the NIHR to undertake research shall ensure that the outcome of the research is prepared as a research paper for publication in a suitable peer-reviewed journal. There is also a contractual obligation that the researchers should, at the time of submission of their research paper to a peer-reviewed journal, send a copy of this to the NIHR Programme issuing the contract. This is to fulfil reporting requirements. It will also allow a mechanism by which NIHR Programmes can monitor the contractual obligation of researchers to prepare such a research paper on all NIHR funded research.

Full reporting should include: full title, structured abstract, full report to include aims, methods, results, conclusions and research recommendations. Depending on the publication, research materials should also be included, for example, patient questionnaires. Reporting must be in line with best guidance (e.g. CONSORT for clinical trials) according to study design listed on the EQUATOR website www.equator-network.org.

Publicly available means that the paper should be available on the web, able to be found using a recognised search facility, and as a minimum the abstract should be freely available.

It is expected that research funded by one of the NIHR Programmes that now has its own peer-reviewed journal as part of the NIHR Journals Library will publish a full and complete account of that research in the NIHR Programme specific journal. This will ensure that this research is reported fully, is publicly available with the abstract and full report freely available via the NIHR Journals Library website and the abstract freely available via Europe PubMed Central. The NIHR Programmes with journals in the NIHR Journals Library are: Efficacy and Mechanism Evaluation Programme; Health Technology Assessment Programme; Health Services and Delivery Research Programme; Public Health Research Programme; and Programme Grants for Applied Research.

We expect that research funded by a NIHR Programme without a journal in the NIHR Journals Library shall ensure that the outcome of the research is prepared as a research paper for publication in a peer-reviewed journal. Where this research paper is not accepted for publication by a suitable peer-reviewed journal an alternative solution should be sought to ensure that this research is able to be reported fully and be publicly available.

We would also encourage all researchers to disseminate their research findings to the broader public community as well as to the research participants when the study has completed.

Reference:

1. Chalmers I, Glasziou P. Avoidable waste in the production and reporting of research evidence. Lancet 2009;374:86-89

Appendix 5 – Guidance on Funding Information Resources

Patients not only have a right to information about their condition but such information may help them in coming to terms with their illness and/or in supporting them make decisions about treatment options. In the past RfPB has contributed to these information resources by funding studies that have produced leaflets, videos, websites, etc. Sometimes these information resources have had a research evaluation attached though sometimes the value to the patient has seemed self-evident.

Now that the amount of information available on the web is so great (and access is almost universal) it seems appropriate to clarify RfPB's policy with regard patients' needs for information.

1. RfPB will continue to view high quality accessible information as conferring potential patient benefit. 'Medicine' rarely provides all the answers that patients would like and others' experiences, decision aids, treatment/prognostic information, etc, can be of value. It is however incumbent on the applicant to demonstrate that relevant information is not already available on the web. So as well as the usual 'scientific' review of the field as part of the project justification, an RfPB application that proposes an information resource output will also need to review existing information available on the web and make a cogent case why this is deficient.

2. Any study that proposes generating an 'information resource' for patients will still have to conform to the usual RfPB requirement of being a research project (with appropriate methods, evaluation, etc) and not just 'service development'.

3. Project results may be used for a website but this is likely to be a part of dissemination and not a major part of the project proper.

Appendix 6 – Guidance on Further Evaluations of Established Interventions

Many types of intervention such as cognitive behavioural therapy (CBT), exercise and outreach have been shown to be widely effective. Even so RfPB, together with other NIHR programmes, frequently receives applications for further evaluations of the effectiveness of such approaches or variants of them in different populations and for different indications. In judging such applications, three common questions arise:

Is a new trial in a different target population justified?

A common type of proposal is to evaluate (through a trial or trial feasibility study) the effectiveness of an intervention for a condition for which it has already been tested, but in a new population – for example, an exercise intervention in young people, old people or ethnic minorities. Another common application is for funding to evaluate the intervention in a familiar population that has a physical condition not previously included in previous research – prostate cancer, multiple sclerosis, frequent attendance in primary care and so on. These may be important research questions but a panel will reasonably ask if results suggesting effectiveness in previous research can be extrapolated to the new population or condition so that further research is not needed. After all, the popularity of some interventions such as CBT and exercise encouragement resides in being flexible therapies defined by some general principles, the detailed content of the intervention often being tailored to individual need during therapy.

When submitting applications for evaluating an established intervention in a new target population or condition it is therefore important to identify why and how the new target is different from others that have already been researched. An application justified simply by stating that the intervention has never been tested in the proposed target population is unlikely to be successful if that is the only rationale. A case needs to be made that the new target population or condition has important differences that make extrapolation from previous work inadvisable - for example that the new population has been shown to have a different response to other therapies in other studies, or the new physical condition poses challenges that have not been addressed in previous trials. In short, it is not the absence of evidence that best justifies new studies but the distinctiveness of the target population.

Is a trial of a new variant of an established intervention justified?

The second type of study that is frequently received by the programme is testing of another therapy based upon modifying the form or content of an established one. There are two issues for panels to consider here.

First, proposals may not change the content of therapy but propose different formats for delivery – for example using computerised CBT, smartphone apps or therapists from different disciplines to deliver the intervention. In this situation it is unlikely that the new variant would have considerably greater effectiveness than the conventional therapy and the rationale is usually that cost-effectiveness can be increased by the new format. In many instances further research may not be justified: it might seem a reasonable inference that if, say, chronic obstructive pulmonary disease (COPD) nurses can deliver CBT effectively than

cancer nurses or health visitors can too. But if a trial is proposed, the required non-inferiority design will need a large and therefore expensive study and applicants need to bear in mind that the cost of any trial might be judged as outweighing the potential incremental benefit to be achieved. Alternatively, new formats need to be justified by evidence that they are likely to increase coverage or retention in therapy and will therefore be more effective at a population level.

Second, a new variant is sometimes proposed because it is argued that an existing generic intervention does not adequately treat the population or the condition under consideration. Examples might include modification to respond to specific symptoms not otherwise addressed or to specific features of the target population. Since, as noted above, many of these interventions are characterised by their flexibility, a panel will reasonably ask if the proposed variant is really new or simply codifies what a competent therapist would do anyway. Applications for variants of established interventions therefore need to make a strong case either that the new therapy is likely to be considerably more effective (or cheaper) than the existing one if the latter is delivered according to accepted standards.

What facet of the intervention is being evaluated?

The exact active ingredient in many interventions is not well understood. For example, there are two other components of the response to talking therapies from which the CBT effect needs to be differentiated. One is the non-specific effect of concerned attention, represented for example in the frequency and number of sessions. The other is generic therapeutic effects - the therapist's skills and experience, the strength of the therapeutic alliance and so on. CBT is a limited and expensive resource in the NHS and applications will need to demonstrate that any effect demonstrated by the proposed intervention can reasonably be attributed to CBT and not to something that could be delivered more cheaply and just as effectively by other means.

Appendix 7 – Completing the Form

These notes should be read in conjunction with the online application form and are designed to help you by providing the general information required. Please note that you must use the correct online application form for the current competition by selecting the appropriate programme (RfPB).

The online application form will automatically close at 1pm on the submission deadline day and we are unable to accept late submissions.

RfPB, like the other NIHR programmes, uses the Standard Application Form (SAF). For Stage 1 applications only certain sections of the SAF are required to be completed. If the Panel invites a full Stage 2 application, those sections of the form that have been completed for Stage 1 will be automatically used to populate the Stage 2 application though there will be opportunity to revise sections according to the feedback given by the Panel. The remaining sections of the SAF that are required at Stage 2 can also be completed. In effect, applicants invited to Stage 2 will receive constructive advice part way through their completion of the Standard Application Form to ensure that further work is worth the effort.

STAGE 1 APPLICATIONS:

Reference number
While preparing your application and until you '**Submit**', a randomly generated 5-digit number will be assigned to your entry online. You should note this 5-digit identifier as you will need it for subsequent enquiries whilst the call is open prior to completing your submission.

Once you have successfully submitted your form a reference number for your application will be generated that will be unique to your submission. This will take the form of a standard reference (PB-PG-1216-10XXX).

Please note that this reference number is not filled in by the applicant and will be generated automatically when the form is submitted online.

NOTE: The information provided below has been taken from the contextual help from the online application form and is meant to guide you through how to complete the form question by question.

Section: Research Details

Research Title:
Please provide the title for the research. This should be both concise and clearly descriptive and should contain keywords relevant to the research.
NOTE: If the application is for a pilot or feasibility study, ensure this is referenced in the title.

Host organisation (which will administer any award):
Please indicate which NHS body or other provider of NHS services would act as the contracting organisation, should the application be successful. Note that RfPB awards will only be administered through NHS bodies or other providers of NHS services in England.

NOTE: If your organisation does not appear on this list, please contact the Central Commissioning Facility

Research Duration:
Please indicate the expected length of the proposed research in months.

NOTE: RfPB project grants can be up to 36 months in duration.

Proposed start date if awarded funding:
Please indicate the proposed date on which the research would start. A 'cannot be before' date has been suggested to ensure that you allow sufficient time to obtain any regulatory approvals necessary and/or so that any documents required by the RfPB Programme can be submitted, prior to commencement of the actual research, should your application be supported. NOTE: You may not know this date exactly, but an estimate must be supplied.

Application Type:
These definitions have been agreed by the NIHR EME, HTA, PHR and RfPB programmes. We expect that when pilot or feasibility studies are proposed by applicants (or specified in commissioning briefs) a clear route of progression criteria to the substantive study will be described.

Feasibility studies:
Feasibility studies are pieces of research done before a main study in order to answer the question “Can this study be done?”. They are used to estimate important parameters that are needed to design the main study. For instance:

- Standard deviation of the outcome measure, which is needed in some cases to estimate sample size
- Willingness of participants to be randomised
- Willingness of clinicians to recruit participants
- Number of eligible patients, carers or other appropriate participants
- Characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure
- Follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc.
- Availability of data needed or the usefulness and limitations of a particular database
- Time needed to collect and analyse data

Feasibility studies for randomised controlled trials may not themselves be randomised. Crucially, feasibility studies do not evaluate the outcome of interest; that is left to the main

study. If a feasibility study is a small randomised controlled trial, it need not have a primary outcome and the usual sort of power calculation is not normally undertaken. Instead the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision.

Pilot studies:
Pilot studies are a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It will therefore resemble the main study in many respects, including an assessment of the primary outcome. In some cases this will be the first phase of the substantive study and data from the pilot phase may contribute to the final analysis; this can be referred to as an internal pilot. Or at the end of the pilot study the data may be analysed and set aside, a so-called external pilot.

Please refer to **Appendix 1 of the RfPB Guidance to Applicants** for further information on applications for feasibility studies to RfPB.

Section: Lead Applicant Details

The Lead Applicant may be an NHS or University employee; in the latter case, the individual would need to have an appropriate relationship with the host NHS body to ensure proper governance and accountability. **As a minimum, the Lead Applicant must have an honorary contract with the NHS body (or other provider of NHS services) submitting the application.**

The RfPB programme particularly encourages junior investigators to apply to the programme, provided that sufficient support is provided through an experienced and appropriately skilled research team.

NOTE: It is mandatory for all Lead Applicants to register for an ORCID ID prior to submitting an application. Further details on how to register can be found at http://orcid.org/. Your details will have been pre-populated based on the information provided in the Manage My Details section of your account. These can be edited prior to submission.

Section: Co-applicant details:

Please note there is a maximum limit of 10 co-applicants.

All co-applicants are expected to make a substantive contribution to the management and delivery of the research. To reflect this, each co-applicant invited **must have both confirmed and approved this application before the submission deadline.**

Add Co-applicant:
The co-applicants in the team MUST be listed here or the composition of the research team may be unclear to the Panel who assesses the application. co-applicants' full job title, expertise and their role in the proposed research must be specified. All co-applicants listed must each confirm their participation in the project and also approve the application prior to the Lead Applicant submitting it.

Section: Patient and Public Involvement

The NIHR expects the active involvement of patients and the public in the research it supports. The NIHR recognises that the nature and extent of active patient and public involvement (PPI) is likely to vary depending on the context of each study or award. However, a successful application to the Programme is likely to have PPI embedded throughout the design of the proposed research. This should be clearly demonstrated within each stage of the application process. Therefore, when completing the Stage 1 application form, the NIHR expects that PPI is clearly demonstrated throughout the proposed research plan where possible. The Guidance for Applicants document provides more information on PPI in research.

In addition: a definition of patient and public involvement in research, further information and resources are available from INVOLVE; the NIHR Research Design Service provides advice on applications and the James Lind Alliance has a step-by-step guidebook on involvement in research identification and priority setting.

Were patients and the public actively involved in identifying the research topic, prioritising the research questions and/or preparing this application?:

Please indicate the ways in which patients and the public will be actively involved in the proposed research:

Section: Case for Support – part 1

You may find it helpful to refer back to the aims and scope and criteria sections of this document. The key is that the reasoning underlying all stages of the research should be transparent. Whatever the nature, it is vital to add as much detail as possible on design and methodology, including justification of sample size, power calculations and sample selection and exclusion criteria where applicable.

Research Title:
This is largely administrative and has been auto-populated based on your previous entry within Research Details.

NOTE: If you wish to amend it, you must go back to the Research Details section.

Aims and Objectives:
This section should be used to indicate the main aims/objectives of the research, outlining the research question which the work will address and, where appropriate, the main hypothesis.

Plain English summary:
The importance of a plain English summary

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

Many reviewers use this summary to inform their review of your funding application. They include clinicians and researchers who do not have specialist knowledge of your field as well as members of the public. If your application for funding is successful, the summary will be used on 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 we feel that your plain English summary is not clear and of a good quality then you may be required to amend your summary 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 www.involve.nihr.ac.uk/makeitclear.
For further support and advice on writing a plain English summary, please contact your local Research Design Service (where applicable) http://www.rds.nihr.ac.uk

Background and rationale:
Please provide evidence explaining why this research is important. Please also explain the size and nature of the problem to be addressed. In particular, applicants should be aware of ongoing research in this area and comment on any other research which might be deemed to overlap with the contents of the proposal. Applicants are advised to use both PubMed Central and Europe PubMed Central for recent material on the topic area they are applying for. Applicants should also be aware of any current commissioned calls on related topics, such as through the 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 present a summary of the findings of this in their proposal. All applicants must also include reference to relevant on-going studies, e.g. from trial registries such as the International Standard Randomised Controlled Trial Number (ISRCTN) registry, ClinicalTrials.gov and the European Union Clinical Trials Register.

What is the problem being addressed?
Describe the background to the research, describing the limitations identified in the evidence base that the research is trying to address.

Section: Case for Support – part 2

Research Plan:
Describe the proposed research plan, providing descriptions of the overall research design and a strong justification of sampling strategies, methods of data collection and analysis.

RfPB wishes to encourage both qualitative and quantitative research designs and recognises that these need to be presented in different ways.

It is vital to add as much detail as possible on design and methodology, including justification of sample size, power calculations and sample selection and exclusion criteria where applicable. Please provide enough information to allow the sample size calculation to be independently verified. Applications which propose to exclude non-English speakers will need to provide strong justification. The assessing Panel will consider the nature of the research/intervention being tested and will make a judgement on whether excluding non-English speakers is justified.

Researchers may find the SPIRIT 2013 statement a useful resource when preparing their protocol.

Please note that the references must be provided in Microsoft Word format or PDF. If a different format is used, you may not be able to submit your application or it may be difficult for the Panel to view the required information in order to assess your application. Please ensure that the document uploaded containing the list of references does not contain its own page numbering.

Section: Finances

The RfPB programme has a funding limit of £350,000 and the Panel will take into account the value for money provided by an application. Any application for a feasibility or pilot study is expected to cost less than £250,000, and applications for more upstream research, and where the patient benefit may not be directly realised through the proposal are expected to cost less than £150,000. Further details on funding limits can be found in Appendix 3 of the Guidance for Applicants, including a list of the types of applications which would be expected to cost less than £150,000.

This excludes any NHS Support and NHS Treatment Costs, which will not be met *via* any RfPB award.

NOTE: Please note costs entered should reflect total research costs.

These should be in FULL numeric value in £'s only. You should avoid the use of shorthand, inclusion of commas or decimal places.

When evaluating Stage 1 applications, panels will consider the value for money of the research, and the estimate you provide will guide them. If your subsequent Stage 2 application varies considerably from this estimate, the Panel might decide that it is no longer good value for money and therefore decline it. Therefore, we appreciate that if invited to Stage 2 the total Research costs may change, however if there is a significant change it would need to be clearly and strongly justified.

STAGE 2 APPLICATIONS:

If the Panel has invited a Stage 2 application then you will find that many of the sections have been pre-populated from your Stage 1 application. You must, however, be aware that:

- Sections that you submitted as part of your Stage 1 application might need revising in the light of the Panel's comments.

- Sections you have not yet completed are important in getting through a successful assessment. Bear in mind that the Panel has not seen or commented on these other sections so you will need to ensure that they are of high standard.

This part of the guidance details the additional sections/questions required as part of a Stage 2 submission, with the accompanying online guidance.

Section: Lead Applicant Details

Provide an approximate breakdown (%) of how your current appointment is divided between the following activities:
Please use this section to provide an approximate breakdown of how your current appointment is divided.

Administrative contact details:
Please provide contact details for any administrative contact, in the host NHS body, who you would wish to nominate as a secondary point of contact for any queries relating to the research, should it be supported.

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

Section: Lead Applicant CV
Information provided by the lead applicant will have been used to pre-populate this section. Whilst a Curriculum Vitae (CV) for the Lead Applicant is considered mandatory for submission, these details will automatically be populated into the online application from those entered as part of basic detail information.

Section: Applicant Publication Details
Each co-applicant must log into the RMS and open the application form to select the publications that they would like to appear in their CV, which is appended to the application form. Up to ten publications can be selected. All of the other CV details will populate from the 'My Details' page of their RMS account. **If a co-applicant does not select any publications in this section then no publications will pull through to the application form**. This may have a detrimental effect during the assessment of the application as the Panel will not have any evidence of the co-applicant's publication record.

Further information on how to complete an application for funding is available in appendix 7 and appendix 8

Applications submitted for consideration will be judged on the experience of the team and therefore it is advisable that each applicant select the most relevant publications relating to their application.

Section: Add Co-applicant:
Please note there is a maximum limit of 10 co-applicants.

The co-applicants in the team MUST be listed here or the composition of the research team may be unclear to the Panel who assesses the application. Co-applicants listed must each confirm their participation in the project and also approve the application prior to the Lead Applicant submitting it.

NOTE: 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. A separate text box is provided for this purpose in the 'Add applicant role and % FTE commitment...' section.

Please note, if you plan to involve more colleagues, these additional members of the team must be listed as collaborators and their contribution to the research must be detailed in the 'relevant expertise and experience' element within the **Case for Support** section.

Section: Co-applicant CV details:

Please note that completed CVs for all co-applicants are a mandatory requirement for submission and will be 'pulled through' into the application. To update these details, each co-applicant should visit the Manage My Details section by selecting 'Save and Close' at the top of this screen and accessing this section using the left hand menu toolbar.

All co-applicants are expected to make a substantive contribution to the management and delivery of the project. To reflect this, each co-applicant invited **must have both confirmed and approved this application before the submission deadline.**

Add applicant role and % FTE commitment...
Specify role in research: %FTE commitment:
For each co-applicant you will need to provide a brief overview of their role in the proposed research, elaborating upon this further in the 'relevant expertise and experience' element of the Case for Support section.

Each co-applicant should include the percentage of time that they will devote to the research. NOTE: Full-Time Equivalent (FTE) = percentage of full-time hours per week.

Note that if this is not completed then the Panel will not be able to assess the strength of the research team.

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.
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: Research and Development Office Contact details

R&D Contact Name:
Please provide the name, contact details and job title of the contact person in the R&D office of the contracting organisation so that we are able to notify this person of the outcome of this application including any associated feedback. In the event of this project being recommended for funding, we would also need to communicate with this person with regards to contract negotiations and general management of the project throughout its duration.
NOTE: Please note this person does not need to be included as a co-applicant.

Section: History of this application

Has this application, or a similar application, previously (or currently) been submitted to this or any other funding body?
Select 'Yes' if this application, or part of this application, has previously been submitted to this or another funding organisation, or any other NIHR or DH funding scheme. If this application has previously been submitted elsewhere, please ensure you revise your application in line with the scope of the RfPB Programme.

Title of previous application:
Provide the full research title of the application.

Funding body to whom it was submitted:
Identify the organisation to which it was submitted.

Funding scheme under which the application was submitted
Identify the funding scheme to which it was submitted.

Please indicate whether this was a Stage 1 (outline) or Stage 2 (full) application.
For applications submitted to a one stage funding programme, please select 'Stage 2 (full) application'

The reference number of previous application
Provide the reference number of the application.

If unsuccessful, please indicate why.
NOTE: instead, you may upload a copy of the relevant funding organisation assessment of the application and/or any pertinent reviewer comments/reports as part of the Supporting Documentation file.

Where a previous, related application was made to this funding scheme, please indicate how this research proposal differs from the previous application.
Please summarise the key changes made to the research in response to the feedback provided, if the related application was previously submitted to this funding scheme.

Section: Patient and Public Involvement

The NIHR expects the active involvement of patients and the public in the research it supports. The NIHR recognises that the nature and extent of active patient and public involvement (PPI) is likely to vary depending on the context of each study or award.

In addition: a definition of patient and public involvement in research, further information and resources are available from INVOLVE; the NIHR Research Design Service provides advice on applications and the James Lind Alliance has a step-by-step guidebook on involvement in research identification and priority setting.

Were patients and the public actively involved in identifying the research topic, prioritising the research questions and/or preparing this application?:

Please further describe how patient and public involvement has informed and/or influenced the development of the application and how patients and the public have been involved:
If you have selected either of the boxes please further describe the ways in which you have involved patients and the public.

Explain how patient and public involvement has informed and/or influenced the development of the research application including any of the following:

- Identification and/or prioritisation of the research topic
- Identification and/or prioritisation of the research questions

- Development of the research design
- Preparation of the application.

If patients and the public were not actively involved please explain why this was considered unnecessary:

Please indicate the ways in which patients and the public will be actively involved in the proposed research:

Please give more details, including how patient and public involvement will benefit the research, the reasons for taking this approach, and arrangements for training and support:
For the boxes ticked above, please outline:

- The aims of the patient and public involvement,
- The ways in which patients and the public will be involved (where appropriate, provide names of the individuals and/or groups (with consent)) and
- A description of any plans for training and/or support

Please note that a budget line for costs of patient and public involvement is included in the finance section which applicants are expected to complete.

For further information you can access an involvement cost calculator and a budget guide via INVOLVE's website.

If there are no plans for involvement, please explain why patient and public involvement is not necessary

Section: Case for Support – part 1

Scientific abstract of research:
Please note that this section of the application will be used as an overall summary, and therefore, should be a stand-alone section. Therefore, any abbreviations used elsewhere in the proposal should be defined here.

Why is this research important in terms of improving the health of the public and/or patients and the NHS?
Please provide evidence explaining why this research is important.

The rationale should aim to detail the:

- Likely benefits of the proposed research to patients
- Implications for the further development of clinical or public health practice
- Potential impact on local policy-making and improvement in service delivery

If your previous application was submitted in relation to one of the past NIHR themed calls, please indicate which call here.

Section: Case for Support – part 2

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

NOTE: your Gantt chart must be provided in Microsoft Word or PDF format for you to be able to submit your application and for the panel to view the required information in order to assess your application. A Gantt chart prepared in portrait format will result in a better presentation within the application; however, only a one page file is permitted.

Section: Case for Support – part 3

Projected Outputs and Dissemination:
In addition to traditional publication routes, please also indicate how any findings arising from the research will be disseminated so as to promote or facilitate uptake by users in the NHS. This may well include plans to submit papers to peer reviewed journals but it will be particularly important to identify additional forms of presentation that will maximise impact on practitioners and service managers if appropriate. Describe also how you will engage with patient or service user groups, health care planners, practitioners and/or policy makers and patient/service user groups, where appropriate.

We expect that when pilot or feasibility studies are proposed by applicants, a clear route of progression criteria to the substantive study will be described here, including identification of the potential funder of the substantive study.

NOTE: Please also provide information about plans for sharing the findings of the research with the research participants and patients/members of the public who were involved in the research project.

Dissemination
In line with the NIHR Policy on Open Access for its funded research, the RfPB programme anticipates that funded researchers seek to publish their research outputs in a peer-reviewed journal that is compliant with the policy on Open Access.

NOTE: Open access and publication costs can be included within the Finance section of the application form.

Expected Outputs of Research/Impact:
This could include plans to submit papers to peer reviewed journals but it will be particularly important to identify forms of presentation that will maximise impact on practitioners and service managers if appropriate.

It is expected that as part of the long-term research and/or implementation strategy, all research funded by DH or through the NIHR should be able to demonstrate that it is capable of generating outcomes that are likely to contribute to the benefit of those who use the services of the NHS.

Please also identify the anticipated timeframe of any potential impact on NHS services and/or benefit for users of NHS services.

Relevant expertise and experience:
Explain why the group is well qualified to do this research, describing the track record of the research team in applied health research. If members of the research team are international partners, justification should be provided for this along with an explanation of why this expertise could not be found within the UK.

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.

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

NOTE: If the salary costs of members of the team are not being sought via this application, it should be clarified how their contribution will be supported within the Finances section.

Section: Management & Governance

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

Research management arrangements:
Please outline the process that will be put in place to ensure that the project is well managed, commenting on the management structure that will ensure that milestones are achieved in a timely manner, identifying the project manager and clarifying the meetings schedule and financial management. Please also highlight the role of any advisory or reference groups associated with the research.

Researchers may find the SPIRIT 2013 statement a useful resource when preparing their protocol

Success criteria and barriers to proposed work:
A risk is defined as any factor which may delay, disrupt or prevent the full achievement of a research objective. Please 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 deal with them. This section should identify appropriate actions that would reduce or eliminate each risk or its impact. 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).

Does the proposed research raise ethical issues?
If Yes, discuss how these issues will be addressed.
Please outline any ethical issues associated with this research and the arrangements for handling them.
Please also describe any research governance arrangements that would apply to the proposed research.
NOTE: Research must adhere to the Research Governance Framework.

If yes, please detail how you intend to get an ethical review completed?

If no, please justify why you consider ethical review is or will not be required.

Have any appropriate regulatory bodies already granted a favourable opinion?:
If you select yes, please ensure that the name of the committee and date of the approval letter is specified.

Involvement of Clinical Trials Units

Is Clinical Trials Authorisation required?
Yes/no

All applications claiming CTU involvement must include a letter confirming support from the CTU involved as part of their submission, and enter the relevant CTU ID number (if a UKCRC registered unit) in the application form. A list of UKCRC CTU ID numbers can be accessed via http://www.ukcrc-ctu.org.uk/.

Applicants including a letter of support from a CTU should include the letter in the Supporting documentation section

Is a Clinical Trials Unit (CTU) involved with this research proposal?
Yes/no

If a CTU is not to be used, please explain why and who/what will be involved instead

If yes, what is the name of the CTU?
Please provide the name of the CTU involved.

Does the CTU hold a UKCRC registration number?
Yes/no

If yes, please provide the Registration Number.

Please describe how you have worked with the CTU in developing your application and what support they will provide if funding is approved
Please explain the involvement of the CTU in all stages of your research, including design and follow up, should the research be funded.

Clinical Trials Units are regarded as an important component of any trial application and can advise and participate throughout the research process from initial idea development and design through to project delivery and reporting. However they may not be essential for all types of research studies, and if you feel this is the case please justify the reasons in your application.

NIHR CTU Support Funding (http://www.nets.nihr.ac.uk/programmes/ctu) has been provided to some Clinical Trials Units to collaborate on NIHR research applications and funded projects, and these units will be especially interested to hear about potential research ideas and collaborations.

The UKCRC CTU site (http://www.ukcrc-ctu.org.uk) provides information and a searchable information resource on all registered units in the UK.

Clinical Trials Toolkit

Researchers designing or undertaking clinical trials are encouraged to consult the Clinical Trials Toolkit (http://www.ct-toolkit.ac.uk). This NIHR resource is an innovative website designed to help researchers navigate through the complex landscape of setting up and managing clinical trials in line with regulatory requirements. Although primarily aimed at those involved in publicly funded Clinical Trials of Investigational Medicinal Products (CTIMPs), the Toolkit will also benefit researchers and R&D staff working on trials in other areas, who will find useful information and guidance of relevance to the wider trials environment

The Medical Research Council's Guidelines for good clinical practice in clinical trials (http://www.mrc.ac.uk/documents/pdf/good-clinical-practice-in-clinical-trials/) provides further information on the involvement of CTUs.

Section: Intellectual Property and Innovation

The definition of Intellectual Property (IP) includes copyright (such as new software, checklists, scales, protocols, questionnaires, toolkits, guidelines or similar) and research tools (such as data analysis techniques, assays, cell lines, biomarkers, materials or equipment and devices) patents, trademarks and designs.

What relevant IP *(*patents, design right, copyright *etc.*) is held by the applicants and how does it relate to this application?:
The definition of Intellectual Property (IP) includes:

- Copyright (such as new software, checklists, scales, protocols, questionnaires, toolkits, guidelines or similar)
- Research tools (such as data analysis techniques, assays, cell lines, biomarkers, materials or equipment and devices)
- Trademarks
- Designs
- Patents

NOTE: The NIHR needs to understand your starting IP position in order to place that in context with any IP you may generate during your research, and also with reference to third parties' rights which may be found during due diligence searches. This knowledge will delineate the "rights" and who might own them.

Has a freedom to operate search been conducted and by whom?
If yes, please provide details of all relevant IP and how it relates to the application:
All related IP not owned by any of the applicants should be listed, including details relating to third party licence requirements.
Please indicate briefly the procedure you used to search for existing IP.
NOTE: You should indicate here what you have found from your searches, even if you have found nothing.
If no search has been conducted, please set out the rationale.

Will any IP be produced or improved during the proposed research?
If yes, please describe what IP will be produced or improved.
Indicate where and when new or improved IP will arise. Link this back to any existing IP that you may have previously mentioned. Indicate why you think the new IP is novel over what is already known in the literature.

Please describe how any new IP generated through the proposed research will be managed, protected and exploited, either through adoption in the healthcare service or through commercial exploitation:
Please indicate the plans for benefit realisation (adoption and/or commercial exploitation) of IP or products of your research applications, and whether you have commercial partners in place or in view. Please further detail what is likely to be the ultimate impact on the health service.
NOTE: It is important to demonstrate that you have plans and competent staff in place to manage any new (or existing) IP, as:

- NIHR funding requires benefit realisation from all resulting IP of value, this is not restricted to Patents and Devices, but includes Copyright and Knowhow, encapsulated in software, checklists, scales, protocols, questionnaires, toolkits, guidelines or similar that have a market within the healthcare service.
- Adoption in the healthcare service can also be achieved through the application of commercial exploitation models

What are the key current and future barriers to utilising any new IP/innovation through dissemination and adoption in the healthcare service or through commercial exploitation e.g. potential regulatory hurdles?
Please indicate where and when any regulatory hurdles will arise.

You should provide an indication of timing and any delays that may occur and whether this is something you or a commercial partner will have to deal with.

Section: NIHR Infrastructure and Other Partner Organisations

Please describe links to NIHR networks, identifying, if appropriate, any benefits that have already accrued from working with networks:
The programme expects, where appropriate, that the applicants will work with the relevant Local Clinical Research Network (LCRN).
Please indicate which network(s) (Clinical Research Networks) you intend to work with and the extent to which any links have been established. If appropriate, also add details of any other networks you may have been involved with in relation to the proposed study.

Research Design Services (RDS) Involvement

Please indicate, if applicable, which organisations (e.g NIHR Research Design Service) you have contacted in the course of preparing this application.
The NIHR Research Design Service (RDS) supports researchers to develop and design high quality research proposals for submission to NIHR and other national, peer-reviewed funding competitions for applied health or social care research. This includes giving advice on patient and public involvement in the development of applications, and any other aspects of research design.

Please find below details of the ten NIHR Research Design Services:

- East of England
- East Midlands
- London
- North East
- North West
- South Central
- South East Coast
- South West
- West Midlands
- Yorkshire and The Humber

Please describe the RDS's input.
Please give details of any advice you have received in preparing your application, e.g. from a statistician or health economist. Please also state at what stage in the development of the proposal the RDS were involved. It will be helpful to indicate whether this advice has been restricted to a single element of the design or has been more wide-ranging.

Involvement with other partners:
What, if any, other partner organisations will partner this research?

If other, please specify what other organisations will partner this research.
Please provide details of the other organisations involved (including international collaborations).

Describe the role, if any, these partners will have/have had with this research.

Section: Finances

REQUIRED READING

Prior to completing the finance section of the application it is important applicants have a good understanding of the following:

Attributing costs of health and social care Research and Development (AcoRD) guidance

The AcoRD guidance clarifies the distinction between the three categories of costs associated with non-commercial research studies/programmes:

- Research Costs
- NHS Support Costs
- NHS Treatment Costs

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
NIHR/DH will only fund activities attributed to Research Costs. However, for funding panel's to be able to make an overall value for money judgement, we require that both NHS Support Costs and NHS Excess Treatment Costs are outlined in the finance form.

We strongly recommend that applicants familiarise themselves with these definitions, and consult:
AcoRD Annex A: List of common research activities attributed to the Research Costs, NHS Treatment Costs and NHS Support Costs:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/351185/AcoRD_Annex_A_-__List_of_Common_research_Activities_March_2013_for_publication.pdf
AcoRD Annex B: FAQ:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/484554/Annex_B_AcoRD_FAQs__Dec_15.pdf

NHS England Guidance on Excess Treatment Costs

Before applications are submitted to the NIHR/DH, it is our expectation applicants have already contacted the appropriate NHS commissioner(s), to discuss and secure (in principle) the NHS excess treatment costs relating to the study.

NHS England has been working in consultation with Department of Health (DH) and other key stakeholders to develop an NHS England strategic plan on the process and funding of Excess Treatment Costs that delivers DH policy. As a result, NHS England has published new guidance to help clarify the rules and expectations which is available on the NHS England website. We strongly recommend that applicants familiarise themselves with this guidance: https://www.england.nhs.uk/ourwork/research/etc/

Clinical Research Network Study Support Service

Before applications are submitted to the NIHR/DH, it is our expectation applicants have already contacted the appropriate NIHR Clinical Network(s), to discuss and secure (in principle) the NHS support costs relating to the study.

The NIHR Clinical Research Network supports researchers and the life-sciences industry in developing, setting up and delivering high quality research to time and target in the NHS in England.

For any study that is eligible or applying for Network support, whether commercially or non-commercially sponsored, they offer a range of services across the research pathway that will help study feasibility, set up and delivery to time and target. Regardless of the location, study type, study size or therapy area of the research, the CRN will provide consistent and high quality support.

Whether it is help with regulatory approvals, assistance with site identification, or guidance with the costings for a study, our dedicated advisors are here to help. This infrastructure provides unparalleled access to, and understanding of, the NHS research environment. We strongly recommend that applicants familiarise themselves with the support service section of the NIHR CRN Website: https://www.crn.nihr.ac.uk/can-help/study-support-service/

Health Research Approval(s) (HRA) – Schedule(s) of Events

HRA Approval is a new process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent Research Ethics Committee (REC) opinion provided through the UK research ethics service.

It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.

The following types of trial will require HRA approval:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Any study type where the only site is also the NHS sponsor

One aspect of HRA Approval is ensuring that there is clarity on the resource implications for participating NHS organisations and others delivering research within an NHS care setting. The documentation required for submission to the HRA enables participating NHS organisations In England to assess and confirm their capacity and capability to deliver the research.

The HRA requires Statement(s) of Activities and Schedule(s) of Events documents: http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/before-you-apply-for-hra-approval/, for each type of research site in the study. The NIHR/DH recommends that prospective applicants use the HRA Schedule of Events document at the application stage as a tool to formulate site specific activities and to ensure consistency of format for when HRA approval is required. For more information on HRA approval please visit the HRA website: http://www.hra.nhs.uk/ (note that these documents do not replace the collaboration agreement(s) with the research collaborator(s) which is a NIHR/DH contractual requirement).

GENERAL INFORMATION

- Stage 1 applications are expected to provide an overview figure for the funds being requested. Detailed costs are required as part of stage 2 applications only; however, significant variations in the level of funds requested between stage 1 and stage 2 applications must be fully justified.
- The finance section should provide a breakdown of costs associated with undertaking the research as described in the application.
- The information entered in this section should provide an analysis of the total funds requested and should be based on current prices (an adjustment for inflation will be made annually thereafter at rates set by the Department of Health). These costs will be used to assess value for money.
- The NIHR/DH will not support any costs incurred prior to or following the Research Award.
- It is in your best interests to undertake a thorough, realistic and accurate costing approach. For stage 2 applications, the Selection Panel will pay close attention to any material increase in costs.
- You must provide clear and full justification for all costs; further itemisation of costs and methods of calculation may be requested to support the application at a later date.
- All applications are expected to have appropriate NHS, HEI, commercial and other partner organisation input into the finance section of the application form.

- 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 collaboration agreements or sub-contracts agreements must be put in place for any element of the R&D which is to be paid to another organisation.
- Years should be calculated starting from the estimated start date of the proposed research. For example, if your project is expected to start on 1 October 2016, then its second year starts on 1 October 2017.
- Once an award has been made, the Department of Health will require NHS organisations to provide regular financial statements regarding the use of funds provided under the NIHR/DH funding scheme. The Department reserves the right to send independent auditors to the organisation to confirm the actual use of funds.

INFORMATION FOR DIFFERENT TYPES OF ORGANISATION

Please note, cost items for *all* organisations types should be listed at 100 percent of the cost value. Subsequently, within the 'Research Costs Requested From Funder' summary table, the relevant percentage, as paid by the Funder, will automatically apply the percentage to be paid (by the Funder) to the total organisation type cost requested (i.e. 80% or up to 100%).

For organisations wishing to to claim less than the maximum percentage allowed, when adding a cost item you must select *'Other'* as the *'Type of cost'* and instead enter the percentage you wish to be paid against the relevant category in the summary table.

Higher Education Institutions (HEIs)

HEIs should determine the Full Economic Costing (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 organisations

Up to 100% of direct costs incurred by NHS organisations will be funded.

Commercial organisations

For commercial organisations or consultancies, please fill in direct costs and commercial indirect costs. Indirect costs should be charged in proportion to the amount of research staff effort requested. Up to 100% of costs will be paid, on the basis that all relevant parties have agreed to the commercial terms as laid out in the NIHR standard contract.

Other partner organisations

For other partner organisations (charities, Non-governmental Organisations, etc.), 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. Up to 100% of costs will be paid.

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

APPLICATION FINANCES

The NIHR/DH will **ONLY** fund Research Cost activities as described in AcoRD. The finance template categories the Research Costs into the following:

- Direct Costs
- Indirect Costs

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. Only costs that can be classified as research costs can be itemised under Direct Costs. Research costs are derived from the core research activities that are being undertaken to answer the research question(s), and will end when the research ends.

Direct Costs are further categorised into the following:

- Staff Posts and Salaries & Annual Costs of Staff Posts
- Travel, subsistence and conference fees
- Equipment (including lease versus purchase costs)
- Consumables
- Patient and public involvement
- Other Direct Cost
- Patent and Legal
- Sub-contracts

Staff Posts and Salaries

This section outlines the staff salaries and relevant on-costs (i.e pay increment dates, geographic weighting, superannuation, national Insurance). Salary costs should feed into the Annual Costs of Staff Posts section.

All staff members working on the project must be listed and their annual salaries must be stated. If there are any applicants whose costs are not being claimed, you will need to state the applicants' names and explain briefly why no costs are being claimed and how their contribution will be covered.

Use current rates of pay and build in any known annual increments. Nationally or locally agreed pay increases should be excluded. Once your project has started, you will not be able to claim for salary increases (through promotion) or pay awards retrospectively.

Annual Costs of Staff Posts
This section specifies the total annual costs of each applicant contributing to the Award. You should now allocate the individual staff member costs to each year of the Award, allowing for increments. Please note inflation should **NOT** be applied when calculating annual costs of staff posts.

Please note that the 'percent full time on this research' means the actual time spent on this research for the duration of employment through this project and should not be the average percentage over the whole project if a person is only employed for a certain amount of time. The 'Year' columns should reflect the actual annual costs of an individual for the research.

For example, if an individual's total annual salary costs are £20,000 and this person is expected to work 50% of their time on the research for 18 months, the 'percent full-time on this research' column should state 50 and the 'Total months on this research' column should state 18. The salary costs that should be entered into the 'Year' columns are £10,000 for 'Year 1', £5,000 plus any increments for 'Year 2' and £0 for 'Year 3'.
If an individual's involvement varies over the course of the research, it may be easier to make a separate line entry each time it changes.

Ensure that you check the column describing the employing organisation for a member of staff as this has an impact on the level of funding provided. Staff employed by an HEI are funded at 80 percent of cost and staff employed by the NHS, commercial or other partner organisation at up to 100 percent of cost.

Please note, NIHR/DH does not fund PhD studentships through its research grants (NIHR's main training opportunities can be accessed here: http://www.nihr.ac.uk/funding-and-support/funding-for-training-and-career-development/). It is possible, however, for a researcher employed on an NIHR/DH grant to register for a PhD based on the funded project, although the NIHR/DH will not reimburse fees.

Shared Staff Costs
This section also includes 'Shared Staff Costs' which are located under directly allocated costs in some other funders' applications. These are a share of the costs of a resource used by an project, where the same resource is also used by other projects or activities. These are different to the Direct staff costs listed above because these costs are not exclusively related to any individual project. However, the cost of the resource still needs to be recovered, and making a fair and reasonable charge to all Awards using the resource does this. Staff such as academics and research staff (who work on more than one project) and pooled laboratory technicians should be identified in the finances as shared staff. Charge-out rates for shared staff are generally applied to researcher FTEs to derive an estimated cost for each project, and do not change during the life of the Award. Please note, additional HEI

indirect costs cannot be claimed on shared staff, as indirect costs and estate costs are already inclusive in the charge-out rate.

Maternity/paternity and sick leave
Maternity/paternity or sick leave costs are not funded by the NIHR/DH funding awards. For the NHS these costs are met through Research Capability Funding (RCF). The net costs incurred by a host organisation in meeting the salary of an individual supported by NIHR, while on maternity, paternity or long-term sick leave, less any recoverable statutory pay that the employer is entitled to claim. RCF should only be used to fund the share of costs that relate to the proportion of a person's WTE that NIHR/DH meets on a research grant. RCF is only available to NHS organisations in receipt of NIHR/DH funding. We expect equivalent costs associated with maternity, paternity and sick leave incurred on NIHR research awards to universities to be met from within the full economic cost envelope, which is provided to the host university by NIHR/DH.

Travel, subsistence and conference fees

This section of the Financial Form includes journey costs, subsistence and conference fees.

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/DH programmes do not usually fund first class travel.

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

Conference fees
Where national conference fees are included, a statement naming the conference or purpose of travel and the benefit to the award must also be made; failure to adequately justify your attendance at a conference will mean the NIHR/DH will not fund this cost.

This section includes journey costs, subsistence and conference fees. Where applicable, you will need to include the travel and subsistence costs of your steering committee, data monitoring committee and ethics committee. Travel and subsistence costs relating to dissemination should also be included here. For research of up to three years, the programme will usually fund up to a maximum of two international conference attendances (two people attending one conference or one person attending two conferences). There are no limits on the number of UK conference attendances.

Equipment

Purchase or lease costs for essential items of equipment plus maintenance and related costs not included as part of estates can be requested from the NIHR/DH. Only purchase costs of pieces of equipment 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 the same type of equipment is permitted. Costs of computers are normally restricted to a maximum of £650 each excluding VAT. 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 or recover the VAT on a piece of equipment, you should check the column 'VAT cannot be reclaimed'. You will need to seek advice from the organisation the piece of equipment is purchased from regarding its VAT status. If you check the 'VAT cannot be reclaimed' column, VAT will be calculated at 20 percent into the overall cost of that item.

Applicants are asked to provide the 'Expected lifetime' of each item of equipment in months. This relates to the depreciation rate of the equipment. All purchases under £5k are are depreciated immediately at the time the payment is made. In general, we would expect computer equipment to depreciate over a 3 year period (1/3 of its value per year). 5 years minimum and 10 years maximum for scientific equipment.

Consumables

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

Patient and public involvement (PPI)

Please itemise and describe fully all patient and public involvement and engagement costs. This will include:

Payments for time, skills and expertise:
Offering members of the public payment for their time, skill and expertise is considered good practice in structuring and operating the proposed CRF. Rates of payment can vary and may be offered at either an hourly or daily rate. The following activities should be considered:

- Reviewing documents
- Attending meetings
- Attending training courses and conferences
- Outreach and dissemination

All out of pocket expenses should be covered. Equal opportunities for involvement are facilitated if expenses are covered. Members of the public should not end up financially worse off for providing a public service. The following expenses should be carefully considered:

- Travel (public transport, taxi fares, or an agreed private car mileage rate which includes wear and tear).
- Overnight accommodation (max inside London is £115 and outside London is £85).
- Subsistence (food and refreshment whilst on 'business' or bought due to having to be at a certain place at a certain time, but no alcohol) (somewhere in the region of £20-£30 per day).
- Childcare or replacement carer/person providing support (somewhere in the region of £100 per day).
- Costs of a Personal Carer or Support Worker of the individual's choice.
- Telephone, internet access, fax costs, stationery and other equipment – covering these costs is particularly important for members of the public who work from their own home and therefore may incur considerable costs which may be 'invisible' in organisational settings (somewhere in the region of £10 to £20 per day).
- Conference fees and training courses.

INVOLVE has produced an online cost calculator to help staff supporting research identify and calculate the costs of public involvement in their research-facing activities. It includes a guide - **Budgeting for Involvement** with step-by-step practical advice, examples and tips. The **Involvement Cost Calculator** can then be filled in and downloaded.

Other Direct Costs

These are costs, not identified elsewhere, that are specifically attributed to the research. For example, costs associated with the use of research facilities, external consultancy costs, specialist publications, open access publications, 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 cost 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, specifying the hourly rate and the number of hours. Please 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.

Any costs associated with publication, presentation or dissemination of findings (except related travel and subsistence or consumables costs) should be itemised and included here. 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.

Indirect Costs

Indirect costs are for activities or services that benefit more than the proposed Award. Their precise benefits to a specific research study are often difficult or impossible to trace.

Indirect Costs should be charged in proportion to the amount of 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
- Central and distributed computing
- Charge out rates for shared equipment
- Cost of capital employed

Each organisation involved in the award should have their indirect costs individually itemised in the finance form. Please note, this is only applicable to organisations eligible to apply for indirect costs (see below for more detail).

NHS Bodies or other providers of NHS services indirect costs

NHS Indirect Costs **cannot** be claimed through NIHR/DH programme funding. From April 2012, 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. The RCF is allocated by the Department of Health to research-active NHS bodies or other providers of NHS services in receipt of NIHR/DH income, or via NHS bodies or other providers of NHS services that host local NIHR Clinical Research Networks. It will enable NHS bodies or other providers of NHS services to meet some, or the entire research-related component of the salary of their researchers and research support staff working on clinical and applied health research, where that component is not already provided by another funding source. It will also contribute towards costs relating to sponsorship and governance, accommodation, financial management, and human resource management. For more information please click on the link below:

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

Higher Education Institutions (HEIs) Indirect Costs

HEIs can claim for Indirect Costs in proportion to the amount of research staff effort (FTE) requested on the award. Individual institution Indirect Costs rates should have been calculated using Transparent Approach to Costing (TRAC) methodology. Indirect and Estates Costs should not be calculated against shared staff FTE.

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. It is our expectation that Commercial/Other Partner Organisation Indirect Costs show good value for money.

Commercial/Other Partner organisation's indirect costs need to demonstrate value for money. The NIHR/DH reserves the right to set limits on indirect costs charged.

NHS Support, Treatment and Excess Treatment Costs

Applicants are required to provide an estimate of the patient care costs associated with the research (if applicable). Each patient care activity (e.g.staff costs and non staff costs) should be broken down into per patient cost, which is normally calculated by dividing the patient care cost (e.g. staff time consenting, staff time to delivering the patient care intervention, drug cost etc) by the number of patients receiving the patient care.

Please be aware, although the NIHR/DH does not fund NHS support and/or NHS Treatment and Excess Treatment Costs, to make a value for money judgement on the award all cost categories (i.e. Research, Support and Excess Treatment costs) need to be considered.

A representative of the NHS organisation incurring any NHS support and excess treatment costs must sign off the application. The 'Declarations and signatures' 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 staff time to recruit and consent patients, or additional patient safety activities which will not form part of the on-going intervention.

Please note, the Support Cost activities (such as consenting patients) should always be attribute to NHS Support Costs regardless of whether a member of staff is/is not employed by the NHS.

The NIHR Clinical Research Network (CRN) is responsible for funding NHS Support costs.

NIHR Clinical Research Network (CRN)

The NIHR CRN fund research support posts in the NHS, and provide training, so that researchers have access to experienced "front-line" staff, who can carry out the additional

practical activities required by their study such as obtaining patient consent for participation, carrying out extra tests, and collecting the clinical data required for the research.

NIHR/DH funded Awards are eligible for Network support, whether commercially or non-commercially sponsored, they offer a range of services across the research pathway that will help study feasibility, set up and delivery to time and target. Regardless of the location, study type, study size or therapy area of the research, they will provide consistent and high quality support.

NIHR CRN Route Map:
http://www.nihr.ac.uk/funding-and-support/documents/Study-Support-Service/CRN_support_routemap_2016_final.pdf

NIHR Study Support Service:
http://www.nihr.ac.uk/funding-and-support/documents/Study-Support-Service/CRN_SSS_leaflet_Sept16_forweb.pdf

Under the *'Have you discussed and agreed these costs with the Lead Network?'* section, applicants have the option to select Yes or No. We would only expect 'No' to be selected if the Award does not include patient recruitment, patient consent or patient care activities within an NHS setting. If applicants select 'Yes' then we would expect the applicant to provide the name and contact details of the network officer who signed off the NHS Support Costs. In addition, we recommend the applicant obtains a letter of support from the Lead Network agreeing to supply the resources to cover the NHS Support Costs, and attach it to the application as an appendices.

NHS Treatment and Excess Treatment Costs

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.

Please note, activities and items, which are integral to delivering the patient care intervention (and would form part of the ongoing intervention) should always be attributed NHS Treatment Costs.

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 trust partner(s) 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.

Awards that are testing patient care interventions in a ***Phase 1*** or a ***First in man*** trial (i.e. the first time intervention has been tested on patients/healthy volunteers, small patient sample sizes, focused on the safety rather than efficacy of the patient care intervention), the costs relating to manufacturing the patient care intervention at this stage should be attributed to Research Costs. However, the delivery of the intervention should follow the normal attribution process, i.e. NHS Treatment Costs. In contrast, Awards testing patient care interventions in a ***Pilot*** or ***Feasibility*** trial, the costs relating to both manufacturing and delivery of the patient care intervention at this stage should be attributed to NHS Treatment Costs.

Under the *'Have you discussed and agreed the NHS costs with the Lead Trust?'* section, applicants have the option to select Yes or No. We would only expect 'No' to be selected if the Award is not testing a patient care intervention. In addition, we recommend the applicant obtains a letter of support from the Lead Trust agreeing to supply the resources to cover the NHS Excess Treatment Costs, and attach it to the application as an appendices.

NHS England

Research is an important core activity of the NHS that NHS England is keen to promote and support in line with its statutory responsibility. It also has a responsibility to ensure that the treatment costs of patients, involved in non-commercial research, funded by the Government and research charities, are met.

NHS England has been working in consultation with Department of Health (DH) and other key stakeholders to develop an NHS England strategic plan on the process and funding of Excess Treatment Costs that delivers DH policy. As a result, NHS England has published new guidance to help clarify the rules and expectations:
https://www.england.nhs.uk/ourwork/research/etc/

Justification of costs

Under the *'Please explain how the research costs requested have been calculated and justify how they have been allocated'* section, applicants should provide a justification of each cost item requested in the finances (i.e. staff, travel and subsistence, equipment, consumables, PPI, other direct costs and indirect costs), explaining why they are essential and how they have been calculated.

Under the 'Please explain how the NHS Support and Treatment costs requested have been calculated and justify how they have been allocated' section, applicants should justify the NHS costs associated with undertaking the research and the resources required. If there are no NHS support costs or excess treatment costs associated with the research, you must

explain why this is the case. You should also indicate here how your research will potentially benefit the NHS (likely cost savings, treatment times, etc.)

Under 'Please explain how the research provides value for money' section, applicants are expected to demonstrate how the study provides value for money. Contrary to how it sounds, value for money isn't just about saving money, it is about ensuring that the study is efficient, effective, and economical. It is not the case that the cheapest Award always represents better value for money. Pointing to the conversion of inputs-outputs and outputs-outcomes is of real interest when making value for money judgements.

Section: DH Monitoring information

UKCRC Health Categories:
Please select all appropriate categories from the UKCRC Health Categories list.
NOTE: For guidance please see the UKCRC Health Research Analysis.
http://www.ukcrc.org

Programme Monitoring Data
For each category below please tick all that apply:
Please use the drop-down menus and tick boxes to provide the information requested. This will be used by the Department of Health and the NIHR for accountability, audit and monitoring purposes.

Section: Research Design Service (RDS) Involvement

The NIHR Research Design Services (RDS) support those developing application submissions. If you have received advice, we would value your feedback on the services you received from your local RDS in order to improve service; your individual comments will not be attributed to you.

NOTE: Responses to these questions will not constitute a part of the assessment of your application by the NIHR.

Section: Suggested Reviewers

Please suggest three potential peer reviewers who have the relevant expertise to provide appropriate peer review for your application:
These reviewers should be independent (i.e. not have worked with you directly in the recent past) and should have no competing/conflicting interests with your application (such as being from your own institution/university). Your suggestions will be used as only one source of peer reviewers and these individuals may not be approached to undertake a review.

Section: Reviewers NOT to approach

Please list up to three individuals who would not be suitable to review this application due to competing/conflicting interests.

Section: Supporting Documentation

The following file(s) are considered non-mandatory annex(es) to submission; if you wish, please attach;

- Any further supporting documentation (e.g. diagrams, pictures, trial protocols, any letters of support *etc.*)

Please note that all supporting documentation should be uploaded in one single file, in PDF format and should be given the file name "Supporting documentation", including your five digit pre-submission number.

Please note that it is not a requirement to provide the Panel with any specific details about patient data, for example names and addresses. However, if you do provide this information please ensure and state that you have consent to share this information.

NOTE: All supporting documentation must be combined into one PDF file to upload on to the system. The file must also contain a summary page at the beginning, with a list of the documents contained within it.
The total file size of supporting documents should not exceed 5MB. Files larger than this may not be considered as part of this submission.

Section: Declaration

Please declare any conflicts or potential conflicts of interest that you or your co-applicants may have in undertaking this research, including any relevant personal, non-personal and commercial interest that could be perceived as a conflict of interest.
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.

I confirm that I have read the NIHR Carbon Reduction Guidelines and, where possible, taken steps to reduce the carbon emissions generated by this research:
Please tick the box to confirm that you have read the NIHR Carbon Reduction Guidelines and, where possible, taken steps to reduce the carbon emissions generated by this research.

NOTE: Researchers applying for funding are asked to consider the carbon footprint of their research and take steps to reduce carbon emissions where appropriate. Advice on how to do this can be obtained from the NIHR Carbon Reduction Guidelines.

Section: Declarations and Signatures
(Please note this is now completed online via the RMS prior to submission)

Before submitting an application, applicants are expected to have discussed their research with their own and any other body whose co-operation will be required in the conduct of the research. The Declarations and Signatures section must be completed online via the RMS. An electronic signature should be provided by the **Lead Applicant** to confirm that the content of the application is complete and correct. An **administrative** or **finance officer for the NHS host** (contracting) **body** should electronically sign to confirm that the financial details of the application are correct and that the host organisation will agree to administer the award if made. A **representative of the NHS host body** must also sign off the application to ensure that the organisation is satisfied that all costs in the research are correct, including any element to be passed on to a university or other partner (through a collaboration agreement and/or sub-contract), and that the host organisation agrees to administer any award which is made and is capable of fulfilling the role of research sponsor as set out in the Research Governance Framework for Health & Social Care. **This section must be completed by the NHS partner, as this will be the contracting organisation.**

Guidance on how to complete the Declarations and Signatures can be found in Appendix 8.

Appendix 8 – Guidance on using the Form

Additional guidance on using the online NIHR Application Form

To submit an application you must complete all the relevant sections of the online form managed by the **Central Commissioning Facility Research Management System (CCF RMS)**. Please note that the RMS functions best in the Internet browsers Chrome and Internet Explorer 9 or above.

Registration
Only registered users of the system can apply and applicants should follow the online prompts and system help guidance for specific issues.

Managing your details
The home page is your starting point to create applications, or to update your details, including your professional and academic CV. Applicants and co-applicants can manage their CVs in 'Manage my Details'. Please note your CV details are considered mandatory to submission and will automatically be included in the application submission (except for your publications which each co-applicant needs to select from within the application form. The co-applicant details section of the online form allows PPI co-applicants to provide further details about their knowledge, skills and experience relevant to their role.

Creating an application
The Lead Applicant must be the one who creates the application, but it can be jointly completed by the Lead Applicant and any co-applicants. Once an application has been created by a Lead Applicant it is not possible to change the Lead Applicant on this application.

Co-applicants may be added to the application at any time before application submission. When a co-applicant is added, the RMS will automatically email them to invite their participation. Co-applicants can then decide whether to accept their inclusion, and later to consent to the application being submitted jointly in their name.

Please ensure that all co-applicants invited to collaborate on this application have confirmed their involvement and approval of the application form content or you will be unable to submit the application.

Completing an application
The sections of the application form are listed as a menu down the left-hand side of the screen. To submit the application all sections must be completed. You can move from page to page using the '**Previous**' and '**Next**' buttons, or using the menu on the left-hand side.

To assist with completing the online application form the 'Page Tracker' icons provide an overview of whether a particular section of the form is complete or not. Once all of the

mandatory fields have been completed within a section a green tick will replace the red cross on the 'Page Tracker'.

On screen help is provided throughout shown as a '?', and you should refer to this for specific guidance on individual questions as you complete your application form online.

Remember to save your work. You will be prompted to save your work if you leave the screen but it is always good practice to save work often in case of computer problems. **You can save and return to the application form as often as you like before the submission deadline.**

The system will prevent your co-applicants accessing your application at the same time as you. This stops the Lead Applicant and co-applicants inadvertently making changes to the same part of the application at the same time and overwriting each other's work.

Applicant Publication Details

Each co-applicant must log into the RMS and open the application form to select the publications that they would like to appear in their CV, which is appended to the application form. Up to ten publications can be selected. All of the other CV details will populate from the 'My Details' page of their RMS account. **If a co-applicant does not select any publications then no publications will pull through to the application form**. This may have a detrimental effect during the assessment of the application as the Panel will not have any evidence of the co-applicant's publication record.

- Each applicant must first update the publications in their personal 'My Details' page. See section 5.2 of the 'system text' document for further details on updating your CV.
- To select the publications each co-applicant must log into their own RMS account, open the application form and navigate to the fourth section, 'Applicant Publication Details'.
- To select the publications, click on the green button next to the text 'add publication' to open up the first slot. Select a publication from the dropdown box.
- To select another publication click on the green button again to select the next slot. Up to ten slots can be opened.
- When you have selected the publications click on the double headed green arrow button to drag the publications into the correct order.
- Use the red delete button to remove a publication slot from the list.
- The save button must be used to save the selections in their respective order.
- To view Lead and co-applicant publications and CV details download the PDF of the application form. CVs are appended at the bottom of the application PDF.

Applications submitted for consideration will be judged on the experience of the team and therefore it is advisable that each applicant select the most relevant publications relating to their application.

Please note that if applicants do not select any publications in this section no

publications will be visible on the final application form PDF

Electronic Declaration and Signatures
Before a Stage 2 application can be validated and submitted, applicants are now required to gain electronic approval from the relevant authorities within the contracting organisation **before the application deadline**. The signatories (Grants and Contracts Manager/Chief Executive/Senior Manager and Director of Finance) from the contracting organisation must be added to the online RMS application form. This will send an automated email with a link inviting the contact to create an RMS account. The contact will then have access to the application form so they can approve the application and tick the appropriate box. **Until this has been completed the lead applicant will be unable to validate and submit the application**

Instructions for the signatories
The signatories will receive an email inviting them to participate on the application.
1. Please create an RMS account and navigate to the relevant application form.
2. Click on the 'edit' button in the right side menu in order to view the application form.
3. Once happy with the content of the application form navigate to the Declaration page and tick the box to electronically sign the application form.
4. Click 'save and close' to save changes to the application form.This will take you back to the main screen.
5. Click the 'approve' link in the bottom right hand corner for the application.

Submission and beyond
When the application form is complete it must be validated prior to submission. This will highlight any omissions in the form, and allow these omissions to be corrected. After successful validation the Lead Applicant may submit the application.

The Lead Applicant and co-applicants can preview the progress of their application at any time by selecting the '**View/Print**' option to generate the application as a PDF File.

On completion of the validation
Upon submission a reference number will be assigned to the application. The application automatically enters the process of being considered for funding, which begins after the competition round closes.

Exiting and returning to work on your form
Should you wish to exit your form, you can return to the form at any time; simply log in using your username and password and select 'My Applications' from the menu. You will then be presented with a list of all the applications you are currently involved with as well as providing details as to their stage in the submission process.

[1] Under schedule 4 paragraph 138 (2) (c) of the Health and Social Care Act 2012, “NHS body” means: (a) the Board; (b) a Clinical Commissioning Group; (c) a Special Health Authority; (d) an NHS trust; and (e) an NHS Foundation Trust.