

RfPB STANDARD APPLICATION FORM (STAGE 1)

Please note that this Word template <u>cannot</u> be submitted as an application. Only applications submitted online via the CCF RMS will be accepted, however information can be copied from the Word template into the online application form.

Section: Introduction

Please note the following information and guidance is intended for applicants submitting an application to the Research for Patient Benefit (RfPB) programme ONLY.

There are a number of **online guidance prompts** (marked as a ?) available to you throughout the online form to help you when completing an application. It is **strongly advised that you also read the <u>Guidance for Applicants</u> document before completing your application. Applicants should observe the maximum word limits as indicated throughout the form.**

The deadline for this call is 1pm on 22 March 2017

Any colleague(s) invited to participate on this bid will be required to log into the system, access the application and actively select both the 'confirm' and 'approve' options. 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**.

Whilst confirming and approving an application can be done at any time during the submission of an application it is strongly encouraged that this is done well in advance of the deadline. Note that coapplicants who have not confirmed their role and approved the application by the 1pm deadline on 22 March 2017 will need to be removed from the application in order for the form to be submitted through the online system.

Before submitting an application, applicants are expected to have discussed it with their host organisation and any other body whose co-operation will be required to conduct the research. The host organisation must be capable of fulfilling the role of research sponsor as set out in the Research Governance Framework for Health & Social Care and agrees to administer any award which is made and provide the associated NHS costs.

Please note that any information included in the Stage 1 application form is automatically included in the subsequent Stage 2 application form, if invited. Any information automatically included in an invited Stage 2 application form can be edited at a later date and revised in line with any feedback from the Panel.

Should you require assistance in completing the online form, please contact the CCF at 020 8843 8057 or by emailing rfpb@nihr.ac.uk.

Reference: RfPB comp 32 Stage 1-v3 Date updated: 18 November 2016

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.

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 lead in 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.

01/04/18

Research duration (up to 36 months):

Please indicate the expected length of the proposed research in months.

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

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

Reference: RfPB comp 31 Stage 1-v6 updated: 01 December 2016

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.

Feasibility Study/Pilot Study/Primary Research/Secondry Research/n/a

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: An Orchid ID is a required field. 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.

Forename(s) Auto populated from the	Surname Auto populated from the 'Manage my details'
'Manage my details' section	section

Reference: RfPB comp 31 Stage 1-v6

Post held:

Please specify if other

post is held:

Organisation:

Specialty:

Please specify if other:

All information in this box is auto populated from the 'Manage my details' section within the Lead Applicant's CCF RMS Portal account, which

Department:

Address: should be updated and edited prior to submission.

Post Code:

Country:

E-mail:

Tel/Ext/ Mobile No:

Reference: RfPB comp 31 Stage 1-v6 updated: 01 December 2016

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 listed must each confirm their participation in the project and also approve the application prior to the lead applicant submitting it.

The section below must be completed for each co-applicant.

For each co-applicant you **MUST** provide a brief overview of their role in the proposed research and include the percentage of time that they will devote to the research. When you have added a co-applicant to the application form click on the link below and select the applicant from the drop-down box to enter their expertise and FTE commitment. Failure to do so will mean that the Panel may not be able to adequately assess the strength of the research team.

Add applicant role and %FTE commitment...

Forename(s)

Surname

Name of co-applicant

Please note once a co-applicant has been 'invited' their details will automatically appear in the field below.

Reference: RfPB comp 31 Stage 1-v6

Is this a patient/public co-applicant?	Yes/No
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. (500 words)	
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.	
Specify job title, expertise and role in research (75 words):	
For each applicant you will need to provide job title, their expertise and a brief overview of their role in the proposed research.	
%FTE commitment 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.	

Reference: RfPB comp 31 Stage 1-v6 updated: 01 December 2016

Section: History of this application

Has this application, or a similar application previously 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.

NOTE: If this application has previously been submitted elsewhere, please ensure you revise your application in line with the scope of the RfPB programme.

Yes/No

Title of previous application (100 words)

Provide the full research title for the application.

Name of Lead Applicant

Funding body to whom it was submitted

Identify the organisation to which it was submitted previously.

Funding scheme under which the application was submitted

Identify the funding scheme to which it was submitted previously.

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'.

Stage 1/Stage 2

The reference number of previous application

Provide the reference number for the application.

Outcome

Funded/Pending/Unsuccessful

Please state the outcome date, if a decision is still pending.

If unsuccessful, please indicate why. (200 words)

Where a previous, related application was made, please indicate how this research proposal differs from the previous application. (200 words)

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.

Reference: RfPB comp 31 Stage 1-v6

Section: Patient & Public involvement

research questions and/ or preparing this application?

If yes, please tick all relevant boxes below.

The NIHR expects the active involvement of patients and the public in the research it supports. 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.

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

	Yes	No	
Involved in identifying the research topic/prioritising the research questions			
Involved in preparing the application			
Please indicate the ways in which the publ ticking all relevant boxes below:	ic will be actively	y involved in the	e proposed research, by
tioning an iolovant boxoo bolow.			
Design of the research			
Management of the research (e.g. steering/advisory group)			
Developing participant information resources			
Undertaking/analysing the research (e.g. member of the research team)			
Contributing to the reporting of the study report			
Dissemination of research findings			
No plans for involvement			
			4

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Other

Section: Case for Support - part 1

You may find it helpful to refer back to the aims and scope and criteria sections of the <u>Guidance for Applicants</u> 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.

ResearchTitle

This has been autopopulated based on your previous entry within Research Details.

NOTE: Any amendments made to the Research Title here will automatically update the previous entry within Research Details.

Auto-populated from the Research Details Section

Aims and objectives

Describe the overarching aims of the research, outlining the research question which the work will address. **(500 words)**

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

Please summarise your proposed research in plain English. (300 words)

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

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Date

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

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. (1000 words)

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.

Reference: RfPB comp 31 Stage 1-v6

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.

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. (2500 words)

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.

The following file is a mandatory annex to submission, please attach:

• A list of references cited in the application. This MUST be provided as a Word or PDF document.

NOTE: Please note that the references **MUST be provided as a Word of PDF document** or 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.

Reference: RfPB comp 31 Stage 1-v6

Section: Finances

Summary 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: 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.

Please provide an estimate of the total research costs of this project in line with the funding limits outlined within Appendix 3 of the Guidance for Applicants.

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.

Total Research funder	costs from	

Section: Validation Summary

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Date

Please follow the next steps in order to complete your aplication submission process;

- Validate all mandatory/required fields listed below (that are required to be completed/amended before submitting)
- Click 'Save and Close'
- Click the 'Submit' option (this must be completed by 1pm, 22 March 2017)

You will receive and automated email containing the acknowledgment that we have received your application.

SAMPLE

Bottom

If there are no validation requirements above you may be ready to submit the application. To do so 'Save and Close' the application.

Please note that your submission will not be considered complete until <u>all</u> applicants have both confirmed and approved the application and the 'Submit' button becomes available and is then used.

Reference: RfPB comp 31 Stage 1-v6