

Research for Patient Benefit
Supporting Information for Stage 1 and Stage 2 Applicants

Section 1: Introduction	2
Section 2: Privacy and Data Protection	2
Section 3: Research Design Service	3
Section 4: Clinical Trials Unit (CTU) Support	3
Section 5: Resubmission Policy	3
Section 6: INVOLVE/Public Involvement	4
Section 7: Systematic Reviews	4
Section 8: Ethics / Regulatory Approvals	4
Section 9: UK Biobank	4
Section 10: Carbon Reduction Guidelines	5
Section 11: Transparency Agenda	5
Section 12: Guidance on Completing the Application Form	5

Section 1: Introduction

This document contains information to assist applicants in submitting an application to the RfPB programme. Applications for funding are made online through the CCF Research Management System (RMS). You must register or log-in to the RMS to complete and submit your application.

Please also ensure that you have read the appropriate Stage 1 or Stage 2 application form guidance notes fully. Potential applicants are also encouraged to visit the programme [website](#).

The following supporting information is available on the RfPB webpage:

[Programme aims, scope and eligibility](#)

[Guidance on funding limits](#)

[RfPB finance guidance](#)

[Review of Tier 3 funding](#)

[Guidance on applying for feasibility studies](#)

[Guidance on further evaluations of established interventions](#)

Advice on developing information resources (see [FAQ](#))

[Frequently asked questions](#)

Other supporting information:

[MRC complex intervention guidance](#)

[ISRCTN registry](#)

Section 2: Privacy and Data Protection

The CCF Research Management System (RMS) is hosted by Pulsant (<http://www.pulsant.com/>). The Data Controller for the website is the Department of Health (DH). The Data Processor is the CCF, based at LGC.

The purpose for which personal information is collected through the RMS is to deliver the work of the CCF in relation to the operation of research programmes, faculty and infrastructure work-streams. Data will not be used for any other purpose without the consent of the supplier.

Use of the registration and application facility on the CCF RMS is entirely voluntary and the personal information stored will be used solely by the CCF, its subcontractors and partners in order to respond to your enquiries and send information relevant to its work.

To prevent unauthorised access, maintain data accuracy, and ensure the correct use of information, the CCF has put in place appropriate physical, electronic, and managerial procedures to safeguard and secure the information it collects online. The information you provide will be held securely and in accordance with the Data Protection Act 1998. The Department of Health, National Institute for Health Research (DH NIHR) is the Data Controller. Your personal details provided on registration will not be disclosed to third parties. Details that are provided on research application forms must necessarily be shared in confidence with third party individuals involved in making funding decisions.

Your information may also be shared with other DH NIHR bodies for the purposes of statistical analysis and other DH NIHR management purposes, including targeted communications with selected groups of

Supporting Information for RfPB Applicants

researchers. In addition, information collected is used by the CCF, its subcontractors and partner organisations:

- To administer the grant application process
- To identify peer reviewers for grant applications
- To notify users about funding opportunities by email
- To notify relevant users about application deadlines by email
- To notify users of any issues of service interruptions, holiday closures and other situations affecting the operation of the CCF RMS.

If we change our privacy policy, for example, in response to changes in legislation, we will post details of any changes on our website. This will help ensure that you are always aware of what information we collect, how we use it, and under what circumstances, if any, we share it with other parties. In some circumstances, explicit consent to continue use of the Services may be required. Otherwise, your consent to changes will be implied by your continued use of the Services. If you do not consent to the changes, then you must terminate your agreement as set out in section 12 of the NIHR CCF AND PRP CCF Grant Application System Terms and Conditions.

More information can be found at:

<http://www.nihr.ac.uk/funding-and-support/documents/Confidentiality-guidance.pdf>

Section 3: Research Design Service

Applicants may wish to seek advice on the content of an application *via* their regional [Research Design Service](#) (RDS). It is advisable to make contact as early as possible to allow sufficient time for discussion and a considered response.

Section 4: Clinical Trials Unit (CTU) Support

CTUs are regarded as an important component of any trial application and can advise and participate throughout the 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. If you feel this is the case please justify the reasons in your application in the appropriate section.

If you are looking for a CTU to collaborate with in your application, then the following sources can provide more help:

[CTU Support Funding](#) provides information on units receiving funding from the NIHR to collaborate on research applications to NIHR programmes and funded projects.

The [UKCRC CTU Network](#) provides a searchable information resource on all registered units in the UK, and lists key interest areas and contact information.

Section 5: Resubmission Policy

Although RfPB does not prohibit the submission of applications which were submitted unsuccessfully in previous competitions, applicants should recognise that the original application was judged to be uncompetitive in that round, or significantly flawed, and is therefore likely to need substantive modification to have a realistic chance of being funded in future competitions. Applicants considering resubmission should therefore pay particularly close attention to any specific feedback provided on their previously unsuccessful application, as well as to the generic feedback provided in the RfPB guidances and on the website.

Please note that resubmitted applications will be treated as a new application, and there is no guarantee that addressing the feedback points from the previous unsuccessful application will result in funding. In addition, there is no guarantee that the new application will be evaluated by the same reviewers or Regional Advisory Panel members as the previous application. Applicants looking to resubmit an application should consider

Supporting Information for RfPB Applicants
seeking advice from the RDS.

Section 6: INVOLVE/Public Involvement

INVOLVE has issued guidance for researchers about involving patients and the public in research.

Further information and resources can be found on the INVOLVE website <http://www.invo.org.uk/>. This includes a detailed [definition](#) of patient and public involvement in research, [briefing notes for researchers](#) on how to involve patients and the public and an [involvement cost calculator](#) and budgeting guide.

The NIHR Research Design Service provide advice on developing research applications including involving patients and the public and the James Lind Alliance has a step-by-step guide on involvement in research identification and priority setting.

Section 7: Systematic Reviews

Applicants undertaking systematic reviews should note the commitment of NIHR to publication in the [PROSPERO](#) database. PROSPERO was developed by the NIHR's Centre for Reviews and Dissemination (CRD), and is the first online facility to register systematic reviews for research about health and social care from all around the world. Access is completely free and open to the public. PROSPERO registration is a condition of NIHR funding for eligible systematic reviews.

Section 8: Ethics / Regulatory Approvals

Guidance on the application process for ethical and other approvals can be found on the [HRA website](#). Please note that if your study is led from England and involves the NHS in England you should apply for [HRA approval](#).

If you are using patient information from an existing database, you should check whether the patients have given their consent for their data to be included in that database for research purposes, or if not whether the database is exempt under Section 251 of the NHS Act 2006. Where exemptions are not already in place, approval to use confidential patient information without consent must be requested from the HRA who make decisions with advice from the [Confidentiality Advisory Group. \(CAG\)](#).

NOTE: The programme is interested in taking advantage of the growing utility of routine data (such as HES, GP records etc.), and would like investigators, where appropriate, to ask study participants to consent to long term follow up (e.g. beyond the outcomes to be collected in the funded trial) using routinely collected data, and appropriate linkage to allow this data to be best used.

Section 9: UK Biobank

[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 – including cancer, heart diseases, stroke, diabetes, arthritis, osteoporosis, eye disorders, depression and forms of dementia. 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.

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.

Section 10: Carbon Reduction Guidelines

Researchers applying for NIHR 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 [Carbon Reduction Guidelines](#)

Section 11: 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 can be found at [Transparency Agenda](#).

Section 12: Guidance on Completing the Application Form

To submit an application you must complete all the relevant sections of the online form available within the **Central Commissioning Facility Research Management System (CCF RMS)**. This can be accessed through this link (<https://ccfrms.nihr.ac.uk/Login.aspx>).

The '**System Help**' document found on the CCF RMS's web pages provides extensive step by step instructions on how to make use of the CCF RMS.

Registration

Only registered users of the CCF RMS can apply. Applicants new to using the CCF RMS should register as a new user. Once logged into your account the RMS home page is the starting point to create applications, access co-applications and to update contact information and professional details.

Managing my details

Lead applicants and co-applicants can manage their basic contact information and curriculum vitae (CV) through the '**Manage my Details**' link on their RMS home page. Lead and co-applicant contact information and CV details are integrated by the RMS into the relevant fields during the application process. Please note that only lead applicant CV details are mandatory at Stage 1 while basic contact information is required for co-applicants. At Stage 2, lead and co-applicant CV details are mandatory.

Creating an application

The lead applicant must initially create the new application. Clear instructions on how to start a new application can be found in the '**System Help**'. The research team can collaborate with the lead applicant to edit the content in the application by being invited to be a co-applicant through the co-applicant section of the application form.

The lead applicant can use the search tool to find co-applicants and then to invite them to join the application. The RMS will automatically dispatch an email inviting the co-applicant to confirm their participation in the application. Co-applicants can then decide whether to accept the invitation and consent to the application being submitted jointly in their name. They will need to log into the RMS and follow the links to '**Confirm**' their involvement on the co-application summary page. Once confirmed, the co-applicant will be granted access to edit the online application form.

All co-applicants must not only '**Confirm**' but also '**Approve**' their invitation to participate in the application electronically on the co-application summary page in advance of the submission deadline.

Completing an application

From the application summary page, the application can be edited by clicking on the '**Edit**' button. The different sections of the application form can then be accessed via the list of hyperlinked buttons on the left hand side of the RMS webpage. You can move from page to page either by using the '**Previous**' and '**Next**' buttons, or using the list on the left-hand side of the web page.

Supporting Information for RfPB Applicants

Most questions are associated with contextual help  buttons and clicking on them will open up pop up windows containing brief guidance notes that supplement the published guidance for applicants. **It is strongly advised that applicants refer to the published guidance first and then use contextual help**

 as they complete and review each question as contextual help is not designed to replace it.

Mandatory questions are flagged with a red dot.

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

For more details on the electronic approvals required from official representatives of the host organisations in advance of submitting your application, please refer to the published guidance for applicants.

Remember to save your work

You will be prompted to save your work if you leave the browser in application editing mode. We recommend you save your work regularly to minimise the risk posed by any local computer or internet problems. You can save and return to the application form as often as you like prior to submission.

Exiting and returning to work on your form

Should you wish to exit your form, you can return 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.

Validation and submission of the form

The lead applicant can review the progress of their application at any time by selecting the '**View/Print**' option on the application summary page to generate the application as a PDF File.

When the application form has been completed, the lead applicant must use the '**Validate form**' tool within the online application form. The validation step is a check run by the RMS to assess whether all the mandatory questions contain information. It will provide a list of links to any parts of the form where corrections or additional content are needed.

Once the application has been validated successfully and no further corrections are needed, the lead applicant can submit the application by clicking on the '**Submit**' button on the lower right hand side of the application summary page.

Following submission

A programme specific reference number will be assigned to the application once it has been submitted. After the relevant competition round closes, the application will automatically enter the process of being considered for funding.