

# Call for research to improve adolescent health in LMIC settings – Guidance for Full Stage Proposals

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**PLEASE NOTE THE DEADLINE FOR THIS CALL IS TUESDAY 18<sup>th</sup> SEPTEMBER 2018 16:00 BST**

If you have any questions regarding your application please contact:

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## 1. Important Application Information

Your full stage application should be submitted through the [Joint electronic-Submission \(Je-S\) system](#) to the **Joint Adolescent Health 2018** call by **16:00 BST, 18th September 2018**.

Most of the requirements are the same as for a standard MRC application. The MRC Guidance for Applicants and Award holders can be found on the MRC website: <http://www.mrc.ac.uk/funding/guidance-for-applicants/>

This present document provides additional information specific to the call for research to improve adolescent health in LMIC settings. Where guidance in the present document differs from that in the MRC Guidance for Applicants, you should follow the guidance in this scheme specific document.

For this scheme we have provided specific guidance on the **Case for Support** please pay particular attention to the guidance provided in this document on this section. Please note that different Case for Support guidance is given depending on the research proposed. There are specific requirements for proposals involving clinical trials.

### Updated guidance for research involving human participants in lower and middle income countries (LMICs)

MRC recently updated its ethical guidance for research concerning research involving human participants in LMICs; please refer to [Section 5.2.2](#) of MRC's guidance for applicants for important information concerning what information is required concerning the ethical implications of the proposed research.

### MRC guidelines for management of global health trials

Applications proposing the use of clinical trials are required to adhere to the UK Clinical Trials Regulations 2004. MRC policy on UK clinical trials regulations can be found on our [website here](#). In addition to this MRC has recently put together specific guidelines for the management of global health trials which can be [downloaded here](#). It is essential that applicants proposing the use of clinical trials consult these resources as they put together their applications.

### Responding to Peer Review

All applications will be peer reviewed by independent scientific experts. Information can be found in [section 2.12](#) of the guidance for applicants and also on [MRC's peer review webpages](#). All applicants will have access to the reviewer comments received.

Please note that applicants who are successful at the shortlisting stage will be given an opportunity to respond to peer review comments as per MRC standard policy. **This will be around mid-February 2019.**



## 2. Creating your full application on Je-S

Please note that for all queries relating to the Je-S system please contact the **Je-S Helpdesk**.

Email: [JeSHelp@rcuk.ac.uk](mailto:JeSHelp@rcuk.ac.uk)

Phone: +44 (0) 1793 44 4164

The **Je-S handbook** is also a useful resource that will answer many questions about Je-S.

Website: <https://je-s.rcuk.ac.uk/Handbook/Index.htm>

### Je-S registration for co-investigators:

**All co-investigators should be registered on the Je-S system and added to the online application.** It is important that you do this so that reviewers can immediately see who is providing the scientific leadership for the proposed research.

Please ensure your Je-S registrations are completed at least 10 working days in advance of the submission deadline as the accounts have to be manually processed before investigators can be included in the proposal. Registration is not an instant process and if you leave registration until the last week before the deadline it may not be possible for your co-investigators to be registered in time.

### Creating your Je-S application:

In order to submit your proposal to the correct scheme please ensure you select the correct categories when you create your application.

- Select Council: **MRC**
- Select Document Type: **Standard Proposal**
- Select Scheme: **Research Grant**
- Select Call/Type/Mode: **Joint Adolescent Health 2018**
- Select '**Create Document**' option



## Application submission:

The deadline for submission is the date by when your research organisation needs to submit your proposal to the MRC. You may need to submit your proposal to colleagues within your research organisation several days before the deadline so that they have time to approve the proposal for submission to the MRC.

**Please ensure you comply with your research organisation's rules with regards to application submission.**

Once you have completed the Project Details section of the Je-S form you are able to find out the submission arrangements for your organisation. **Select the Document Actions Button** and then **Select Show Submission Path**.

If the screen shows **With Owner** and **With Council** then the proposal will be submitted directly by you.

If the screen shows **With Owner** and **Submitter Pool** (there should be names listed against this section) and **With Council** then the Proposal has to be approved and submitted by one of your research organisation's named submitters. You should allow at least 48 hours for them to do this, your RO may require longer and we would strongly advise you check this.

Please check that at least one of your organisation's named submitters will be available on the day you plan to submit it. Please note that they will need to do this no later than 16.00 UK time on the date the call closes.

## 3. Online Je-S Proposal Form

The Je-S form will cover the administrative and financial aspects for your application. It includes: Objectives; Summary; Technical Summary; Academic Beneficiaries; Communication Plan; Impact Summary. You will also be required to provide details of all researchers and staff on the award.

**There is additional guidance, such as the word limits for these sections, in the [Je-S Handbook](#).**

Please access the Je-S system well in advance of the deadline so that you have time to complete these sections. You do not have to use the whole word limit for each section, especially if you feel you have provided sufficient detail for some items already in your case for support.

Highlighted below is guidance for two areas of the JE-S proposal form. These are two areas where we feel that specific guidance may be helpful.

Further information on the Je-S proposal form can be found in the [MRC Guidance for Applicants](#) and in the [Je-S Handbook](#).

## Completing the Budget on Je-S:

Applicants are required to provide detailed financial information as part of their full application. [Section 3](#) of the MRC Guidance for Applicants describes the MRC's rules for requesting resources. It is important that all of this information is entered correctly as the total amount requested is determined by the information provided here.

The majority of queries received by the office concern the financial section of the Je-S form. Please note the following common issues:

- All UK costs entered should be in line with the standard MRC costs guidance. Please note, **for this scheme all costs claimed by UK investigators should be claimed at 80% of the full economic cost (FEC) (the MRC standard).**
- **All overseas costs need to be entered as Exceptions and claimed at 100% full economic cost (FEC).** For example all salary costs incurred by overseas investigators should be entered as Exceptions and claimed at 100%. All other exceptional costs associated with an overseas organisation should be claimed under the appropriate fund heading and marked as "Exceptions".
- A contribution towards Indirect and Estates costs at the overseas organisations is permissible where the research is being undertaken in a low or middle income country. This should be calculated using the overseas institution's standard overhead calculations, but cannot exceed 20% of the total costs claimed by the overseas organisation's costs. **Please note that these costs need to be entered on the Je-S form as "Other Directly Incurred Costs" and entered as Exceptions funded at 100%.**
- Indirect and Estates costs cannot be claimed by research organisations based in a high income country outside of the UK.
- Please note that **only single pieces of equipment over the value of £10,000** should be categorised under the "Equipment" heading on the Je-S system. All equipment under the value of £10,000 should be categorised as "Other Directly Incurred Costs". For example 20 laptops with a total cost of £20,000 should NOT be entered under the Equipment heading, as in this scenario a single laptop would cost less than £10,000.

## Project Partners

Applicants are strongly encouraged to engage with local stakeholders and to engage with local government especially, projects may also involve collaboration with industry. Partners who provide a substantial intellectual contribution to the project and those that provide a financial contribution should be listed as project partners on the proposal. Please refer to [section 1.3.3](#) of the MRC guidance for applicants for details.

**Please note that all listed project partners must provide a letter of support. Please also note that you should include a nominal sum of £1 when adding project partners who are not contributing financially to the project.**

## 4. Required application documentation (attachments)

You are required to submit several attachments with your Je-S submission. Please carefully read the following information regarding each attachment.

[Section 2.2](#) of the MRC guidance for applicants provides guidance on the required attachments.

**Where this document differs from the MRC guidance please follow the guidance provided in this document.**

The following table summarises the required documents along with the maximum accepted page lengths for each document:

Required Documents	Page Limit
Online Je-S Proposal Form	Word limit specified in Je-S
Covering Letter	Maximum 2 Pages A4
CV's	Maximum 2 Pages A4 each
Publications	Maximum 1 Page A4 each
Case for Support – If your application does <b>NOT</b> involve a clinical trial	Maximum 8 Pages A4 including references for a three year award (or shorter) Maximum 12 Pages A4 including references for an award longer than three years
Case for Support – If your application involves a clinical trial	Maximum 12 Pages A4 including references
Justification of Resources	Maximum 2 Pages A4
Pathways to Impact	Maximum 2 Pages A4
Data Management Plan	Maximum 3 Pages A4
Letters of Support	Maximum 2 Pages A4 each

### Covering Letter

You may wish to provide a cover letter with your full stage application, maximum **2 pages A4**.

Please see [Section 2.7](#) of the MRC Guidance for Applicants for full details on the requirements for the Covering Letter.



## CVs and Publications

A CV should be provided for each investigator and each named researcher. Each CV should not exceed **2 pages A4**.

A list of publications should be provided for each investigator and each named researcher. Each list of publications should not exceed one side of A4.

**Please upload all CVs and publications as one attachment with the publication document following on from the CV of each researcher.**

Please see [Section 2.3.1](#) of the MRC Guidance for Applicants for more information about CVs and see [Section 2.3.2](#) for more information about Publications. Please disregard the requirement to upload these documents separately.

## Case for support

The case for support should be a self-contained description of the proposed work with relevant background information, and should not depend on additional information.

### IMPORTANT:

- **If your proposal does not involve a clinical trial then please follow the case for support guidance as outlined in the MRC guidance for applicants.**
- **If your proposal involves a clinical trial please follow the trial specific case for support guidance below.**

**FOR PILOT/DEVELOPMENT WORK YOU SHOULD USE THE STANDARD CASE FOR SUPPORT GUIDANCE (FOLLOWING THE APPROPRIATE PAGE LIMIT AS SPECIFIED IN THE TABLE ABOVE), BUT YOU ARE WELCOME TO USE HEADINGS FROM THE TRIAL GUIDANCE WHERE APPROPRIATE.**

Please see [Section 2.2.3](#) of the MRC Guidance for Applicants for general guidance on the requirements for the case for support. The general guidance applies to both trial and non-trial applications.

Please remember that your application and case for support will be circulated for external peer review and will be reviewed by a panel of experts. Feedback has shown that it is important the case for support is clear, succinct and accessible.

If you plan to include unpublished data, it must be included in the case for support. Manuscripts in press or submitted to journals should not be included.

## Case for support content for non-trial applications

Applications that are not proposing to involve a clinical trial in the project should follow the standard case for support format as outlined in the MRC guidance for applicants [section 2.2.3.3](#). The page limit for a “non-trial” case for support is **8 pages A4 for three year awards and 12 pages A4 for awards longer than three years** both including a page for references.

The “non-trial” case for support should use the following headings:

- Importance
- Scientific potential
- Ethics and research governance
- Exploitation and dissemination
- Project Partners

Full information of what information should be provided under each of these headings can be found in the MRC guidance for applicants [section 2.2.3.3](#).

## Case for support content for clinical trial applications

Applications that are proposing to involve a clinical trial in their project need to use the specific trial case for support format as outlined in [Annex 1](#) of this document. The page limit for a trial case for support is **12 pages A4** including a page for references.

The trial case for support should use the following headings:

- Trial summary information
- The proposed trial
- Rationale for the trial
- Trial Management
- Trial Partners
- Proposal History

Full information of what information should be provided under each of these headings can be found in [Annex 1](#).

## Capacity building and stakeholder engagement (required annex)

Applicants are **required** to include an annex with their case for support to provide important additional information on capacity building and stakeholder engagement. This annex should be included as part of the case for support submission at the end of the document. It should be clearly titled and can be a maximum of **1 page A4**.

All funders are committed to supporting capacity building and stakeholder engagement in research. Capacity-building and stakeholder engagement elements should be set out in relation to the core intellectual agenda of the research proposal and not treated separately; the focus should be on the quality and impact of the research, and how increasing research capacity and stakeholder engagement contributes to this.





## Capacity Building

If the Principal Investigator (PI) is based in the UK, there must be clear partnership with, and scientific leadership from, co-investigators (Co-Is) based in the countries where the project will take place. Proposal should demonstrate how capacity building for junior UK and developing country staff will lead to developing future scientific leadership. Good examples of capacity-building include:

- Co-design of research and implementation
- Field-based research methods training for developing country partner staff
- Opportunities for staff to author/co-author journal and conference papers and participate in national and international conferences.

UK investigators should demonstrate an understanding of the national and local health systems context, and work harmoniously and effectively with local stakeholders to ensure the research programme does not undermine local research capacity. These factors will be taken into account by the commissioning panel.

## Stakeholder Engagement

There must be clear involvement of stakeholders in the development, implementation, and dissemination of the proposed work. This includes engagement with policy stakeholders and local adolescent stakeholders. Please provide detail of engagement activities already conducted in developing the proposal as well as those proposed during the course of the research and beyond.

## Reproducibility and statistical design (recommended annex)

Applicants are encouraged to include an annex with their case for support to provide important additional information on reproducibility and statistical design. This annex should be included as part of the case for support submission at the end of the document. It should be clearly titled and can be a maximum of **1 page A4**.

Please refer to [Section 2.2.3.4](#) of the MRC guidance for applicants for more information as to the correct usage of this annex.

**Please note that this reproducibility and statistical design annex should NOT be included in applications involving clinical trials. Applications involving clinical trials have already been given additional pages in their case for support and have been asked to address these issues as part of the clinical trial case for support guidance set out in [Annex 1](#).**



## Justification of Resources

It is important that all resources requested in your application are fully justified. The Justification of Resources should be used to justify the resources required to undertake the research project and is mandatory. It should be no longer than **2 sides of A4**.

Please see [Section 2.2.4](#) of the MRC Guidance for Applicants for full details on the requirements of the Justification of Resources.

Full details of costings should be detailed on the Je-S online form. In addition to this, applicants should prepare a Justification of Resources document that should clearly and concisely state the rationale for the resources requested from MRC.

**It is important that the figures quoted in the Justification of Resources clearly match up with those entered in the Je-S online form.**

As part of your justification of resources for this scheme, please include the following table:

### Financial breakdown per participating research organisation

Participant organisation name	Total amount	Total amount requested from this scheme*
Participant Organisation 1 (please enter name)		
Participant Organisation 2 (please enter name)		
etc.		
<b>TOTAL</b>		

\*Costs claimed by UK institutions should be calculated at 80% FEC. **Costs claimed by institutions in low and middle income countries must be claimed at 100% of the full economic costs.**

## Pathways to Impact

The pathways to impact document should be used to clearly demonstrate the potential economic and societal benefits of the proposed work. Funded projects must have clear potential to have an impact on the health of adolescents in LMICs. This document should be no longer than **2 pages A4**.

Please see [Section 2.2.5](#) of the MRC Guidance for Applicants for full details on the requirements of the Pathways to Impact.

## Data Management Plan

The Data Management Plan should demonstrate how the PI will meet, or already meets, their responsibilities for research data quality, sharing and security. Please see [Section 2.2.8](#) of the MRC Guidance for Applicants for full details on the requirements for the Data Management Plan. This document should be no longer than **3 pages A4**.

## Letters of Support

It is expected that the proposed project engages with stakeholders and especially local government, it is therefore very important that you obtain the necessary letters of support from the relevant parties. Letters of support are required from all named project partners, but can also be provided to demonstrate support from other stakeholders who may not be listed as project partners. Each letter of support should be no longer than **2 pages A4**.

Please see [Section 2.2.7](#) of the MRC Guidance for Applicants for the full details on the requirements for Letters of Support for Project Partners.

## 5. Further guidance documents

For further guidance about your proposal please refer to:

Je-S Helpdesk pages

<https://je-s.rcuk.ac.uk/Handbook/Index.htm>

Please note for any submission issues please email the Je-S Helpdesk directly: [JeSHelp@rcuk.ac.uk](mailto:JeSHelp@rcuk.ac.uk)

MRC Guidance for Applicants

<http://www.mrc.ac.uk/funding/guidance-for-applicants/>

MRC Terms and Conditions

<http://www.mrc.ac.uk/funding/guidance-for-mrc-award-holders/>

MRC Research Policy and Ethics (including MRC data sharing policy)

<http://www.mrc.ac.uk/research/research-policy-ethics/>

MRC Guidelines for Management of Global Health Trials

<https://www.mrc.ac.uk/documents/pdf/good-clinical-practice-in-clinical-trials/>

United Kingdom Research and Innovation guidance on pathways to impact

<https://www.ukri.org/innovation/excellence-with-impact/pathways-to-impact/>

Department for International Development guidance on research uptake

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/514977/Research\\_uptake\\_guidance.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/514977/Research_uptake_guidance.pdf)

## 6. Assessment Criteria

The panel will assess your application based on the following criteria:

### Importance of the question/ likely impact of the study

- Does the study address an important research question of relevance to adolescent populations in LMICs and propose a high quality research approach to addressing that question?
- Is the study relevant and novel in the proposed location(s)?
- How important an advance would this be?
- What is the likelihood that the findings will be taken up and implemented?
- Can the approach be scaled up; is it cost effective?
- Is it likely to lead to significant improvements in health of adolescents?

### International track record/ appropriateness of the team

- Experience of conducting studies to a high standard; evidence of uptake of findings (e.g. changes in policy and practice)
- International standing
- Balance of expertise to undertake the study (e.g. are methodological, social, health systems, economics, cultural issues covered?)
- Links with local research/health institutions and involvement of investigators from low and middle income countries

### Study design and feasibility (limited detail will be available in outline applications)

- Is the design of the study appropriate to answer the question?
- Are the methods and study designs appropriate?
- Is the timeline realistic and achievable?
- Are there any ethical concerns?
- Have major scientific, technical or organisational challenges been identified, and will they be tackled well?

### Financial aspects; at this stage, applicants have not been asked to provide detailed costings.

- Does the study and its suggested size and scale represent value for money?
- Are there any financial dependencies, e.g. co-funding arrangements
- Guidance for applicants specified that the panel welcomed applications for both small and larger-scale projects

## Annex 1 – Clinical trial case for support content

### 1 Trial Summary Information

- 1.1 Full title of trial (no more than 150 characters)
- 1.2 Acronym (if applicable - this is not a requirement)
- 1.3 In which country(ies) will the trial take place?
- 1.4 Duration in months
- 1.5 What is/are the principal research question(s) to be addressed?

### 2 The Proposed Trial

When completing this section please ensure you give adequate attention to the below issues:

- Please include relevant pilot data and ensure it is clearly described.
- Please provide as much information as possible about the feasibility of the proposed intervention.
- Please clarify why you believe that it is specifically a trial, using your proposed methodology, which is needed in order to address the research question.
- Be specific about the nature of the intervention so that it is clear to the panel exactly what will take place in the experimental and control arms and how this compares to usual practice and standard of care in the trial locations.
- Ensure that all statistical aspects of the trial and the assumptions on which these are based (such as power calculations, sample sizes and effect sizes) are clearly explained and well-justified. Please ensure that you allocate sufficient space to this aspect of the proposal so that it can be clearly understood by reviewers. In previous years, incomplete or poorly explained trial statistics has been a common reason for reviewers to have concerns about proposals.
- Justify clearly the outcome measures to be used. Having the right primary and secondary outcome measures, and a robust methodology to collect data for those outcome measures, is a major issue considered by the panel at peer review
- It is important that all studies funded by this scheme have outcomes that might offer a realistic and cost-effective opportunity to improve health. Please consider and explain whether your proposal needs a health economic analysis, and provide information and justification on how that analysis will be conducted, and who by.

#### 2.1 The proposed study

Give a summary of the proposed trial (<100 words)

#### 2.2 What is the proposed trial design?

(e.g. open, double or single blinded, number of arms, etc)

### 2.3 What are the proposed outcome measures?

Please provide justification of the outcomes and their measures and clarify how they are appropriate to the scientific hypothesis.

Primary:  
Secondary:

### 2.4 Has any pilot work been carried out?

Please provide a clear description of relevant feasibility or pilot data.

### 2.5 Which centres will be involved?

Please give numbers and brief details of participating centres, including a rationale for their selection.

### 2.6 What are the planned trial interventions?

Give clear details of both experimental and control – if control is ‘usual care’ please describe. Please describe the interventions clearly, and explain clearly why those interventions have been chosen.

### 2.7 What are the proposed practical arrangements for allocating participants to trial groups?

*(e.g. randomisation method. If stratification or minimisation is to be used, give reasons and factors to be included.) Applications involving the use of sealed envelopes are asked to consider other options and explicitly outline the reasons for their choice.*

### 2.8 Please detail any risks to the safety of the patients in the trial

### 2.9 What are the proposed methods for protecting against sources of bias?

*(e.g. blinding or masking. If blinding is not possible please explain why and give details of alternative methods proposed, or implications for interpretation of the trial's results.)*

### 2.10 What are the planned inclusion/exclusion criteria?

### 2.11 What is the proposed sample size and what is the justification for the assumptions underlying the power calculations?

Include both control and intervention groups, a description of the power calculations detailing the outcome measures on which these have been based, and give event rates, means and medians etc. as appropriate.

NB It is important to give the justification for the size of the difference that the trial is powered to detect. Does the sample size calculation take into account the anticipated rates of non-compliance and loss to follow-up?

**2.12 What is the proposed duration of treatment period?**

**2.13 What is the proposed frequency and duration of follow-up?**

**2.14 How will the outcome measures be measured at follow up?**

**2.15 What is the planned recruitment rate?**

How will the recruitment be organised? Over what time period will recruitment take place? What evidence is there that the planned recruitment rate is achievable? Has the study sample been defined adequately in relation to the target population so that the results will have meaning?

**2.16 Are there likely to be any problems with compliance?**

On what evidence are the compliance figures based?

**2.17 What is the likely rate of loss to follow-up?**

On what evidence is the loss to follow-up rate based?

**2.18 Are there any planned subgroup analyses?**

**2.19 What is the proposed type of analyses?**

**2.20 What is the proposed frequency of analyses?**

**2.21 What are the potential hazards inherent in the trial which might cause problems in implementing the trial? Give details of the risk assessment (*this can be a separate pdf annex*).**

**2.22 How will health economics issues be addressed?**

Please justify inclusion/exclusion of any health economics analysis. If a health economics study is planned please include details of the perspective adopted (e.g. health service vs societal), analytical approach (e.g. cost-effectiveness, cost-minimisation, cost-utility analysis etc.), choice of any outcome measures (e.g. DALYs or QALYs) and whether the study will include any modelling analysis. Where relevant, please outline whether the study will also consider issues around the overall affordability and sustainability of the intervention. Please state whether an economist is already in place to design the economics study in advance of the start of the main trial.

**2.23 Will there be local health service cost implications for this trial?**

**2.24 What involvement from local patient and/or community groups has there been in developing the trial design?**

**2.25 What on-going involvement would patient and/or community groups have in the trial?**

**2.26 Please provide a brief timeline for the trial.**

### 3 Rationale for the Trial

#### 3.1 Why is a trial needed now, and why is it needed in the proposed location?

*(evidence from the medical literature, professional and consumer consensus and pilot studies should be cited if available; include any ongoing or planned studies elsewhere).*

In responding to this point, please consider issues such as burden of disease and priority for the relevant local, regional and national health services etc.

#### 3.2 Give references to any relevant systematic review(s) and discuss the need for your trial in light of these review(s)

*(if you believe that no relevant previous trials have been done, give details of your search strategy for existing trials)*

#### 3.3 Describe how the proposed trial will differ from or complement any relevant planned, ongoing or recently completed trials internationally.

#### 3.4 Further to your Impact Summary and Pathways to Impact document, please summarise briefly how the results of the trial will be generalisable beyond the immediate research setting of the trial in a way that will maximise the impact of the results?

### 4 Trial Management

#### 4.1 What are the arrangements for day to day management?

*(e.g. randomisation, data handling, and who will be responsible for co-ordination)*

#### 4.2 What will be the responsibilities of the applicants?

Please give details of the roles of the named applicants. Please indicate which investigators have experience in successfully running large multi-centre trials. Please highlight if you will be working with a clinical trials unit/office. Please also particularly highlight how social sciences, health services/economics/operations research expertise will be incorporated into the study to ensure that the results are implementable in local settings.

#### 4.3 To what extent are institutions in the countries where the trial will take place involved in scientific leadership of the trial?

#### 4.4 What will be the responsibilities of the staff employed on the grant?

Please give details of the roles of the staff requested on the grant.

#### 4.5 What will be the roles of the named collaborators?

Please give details of the roles of the named collaborators.

#### 4.6 Who is providing statistical support?



#### 4.7 Who will be the Sponsor(s) for the trial?

The sponsor is the individual, or organisation (or group of individuals or organisations) that takes responsibility for confirming there are proper arrangements to initiate, manage, monitor, and finance a study. We would usually expect the sponsor to be the Principal Investigator's Host Institution. If the sponsor will be a different organisation, please provide a rationale for this decision in your proposal.

The funders will not act as sponsor to the funded trials, unless the PI's Host Institution is an MRC Unit or Institute, in which case MRC would normally be the sponsor.

A letter of agreement from the sponsor should be uploaded to the Je-S application.

#### 4.8 Please describe the ethical review and research governance arrangements that would apply to the work done.

#### 4.9 Trial Steering Committee

Please give names and affiliations of the proposed trial steering committee to include - independent Chairman, independent members, principal investigators.

#### 4.10 Intellectual Property/Commercial exploitation – please address the following points:

- Does the proposed research use technology, materials or other invention that, as far as you are aware, is subject to any patents or other form of intellectual property protection? If yes, give brief details.
- Is the proposed research, in whole or in part, subject to any agreements with commercial, academic or other organisations? If yes, give brief details.
- Is proposed research likely to lead to patentable or commercially exploitable results? If yes, please give brief details.
- If any potentially commercially exploitable results may be based upon tissues or samples derived from human participants, please confirm that there has been appropriate informed consent for such use.

**4.11 Risks of research misuse:** it is the responsibility of institutions in receipt of funding from this scheme to ensure that any risks that research could be misused for harmful purposes are managed in the appropriate manner. Please confirm that you have considered whether your proposed research could generate outcomes that could be misused for harmful purposes.

- Have you identified any tangible risks of this type?
- If yes, please briefly describe these risks and the steps that you and your institution will take to manage them.

## 5 Trial Partners

### 5.1 Indicate any commercial or other organisation involved

If a company or other organisation is being approached for the supply of the intervention (experimental and control), what arrangements have been made?

### 5.2 Please give details of any other major funding partners

Include anticipated contribution and the status of discussions.

### 5.3 Please give details of links which are likely to improve the likelihood of successful implementation of results of the trial.

*(e.g. health service providers, community/patient groups)*

### 5.4 Please give details of other key partners

Whose participation is necessary to the success of this – what agreements have been made.

## 6 Proposal history

### 6.1 Has the proposal been submitted to other funders?

If so please indicate the status of your submission to other funders.