UKRI GCRF Health and Context call 2019 – Full (Invitation Only) Applicant Guidance

PLEASE NOTE THE DEADLINE FOR SUBMITTING AN INVITED FULL APPLICATION IS 12 September 2019 16:00 GMT +1

If you have any questions regarding your application, please contact:

Samantha Palmer, GCRF Science Manager, international@mrc.ukri.org

This guidance is relevant to applicants submitting an invited full research grant proposal to the UKRI GCRF Health & Context call 2019. Only invited applications are eligible.

As this call is being administered by the MRC, reference is made to MRC procedures throughout this guidance. Please note that in line with the interdisciplinary nature of the call applications are invited from all relevant disciplines with the call being overseen by the MRC, Economic & Social Research Council (ESRC), Arts & Humanities Research Council (AHRC), Natural Environment Research Council (NERC) and Biotechnology and Biological Sciences Research Council (BBSRC).
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1. Important Application Information

Your application should be submitted through the Joint electronic-Submission (Je-S) system.

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 document provides additional information specific to invited research grant applications under the health and context call. 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.

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

The MRC recently updated its ethical guidance for research involving human participants in LMICs; please refer to Section 5.2.2 of MRC’s Guidance for Applicants for further information (if the research is led by an LMIC Principal Investigator (PI) and based wholly outside of the UK, the requirement for UK ethical approval to be obtained is not applicable).

1.1. 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 and any relevant amendments. MRC policy on UK clinical trials regulations can be found on our website. 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 application.

1.2 Responding to peer review

All invited research grant applications will be peer reviewed by independent scientific experts. Information can be found in section 2.5 of the Guidance for Applicants and also on MRC’s peer review webpages. All invited research grant applicants will be given an opportunity to respond to peer review comments as per MRC standard policy in December 2019 (approximately).
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@je-s.ukri.org
Phone: +44 (0) 1793 44 4164

The Je-S handbook is also a useful resource that will answer many questions about Je-S: [https://je-s.rcuk.ac.uk/Handbook/Index.htm](https://je-s.rcuk.ac.uk/Handbook/Index.htm).

2.1 Je-S registration for co-investigators

All co-investigators (Co-Is) must 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.

Investigators based in LMICs should ensure their Research Organisation has been added to the Je-S database, preferably before they start their proposal. Applicants have the option to self-register their overseas organisation which allows the direct submission of proposals by LMIC applicants, when their organisation has not been through the IRO Je-S Registration process. This applies to the Research Organisation of the Lead Applicant and any Research Organisations (including NGOs) of individuals listed as Co-Applicants, but not Project Partners or sub-contractors.

Please ensure your Je-S registrations are completed at least 10 working days in advance of the submission deadline as the accounts must 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.

2.2. Creating your Je-S application:

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

- Select Council: MRC
- Select Document Type: Standard Proposal
- Select Scheme: Research Grant
- Select Call/Type/Mode: Invite Only - UKRI GCRF Health and Context Sept 2019
- Select ‘Create Document’ option

Please note: All mandatory sections on the application need to be completed.
2.3 Application submission:

The deadline for submission is the date by when your research organisation (RO) 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 must 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 of your application. It includes: Objectives; Summary; Technical Summary; Academic Beneficiaries; Communication Plan; Impact Summary; Resource Summary; Details of all researchers and staff; Animal Costs (if relevant), Estates and Indirect costs; Ethical Implications. You will need to provide details of all researchers and staff on the award.

Please access the Je-S system well in advance of the deadline so that you have time to complete these sections. Further information on the Je-S proposal form can be found in the MRC Guidance for Applicants and in the Je-S Handbook.

Highlighted below is guidance on completing the Budget and the Project Partners sections 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.
3.1 Completing the Budget section 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 total cost of the research proposal claimed from UKRI should be within the range of £1-2m once differing FEC rates for UK and overseas research have been accounted for, i.e. total UK costs of £1m would translate to £800k against the grant.

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 resources 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%.
- 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 (LMIC). 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. 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 (HIC) outside of the UK. NB. Inclusion of overseas CoIs from HIC and any costs associated with their activities must be discussed and agreed with the programme manager in advance of application (please email any queries to international@mrc.ukri.org). We would not expect high-income country Co-I costs to exceed 30% of the total award value.
- Staff costs cannot be included for staff based at MRC Units whose salary costs are already met through core support (i.e. as part of Unit funding rather than other awarded grants).

Grants will be managed under MRC and UKRI standard terms and conditions. Funding is not available for PhD or Master studentships, or for capital equipment.

All costs associated with overseas Co-Is, whether salary, fieldwork, equipment or travel and subsistence should be entered as ‘Other Directly Incurred Costs’ and should be marked as an ‘Exception’ using the tick box. To enable MRC to meet transparency and external reporting requirements all overseas costs must be entered into this section using the format ‘Organisation: Country: Cost Category: Cost Description’. For example:

- University of Nairobi: Kenya: Staff: 1 x PDRA
• University of Nairobi: Kenya: Travel and Subsistence: 4 x flights
• University of Nairobi: Kenya: Other Directly Incurred Costs: 5 x Workshops including catering and accommodation

Costs for work undertaken at an overseas organisation should be calculated in GBP based on prevailing exchange rates at the time of application (see MRC Guidance for Applicants Section 3.3). Applications led by a UK Research Organisation must consider how the finances will be managed and deployed between partners, and the financial controls and risk mitigations that will be put in place for the transfer of funding to overseas organisations. The time taken for these assurances to be put in place should be factored in to the proposal.

Please note: NERC Facilities - Prior to submitting a proposal, applicants wishing to use a NERC service or facility must contact the facility to seek agreement that they could provide the service required. Applicants wishing to use NERC facilities will need to submit a mandatory ‘technical assessment’ (a quote for the facility work, supplied by the facility), with their proposal, which should be uploaded alongside the proposal as an ‘Other Attachment’. This technical assessment is required for aircraft but not for NERC Marine Facilities (NMF – Shiptime and/or marine equipment) and HPC. A full list of the Facilities requiring this quote can be found on the NERC website. The costs for the service or facility (excluding NMF and HPC costs) must be included within the Other Directly Incurred Costs section of the Je-S form and justified in the Justification of Resources attachment. Further information on NERC services and facilities can be found on the NERC website.

Requests for use of NERC Ship time and/or marine facilities and aircraft facilities are not expected on this call. Please contact international@mrc.ukri.org if you are considering requesting the use of these facilities for specific guidance.

3.2 Completing the Project Partners section on Je-S:

PLEASE NOTE: Institutions where the PI and Co-Is are based are not classed as Project Partners and should not be listed in this section.

Applicants are strongly encouraged to engage with local stakeholders, including local government, policy makers, and local communities. A project partner provides a substantial intellectual contribution to the project, and their organisation may also provide resources either in-kind or financially. Project partners are not expected to request MRC funding to participate. The contribution and involvement of project partners should be acknowledged in the project partner section of the application form and described in detail in the Case for Support.

Projects may also involve collaboration with industry. If the project partner is from industry, applicants must follow the guidance relating to the MRC Industry Collaboration Agreement (MICA). Please see the MRC MICA webpages and Section 1.3.4 of the MRC Guidance for Applicants for more information.
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:

<table>
<thead>
<tr>
<th>Required Documents</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online Je-S Proposal Form</td>
<td>Includes: Objectives; Summary; Technical Summary; Academic Beneficiaries; Communication Plan; Impact Summary; Resource Summary; Details of all researchers and staff; Animal Costs, Estates and Indirect costs; Ethical Implications. (Character limits specified in Je-S)</td>
</tr>
<tr>
<td>Case for Support</td>
<td>Maximum 8 sides A4 including references, plus:</td>
</tr>
<tr>
<td></td>
<td>• Capacity Building annex (additional 1 side A4; mandatory)</td>
</tr>
<tr>
<td></td>
<td>• Reproducibility and Statistical Design annex (additional 1 side A4; recommended)</td>
</tr>
<tr>
<td>ODA Compliance Statement (Please use Je-S attachment option: Non-UK Components)</td>
<td>Maximum 1 side A4</td>
</tr>
<tr>
<td>Pathways to Impact</td>
<td>Maximum 2 sides A4</td>
</tr>
<tr>
<td>Justification of Resources</td>
<td>Maximum 2 sides A4</td>
</tr>
<tr>
<td>Data Management Plan</td>
<td>Maximum 3 sides A4</td>
</tr>
<tr>
<td>Letter(s) of Support</td>
<td>Maximum 2 sides A4 each</td>
</tr>
<tr>
<td>Covering Letter</td>
<td>Maximum 2 side A4</td>
</tr>
<tr>
<td>CV’s</td>
<td>Maximum 2 sides A4 each</td>
</tr>
<tr>
<td>Publications</td>
<td>Maximum 1 sides A4 each</td>
</tr>
<tr>
<td>Other attachment (NERC facility requests)</td>
<td></td>
</tr>
</tbody>
</table>
4.1 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.

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.

Applications should follow the standard case for support format as outlined in the MRC Guidance for Applicants section 2.2.3.3. The page limit is eight pages, including a maximum one page for references, with an additional one page each for the Capacity Building annex (mandatory) and Reproducibility and Statistical Design annex (recommended).

The 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.

There is no distinct case for support document for applicants proposing clinical trials. However, it is the applicant’s responsibility to ensure that the case for support includes all necessary information to judge the proposed trial. Where a trial is proposed applicants may choose to use the following headings:

- Trial summary information
- The proposed trial
- Rationale for the trial
- Trial management

Details of information that may be provided under each of these headings can be found in Annex 1.

4.1.1 Capacity Building annex (mandatory)

Applicants are required to include an annex with their Case for Support to provide important additional information on capacity building. 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 should be a maximum of 1 side A4.

All funders are committed to supporting capacity building in research. Capacity-building 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 contributes to this.

Examples of capacity building include:

- increasing capability of staff to work across disciplines and in partnerships
- support and mentoring for more junior team members
- building leadership skills amongst early career researchers
- mentorship opportunities
- co-design, analysis and dissemination of research
- opportunities for those with relevant skills to orient their research towards global issues
- formation of LMIC research networks.

UK investigators should demonstrate an understanding of the national and local context and work harmoniously and effectively with local stakeholders to ensure the research programme does not undermine local research capacity. These factors will be considered by the panel of experts.

4.1.2 Reproducibility and statistical design (recommended annex)

It is strongly advised that a one-page annex to the case for support is included, in addition to the case for support page limit (eight), to provide additional information specifically relating to the statistical analyses, methodology and experimental design aspects of the proposal (beyond that contained in the main case for support). Please note that you should not duplicate information presented elsewhere in the application.

The purpose of this annex is to provide important additional information on reproducibility, and to explain the steps taken to ensure the reliability and robustness of the chosen methodology and experimental design. Please note in this context, methodology refers to the rationale for choosing which method to use and not the provision of detailed descriptions of the methods to be used.

Full and detailed information can be found in the MRC Guidance for Applicants section 2.2.3.4.

4.2 ODA Compliance Statement

Research funded through this call will form part of the UK’s Official Development Assistance (ODA), as defined by the Development Assistance Committee (DAC) of the Organisation for Economic Co-operation and Development (OECD). The ODA compliance statement should explain how your proposed research is compliant by answering the following questions:

1. Which country/countries on the DAC list of ODA eligible countries will directly benefit from this proposal?
2. How is your proposal directly and primarily relevant to the development challenges of this country/these countries?
3. **How do you expect that the outcome of your proposed activities will promote the economic development and/or welfare of this country/these countries?**

**Please note:** this document should make clear the ODA relevance of the proposed research without reference to other documents in the proposal (i.e. Case for Support, Pathways to Impact). It should also include meaningful project specific detail. Proposals that do not articulate clearly the ODA relevance of the research throughout their application will be rejected prior to peer review.

### 4.3 Pathway to Impact

The Pathway to Impact document should be used to clearly demonstrate the potential health benefits of the proposed work. Applications should have clear potential to break the causative link between context and disease. This document should be no longer than 2 sides of A4.

Please see **Section 2.2.5** of the MRC Guidance for Applicants for full details on the requirements of the Pathway to Impact.

### 4.4 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. **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**

<table>
<thead>
<tr>
<th>Participant organisation name</th>
<th>Total amount</th>
<th>Total amount requested from this scheme*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant Organisation 1 (please enter name)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant Organisation 2 (please enter name)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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*Costs claimed by UK institutions should be calculated at 80% of the full economic cost (fEC). Costs claimed by institutions in low and middle income countries must be claimed at 100% fEC.

4.5 Data Management Plan

The Data Management Plan should demonstrate how the Principle Investigator (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 sides A4.

Please note: where specific types of data are collected, applicants must refer to relevant council guidance for archiving such specific data. For example, where data are the main assets of economic and social research, applicants should consult the ESRC Research Data Policy and the Research Funding Guide and clearly explain how requirements will be met. This information should complement but not duplicate the information provided in the Data Management Plan as explained above. If specific environmental data is produced, applicants should follow the NERC data policy, contact the relevant NERC Environmental Data Centre and include appropriate estimation costs for archiving the environmental data within the ‘Other Directly Incurred Costs’ section of the Je-S form.

4.6 Letters of Support

It is very important that you obtain the necessary letters of support from stakeholders engaged in the project. Stakeholders may include the lead research organisation, collaborating research organisations in the UK and overseas, local or national government authorities, and project partners (e.g., industrial partners, NGOs). 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.

4.7 Covering Letter

You may wish to provide a cover letter with your full stage application, maximum 2 sides A4. Please see Section 2.7 of the MRC Guidance for Applicants for full details on the requirements for the Covering Letter.

4.8 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.

5. Applicant Eligibility

Principal Investigators (PIs) should be based at an eligible LMIC or UK Research Organisation.

UK PIs or Co-Investigators must be based at a UK higher education institution or at an eligible independent research institution.

LMIC PIs or Co-Is must be based at higher education institution, non-profit research institution, or non-governmental organisation. Applicants should check with their Research Office whether previous applications have been submitted to MRC. If they have not, applicants should contact international@headoffice.mrc.ac.uk to determine eligibility prior to submitting their application.

Researchers based at MRC University Units and the Francis Crick Institute are eligible to apply for funding, as either a PI or Co-I. However, they should address in their cover letter how the proposed research is distinct from that already supported through existing ‘core’ support.

Researchers from overseas research organisations not based in LMICs may be Co-Is if they provide expertise not available in the UK or an LMIC. Inclusion of these Co-Is and any costs associated with their activities must be discussed and agreed with the programme manager in advance of application (please email any queries to international@headoffice.mrc.ac.uk). We would not expect high-income country Co-I costs to exceed 30% of the total award value. The balance of intellectual leadership and costs between high income countries and LMICs will be considered in the assessment of proposals.

The role of any project partners should be detailed in the Case for Support. Project partners provide a substantial intellectual contribution to the project, and their organisation may also provide resources either in-kind or financially. Project partners are not expected to request MRC funding to participate. Industrial collaborators are welcomed, but it should be noted that they cannot be recipients of funding. The role of industrial partners must be clearly explained, with special emphasis on the benefit to LMICs. When an industrial collaborator is involved, an MRC Industrial Collaboration Agreement (MICA) form and Heads of Terms must be submitted with the proposal.
6. Assessment Process

Proposals will be externally peer reviewed following MRC’s standard review processes, which includes PI response, before being considered by an expert review panel in March 2020. Panel members are from a range of disciplines that reflect the interdisciplinary nature of the call. The Panel will make funding recommendations and the final funding decisions ratified by the funders in late March 2019. Funding decisions are final and there will be no opportunity to respond to the decision and/or feedback.

The Panel will assess your outline application based on the following criteria:

- **Importance and likely impact of the study**
  - Does the study focus on contextual drivers of infectious or non-communicable diseases (NCDs) and/or culturally-sensitive intervention?
  - Does the study justify the importance of the research and propose a high-quality research approach to address the issue?
  - Is the study relevant in the proposed location(s)?
  - Is there evidence of substantial, relevant preliminary work, existing relationships with stakeholders in the location where the project will take place, and existing partnerships with other named researchers?
  - How important an advance would this be?
  - What is the likelihood that the findings will have an impact/reduction on the disease burden in the participating LMIC?
  - Are the findings likely to be of relevance to LMIC locations outside of those named in the application where similar contextual health issues are faced?

- **Study design and feasibility**
  - Is the design of the study appropriate to answer the question?
  - Does the methodology allow a rigorous, valid, and reliable investigation?
  - Is the timeline realistic and achievable?
  - Is the sample size sufficient and based on a reproducible power calculation? Is there a feasible recruitment strategy? Has attrition been realistically accounted for?
  - Are there any ethical concerns?
  - Have major scientific, technical or organisational challenges been identified, and are plans in place to address them?

- **Research team**
  - Do the named investigators have experience of conducting studies to a high standard?
  - Does the research team have the necessary interdisciplinary expertise to undertake the study?
  - Have LMIC researchers had intellectual input into the setting of the research agenda and its ongoing strategic direction? Is the partnership equitable?
  - Have relevant stakeholders been identified and engaged from outside of the academic community?
  - Do the named investigators have experience of achieving academic and/or economic and societal impact?
  - Are appropriate and equitable governance processes in place?
o How suitable is the host organisation(s) (i.e. commitment to providing appropriate levels of support to the research team)?

- Capacity building and international partnerships
  o Have appropriate capacity building activities been embedded within the research proposal?
  o Are opportunities for the development of LMIC/early career researchers provided?
  o Where relevant, are early career researchers provided with sufficient support and mentorship to enable them to lead/participate in the project?

- Justification of resources and appropriate financial management/risk assurance
  o Does the study and its proposed size and scale represent value for money?
  o Is the distribution of funding across UK and LMIC partners appropriate for the intended contribution of partners within the research proposal?
  o Are there any financial dependencies, e.g. co-funding arrangements?
  o Have risks to the work been identified and appropriate plans for mitigation outlined?
  o Has appropriate time been allocated for risk assurance and establishing financial management arrangements with partners?

- Clear and effective pathways to impact
  o Have the potential beneficiaries of the research been identified?
  o Where appropriate, has consideration been given to how scale up of the research findings into practice and/or policy would occur? What is the likelihood of uptake of the research findings e.g. has a cost effectiveness evaluation, where relevant, been included as part of the proposed research?
  o Where relevant, are the capacity building activities proposed likely to yield tangible benefit in the near future?
  o Is there sufficient engagement with relevant stakeholders within the country/countries of focus?

- Compliance with ODA eligibility requirements
  o Will the research directly benefit a country or countries on the OECD DAC list of ODA eligible countries?
  o Is the proposal directly and primarily relevant to the development challenges of this country/these countries?
  o Could the proposal’s outcomes promote the economic development and/or welfare of a country or countries from the OECD DAC list of ODA eligible countries?

7. 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:
Email: JeSHelp@je-s.ukri.org
Phone: +44 (0) 1793 44 4164

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/

United Kingdom Research and Innovation guidance on pathways to impact

Department for International Development guidance on research uptake

UKRI funded report on equitable partnerships - ‘The Rethinking Research Collaborative’

UKCDR report on ‘Finding and building effective and equitable research collaborations or partnerships’
Annex 1 – Clinical trial case for support content

1 Trial Summary Information

- Full title of trial (no more than 150 characters)
- Acronym (if applicable - this is not a requirement)
- Country(ies) in which the trial will take place
- Principal research question
- Study design and sample size

2 The Proposed Trial

- Work leading to the proposal
  Please provide a clear description of relevant feasibility or pilot data.
- Trial type and proposed design
  Including randomisation details, study arms, intervention components, and duration
- Participating centres
  Please give numbers and brief details of participating centres, including a rationale for their selection.
- Participants
  Selected Inclusion/exclusion criteria, recruitment methods
- Overall trial timeline
- Outcome measures
  Please provide description and justification of all primary and secondary outcome measures.
- Sample size and 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.
- Community and participant group involvement
- Challenges and ethical concerns

3 Rationale for the Trial

- Why is a trial needed now, and why is it needed in the proposed location?
  Please consider issues such as burden of disease and priority for the relevant local, regional and national health services etc.
- Relationship to other trials
  Describe how the proposed trial will differ from or complement any relevant planned, ongoing or recently completed trials internationally.
- Impact & Outcomes
  How will the results of the trial be used? Will they be generalisable beyond the immediate research setting in a way that will maximise their impact?

4 Trial Management

- Applicant responsibilities
  Please give details of the roles of the named applicants.
- LMIC involvement
  To what extent are institutions in the countries where the trial will take place involved in scientific leadership of the trial?
- **Statistical support**
- **Trial sponsor**
  The sponsor is the individual, or organisation 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 PI'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.
- **Ethical review**
  Which approvals would be applied for?