Call for research in Global Maternal and Neonatal Health – Research Grant Outline Applicant Guidance

Please note the deadline for submitting a research grant outline application is 24 APRIL 2019 16:00 BST.

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

Samantha Palmer, GCRF Science Manager, international@headoffice.mrc.ac.uk

This guidance is relevant to applicants submitting outline research grant proposals to the Global Maternal and Neonatal Health funding call 2019. Separate guidance will be made available in approximately April 2019 for applicants submitting seed-funding applications and for those invited to submit a full research grant proposal.

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 present document provides additional information specific to the call for research to improve maternal and neonatal 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.

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

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 PI and based wholly outside of the UK, the requirement for UK ethical approval to be obtained is not applicable).

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. It is essential that applicants proposing the use of clinical trials consult these resources as they put together their application.

2. Creating your outline 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
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.

Je-S registration for co-investigators:

All co-investigators (co-Is) 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 following categories when you create your application:

- Select Council: MRC
- Select Document Type: Outline Proposal
- Select Scheme: Standard Outline
- Select Call/Type/Mode: Global Maternal and Neonatal Health 2019
- 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.

**Resubmissions of proposals that have been previously rejected by other MRC or DHSC panels must be discussed with either MRC** ([international@headoffice.mrc.ac.uk](mailto:international@headoffice.mrc.ac.uk)) **or DHSC** ([globalhealthresearch@dhsc.gov.uk](mailto:globalhealthresearch@dhsc.gov.uk)) **prior to submission.** Any resubmission must have clearly addressed issues that had previously prevented funding, and this should be communicated in the cover letter. Simultaneous submission of the same proposal to more than one MRC or NIHR scheme is not permitted.

### 3. Online Je-S Proposal Form

The Je-S form will cover the administrative and financial aspects for your application. For the outline application you are required to submit: a summary of resources required for project, case for support, publications, CV, covering letter. 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](mailto:MRC Guidance for Applicants) and in the [Je-S Handbook](mailto:Je-S Handbook).

At the outline application stage, you do not need to complete the objectives, impact summary, and summary sections of the Je-S form. Please enter “Please see case for support” in these text boxes and enter the relevant information in the case for support.

### 4. Required application documentation

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:
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.

Please remember that your outline application, including the case for support, will be reviewed by a panel of experts. Previous panel feedback has highlighted that the case for support should be 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.

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 six pages including a maximum one page for references.

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.
Where research proposed includes the development or evaluation of an intervention information on potential for replicability, acceptability, scalability, and affordability should be included. Projects which assess the effectiveness of a particular intervention without situating that assessment within a broader research and policy context will not be funded. It is up to applicants to consider how the cost of any intervention is supported. Researchers are advised to refer to the MRC framework on the development and evaluation of complex interventions for further guidance on interventions, where appropriate to their proposed plans.

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 (for example, industrial partners, NGOs). Each letter of support should be no longer than two pages A4. Please use Je-S Other Attachment’ type, using the Description 'Letter of Support - 'then the name of the designated Stakeholder.

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 (upload support letters to the Project Partners section).

Covering letter

You may wish to provide a cover letter with your full stage application, maximum two pages A4. Please see Section 7.7 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 two 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 either upload all CVs and publications as one attachment with the publication document following on from the CV of each Investigator/researcher, or alternatively upload each individual CV and Publication List separately, using both CV and Publication Je-S attachment types.

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).

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, a MICA form must be submitted within the proposal.

6. Eligible costs

A summary of resources required for the project is requested including estimates of directly incurred costs, directly allocated costs, indirect costs, and exceptions. A full breakdown of costs is not necessary at the outline stage. However, the following points are commonly queried by applicants and may help when calculating summary figures:

- 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 in this application. 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.
- Staff costs cannot be included for staff based at MRC units whose salary costs are already met through core support (for example as part of unit funding rather than other awarded grants).
Requested costs for UK partners should be 80% of full economic costs (FEC), and overseas costs should be 100% FEC and should be listed as exceptions. Grants will be managed per UKRI and MRC standard terms and conditions. Funding is not available for PhD or Masters studentships, or for capital equipment.

All costs associated with overseas co-investigators, 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.

7. Assessment process

All proposals will be assessed by a sift panel of experts that will convene in July 2019. Pre-selected panel members will be allocated a number of proposals and asked to provide comments in advance. These comments will inform the discussion when the panel convenes. Applicants will be contacted via email shortly after the panel to inform them of the panel’s decision (unsuccessful or invitation to submit full application). Panel decisions are final. Invited applications will be encouraged to respond to sift panel and peer reviewer feedback when submitted their full application.

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

- compliance with ODA eligibility requirements
- research excellence, importance and novelty of the research and approach
- fit to call
- relevant capability and interdisciplinarity of the research team
- capacity building and equitable partnerships
- justification of resources and appropriate financial management/risk assurance
- clear and effective pathways to impact
- value for money.
8. 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

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/

UK Research and Innovation guidance on pathways to impact

Department for International Development guidance on research uptake
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 (or countries) 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.
- Relationship to other trials
  Describe how the proposed trial will differ from or complement any relevant planned, ongoing or recently completed trials internationally.
- Impact and 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?