

UKRI GCRF Health and Context call 2019 – Outline Applicant Guidance

Please note the deadline for submitting an outline application is 2 APRIL 2019 16:00 BST.

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 outline proposals to the UKRI GCRF Health & Context call 2019. Separate guidance will be made available for applicants invited to submit a full research grant proposal.

An <u>FAQ document</u> is also available and should be consulted along with this guidance and the call text.

As this call is being administered by 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 MRC, ESRC, AHRC, NERC and BBSRC.

Background

The <u>Global Challenges Research Fund (GCRF)</u> is a key component in the delivery of the <u>UK Aid Strategy</u>: tackling global challenges in the national interest. The fund aims to ensure that UK research takes a leading role in addressing the problems faced by developing countries through:

- challenge-led disciplinary and interdisciplinary research
- strengthening capacity for research and innovation within both the UK and developing countries
- providing an agile response to emergencies where there is an urgent research need.

The Collective Programme under the UKRI GCRF Collective Fund is a series of calls designed to enhance the coherence, strategic focus and overall impact across the six strategic GCRF Challenge portfolios:

- · Cities and Sustainable Infrastructure
- Education
- Food Systems
- Global Health
- Resilience to Environmental Shocks and Change
- Security Protracted Conflict, Refugee Crises and Forced Displacement.

The programme is being delivered by UKRI and steered by the <u>GCRF Challenge Leaders</u>. Interdisciplinary research excellence is central to the GCRF and investigators from all disciplines are encouraged to apply for calls within the parameters of each call regardless of the host function. All proposals received will be shared with other constituent parts of UKRI as necessary to assist with processing.

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 this 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 low and middle-income countries (LMICs)

MRC recently updated its ethical guidance for research involving human participants in LMICs; please refer to <u>Section 5.2.2</u> 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 <u>website</u>. In addition to this, MRC has recently put together specific guidelines for the management of global health trials which can be <u>downloaded here</u>. It is essential that applicants proposing the use of clinical trials consult these resources as they put together their application.

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: <u>JeSHelp@rcuk.ac.uk</u> 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-ls) 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: Research Grant

Select Call/Type/Mode: UKRI GCRF Health and Context call 2019

• Select 'Create Document' option

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 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 UKRI Council funding panels must be discussed with MRC (lnternational@headoffice.mrc.ac.uk) prior to submission. MRC will discuss with the other councils involved in this call. Any resubmission must have clearly addressed issues that had previously prevented funding, and this should be communicated in the cover letter. Re-submission of an unsuccessful application within one year of the previous submission is not permitted. Simultaneous submission of the same proposal to more than one UKRI scheme is not permitted.

Online Je-S Proposal Form

The Je-S form will cover the administrative and financial aspects of your application. For the outline application you are required to submit: 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 and in the 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. Please also note that the 'Board or Panel Portfolio' is NOT required to be completed.

Required application documentation

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

<u>Section 2.2</u> 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	Notes
Online Je-S proposal form	Enter "Please see case for support" into Objectives, Impact Summary, and Summary text boxes and ensure the relevant information is included in case for support.
Case for support	Maximum 5 Pages A4 including references
Letter(s) of support (use Je-S 'Other Attachment')	Maximum 2 Pages A4 each
Covering letter	Maximum 2 Pages A4
CVs	Maximum 2 Pages A4 each
Publications	Maximum 1 Page A4 each

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 five 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 <u>section 2.2.3.3</u>.

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.

Letters of support (Use 'Other Attachment' type in Je-S)

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 2 pages A4. Please use Je-S Other Attachment' type, using the Description 'Letter of Support - 'then the name of the designated Stakeholder'

Please see <u>Section 2.2.7</u> 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 **2 pages A4**. Please see <u>Section 2.7</u> 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 <u>Section 2.3.1</u> of the MRC Guidance for Applicants for more information about CVs and see <u>Section 2.3.2</u> for more information about publications. Please disregard the requirement to upload these documents separately.

Applicant eligibility

Principal investigators (PIs) should be based at an eligible LMIC or UK research organisation.

UK PIs or Co-Is must be based at a UK higher education institution or at an eligible <u>independent</u> research institution.

LMIC Pls or Co-ls must be based at a 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 included 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, a MICA form must be submitted with the proposal.

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 UKRI 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 direct 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%.

- Co-Is can be based in high-income countries outside of the UK as per usual MRC funding rules. These Co-Is can claim 100% of their direct costs but no indirect or Estate costs. These should be included within the exceptions cost section. However, as the scheme is intended to fund work in low- and middle-income countries, high-income country applicants are advised to keep their costs claimed to a minimum.
- 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).

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

The total cost of the research proposal claimed from UKRI should be within the range of £1-2 million once differing FEC rates for UK and overseas research have been accounted for, for example total UK costs of £1 million would translate to £800,000 against the grant.

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 UKRI 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.

Assessment Process

All proposals will be assessed by a sift panel of experts that will convene in June 2019. Panel members will be drawn from a range of disciplines that reflect the interdisciplinary nature of the call. 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 and there will be no opportunity to respond to the feedback.

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

- research excellence
- · capability and interdisciplinary research team
- capacity building and international partnerships
- community engagement in the development of the proposal and its delivery
- likelihood and pathways to impact
- leadership and management
- organisation governance and evaluation
- ethics
- value for money.

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/

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/51 4977/Research_uptake_guidance.pdf

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 and so on, 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 and so on
- 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?