



Medical  
Research  
Council

**NIHR** | National Institute  
for Health Research



# DFID/MRC/NIHR/Wellcome Joint Global Health Trials

Outline Application Guidance: Call 11

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## 1. Important Information

Up to £20m is available for global health trials funded under this call for proposals. This funding is expected to support several trial development grants (total budget ~£1-2m) and full trial grants (total budget ~£18-19m). Value for money is an important part of the assessment criteria.

Funding for projects awarded under this call for proposals is jointly provided by the UK Department for International Development (DFID), Department of Health and Social Care (DHSC) through the National Institute for Health Research (NIHR), the Medical Research Council (MRC), and Wellcome.

MRC administer the call for proposals on behalf of the funders and so all applications should be submitted to the MRC and will be awarded according to [UKRI Terms and Conditions](#).

General information about how to apply to the MRC can be found in the MRC Guidance for Applicants: <https://mrc.ukri.org/documents/pdf/guidance-for-applicants/>

Where guidance in the present document differs from that in the MRC Guidance for Applicants, you should follow the direction in this present, scheme specific, document.

Please complete the proposal in English and use British Pounds Sterling for all costs.

The submission deadline for outline grants is: **16:00 British Summer Time (BST) on 8th October 2020.**

All proposals must have a Principal Investigator (PI) based at either an eligible UK Research Organisation (RO) or an eligible RO in a low- or middle-income country (LMIC). It will be the ROs hosting the successful PIs that receive the funding and manage distribution of the funding to any Co-Investigator RO(s). PIs from high income countries outside the UK are not eligible to apply for this scheme.

### The application/review process in summary:

1. Outline grant application deadline: 8<sup>th</sup> October 2019
2. Panel meeting of academic experts: December 2020
3. Successful applications will be notified and given Panel feedback in December 2020 to be incorporated into full applications
4. Full application deadline: February 2021
5. Full applications will be sent out for external peer review and the applicants will be given the opportunity to respond to those comments in May 2021
6. Panel meeting of academic experts: June 2021
7. Final decisions are expected to be relayed in July 2021

Queries should be sent to: [JGHT@mrc.ukri.org](mailto:JGHT@mrc.ukri.org)

## 2. Who can apply?

The intellectual challenge should be the determining factor when configuring appropriate partnerships and collaborations. Proposals must demonstrate equitable partnerships in line with the UK Collaborative on Development Research '[Building Partnerships of Equals](#)' report, which includes demonstrating clear leadership roles across the proposed partnership. The balance of intellectual leadership and costs between high income countries and LMICs will be considered in the assessment of proposals.

### Principal Investigators (PIs)

**This call differs from the standard MRC rules as for this call Principal Investigators can be based either in the UK (as per standard MRC rules) or in an eligible low- or middle-income country (LMIC).**

Projects with PIs from LMICs are strongly encouraged and all proposals must include Co-Investigators (Co-Is) from the LMIC(s) in which the research is taking place. Funding is not dependent on the involvement of a UK-based research organisation. The PIs are responsible for the intellectual leadership of the research project and for the overall management of the research. The PI will be the funding agencies' main contact for the proposal.

Exceptions: applicants based in China or India are not eligible to be the PI of an

application to this call but are welcomed as international Co-Is within proposals.

Applicants without experience of UK funding are encouraged to seek mentorship or guidance on grant writing from colleagues with experience of winning UK funding.

For administrative purposes when completing the Je-S form, you will only be able to list one PI. While there is formally only one PI, you can make it clear in your Case for Support that the scientific leadership is shared and that in this respect, the applicants listed are Co-Principal Investigators.

It is not permitted for the same person to be PI on more than one Research Grant application submitted at the outline stage. It is possible to submit one Research Grant application and one Development Grant application within the same round.

Please note, the PI is responsible for ensuring that each investigator's overseas research organisation has been successfully added to the Je-S database and has the required level of Je-S account.

### Co-investigators (Co-Is)

The PI may be supported by a number of Co-Is named on the application. A Co-I assists the PI in the management and leadership of the research project.

All UK and international Co-Is must have verified Je-S Accounts and must be added to the Je-S form under "Co-Investigator". Please see section 5 [Creating a Je-S application](#) for information on how to add an organisation on Je-S. **There is a delay between registration and the investigator being available on the online system to add to the application, so please ensure that registration is completed well in advance of the submission deadline.**

Investigators employed by an institution in China, India or a high-income country outside the UK cannot be a PI on a proposal but can be a Co-I and are expected to make a significant contribution to their own research costs, including covering their own overheads. As the scheme is intended to fund work in LMICs, high-income country applicants are advised to keep their costs claimed to a minimum.

### Project Partner/s

A Project Partner is an organisation or individual who is providing a substantial contribution to the project and will not take any funds out of the project. Therefore, any persons already named on the proposal (e.g. as PI, Co-I or Named Researcher), should NOT also be included as a Project Partner.

For further guidance regarding Project Partners, please see MRC Guidance for applicants at [who can apply](#) (section 1.3.4).

### Research Organisation Eligibility

UK PI's **must** be based at one of the following:

- Higher Education Institutions
- [Independent Research Organisation \(IRO\)](#)
- UK Government Funded Organisation (other than MRC funded Units and Institutes)
- MRC Units/Institutes
- University Units (former MRC Units)

LMIC PI's **must** be based at one of the following:

- Higher Education Institutions
- Non-profit Research Institutions

The PI must be employed by an organisation that is legally registered in the UK or LMIC. PIs cannot be based in India, China or a high income country outside the UK.

Many non-UK organisations and some UK organisations will not currently be recognised to hold UK Research and Innovation grants. Lead institutions which are not currently recognised will have to obtain recognition (further eligibility and financial checks) before any grant can be confirmed. In order to minimise administrative burdens and costs to both applicants and funders, formal recognition will only be pursued if the grant is successful.

For further information on UK eligibility for research funding see:

<https://www.ukri.org/funding/how-to-apply/eligibility/>

If you are unsure about your LMIC organisation's eligibility, please [contact us: JGHT@mrc.ukri.org](mailto:JGHT@mrc.ukri.org)

### Eligible Countries

The scheme funds research in LMICs. Please refer to the OECD DAC list to check eligibility: <http://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/daclist.htm>

Exceptions: please note that from 2020/21 our partnerships with China and India have a renewed focus: applications involving China or India must have global or regional development impact as the primary objective, with local or national impacts within China or India as secondary objectives.

If your project is based in a middle-income country, then it will be important to clarify that the target population of the proposed research will be the most vulnerable populations and those living in low-resource settings within LMICs.

Applications can focus on either a single or multi-country assessment if the key aims of the call are met and all of the countries in which the research takes place are LMIC's. Please note, Call 11 specifically invites applications for definitive randomised controlled trials (RCTs) that provide generalisable data, beyond a single country or setting.

## 3. Required documents for an outline application

Only applications submitted through Je-S will be recognised: <https://je-s.rcuk.ac.uk/>

Applications must be submitted by the PI on behalf of the research team. Outline applications must include the following:

- A completed application form on Je-S: All investigators **must** be included. This form reflects the project costs so please include **all** costs, UK or otherwise. See '[Costs](#)' section for clarification
- A jointly prepared Outline Case for Support (see additional guidance below) must be uploaded as a Word or PDF attachment
- CV's and publication lists must be uploaded for all named investigators.

All attachments should be completed in 11-point Arial typeface, with a minimum of 2cm margins. Applications will not be accepted where smaller or narrow typefaces have been used. If you exceed the maximum page length or attach extraneous documents, we may reject your application or return your application to you for amendment.

The online Je-S form requests information such as administrative details of the investigators, financial information and summaries of your research. We recommend that applicants access the Je-S form well in advance of the deadline so that they can see the specific information that they will need to enter and can ensure that they and their Co-Is are registered on the system. It is fine to copy information between your pdf attachments and the Je-S form where there is overlap in information requested.

## Attachments

<b>Mandatory Attachments</b>	<b>Conditions</b>
CVs	Two sides of A4 per person
Publications	One side of A4 per person
Case for support	Six sides of A4 (plus one for references)
Gender Equality Statement	One side of A4
ODA Compliance Statement	One side of A4
<b>Optional Attachments</b>	<b>Conditions</b>
Letters of Support	Two sides of A4 per letter

At the outline stage you do not need to submit a Justification for Resources or a Data Management Plan, these will only be required to be completed by successful outline applicants, when submitting full applications.

## CVs and Publications

Please submit a maximum of 3 pages per investigator: 2-page CV and a 1 page publication list.

Please compile all the documents into one PDF file and include the documents in the same order as the investigators are listed on your Je-S application form. Each publication list should immediately follow its corresponding CV.

We must receive a CV for each of the following:

- Principal Investigators
- Co-investigators
- Named individual research staff

Each CV should cover:

- Trial experience should be highlighted at the top of the CV.
- Employment history
- A description of your current post and the source(s) of funding for this post (including dates)
- List and description of previous posts (including previous dates)
- Educational qualifications (including dates)
- Please also state whether you are:
  - Clinically qualified
  - Clinically active

Please see [Section 2.2.1](#) and [Section 2.2.2](#) of the MRC Guidance for Applicants for the full details on the requirements for CVs and Publications.

## Letters of Support

At the outline stage, letters of support can be included in the application where available. These letters should come from relevant academic and non-academic stakeholders such as local or national government authorities, other public sector actors and project partners (e.g. industrial partners and 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 full details on the requirements for Letters of Support for Project Partners.

## Gender Equality Statement

Official Development Assistance provided by UKRI must comply with the requirements of the International Development (Gender Equality) Act 2014 which states, the “desirability of providing development assistance that is likely to contribute to reducing poverty in a way which is likely to contribute to reducing inequalities between persons of different gender”.

To comply with the International Development (Gender Equality) Act 2014, applications must provide a Gender Equality Statement, outlining how applicants have taken meaningful yet proportionate consideration as to how the project will contribute to reducing gender inequalities. This must be no longer than a one page and is a mandatory attachment.

Applicants are required to address the below criteria, with an understanding that, depending on the nature of their research and innovation, not all questions will be applicable.

Criteria to address while considering gender impact:

- Have measures been put in place to ensure equal and meaningful opportunities for people of different genders to be involved throughout the project? This includes the development of the project, the participants of the research and innovation, and the beneficiaries of the research and innovation.
- The expected impact of the project (benefits and losses) on people of different genders, both throughout the project and beyond.
- The impact on the relations between people of different genders and people of the same gender. For example, changing roles and responsibilities in households, society, economy, politics, power, etc.
- How will any risks and unintended negative consequences on gender equality be avoided or mitigated against, and monitored?
- Are there any relevant outcomes and outputs being measured, with data disaggregated by age and gender (where disclosed)?

Further guidance for applicants on Gender Equality Statements is available [here](#).

## 4. Case for Support scheme specific guidance

Your Case for Support is a document including your scientific proposal, details of the research environment, people involved and references. Your Case for Support should

indicate how your proposal fits the call specification for this scheme.

The outline Case for Support **should not exceed six sides of A4** plus one additional page of references (seven pages in total). Your Case for Support must be attached to your Je-S online application as a PDF. **Additional annexes are not permitted** (including the reproducibility and statistical design annex). Any applications with additional annexes will be returned to the applicants for removal.

Please use:

- Arial font with a minimum size of 11pt (excluding text on diagrams and mathematical symbols)
- A minimum of single line spacing
- Standard character spacing
- Margins of no less than 2cm.

Please number all pages of the Case for Support. 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.

Please use the following headings:

### Research Project summary information

- Full title of the trial (no more than 150 characters)  
*Please use a title that is intelligible to trial participants as well as meaningful to scientific peers.*
- In which country(ies) will the trial take place?
- Duration in months
- What is/are the principal research question(s) to be addressed?
- Study design and sample size
- Total amount requested from this funding scheme.

### The Proposed Trial

Please include relevant pilot data and ensure it is clearly described. At the outline stage it is important for the panel to be able to judge the feasibility of the proposed trial based on existing data.

Give a brief summary of the proposed trial which should include information on and justification for:

- **Trial type**  
Prevention, screening, diagnostic, treatment, quality of life, etc.
- **Proposed trial design**  
Blinded? Number of arms? Factorial/cluster? Applicants are asked to clearly justify the proposed method for randomisation. If randomisation is not being recommended as part of the trial design, a clear and informed justification of why it is to be excluded is required. Many applications to this scheme propose the use of sealed envelopes and applicants are asked to consider other options and explicitly outline the reasons for their choice. If sealed envelopes are believed to be the best option, it must be clear how the risk of bias will be avoided in the study.
- **Interventions**  
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.

- **Target population**  
The procedure for randomising patients and any inclusion/exclusion criteria should be indicated. Any proposed lower and upper age limits for trial participants should be justified on scientific grounds. Normally, for example, there should be no upper age limit on recruitment. Similarly, exclusion on the grounds of gender should be justifiable on scientific grounds.
- **Duration of treatment period and follow-up**
- **Overall trial timeline**  
Please provide realistic timetables for the completion of your studies. In addition to the need for a sound basis for the projected recruitment rate, adequate provision should be made for setting up and staffing the trial team, obtaining ethics approval for all participating centres, a start-up phase and similar activities.
- **Primary outcome measure**  
Justify clearly the outcome measures to be used.
- **Economic, social, qualitative measures (if applicable)**  
We do not require that quality of life measures are included as an outcome in all trials. However, you will need to justify fully why these measures are to be either included or excluded.
- **Sample size and potential power of the trial**  
Ensure that 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, calculated and well-justified.
- **Participating centres**
- **Community and patient group involvement**  
We encourage the involvement of community and patient advocate groups in all stages of trial development, with the aim of better trial design and greater acceptability of both the trial and its findings.

### Why is this trial needed now and why in the proposed location?

- Please consider issues such as burden of disease and priority for the relevant local, regional and national health services etc. Considerations of the impact of this work for policy makers and non-academic stakeholders should be considered.
- Please provide evidence from the medical literature, systematic reviews, professional and consumer consensus and pilot studies should be cited if available; include any on-going or planned studies elsewhere.
- Applicants are encouraged to engage with social science and health economics to ensure research is embedded in an understanding of the needs of populations and has potential for uptake and scalability. Economic evaluations should be included where appropriate.

### How will the results of this trial be used?

Please use this section to provide additional information on how the results of the trial will be used.

- What changes might be implemented as a result of the study? Applicants should consider how this research will lead to implementation and uptake at scale. This should be evidenced in the description of how the research questions have been formulated.
- What impact will the results have on clinical practice or our understanding of the proposed intervention or underlying disease?
- Will the results of the trial be generalizable beyond the immediate research setting in a way that will maximise the impact of the results?

## Trial management

- Who will be the trial sponsor?  
In most instances we would expect the PI's host institution to be the trial sponsor.
- Does the team of investigators proposed incorporate the range of disciplines and experience necessary to carry out the study?
- Will you be working with a clinical trials unit /office? Please give details.
- Has adequate statistical advice been sought and incorporated?
- Has adequate advice been sought and incorporated on other health services research issues (e.g. health economics and quality of life) if they are to be addressed?

## Good clinical practice

The funders require that all funded trials are run according to the [MRC guidelines for management of global health trials](#).

The previous experience of the host institution in participating in trials to similar standards as those of the [MRC guidelines for management of global health trials](#) will be taken into consideration at the evaluation stage.

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 the study. We would usually expect the sponsor to be the PI's RO. 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 RO is an MRC Unit or Institute, in which case MRC would normally be the sponsor. At the full application stage, we will need a letter of agreement from the sponsor.

Regulation, ethical review and liability may vary across different countries. PIs and proposed sponsors should ensure that they have adequately understood the feasibility and costs of participation of proposed international centres. For example, insurance arrangements will vary between countries and the sponsor is responsible for ensuring adequate arrangements are in place at each site.

## Ethics

The funders do not require ethical approval to be in place at the outline proposal stage. If funding is awarded it will be the responsibility of the investigators and the host research organisations to ensure that all the appropriate ethics approvals are obtained and that no research requiring such approval is initiated before the necessary ethics approvals have been granted. Please note that ethics approval must be obtained from a UK ethics committee as well as in any countries hosting the trial.

## Trial managers

In most cases, you will need to consider appointing a trial manager for the study, who will be responsible for:

- The overall efficient day-to-day management of the trial
- Compliance with the protocol
- Secure randomisation process
- Swift recruitment
- Efficient data management
- Problem identification and resolution
- Distribution and maintenance of trial materials in all centres
- Budget control
- Production of progress reports

Recruiting a trial manager with appropriate experience and training is essential if the PI and trial team are to deliver the trial to time and to budget.

## Trial Partners

- Is a commercial or other organisation being approached for the supply of the intervention (experimental and control). What is the status of discussions /arrangements?
- Are other funding partners involved /anticipated to be involved? Which? What is the status of discussions/agreements?
- Are other partners key to the success of this trial e.g. Health Ministry? If so, what is the status of discussions/agreements?

## Financial Information

- Please provide a breakdown of the funding request per institution as per the below table. The cost split between UK and LMIC organisations must be identified to ensure that spending is in line with the aims of this scheme. UK costs are calculated at 74% of the Full Economic Costs (FEC) and all overseas costs at 100% FEC.

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

- Please provide a brief summary and justification of the core items of expenditure that you factored in to the calculation for the total cost of the trial.
- Are you requesting the full amount from this funding source, or would other funding sources contribute to the study? What is status of any other funding contribution?

## Proposal History

Has an application for funding for this trial been submitted previously to DFID, NIHR, MRC, Wellcome or any other funding organisation? If so, please indicate the status of the previous application.

We are not able to accept resubmissions of proposals that have already been considered under this scheme. If you have substantially changed a previous proposal and wish to discuss whether it might be eligible, please contact [JGHT@mrc.ukri.org](mailto:JGHT@mrc.ukri.org).

## 5. The Je-S Application

All proposals submitted to this scheme are required to include investigators based in the LMIC(s) where the research will take place.

All Overseas ROs/Institutes and individual applicants (PIs and Co-Is), are required to be registered on the Je-S system. Please note that a self-registration process is available for overseas organisations to follow from the [Je-S login page](#), or alternatively by following this direct link to the [Je-S organisation set-up page](#).

Both UK organisations and overseas organisations are encouraged to contact the Je-S helpdesk as soon as possible before the call deadline of the 8<sup>th</sup> October 2020, so that we can ensure that the overseas organisation (either Lead or Non-lead) has been correctly added to the Je-S System. Any delays could mean the proposal being rejected because of a late or incomplete submission.

Please login to your Je-S account [here here](#) using the username and password you have chosen.

If you do not have a Je-S account, or have forgotten your password, please see the following guidance:

- New Je-S Users: In order to gain access to the Je-S System, [Create an Account](#).
- Je-S users having problems successfully completing login to their Je-S account: [Retrieve User Name / Password](#).
- Select '**Documents**' from left hand menu list from your Je-S account home page
- Select '**New Document**' from within the Functions/create section of your documents page

Please telephone Je-S Helpdesk +44 (0) 1793 444164 should you require any assistance with the Je-S System.

### Creating your Je-S application:

Please note that all MRC funding calls close at 4pm (16:00 BST), on the advertised closing date.

- Select Council: **MRC**
- Select Document Type: **Outline Proposal**
- Select Scheme: **MRC Jointly Funded Initiatives Outlines**
- Select Call/Type/Mode (optional): **MRC NIHR DfID Wellcome Global Health Trials Call 11– Outline Oct 2020**
- Select '**Create Document**' option

## Je-S Add New Document

To find the council, document type and scheme combination for a particular call please use the call search.

**Call Search** (opens in a new window)

Select Council:

MRC ▼

Select Document Type:

Outline Proposal ▼

Select Scheme:

MRC Jointly Funded Initiatives Outline ▼

Select Call/Type/Mode (optional):

MRC NIHR DfID Wellcome Global Health Trials Call 11 – Outline Oct 2020 ▼

Copy existing document?

Create Document

Cancel

Please note that for this outline call we ask that you provide your substantive information for the proposal in your case for support and that you leave the following boxes on the form blank:

### Objectives:

TO MINIMISE WORK FOR APPLICANTS AT THE OUTLINE STAGE PLEASE FILL THE BOX AS “PLEASE SEE CASE FOR SUPPORT”

### Summary:

TO MINIMISE WORK FOR APPLICANTS AT THE OUTLINE STAGE PLEASE FILL THE BOX AS “PLEASE SEE CASE FOR SUPPORT”

### Entering costs in Je-S

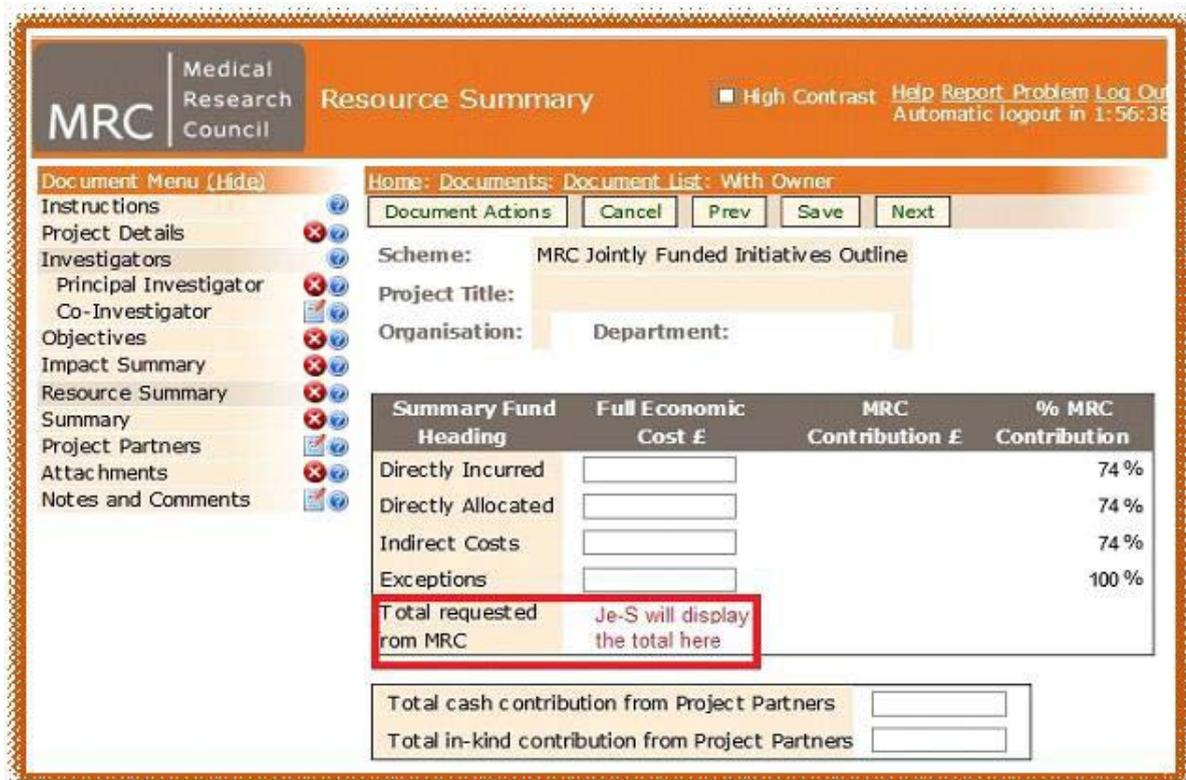
UK investigator research costs (including overseas travel) will be funded at 74% of the Full Economic Cost (FEC). This differs from the MRC’s standard 80% to reflect the varying policies of the joint funders. Please see section 5. Resources – Full Economic Costing in the [Guidance for Applicants](#) for information on FEC.

Research costs incurred by overseas ROs and investigators is eligible to be funded at 100% of FEC.

Please note that research teams should consider the breakdown of budgets between UK/high income costs and LMIC costs, keeping in mind the aims of the scheme.

**Funding for non-UK research institutions that have not previously received funding from MRC will be dependent on further eligibility and financial checks, to be conducted if the proposal is selected for funding. For further advice on eligibility, please [contact us](#).**

The screenshot below is taken from Je-S which will summarise the costs entered for your proposal. **It is important that before submitting your proposal that costs are checked.** All costs outside the UK must be entered as 'Exceptions'. Costs related to the UK elements of the proposal (if applicable) must be entered as either 'Directly Incurred', 'Directly Allocated' or 'Indirect Costs'. Please read on for more detail on the funding available.



Funding available:

Costs	Funding available
Research costs:	
Staff – directly incurred post	Yes
Staff – directly allocated posts (e.g. UK PI and Co-I time)	Yes
Other research costs (including equipment, consumables)	Yes
Exceptions: Overseas Staff/Research costs & up to 20% indirect costs	Yes
Studentships (PhD)	No
Travel and subsistence for exchange/mobility activities	Yes
Cost of workshops, meetings etc.	Yes

'Directly Incurred' and 'Directly Allocated' includes all UK staff and research costs (travel,

consumables etc.), relevant to the project.

'Indirect Costs' should be entered for UK ROs included in the project and should not include any overseas costs. Instructions on how to calculate and input indirect costs for LMIC investigators is provided below.

'Exceptions' costs should include all overseas staff and research costs (consumables, travel, LMIC indirect costs, etc.).

### Direct (salary) Costs:

All UK PI's and Co-I's can claim 74% of their direct costs. These costs should be included as either 'Directly Allocated' or 'Directly Incurred', depending on which is relevant to the individual, see [Section 3.2.2 Directly Incurred Costs](#) and [3.2.3 Directly Allocated Costs](#) in the standard MRC guidance for further details.

All LMIC PI's and Co-I's can claim 100% of their direct costs (and up to 20% as indirect costs as described below). These costs should be entered as 'Exceptions' and claimed at 100%.

Co-I's based in high-income countries outside of the UK should be costed as per standard MRC funding rules. They can claim 100% of their direct costs **but no indirect costs**.

As the scheme is intended to fund research in LMICs, high-income country applicants are advised to keep their costs to a minimum.

### Indirect (infrastructure) Costs:

UK institutions should follow the standard MRC guidance, [Section 3 Resources](#).

Each LMIC RO participating in the project can request indirect costs to cover the cost of hosting researchers participating in the project. Each LMIC RO can request up to 20% of their direct costs as additional indirect costs. For example:

An example of direct costs for an LMIC research organisation may be as follows:

- LMIC PI, total salary costs for the project = £20,000
- LMIC Co-I, total salary costs for the project = £15,000
- LMIC Investigator Travel & Subsistence + Fieldwork costs = £15,000

All these overseas costs are requested as 'Exceptions' (100%) and the total costs claimed would equal £50,000. 20% of these total costs would equal £10,000, therefore the LMIC research organisation is allowed to claim up to £10,000 in indirect costs.

MRC will expect these indirect costs to be requested as '**Exceptions**' (100%) and detailed within the '**Other Directly Incurred Costs**' section of the Je-S form.

Please note that if you are successful at the outline stage, all costs requested on the Je-S form will need to be broken down and fully justified within the Justification for Resources, which will be requested as part of an invited full submission.

### Further Costing guidelines:

For overseas PI's and Co-I's all travel and subsistence costs can be claimed at 100%. UK

based researchers can only claim 74%, even if they are travelling to a LMIC for the project.

For overseas institutions all other exceptional costs associated with the overseas organisation should be claimed under the appropriate fund heading as 'Exceptions' and entered as 'Other Directly Incurred Costs'. These include consumables, consultancy fees, field work fees, equipment (under £10,000) and subcontracting.

Indirect and Estates Costs cannot be claimed by investigators in a high-income country based outside of the UK.

UK ROs are not eligible to request costings for access publishing charges (APCs) or other types of publication in respect of peer reviewed research articles (including review articles not commissioned by publishers) and conference proceedings that acknowledge funding from the MRC as these costs are supported through block grants to UK HEIs, approved independent research organisations and research council institutes. **LMIC RO's can include the aforementioned costs, both when they lead a proposal and when they are involved in a proposal.** These costs should be budgeted under 'Exceptions' at 100% FEC.

If an Investigator does not need to cost their total time allocation to the proposal (i.e. some or all of their salary is already covered), it is important to ensure that their time allocation is accurately reflected as this will form part of the assessment to determine the feasibility of conducting the study. There is a separate section for hours worked and hours charged (costed) when completing the Je-S form. This can be found on the Investigator section in the main document menu in Je-S.

For further Je-S guidance for completing the 'Resource Summary' please refer to the [Je-S guidance page](#).

### Project Partners:

A Project Partner is an organisation or individual who is providing a substantial contribution to the project and will not take any funds out of the project. Therefore, any persons already named on the proposal (e.g. as PI, Co-I or Named Researcher), should NOT also be included as a Project Partner.

Details should be given of project partners and their contributions. An organisation should only be named as a project partner if it is providing specific contributions (either direct or indirect) to the research project and no allocated funding requested. Further guidance can be found [here](#).

If the project partner listed is from industry, applicants must follow the MICA guidance. Applicants with an industrial partner(s) will need to include MICA: as a prefix to their project title. At the outline stage the input/involvement of the industry partner should be detailed in the Case for Support. Please refer to the guidance described below. Applicants invited to submit a full application need to include a MICA Form and Heads of Terms as part of their Je-S application.

### Submitting your application

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

The deadline for submission to the MRC is 16:00 BST 8<sup>th</sup> October 2020. 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.

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 (which will vary depending on how the account is set up). **Select 'Document Actions' and then select 'Show Submission Path'**:

- If the screen shows **'With Owner'** and **'With Council'**, then the proposal will be submitted directly by you (the PI).
- 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 RO'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 that 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. Please note that they will need to do this no later than 16.00 BST UK time on 8<sup>th</sup> October 2020.

## 6. Assessment Criteria

General information on the MRC's approach to peer review is provided in the MRC Guidance for Applicants document which can be found at:

<https://mrc.ukri.org/funding/peer-review/>

There is a two-stage application process for this call. Applicants are initially invited to submit outline proposals, which will be assessed by an outline review panel. Those selected at the outline review panel will be invited to submit full applications, which will undergo external peer review and be reviewed by a full panel.

The outline review panel for this scheme will consider whether outline applications are of world-class standard (being intellectually innovative, well-focused and methodologically sound), and whether the research has the potential to make a real improvement to health outcomes in LMICs.

Panel members will be asked to comment on the following criteria in assessing the outline proposals:

### Project team and track record of applicants:

- Are the credentials of the investigators and host institutions appropriate to deliver the project?
- Is there an understanding of and sufficient involvement of the local research context and decision-makers?
- Does the proposed team of investigators possess the necessary range of expertise and experience to successfully carry out the proposed study and have experience in conducting high standard trials?

### Importance of the question/need for the trial:

- Is there a real need for this study in the proposed location? Is the research question important and appropriate?
- Is an answer to the research question needed by policy-makers and other

- stakeholders beyond the academic community?
- Have similar trials been done previously or are underway now?

#### Project plans:

- Is the proposed study design and timeline feasible?
- Have all potential sources of bias been identified and discussed?
- Is the proposed study innovative, internationally competitive, and methodologically sound?
- Have major scientific, technical or organisational challenges been identified, and will they be well addressed?
- Are there any ethical concerns?

#### Research impact:

- Does the project have real potential to improve health outcomes? How important an advance will this be?
- Is there clarity as to how, and by whom, the research findings will be used? Applications must demonstrate how considerations for future implementation have been considered.
- Does the application demonstrate that there is demand for the research from policy-makers and other stakeholders beyond the academic community?
- Will the trial provide definitive results in order to change international policy and guidance?
- Does the proposed trial include consideration of health services, economics, social science and/or operational research which will increase the likely opportunities to scale-up the findings of the research?
- Is the proposed size and scale of the grant likely to be appropriate in relation to the potential impact of the trial?

#### Value for money:

- Does the study represent value for money?
- Are the costs realistic and reasonable?
- Do the majority of funds requested support the costs in the low or middle income country where the trial will be conducted?

## 7. Contacts

General enquiries can be sent to [JGHT@mrc.ukri.org](mailto:JGHT@mrc.ukri.org)

## 8. Data Protection

### Privacy Notice

All personal data provided to the MRC as part of UK Research and Innovation via the Je-S form will be processed in accordance with current UK data protection legislation. Please see Je-S terms and conditions for guidance on how personal data collected from applicants is used (<https://je-s.rcuk.ac.uk/Handbook/Index>). Further information on how we use personal data can also be found in the UK Research and Innovation Privacy Notice (<https://www.ukri.org/privacy-notice/>). Information on the terms and conditions that guide

the general management of funded grants can be found in the MRC's Guidance for Applicants (<https://mrc.ukri.org/documents/pdf/guidance-for-applicants/>).

### What will be shared and with whom?

As the DFID/MRC/NIHR/Wellcome joint global health trials is a jointly funded scheme, information will be shared between the partners, the Department for International Development (DFID), the Medical Research Council (MRC), National Institute for Health Research (NIHR) and Wellcome.

The data that you provide will be held securely in accordance with the MRC IT and Records Management policies. It will be retained in accordance with the Medical Research Council's disposition schedule for the following schedules:

Business process	Record type	Retention
10.1 Grants	Grant programme policy file	Permanently
10.1 Grants	Grant programme board agenda, minutes and papers (e- volume/CD)	Permanently
10.1 Grants	Grant programme board assessment feedback	Permanently
10.1 Grants	Grant programme board administration and correspondence	3 years
10.1 Grants	Triage meeting agendas, minutes and papers	Permanently
10.1 Grants	Triage decision spreadsheet	Permanently
10.1 Grants	Application processing statistics and summaries	20 years
10.1 Grants	Successful applications	20 years
10.1 Grants	Unfunded applications (unsuccessful, withdrawn, not accepted)	3 years
10.1 Grants	Grant summary record (Siebel etc.)	Permanently
10.6 Research Management	Clinical trials oversight and monitoring information (incl. protocols and annual reports)	Permanently
10.6 Research Management	Research management administration	3 years
10.6 Research Management	Systems training	1 year
10.6 Research Management	Information Systems manuals/guidance	1 year
10.6 Research Management	Induction material	1 year
10.6 Research Management	Council Operating Procedures/Standard Operating Procedures (SOPs)	1 year
10.6 Research Management	Interfaces with other organisations	7 years
10.6 Research Management	Research Portfolio files	Permanently
12.1 Strategy	Research strategy documentation (Inc.	7 years

12.1 Strategy	Internal working groups meeting agendas, minutes and	7 years
12.2 Evaluation	Corporate reports (scorecard, economic impact etc.)	Permanently
12.2 Evaluation	Data analysis and reporting (evil raw data, SQL queries, reports)	Permanently
12.2 Evaluation	Commissioned evaluation and bibliometric reports	Permanently