



DFID/NIHR/MRC/Wellcome Trust

APPLICATION GUIDANCE: Outline stage for full research grants

Contents

A1. The online Je-S form	6
A2. Outline Case for Support	21
A3. CVs	26
A4. Assessment Criteria for outline full-scale research project grants:.....	27

How to apply and assessment criteria; Outline proposals

£20m is available for global health trials funded under this call for proposals. Typically, this funding is used to award up to £1.5m worth of trial development grants, with the remaining £18.5m planned to fund between six and ten full trial grants. 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), the National Institute for Health Research (NIHR), the Medical Research Council (MRC), and the Wellcome Trust (WT).

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 MRC Terms and Conditions.

Important Information

General information about how to apply to the MRC can be found in the MRC Guidance for Applicants and Award Holders

<http://www.mrc.ac.uk/documents/pdf/guidance-for-applicants-and-award-holders/>

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

The first submission deadline for outline grants is 16:00 British Summer Time on **Thursday 14th September 2017.**

The outline grants will be assessed at a panel meeting in November 2017. Applicants
Page **1** of **25**

whose outline proposals are selected for full submission will be asked to submit their full proposals in February 2018. The final selection panel will be in June 2018.

Queries should be sent to:

Cally Walker, Global Health Funding Manager JGHT@headoffice.mrc.ac.uk

+44 (0)1793 416409

Who can apply:

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 usual MRC rules) or in a low- or middle-income country (LMIC).

Eligibility of UK-based PIs is covered in the [Guidance to Applicants and Award Holders](#). The PI must be employed by an institution that is legally registered in the UK or LMIC. Principal Investigators cannot be based in a high income country outside the UK.

For researchers based in low- or middle-income countries, eligible institutions include higher education institutions and non-profit research institutions. Funding for non-UK research institutions that have not previously received funding from one of the funding partners will be dependent on further eligibility and financial checks, to be conducted if the proposal is selected for funding. Please see the JeS guidance documents for further details regarding the registration of overseas applicants. For further advice on eligibility, please contact JGHT@headoffice.mrc.ac.uk.

All LMIC PIs can claim 100% of their direct costs and 20% of indirect costs as exceptional costs.

Direct (salary) Costs: Lead/Principal Investigators (PI's) & Co-investigators (Co-I's), can be based in low- and middle-income countries (LMIC), as per usual MRC funding rules. LMIC PI's & Co-I's can claim 100% of their direct costs (direct costs = the total salary costs for each 'Investigator').

Indirect (infrastructure) Costs: MRC will also allow overseas institutions to request a maximum of 20% indirect costs as a contribution to the overseas institution infrastructure costs that would be incurred by the overseas organisation hosting the project. These indirect costs are calculated by adding all Investigator direct costs together and dividing this total cost requested by 5 (to calculate the 20% total).

Example (indirect costs):

Overseas Lead Investigator (PI), total salary costs for the project = £20,000

Overseas Co-Investigator total salary costs for the project = £15,000

Overseas Co-Investigator travel and subsistence = £15,000

With all these above overseas costs being requested as 'Exceptions' (100%), the total salary costs claimed would equal £50,000. 20% of these total salary costs would equal £10,000 indirect costs.

Please note that these costs need to be entered on the Je- S form as "Other Directly Incurred Costs" and entered as Exceptions funded at 100%. (all costs requested on the Je-S form are required to be should be broken down and fully justified within the Justification for Resources document to be attached to the Je-S application form).

Completing the budget on Je-S.

- All UK costs entered should be in line with the standard MRC costs guidance <http://www.mrc.ac.uk/documents/pdf/guidance-for-applicants-and-award-holders/> Section 5. Please note, for this scheme all costs claimed by UK investigators will be claimed at 74% FEC, not the MRC standard 80%.
- All direct salary costs incurred by overseas PI's and investigators should be entered as Exceptions and claimed at 100%.
- 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 sub-contracting.
- Indirect and Estates costs cannot be claimed by investigators in a high income country outside of the UK.

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. Please see annex I for further details regarding the registration of overseas applicants. For further advice on eligibility, please contact JGHT@headoffice.mrc.ac.uk

It is not permitted for the same person to be Principal Investigator on any more than two proposals submitted to this call.

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-principle investigators.

Co-investigators (Co-Is)

Co-investigators can be based in the UK as per usual MRC funding rules.

Co-investigators can be based in low- and middle-income countries as per usual MRC funding rules. Co-investigators can be based in high-income countries outside of the UK as per usual MRC funding rules. They can claim 100% of their direct costs but no indirect costs. 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.

All Co-investigators should be registered and added to the application. 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.

Project Partner/s

A Project Partner is an organisation or individual who is providing 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 the relevant Je-S guidance page at <https://je-s.rcuk.ac.uk/JeS2WebLoginSite/Login.aspx> and MRC Guidance for applicants at <http://www.mrc.ac.uk/documents/pdf/guidance-for-applicants-and-award-holders/> (page 8, section 2.3.4).

Important Information for lead applicants (UK or Overseas) regarding the inclusion of Overseas Investigators within the Je-S application

All lead applicants (UK or Overseas Lead), MUST ensure that each investigators overseas research organisation has been successfully added to the Je-S database, to allow each overseas investigator to create the required level of Je-S account.

Eligible Countries

The scheme funds research in low and middle income countries. Please refer to the OECD DAC list to check eligibility: <http://www.oecd.org/dac/stats/daclist.htm>

If your project is based in a middle income country (both lower-middle and upper-middle income countries are eligible), 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 as long as the key aims of the call are met through the proposal and all of the countries in which the research takes place are LMIC's.

Application process for Non HEI or IRO UK Organisations

UK Organisations that are not a Higher Education Institution can apply to be an Independent Research Organisation (IRO) if they possess:

- an existing in-house capacity to carry out research that materially extends and enhances the national research base and
- are able to demonstrate an independent capability to undertake and lead research programmes E.G. All NHS Trusts, Hospitals, Boards, Primary Care Trust & GP Practices.

Please see the RCUK eligibility web page <http://www.rcuk.ac.uk/RCUK-prod/assets/documents/documents/eligibilityiros.pdf>, which details the existing IROs.

Important Information for all UK NHS Trusts, Hospitals, Boards, Primary Care Trust & GP Practices. Whilst those listed are all eligible to apply for IRO status, each is advised to contact the Je-S Helpdesk (JeSHelp@rcuk.ac.uk +44 (0) 1793 44 4164), and request that the Helpdesk check to ensure the IRO is fully registered. Please note that this process can take a number of days, therefore we advise that the Helpdesk are contacted as soon as possible to enable them to carry out their checks and advise the organisation what further requirements are necessary to enable the organisation to submit to this call.

When e-mailing the helpdesk for this IRO registration purpose, please include "Application for IRO Status" in the subject heading and provide the full name and postal address of your organisation.

Contact the Je-S Helpdesk JeSHelp@rcuk.ac.uk +44 (0) 1793 44 4164.

How to apply for Joint Global Health Trials Outline Grants

Applying for an outline research project grant is a **two-stage process**. You will therefore firstly (stage one), need to submit an outline proposal in September 2017 and you will be notified in December whether you are invited to submit a full research proposal. Your proposal should include:

- A1. The online Je-S form
- A2. Case for Support
- A3. CVs and Publication lists
- A4. Assessment Criteria

At this outline stage you do **not** need to submit a Justification for Resources, a Pathways to Impact statement or a Data Management Plan, these will only be required to be completed by successful outline applicants, when they submit to stage two of the call in early 2018.

Letters of support are not needed from co-investigators or other organisations requesting funding from the grant. Letters of support are needed for any organisations entered on the Je-S form as 'Project Partners'. A Project Partner is an organisation which contributes in cash or in kind to the project but which is not requesting any money from the project.

Your proposal should be submitted by 16:00 BST on Thursday 14th September 2017.

The assessment panel will meet November 2017. You will receive notification of whether you are invited to submit a full proposal within a fortnight of that meeting.

If you are invited to submit a full application you will be provided with a guidance document for completion of your full application. You may also be provided with panel feedback notes for you to take into consideration when preparing your full application.

Joint Global Health Trials	Maximum No of Pages
Case for Support	6 (plus 1 page for references)
Justification of Resources	X
CV's	2
Publications	1 (per investigator)
Letters of Support	2
Data Management Plan	X
Pathways to Impact	X

A1. The online Je-S form

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-investigators are registered on the system.

The online Je-S form and guidance can be accessed here: <https://je-s.rcuk.ac.uk/JeS2WebLoginSite/Login.aspx>

If you do not already have a Je-S account, you will need to create one and a minimum of 2 working days should be allowed for the account creation. It should be noted that each applicant creating a Je-S account has to be able to select their organisation when they create their Je-S account.

How to apply:

Please login to your Je-S account using the username and password you have chosen when you set-up your Je-S account.

<https://je-s.rcuk.ac.uk/JeS2WebLoginSite/Logout.aspx>

If you have forgotten your Je-S user name or password, please click the below link to request an automatic reminder is sent to you:

<https://je-s.rcuk.ac.uk/JeS2WebLoginSite/Forgot.aspx>

Creating your Je-S application:

Please note, the below '**Call/Type/Mode**' can only be selected when the call opening date has been reached (until the advertised closing date*). Should you require any further information regarding the availability of the below call, please contact RFPD@headoffice.mrc.ac.uk. 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 Outline Sep 2017**
- Select '**Create Document**' option

The screenshot shows a web form titled "Je-S Add New Document". It contains a "Call Search" button, four dropdown menus for selecting Council, Document Type, Scheme, and Call/Type/Mode, a checkbox for "Copy existing document?", and "Create Document" and "Cancel" buttons.

An attachment entitled 'JGHT call 8 JeS Guidance' is available to assist you in completing the online JeS form. Please note that for this schemes 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: <https://je-s.rcuk.ac.uk/Handbook/pages/OutlineProposals/ObjectivesSTFOnly.htm>

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

Impact Summary: <https://je-s.rcuk.ac.uk/Handbook/pages/OutlineProposals/ImpactSummary.htm>

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

Summary of Resources Required for Project: further to the information provided in section 5 of the MRC Guidance for Applications and Award Holders:

All costs incurred by low and middle income country investigators should be entered as 'Exceptions' and will be reimbursed at 100% if funded. You do not need to obtain additional approval from an MRC Programme Manager for the Exceptions costs that you claim; it is assumed that all proposals submitted to this scheme will need to request overseas costs. At the outline stage you do not need to provide a cover letter justifying your Exceptions costs.

Institutions based in low- or middle-income countries can claim indirect costs at a maximum of 20% of their direct costs. If your actual indirect costs are less than 20% of the direct costs, you should only claim the actual costs. The funders reserve the right to check indirect costs rates during the audit of a funded project.

Costs incurred by UK institutions will be reimbursed from this scheme at 74% of Full Economic Costings, not the MRC's usual 80%. This reflects the different costing regimes of the four funders.

For further Je-S guidance regarding the Resource Summary: <https://je-s.rcuk.ac.uk/Handbook/pages/OutlineProposals/ResourceSummary.htm>

Summary: <https://je-s.rcuk.ac.uk/Handbook/pages/OutlineProposals/Summary.htm>

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

Project Partners: 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. <https://je-s.rcuk.ac.uk/Handbook/pages/OutlineProposals/ProjectPartners>.

A2. Outline Case for Support

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.

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 complete the proposal in English and use British Pounds Sterling for all costs. Please number all pages of the Case for Support. 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.

Headings for your outline case for support:

1 Trial 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.

2 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 randomization. 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. 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. 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 trials 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.

3. Why is this 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. 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.

4. 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?

5. Trial management

- Who will be the trial sponsor?
In most instances we would expect the principal investigator'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 Good Clinical Practice in Clinical Trials. <http://www.mrc.ac.uk/research/research-policy-ethics/clinical-research-governance/clinical-trials-regulations/>

The previous experience of the host institution in participating in trials to similar standards as those of the MRC Guidelines for Good Clinical Practice in Clinical 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 a study. We would usually expect the sponsor to be the Principal Investigator's Host Institution. If the sponsor will be a different organisation, please provide a rationale for this decision in your proposal.

The funders will not act as sponsor to the funded trials, unless the PI's Host Institution is an MRC Unit or Institute, in which case MRC would normally be the sponsor. At the full application stage we will need a letter of agreement from the sponsor.

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 approval(s) are obtained and that no research requiring such approval is initiated before the necessary ethics approvals have been granted.

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 annual progress reports

Investing in recruiting individuals with appropriate experience and training where necessary is essential if the principal or coordinating investigators are to deliver the trial to time and to budget.

6. Trial Partners

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

7. Financial Information

- Please provide a breakdown of the funding request per institution as per the below table. The cost split between UK and LMIC organization must be identified to ensure that spending is in line with the aims of this scheme. Costs are calculated at 74 per cent of the Full Economic Costs and the "Exceptions", those incurred outside of the UK, are calculated at 100%.

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)		
TOTAL		

- 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?

8. Proposal History

Has an application for funding for this trial been submitted previously to DFID, NIHR, MRC, the Wellcome Trust or another 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@headoffice.mrc.ac.uk.

A3. CVs

CVs should be a maximum of 2 sides of A4.

Please include separate CV documents/attachments for each of the following:

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

The 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 (inc. dates)
- List & description of previous posts (inc. previous dates)
- Educational Qualifications (inc. dates)
- Please also state whether you are:
 - Clinically qualified
 - Clinically active

List of Publications

The publications list should highlight relevant and recent publications, which should fit on a maximum of one side of A4 in Arial 11-point font (or equivalent).

Please include separate a separate Publications list for each of the following:

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

Please see Je-S Guidance: <https://je-s.rcuk.ac.uk/Handbook/Index.htm#pages/GuidanceonCompletingaStandardG/CaseforSupportandAttachments/MRCSpecificGuidance.htm>

A4. Assessment Criteria for the outline stage of full-scale research project grants:

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

<http://www.mrc.ac.uk/documents/pdf/guidance-for-applicants-and-award-holders/>

The assessment 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 real improvement to health in low and middle income countries.

The panel 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 and 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?
- 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?