



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

APPLICATION GUIDANCE: Development Grant

Contents

1. Important development grant application information	2
2. Who can apply?	3
3. Case for Support: Scheme specific guidance	5
4. Creating a Je-s account.....	7
5. Assessment Criteria.....	11

1. Important development grant application information

Trial development grants will have a duration of 1-2 years. These grants are tailored to assist research teams to develop their future trial application ideas into robust and competitive proposals through conducting feasibility studies and obtaining preliminary data. The size of the grants varies and a general guideline would be up to £150,000. However, grants exceeding this value will still be considered if the costs are fully justified.

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 so all applications should be submitted to the MRC and will be awarded according to MRC Terms and Conditions.

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 directions in this, scheme specific document.

The submission deadline is **16:00 BST Thursday 14th September 2017**

Development grants will be selected after the first panel meeting in late November and the awards are issued shortly after this date.

All projects must have a Principal Investigator based at either a UK Research Organisation (RO) or an RO in a Low/Middle Income Country. It will be the ROs hosting the successful PIs that receive the funding and manage distribution of the funding to any co-investigators' ROs. PI's from High Income Countries outside the UK are not eligible to apply for this scheme.

The application/review process in summary:

1. Development Grant application deadline: 16:00 BST Thursday 14th September 2017
2. Panel meeting of academic experts 28/29th November 2017
3. Successful applications receive funding subject to relevant ethical and financial approvals.

Queries should be sent to: JGHT@headoffice.mrc.ac.uk +44 (0)1793 416409

2. Who can apply?

2.1 Research Organisations (ROs)

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).

The UK Principal Investigator MUST be based at one of the following:

- Higher Education Institutions
- Independent Research Organisations
- Government Funded Organisations (other than MRC funded Units and Institutes)
- MRC Units/Institutes
- University Units (former MRC Units)

See [Guidance for Applicants and Award Holders](#) for further details about eligible institutions.

For researchers based in [low- or middle-income countries](#), eligible institutions include higher education institutions and non-profit research institutions. All LMIC PIs can claim 100% of their direct costs and 20% of indirect costs as exceptional costs.

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.

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.

Development grant holders will not be automatically awarded funds for a full scale research project upon completion of their development grant. Grant holders would need to enter another, future call competitively.

2.2 People named on the grant

Principal Investigators (PI's)

The PI's are responsible for the intellectual leadership of the research project and for the overall management of the research. The PI's will be the funding agencies' main contact for the proposal. For administrative purposes when completing the Je-S form, you will only be able to input 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-principle investigators.

See [Guidance for Applicants and Award Holders](#) for further details about Principal Investigator eligibility.

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

Co-Investigators (Co-Is)

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

All UK and International PI's and Co-I's must have verified Je-S Accounts and must be added to the Je-S form under "co-investigator". Please see section 4 'creating a Je-S account' for information on how to add an account in Je-S.

Other support

For information on other parties involved in research e.g. Project Partners, please see section 2 in the [Guidance for Applicants and Award Holders](#)

Development grant applications

The deadline for development grant applications is Thursday 14th September 2017. (<https://je-s.rcuk.ac.uk/>)

Applications must be submitted by the PI on behalf of the Research team. Development grant applications must include the following PDF attachments:

- **A completed Je-S form:** All investigators MUST be included. This form reflects the project costs so please include ALL costs, UK or otherwise. See 'Costs' section for clarification.

The following attachments:

- **Case for Support** (see additional guidance below)
- **[CV's and publication lists](#)** uploaded individually for all named investigators. Any previous trial experience should be highlighted.
- **[Justification of resources](#)** for the total costs requested for the project
- **[Pathways to Impact](#)** (please click link for details)
- **[Data Management Plan](#)** (please click link for details)
- **Signed letter of supports** (where required)

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 we may reject your application or return your application to you for amendment.

Page lengths (A4 size):

Joint Global Health Trials Development Grants	Maximum No of Pages
Case for Support	4 (plus 1 page for references)
Justification of Resources	2
CV's	2
Publications	1 (per investigator)
Letters of Support	2 (per letter)
Pathways to Impact	2
Data Management Plan	3 (4 for longitudinal studies)

There is scheme specific guidance for the Case for Support. Further guidance and details for all of the other above content can be found in the [Guidance for Applicants and Award Holders](#)

Please note, 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. Other information Je-S will request is highlighted below. It is fine to copy information between your pdf attachments and the Je-S form where there is overlap in information requested.

The online Je-S form and guidance can be accessed here:

<https://je-s.rcuk.ac.uk/Je-S2WebLoginSite/Login.aspx>

Information to be filled out:

- Back ground information
- Project Details
- Investigators
- Other Directly Incurred Costs
- Resource Summary (checking the total funding you have requested from MRC)
- Board or Panel Portfolio
- Grant Type

3. 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. All questions must be answered in order for your application to be considered eligible. Please use the following headings:

1. Research project summary information
2. Research Project Team
3. Project description
4. Importance of the research
5. Research Impact
6. Ethics
7. Financial information
8. Proposal history

1. Research Project summary information

- Full title of the project (no more than 150 characters)
- In which country(ies) will the project take place
- Duration in months
- Total amount requested from this funding scheme
- Principal questions to be addressed by the trial development grant
- Principal research question to be addressed by the proposed future trial

An important part of panel assessment at the trial development grant stage is whether the future trial is likely to be fundable. Therefore it is helpful for the panel to have information about your current plans for that future trial design, even if you think that those plans might change during the course of the development grant:

- What is the primary outcome of your trial likely to be and why?
- What are the intervention arms of your future trial likely to be and why?

2. Research Project Team

How does the team of investigators incorporate the range of discipline and experience necessary to carry out the study? How can the host institution demonstrate that it has the facilities and resources available to manage the study?

3. Project description

The development grant is intended to allow researchers to obtain information needed in order to write a credible, competitive, well-informed full-scale research project proposal once their development grant has been completed.

In your development grant project description you should therefore provide specific information about what gaps in your knowledge your development grant will address as well as providing the wider context of how you would use that information to shape a larger research project and why the topic of that larger scale project would be important. It would be an asset if you can demonstrate that the information generated by your development grant would in itself be of use and needed by policy-makers and other stakeholders as well as informing your own future research plans. For example, would the data be useful independently of whether or not it contributes to the development of a full-scale project?

Please describe your development grant plans; it is compulsory for the grant application that you answer all of the following questions:

- Where will the research take place?
- What is the health issue to be addressed by the proposed research?
- What are the target populations?
- What specific questions will be addressed by the trial development grant?
- How will the answers to those questions be useful in informing the design of a future trial that will be feasible, implementable and useful to policy makers?
- What are your project plans to address the trial development grant research questions?
 - Give details of the methodological approaches, study design and techniques that will be used.
 - Enough detail must be given to show why the research is likely to be competitive in its field.
 - Particular care should be taken to explain any innovation in the methodology or where you intend to develop new methods.
 - Please describe why your proposed methodology is the most appropriate and innovative way of addressing the research question. Applicants are asked to clearly justify the proposed method for randomization, the use of sealed envelopes should be especially justified.
- If the research involves data collection or acquisition you must demonstrate that you have carried out a datasets review, and explicitly state why currently available datasets are inadequate for the proposed research.
- What is the proposed timeline?

4. Importance

Why is this research needed now and in this proposed location? Please consider issues such as burden of disease and priority for the relevant local, regional and national health services.

5. Research Impact

Describe how you have already, or intend to progress as part of this development grant, the appropriate links with relevant stakeholders and policy-makers to ensure the widest possible use of your research findings? The information provided here should summarise the key points detailed in your *Pathways to Impact* statement. Plans for impact should be ambitious but also in link with the limitations of undertaking development work as opposed to a full research grant.

6. Ethics

Please describe the ethical review and research governance arrangements that would apply to the proposal.

7. Financial Information

- a. Are other funding partners involved? Who are the partners and what is the status of the discussions?
- b. In addition to the costings you have provided on Je-S, please provide a breakdown of the funding request per institution using the below table. This will be used to assess the breakdown of funds between UK and LMIC institutions to ensure the split is in line with the aims of the scheme.

Organisation name	Total project costs (GBP)	Total cost requested from this scheme (GBP)*

* UK institution costs are calculated at 74% of the Full Economic Costs. Costs incurred outside of the UK are 'Exceptions' and can be claimed at 100%.

8. Proposal History

Has an application for funding for this project been submitted previously to DFID, DH, MRC, the Wellcome Trust or another funding organisation? If so, please indicate the status of the previous application. If your project has been previously submitted to DFID, MRC or Wellcome Trust please contact the MRC in advance of submission to request approval for a resubmission. Please include in your e-mail a description of how you have revised the project design since your last submission, and, if you previously received feedback, please include a response to each feedback point.

4. Creating a Je-s account

All proposals submitted to this scheme are required to include investigators based in the low or middle income country where the research will take place.

All Overseas Research Organisations/Institutes and individual applicants (Principal and Co-Investigators), are required to be registered on the Je-S system.

Therefore, both UK organisations and overseas organisations are encouraged to contact the Je-S helpdesk at least two weeks before the call deadline of the 14th September 2017, so 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 late submission.

Please login to your Je-S account 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 guidance provided further below). <https://jes.rcuk.ac.uk/JeS2WebLoginSite/Logout.aspx>

- 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

Creating your Je-S application:

- Select Council: **MRC**
- Select Document Type: **Standard Proposal**
- Select Scheme: **MRC Jointly Funded Initiatives Full**
- Select Call/Type/Mode (optional): **MRC/NIHR/DfID/Wellcome Global Health Trials Call 8 – Development September 2017**
- Select '**Create Document**' option



Please telephone Je-S Helpdesk 01793 444164 should you require any assistance with the Je-S System.

Please complete the administrative, summary and financial information as requested by the online Je-S form. The following information provides guidance on specific sections of the Je-S form which we note that applicants frequently required further assistance with.

4.1 Entering costs in Je-S

UK research will be funded at 74% of the Full Economic Cost (FEC). Overseas research is eligible to be funded at 100% of FEC. Please see section 5. Resources – Full Economic Costing in the [Guidance for Applicants and Award Holders](#) for information on FEC.

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 JGHT@headoffice.mrc.ac.uk

4.2 Funding available:

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

Direct Research 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. These costs should be entered as Exceptions and claimed at 100%.

Indirect (infrastructure) Costs:

UK organisations can include indirect costs as usual. MRC will also allow overseas LMIC 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 (LMIC institution 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 costs = £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.

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 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).

Co-investigators (Co-Is)

Co-investigators can be based in the UK as per usual MRC funding rules or in low- and middle-income countries as per usual MRC funding rules. LMIC Co-I's can claim 100% of

their direct costs and up to 20% of costs as indirect costs (for further guidance on these direct and indirect costs, please see the detailed guidance above).

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. 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.

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 costs 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.

If any of the investigators want to enter time allocated to the grant that they will actually spend on the project which could be different from the actual costs worked, this should be specified as there is a separate section for hours worked and hours charged in the budget. This can be found on the investigator section in the main document menu in Je-S.

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 MRC Guidance for applicants at <http://www.mrc.ac.uk/documents/pdf/guidance-for-applicants-and-award-holders/> (page 8, section 2.3.4).

5. Assessment Criteria

Proposals that receive funding will be internationally competitive and at a standard equivalent to that normally expected to be supported by the joint funders.

General information on the MRC's approach to peer review is provided here: <http://www.mrc.ac.uk/documents/pdf/guidance-for-applicants-and-award-holders/>

The assessment panel for this scheme will consider whether applications are of world-class standard (being intellectually innovative, well-focused and methodologically sound). They will consider whether the development grant design is likely to provide answers to important gaps in knowledge which need to be addressed before a full trial is designed.

The assessment panel will comment on the following issues in assessing the trial development grant proposal:

Importance of the research topic and questions

- What is the need for such a trial now on this topic and in the proposed location?
- How important is the problem being addressed
- Novelty and innovation: have similar trials been done previously or are any underway now?

Need for a development grant

- Will the trial development grant provide knowledge that is necessary to inform the design of a future trial?

Study design and feasibility

- Is the proposed trial development grant study feasible?
- Is the design of the trial development grant appropriate to answer the development grant research questions?
- Are the methods and study designs competitive with the best in the field?
- Is the timeline realistic and achievable?
- Have major scientific, technical or organisational challenges been identified, and will they be tackled well?

Project team

- 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?

Research impact

- If the trial development grant, and subsequent trial, takes place, is the outcome likely to be taken up and implemented?
- Is there clarity as to how, and by whom, the research findings will be used?

Ethics

- Is the work ethically acceptable and
- Are there any ethical issues that need separate consideration?
- Are the ethical review and research governance arrangements clear and

acceptable?

Value for money

- Is the budget appropriate and reasonable for the proposed programme of work?
- Is the investigator time and proposed involvement appropriate?
- Do the majority of funds requested support the costs in the low or middle income country where the trial will be conducted?
- Are there any financial dependencies which would affect delivery of the research?
e.g. co-funding arrangements