Department for International Development, Medical Research Council and the Wellcome Trust:

Joint Global Health Trials

How to apply and assessment criteria

Applicants can choose between two proposal types: Global Health Trial research grants (see section A) or trial development grants (see section B).

Section A. Global Health Trial research grants up to 5 years duration. The size of the grants varies according to the needs of the research project. Typically we would have £20m available for any one call, out of which we would expect to fund several projects.

Section B. Trial Development grants with 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, but typically we would not expect a development grant to exceed £150,000.

Funding for projects awarded under this call for proposals is jointly provided by the UK Department for International Development (DFID), 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.

General information about how to apply to the MRC can be found in the Handbook for Applicants and Grantholders: http://www.mrc.ac.uk/documents/pdf/handbook-for-applicants-and-grant-holders/

NB Where guidance in the present document differs from that in the Handbook for Applicants and Grant holders, you should follow the guidance in this present, scheme specific, document.
The first submission deadline for both application types is **16:00 British Summer Time on Thursday 25th September 2014.** Queries should be sent to Meriel Flint, MRC International Strategy Manager, meriel.flint@headoffice.mrc.ac.uk
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).

For this call, a low- or middle-income country status is dependent on World Bank country classifications: http://data.worldbank.org/about/country-classifications/country-and-lending-groups

Eligibility of UK-based PIs is covered in the MRC Handbook for Applicants and Grantees.

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 substantial 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. For further advice on eligibility, please contact meriel.flint@headoffice.mrc.ac.uk

LMIC PIs can claim 100% of their direct costs and up to 20% of those costs as indirect costs.

Principal Investigators cannot be based in a high income country outside the UK.

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)

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. They can claim 100% of their direct costs and up to 20% of those costs as indirect costs.

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.

All co-investigators should be registered and added to the application. If creating a new Je-S Account, please allow 48 hours (longer if the account is created at the weekend) as there is a delay between registration and the investigator being available on the online system to add to the application. Please ensure that registration is completed well in advance of the submission deadline.
Section A. How to apply for a Global Health Trial research grant

Applying for a Global Health Trial research grant is a two-stage process. You will therefore need to submit an outline proposal. Your proposal should include:

A1. The online Je-S form (see A1 guidance below)
A2. Outline Case for Support (see A2 guidance below)
A3. CVs (including publication lists) of investigators (see A3 guidance below)

When completing all of these documents, please refer to Section A4 assessment criteria for this scheme.

At this outline stage you do not need to submit a Justification for Resources, a Pathways to Impact statement or a Data Management Plan.

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. Therefore a Project Partner cannot be either a Co-Investigator or from the Principal Investigator or Co-investigators’ Organisations.

Your proposal should be submitted by 16:00 British Summer Time on Thursday 25th September 2014.

The assessment panel will meet during November 2014. 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. Regrettably, if you are not invited to submit a full application the funders are unable to provide you with feedback due to the high volume of applications received for this scheme.

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/Je-S2WebLoginSite/Login.aspx

If you do not already have a Je-S account, you will need to create one. You and your Co-Investigators need to allow 48 hours to complete the account creation process (more time if the account is created over the weekend) as the accounts have to be manually processed before people can be included in the proposal. To create an account go to the Je-s login Screen: https://je-s.rcuk.ac.uk/Je-S2WebLoginSite/Login.aspx and select Create an Account. When you get to the account type screen please select the top option. When you get to the Organisation screen if your Organisation is not available create a new internet browser tab (to prevent you from losing the information already entered) and follow the Self Registration instructions below. Once you have self-
registered the organisation, return to the account creation screens to complete your account request.

To create an application you will need to log into your personal Je-S account and then

- Select Documents on the Left Side of the Screen
- Select New Document near the top of the screen
- Select Council: MRC
- Select Document Type: Outline Proposal
- Select Scheme: MRC Jointly Funded Initiatives Outline
- Select Call/Type/Mode: MRC/DFID/Wellcome Global Health Trials Out Sep 2014

Once you have completed the Project Details section of the form please follow these instructions to check how the proposal is to be submitted to avoid any last minute problems

- Select the Document Actions Button
- Select Show Submission Path

If the screen shows:
With Owner
With Council
The proposal will be submitted directly by you.

If the screen shows
With Owner
Submitter Pool (there should be names listed against this section)
With Council
Then the Proposal has to be approved and submitted by one of the named submitters. You should allow 48 hours for them to do this. It would be worth checking that at least one of the named people will be available to submit the proposal on the day you plan to submit it. Please note that they will need to do this no later than 16.00 UK time on the date the call closes.

Please complete the administrative, summary and financial information as requested by the online Je-S form. Some points to note are:

Research Organisation Reference: is for any reference number that your research organisation might have assigned to your application for their own administrative purposes.

Duration should be appropriate to the research that you plan to conduct. For a trial, this is usually 3-4 years but can be up to 5 years.

Summary of Resources Required for Project: further to the information provided in section 5 of the MRC Handbook for Applicants and Grant-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 three funders.

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. You will need to prepare the document using a PDF writer such as Adobe Acrobat.

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.

Your proposal cannot be supplemented with further information after the submission deadline.

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.

When completing the Case for Support please consider that the assessment committee will have a copy of your Je-S proposal form which contains the Objectives, Summary and Impact Summary. You therefore do not need to repeat detail which is already contained in those sections.

Please use the following headings when preparing your outline Case for Support

**Headings for your outline case for support:**

<table>
<thead>
<tr>
<th>1</th>
<th>Trial summary information</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>Full title of the trial (no more than 150 characters) <em>Please use a title that is intelligible to trial participants as well as meaningful to scientific peers.</em></td>
</tr>
<tr>
<td>•</td>
<td>In which country(ies) will the trial take place?</td>
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<tr>
<td>•</td>
<td>Duration in months</td>
</tr>
<tr>
<td>•</td>
<td>What is/are the principal research question(s) to be addressed?</td>
</tr>
<tr>
<td>•</td>
<td>Total amount requested from this funding scheme.</td>
</tr>
</tbody>
</table>
1. **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? etc*

- **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.*
  *Where appropriate we encourage applicants to include health economics, social science and implementation research alongside trials, with the aim of providing information relevant for scale up*

- **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 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.
- 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.

4. How will the results of this trial be used?

When completing this section please bear in mind that the panel will also receive a copy of the Impact Summary completed as part of your Je-S form. 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?
- 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/](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. Including a total estimated cost of the trial and the total estimated cost requested from this funding scheme, bearing in mind that UK institution 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%.
Section A. How to apply for Global Health Trial research grant

<table>
<thead>
<tr>
<th>Participant Organisation 1 (please enter name)</th>
<th>scheme (GBP)</th>
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</thead>
<tbody>
<tr>
<td>Participant Organisation 2 (please enter name)</td>
<td></td>
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<tr>
<td>Etc.</td>
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</tr>
<tr>
<td>TOTAL</td>
<td></td>
</tr>
</tbody>
</table>

- 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, 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 meriel.flint@headoffice.mrc.ac.uk.

A3. CVs (including publication lists) of investigators

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

Please compile all of 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.

Once you have fully completed the Je-S form you should see a Submit Document button. This will either allow you to submit the document directly to the Council or to the Submitter Pool depending on how your organisation has been set up. If it is being submitted via a Pool please allow 48 hours for this process to take place.

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

General information on the MRC’s approach to peer review is provided in the MRC Reviewers Handbook: http://www.mrc.ac.uk/documents/pdf/reviewers-handbook/

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 a real improvement to health outcomes in low and middle income countries.
The panel will be asked to comment on the following criteria in assessing the outline proposals:

**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 feasible?
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?

**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?

**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?
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?

**Ethics:**
Is the work ethically acceptable?

**Value for money:**
Is the budget appropriate and reasonable for the proposed programme of work?
Section B. How to apply for Joint Global Health Trials Development Grant with a duration of 1-2 years and a total budget in the region of around £150k. These grants are tailored to assist research teams to develop robust and competitive full-scale proposals through conducting feasibility studies and obtaining preliminary data.

The development grant application process is a one-stage process. There is no outline phase for development grants.

Your application should consist of:

B1. The online Je-S form
B2. Case for Support
B3. Justification of resources
B4. CVs and publication lists
B5. Letters of support
B6. Pathways to impact
B7. Data Management Plan

When completing all of these documents, please refer to Section B8 assessment criteria for this scheme.

Your proposal should be submitted by 16:00 British Summer Time on Thursday 25th September 2014.

The assessment panel will meet in November 2014 and you will receive notification of whether your application has been successful within a fortnight of that meeting.

B1. 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](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. You and your Co-Investigators need to allow 48 hours to complete the account creation process (more time if the account is created over the weekend) as the accounts have to be manually processed before people can be included in the proposal. To create an account go to the Je-s login Screen [https://je-s.rcuk.ac.uk/JeS2WebLoginSite/Login.aspx](https://je-s.rcuk.ac.uk/JeS2WebLoginSite/Login.aspx)

and select Create an Account. When you get to the account type screen please select the top option. When you get to the Organisation screen if your Organisation is not available create a new internet browser tab (to prevent you from losing the information already entered) and follow the Self Registration instructions below. Once you have self-
registered the organisation, return to the account creation screens to complete your account request.

To create an application you will need to log into your personal Je-S account and then

- Select Documents on the Left Side of the Screen
- Select New Document near the top of the screen
- Select Council: MRC
- Select Document Type: Standard Proposal
- Select Scheme: MRC Jointly Funded Initiatives Full
- Select Call/Type/Mode: MRC/DfID/Wellcome Global Health Trials Development Grant Sep 2014

Once you have completed the Project Details section of the form please follow these instructions to check how the proposal is to be submitted to avoid any last minute problems

- Select the Document Actions Button
- Select Show Submission Path

If the screen shows:
With Owner
With Council
The proposal will be submitted directly by yourself.

If the screen shows
With Owner
Submitter Pool (there should be names listed against this section)
With Council
Then the Proposal has to be approved and submitted by one of the named submitters. You should therefore allow 48 hours for them to do this. It would be worth checking that at least one of the named people will be available to submit the proposal on the day you plan to submit it. Please note that they will need to do this no later than 16.00 UK time on the date the call closes.

Please complete the administrative, summary and financial information as requested by the online Je-S form. Some points to note are:

**Research Organisation Reference:** is for any reference number that your research organisation might have assigned to your application for their own administrative purposes.

**Duration** the maximum permitted for a development grant under this scheme is 2 years.

**Resources Required for Project:** Further to the information provided in section 5 of the MRC Handbook for Applicants and Grant-holders:

All costs incurred by low- and middle-income country investigators should be entered as 'Exceptions’ and will be reimbursed at 100% if funded.

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.
Section B. How to apply for Joint Health System Research Initiative Development Grants

You do not need to obtain additional approval from an MRC Programme Manager for the Exceptions costs that you claim; all proposals submitted to this scheme will need to request overseas costs.

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

The total budget for a development grant should be in the region of £100k.

As the development grant is a one stage application process, the Je-S form will require a detailed breakdown of your budget. We therefore strongly recommend that development grant applicants access and complete the financial sections of the Je-S form well in advance of the deadline.

B2. Development grant 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 Case for Support for a development grant should not exceed four sides of A4 plus one additional page of references (five pages in total). Your Case for Support must be attached to your Je-S online application as a PDF. You will need to prepare the document using a PDF writer such as Adobe Acrobat.

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.

Your proposal cannot be supplemented with further information after the submission deadline.

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.

When completing the Case for Support please consider that the assessment committee will have a copy of your Je-S proposal form which contains, amongst other information, the Objectives, Summary and Impact Summary. You therefore do not need to repeat detail which is already contained in those sections.

Please use the following headings when preparing your development grant Case for Support

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
Section B. How to apply for Joint Health System Research Initiative Development Grants

Total amount requested from this funding scheme

Principal research question to be addressed

2. Project description

The development grant is intended to allow researchers to obtain information needed in order to write a credible, competitive, well-informed trial 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. Please also provide 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. I.e. would the data be useful independently of whether or not it contributes to the development of a full-scale project?

Development grant holders will not be automatically awarded funds for a full scale research project upon completion of their development grant. If the Joint Health Systems Research Initiative is still live by that point, they could submit an outline proposal to the full-scale research project route in open competition with all other applicants. If the Initiative is not live anymore, you would need to investigate other potential funding sources either with the three funders for the current joint initiative or elsewhere.

Please describe your development grant plans, ensuring that you cover the following points.

- 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 development grant?
- How will the answers to those questions be useful in informing the design of a future trial?
- What are your project plans to address the 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.
- 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?

3. 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.

4. Research Impact
Section B. How to apply for Joint Health System Research Initiative Development Grants

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 B6 – your Pathways to Impact statement.

5. 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?

6. Ethics

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

7. Financial Information

Are other funding partners involved? Who are the partners and what is the status of the discussions?

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.

<table>
<thead>
<tr>
<th>Organisation name</th>
<th>Total project costs (GBP)</th>
<th>Total cost requested from this scheme (GBP)*</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

* 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, MRC, the Wellcome Trust or another funding organisation?

If so, please indicate the status of the previous application.

B3. Justification of Resources for development grant

See section 4.2.3 of the MRC Applicants’ Handbook.

B4. CVs (including publication lists) of investigators

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

Please compile all of 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.

B5. Letters of support
Section B. How to apply for Joint Health System Research Initiative Development Grants

Please include letters of support from any organisations whose involvement is crucial to you having access to the study target populations, for instance the local health department.

You do not need to include letters of support from all research organisations involved in your project.

B6. Pathways to Impact

See section 4.2.4 of the MRC Applicants’ Handbook. For a development grant you should:

- Provide information on the likely impacts of the specific studies undertaken during your development grant.
- Provide information about how the evidence generated by future related larger research studies might have an impact.

B7. Data Management Plan

See section 4.2.6 of the MRC Applicants’ Handbook.

Once you have fully completed the Je-S form you should see a Submit Document button. This will either allow you to submit the document directly to the Council or to the Submitter Pool depending on how your organisation has been set up. If it is being submitted via a Pool please allow 48 hours for this process to take place.

B8. Assessment Criteria for Development Grants:

General information on the MRC’s approach to peer review is provided in the MRC Reviewers Handbook: http://www.mrc.ac.uk/documents/pdf/reviewers-handbook/

The assessment panel for this scheme will consider whether applications are of world-class standard (being intellectually innovative, well-focused and methodologically sounds). They will consider whether the development grant design is likely to provide answers to important gaps in knowledge.

Peer reviewers will be asked to comment on the following criteria in assessing the outline proposals:

Research agenda:
Is there a real need for this research in the proposed location?
Is the research topic important and appropriate?
Is evidence on this topic needed by policy-makers and other stakeholders beyond the academic community?

Need for a development grant
Will the development grant provide knowledge that is necessary to inform a future larger scale study?

Project plans:
Is the proposed development grant study feasible?
Is the proposed development grant study innovative, internationally competitive, and methodologically sound?
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:
Does the proposed research have realistic potential to improve health outcomes?

Is there clarity as to how, and by whom, the research findings will be used?

Does the application demonstrate that there is demand for the research from policy-makers and other stakeholders beyond the academic community?

Ethics:
Is the work ethically acceptable?

Are there any ethical issues that need separate consideration?

Are the ethical review and research governance arrangements clear and acceptable?

Data Management Plans:
Does the applicant have (or are likely to have) a sound plan for managing the research data funded through the award, taking into account:

- The types, scale and complexity of data being (or to be) managed
- The likely long-term value for further research including by data share
- The anticipated information security and ethics requirements

Value for money:
Is the budget appropriate and reasonable for the proposed programme of work?

Is the investigator time and proposed involvement appropriate?