FDCO/MRC/NIHR/Wellcome Joint Global Health Trials

Development Grant Application Guidance: Call 11

1. Important 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 £200,000. 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 provided by the Foreign, Commonwealth and Development Office (FCDO), the Medical Research Council (MRC) the National Institute for Health Research (NIHR) and Wellcome.

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

General information about how to apply to the MRC can be found in the MRC Guidance for Applicants. Where guidance in the present document differs from that in the standard guidance, you should follow the direction in this present, scheme specific, document.

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

The submission deadline for development grants is: 16:00 GMT on 4th February 2021.

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

The application and review process in summary

1. Development grant application deadline: 16:00 GMT 4th February 2021.
2. Panel meeting of academic experts: June 2021.
3. Successful applications receive funding subject to relevant ethical and financial approvals.

Queries should be sent to JGHT@mrc.ukri.org

2. Who can apply?

The intellectual challenge should be the determining factor when configuring appropriate partnerships and collaborations. Proposals must demonstrate equitable partnerships in line with the UK Collaborative on Development Research report 'Building Partnerships of Equals'. The balance of intellectual leadership and costs between HICs and LMICs will be considered in the assessment of proposals.

Research Organisation Eligibility

UK Principle Investigators (PIs) **must** be based at one of the following:

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

For further information on UK eligibility for research funding see eligibility.

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

- Higher Education Institutions
- Non-profit Research Institutions

Co-Investigators (Co-Is) should follow the same eligibility rules as for PIs but in addition may be based at the following collaborating organisations:

- Local and national government departments based in LMICs:
  Any recognised local or national department of an LMIC, e.g. the Ministry of Health.

- International Intergovernmental Organisations based in LMICs: Any organisation with a footprint in an LMIC formed of member sovereign states established by treaty recognised under international law e.g. the World Health Organisation.
- Stakeholders based at not for profit organisations in LMICs: Individuals with relevant expertise and research capacities to warrant their inclusion in the investigator team (for example policymakers, practitioners, implementers, patient/participant groups).

Institutions based in China or India are no longer eligible to lead applications but are welcomed as collaborating organisations hosting Co-Investigators within applications. Collaborations with Co-Investigators from China or India must have global or regional development impact as the primary objective, with local or national impacts within China or India as secondary objectives. It is expected that Co-Investigators from China and India make a significant contribution to their own research costs, including covering their own overheads. Please note it is not possible for Co-Investigators from China or India to be hosted by local or national government departments, or by international intergovernmental organisations.

Applicants working in India and/or China who wish to apply are strongly advised to contact the office for guidance as early as possible.

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

If you are unsure about your organisation's eligibility, please consult the Programme Manager, by contacting: JGHT@mrc.ukri.org.

Principal Investigators (PIs)

This call differs from the standard MRC rules in that PIs can be based either in the UK (as per usual MRC rules) or in an eligible Low- or Middle Income Country.

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

Exceptions: applicants based in China or India are not eligible to be the PI of any application to this call but are welcomed as international Co-I's within proposals.

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

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

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

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

Co-Investigators (Co-Is)

The PIs may be supported by a number of Co-Investigators (Co-Is) named on the application. The eligibility requirements for Co-Is are broader than those set out for the PI and are set out above under Research Organisation Eligibility.

Where appropriate, applications to this call are expected to include significant engagement with key stakeholders including implementing agencies within the LMIC(s) of focus. Where there is a significant level of engagement from individuals based in international intergovernmental organisations and/or other organisations with relevant expertise, applicants should consider including them as part of the researcher team as a Co-I, or Project Partner if they do not require a budget allocation.

In exceptional circumstances it may be possible to include staff members of government ministries as named co-investigators rather than project partners, where a proportion of their time is spent working on the project. Inclusion of named government officials as co-investigators must be discussed and agreed with the relevant programme manager in advance of application, please contact: JGHT@mrc.ukri.org.

Investigators from HICs outside of the UK are not eligible to apply as PIs but can be named as Co-Is with justification for why the expertise they are providing cannot be found in the UK or an LMIC.

All Co-Is must be registered on the Joint Electronic Submission (Je-S) System in advance of the submission deadline, information on how to register can be found in the MRC guidance for applicants.

Project Partner/s

In addition to the information provided in the MRC guidance for applicants, we encourage applicants to involve key stakeholders (policymakers, practitioners, implementers, patient/participant groups). Stakeholders who are not receiving funding from the project, or are providing a contribution in cash or in-kind, should be included as project partners.

If the project partner listed is from industry, applicants must follow the MICA guidance. Applicants with an industrial partner(s) will need to include MICA: as a prefix to their project title and include them within the application under the 'Project Partner' section in Je-S. A completed MICA form and agreed Heads of Terms should be attached to the application.

3. Required documents for a development application

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

Applications must be submitted by the PI or their research organisation on behalf of the research team. Development applications must include the following:

- A completed application form on Je-S: All investigators **must** be included. This form reflects the project costs so please include **all** costs, UK or otherwise. See 'Costs' section for clarification.
- A Case for Support

- Justification of Resources
- Data Management Plan
- CV's and publication lists must be uploaded for all named investigators in a single PDF document
- ODA Compliance Statement
- Gender Equality Statement
- Signed letter(s) of support (where required)
- MICA Form and Heads of Terms (where required)

Please note, if your proposal is a resubmission this should be discussed with the office prior to applying. Resubmissions must be approved by a Programme Manager and a cover letter should be included in the application describing any changes to the proposal since the earlier submission.

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

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

Attachments

Mandatory Attachments	**Conditions**
Case for support	Four Sides of A4 (plus one for references)
Justification of Resources	Two sides of A4
Data Management Plan	Three side of A4 per person
CVs	Two sides of A4 per person
Publications	One side of A4 per person
ODA Compliance Statement	Two side of A4
Gender Equality Statement	One side of A4
Optional Attachments	**Conditions**
Letters of Support	Two sides of A4 per letter
Cover letter – if it is a resubmission	Two sides of A4 per letter
MICA Form and Heads of Terms	As per guidance

Case for Support

Please see Section 4 of the Case for Support scheme specific guidance.

Justification of Resources

Full details of costings should be detailed on the Je-S online form. In addition to this, applicants should prepare a Justification of Resources document that should clearly and concisely state **why** the resources requested are appropriate for the research proposed taking into account the nature and complexity of the research proposal. It should not just be a list of the resources

required and all items requested within the Je-S form should be justified within the Justification of Resources.

The document is mandatory and should be no longer than **2 sides of A4**. Whilst the document is free text, we strongly advise you follow the headings outlined in the MRC's Guidance for Applicants on the Justification of Resource document. The document must be attached to your Je-S online application as a pdf.

It is important that the figures quoted in the Justification of Resources clearly match up with those entered in the Je-S online form.

As part of your justification of resources for this scheme, please include the following table at the top of the Justification of Resources document:

Participant organisation name	Total amount (£)	Total amount requested from this scheme*
Participant Organisation 1 (please enter name)		
Participant Organisation 2 (please enter name)		
TOTAL		

*Costs claimed by UK institutions should be calculated at 74% FEC. Costs claimed by institutions in LMICs and HICs must be claimed at 100% of the full economic costs.

All MRC funded projects that include a clinical trial or public health intervention are required to register with ISRCTN (www.isrctn.com). The cost of registration can be included in the application for funding. If the proposed research contains a trial, then applicants should include a one-off payment of £200 for the registration of your trial. Please enter this cost as a separate entry under the Other Directly Incurred Costs section of the Je-S application. If the trial is to be led by an LMIC RO, then the costs claimed should be at 100% (Exception cost type).

Please see MRC Guidance for Applicants **Section 2.2.4** for further guidance on Justification of Resources.

Data Management Plan

The Data Management Plan (DMP) should demonstrate how the PI will meet, or already meets, their responsibilities for research data quality, sharing and security. Please see **Section 2.2.7** of the MRC Guidance for Applicants for full details on the requirements for the DMP. It is advisable that all DMPs use the template (DOC, 98KB) to ensure consistency and make it easier to review. This document should be no longer than 3 pages of A4 and must be attached to your Je-S online application as a pdf.

CVs and publications

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

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

We must receive a CV for each of the following:

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

Please see Section 2.2.1 and Section 2.2.2 of the MRC Guidance for Applicants for the full details on the requirements for CVs and Publications.

ODA Compliance Statement

Research funded through this call will form part of the UK's Official Development Assistance (ODA), as defined by the Development Assistance Committee (DAC) of the Organisation for Economic Co-operation and Development (OECD).

An ODA compliance statement is required to explain how your proposed research is compliant. It should be a maximum of two sides of A4 and should be uploaded as a '**Non-UK Components'** attachment.

ODA Compliance questions

Please note the requirement to answer these questions does not supersede the need to discuss impact within your Case for Support. Where necessary please ensure that you request appropriately justified resources to support these activities.

1. Which country/ countries on the OECD DAC list of ODA recipients (DAC list) will directly benefit from this proposal and are these countries likely to continue to be eligible to receive ODA for the duration of the research? Please refer to the DAC list for information about countries that will be considered for graduation at the next review.
2. How is your proposal directly and primarily relevant to the development challenges of these countries? Please provide evidence of the development need and articulate how the proposed activity is appropriate to address this need.
3. How do you expect that the outcome of your proposed activities will promote the economic development and welfare of a country or countries on the DAC list?
4. What approach(es) will you use to deliver development impact within the lifetime of the project and in the longer-term? Please consider the potential outcomes, the key beneficiary and stakeholder groups in the DAC list country/ countries and how they will be engaged to ensure opportunities for them to benefit and to enable development impact to be achieved.

Please note: this document should make clear the ODA relevance of the proposed research without reference to other documents in the proposal (i.e. Case for Support). It should also include meaningful project specific detail. Proposals that do not articulate clearly the ODA relevance of the research throughout their application will be rejected prior to peer review.

Gender Equality Statement

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

To comply with the International Development (Gender Equality) Act 2014, applications must provide a Gender Equality Statement, outlining how applicants have taken meaningful yet proportionate consideration as to how the project will contribute to reducing gender inequalities. It should be a maximum of one side of A4 and should be uploaded using the '**Supporting Data'** attachment type.

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

Criteria to address while considering gender impact:

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

Further guidance for applicants on Gender Equality Statements is available here.

Letters of Support

Letters of Support should be included to demonstrate support from relevant institutions and should come from relevant academic and non-academic stakeholders such as local or national government authorities, other public sector actors and project partners (e.g. industrial partners, NGOs). Each letter of support should be no longer than 2 pages A4.

Please note: Project Partner Letters of Support are mandatory for each relevant organisation and should be uploaded to the 'Project Partner' section of the Je-S application. These should not be uploaded using the 'Letter of Support' attachment type.

Please see Section 2.2.6 of the MRC Guidance for Applicants for the full details on the requirements for Letters of Support for Project Partners.

4. Case for Support scheme specific guidance

Your Case for Support is a document including your scientific proposal, details of the research environment, people involved and references. Your Case for Support should indicate how your proposal fits the call specification for this scheme.

When completing the Case for Support, please bear in mind that the committee will also receive your Je-S proposal form which contains the Objectives, Summary, Technical Summary, Academic Beneficiaries, Communication Plan and Impact Summary as well as your Justification of Resources. You therefore do not need to repeat detail which is already contained in those

documents. Feedback from reviewers has shown that they are keen to see clarity, succinctness and accessibility.

Additional annexes are not permitted, this includes the reproducibility and statistical design annex. Any applications missing or exceeding the case for support page limit may be rejected. Any additional attachments will be removed from the view of the referees.

Please use the following headings:

Research Project summary information

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

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:

- Principal research question to be addressed by the proposed future trial
- 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?

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?

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 trial proposal once their development grant has been completed. In the project description you should 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 future full trial.

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

A) Where will the research take place?
B) What is the health issue to be addressed by the proposed research?
C) What are the target populations?
D) What specific questions will be addressed by the trial development grant?
E) 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?
F) What are your project plans to address the trial development grant research questions?
G) Give details of the methodological approaches, study design and techniques that will be used.

H) Enough detail must be given to show why the research is likely to be competitive in its field.
I) Particular care should be taken to explain any innovation in the methodology or where you intend to develop new methods.
J) 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.
K) 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.
L) What is the proposed timeline?

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.

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?

Plans for impact should be ambitious but also in line with the limitations of undertaking development work as opposed to a full research grant.

Ethics

It is essential that applicants describe the ethical considerations that have informed the proposed research. Details of the ethical review and research governance arrangements that would apply to the proposal must be described.

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.

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%.

Proposal History

Has an application for funding for this project been submitted previously to FCDO, NIHR, MRC, Wellcome or another funding organisation? If so, please indicate the status of the previous application. If your project has been previously submitted to FCDO, NIHR, MRC or Wellcome 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.

5. The Je-S application

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

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

Both UK organisations and overseas organisations are encouraged to contact the Je-S helpdesk as soon as possible before the call deadline of the 4th February 2021, 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 or incomplete 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 following guidance:

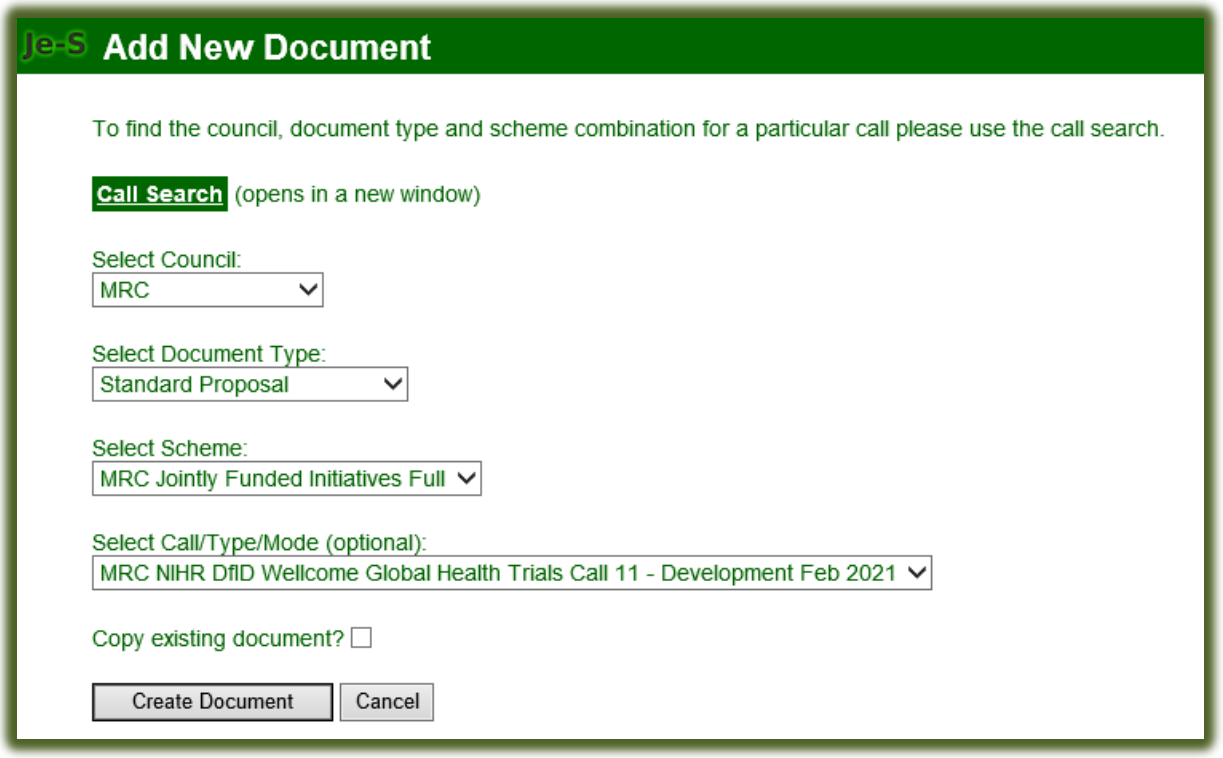
- New Je-S Users: In order to gain access to the Je-S System, Create an Account.
- Je-S users having problems successfully completing login to their Je-S account: Retrieve User Name / Password.
- Select **'Documents'** from left hand menu list from your Je-S account home page
- Select **'New Document'**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

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

Creating your Je-S application

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

- 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 11 – Development Feb 2021**
- Select **'Create Document'** option



Entering costs in Je-S

UK investigator research costs (including overseas travel) will be funded at 74% of the Full Economic Cost (FEC). This differs from the MRC's standard 80% to reflect the varying policies of the joint funders. Please see section 3.1 Resources – Full Economic Costing in the Guidance for Applicants for information on FEC.

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

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

A contribution towards indirect and estates costs at the overseas organisation, where the research is being undertaken in a developing country (LMIC), where it can be shown that it will assist in developing research capacity (calculated as 20 per cent of the overseas organisations' directly incurred costs) can also be claimed. Costs must be entered as exceptions, as a separate item under 'Other Directly Incurred Costs' (Description e.g. Contribution towards indirect and estates costs at the LMIC overseas organisation).

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@mrc.ukri.org.

Fund types

Applicants are required to provide detailed information about the costs requested. Full details of how costs should be entered can be found in the MRC guidance for applicants.

The following specifies the fund types and fund headings that can be used. **It is of paramount importance that overseas costs are only entered as exceptions.**

Directly Incurred (DI)
UK costs that are explicitly identifiable as arising from the conduct of a project. Charged to projects as the cash value actually spent and supported by an auditable record. The following fund headings can be used:

- DI – Staff
- DI – Travel & Subsistence
- DI – Equipment
- DI – Other Costs

Directly Allocated (DA)
UK costs of resources used by a project that are shared by other activities. Charged to projects based on estimates. Do not represent directly auditable costs on a project-by-project basis. The following fund headings can be used:

- DA - Investigators
- DA - Estates Costs
- DA- Other Directly Allocated

Indirect Costs
UK RO overhead costs and should not include any overseas costs. The following fund headings can be used:

- Indirect Costs

Exceptions
All overseas costs. Exceptions costs will be funded at 100% FEC. The following fund headings can be used:

- Exception - Staff (including overseas Investigators)
- Exception - Travel & Subsistence
- Exception - Other Directly Incurred Cost (Research costs e.g. Consumables and 20% Contribution towards overseas Estates and Indirect Costs when associated with LMIC)

Overseas costs

It is expected that all applications to the Board will include overseas costs, **it is not necessary to discuss these costs with a programme manager before submission.**

All costs requested by an overseas organisation should be entered under the exceptions heading and requested at 100% FEC.

MRC will support indirect and estates costs for organisations based in LMICs participating in the project. Each LMIC RO can request indirect costs up to the value of 20% of their direct costs. These costs should be entered under the Exception - Other Cost heading and requested at 100% FEC.

For overseas PI's and Co-I's all travel and subsistence costs can be claimed at 100%. For overseas institutions, all other exceptional costs associated with the overseas organisation

should be claimed under the appropriate fund heading as **"exceptions"**. These include consumables, consultancy fees, field work fees, equipment (under £10,000) and subcontracting.

MRC will support 100% of the direct costs of researchers based in HICs outside of the UK, as well as researchers based in China or India. No indirect or estates costs can be claimed. These costs should be included within the Exceptions costs section and should not exceed 30% of the proposal total.

Further costing guidance

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

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

For further Je-S guidance for completing the 'Resource Summary' please refer to the Je-S guidance page.

Submitting your application

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

The deadline for submission to the MRC is 16:00 (GMT) 4th February 2021. You may need to submit your proposal to colleagues within your research organisation several days before the deadline so that they have time to approve the proposal for submission to the MRC.

Please note that Overseas Organisations (leading on a project), that have followed the Self-Registration process to add their organisation to the Je-S database, submit directly through Je-S through to MRC. These organisations will see a different option than detailed immediately below, with options '**With Owner'** and '**With Council'**.

Once you have completed the 'Project Details' section of the Je-S form you are able to find out the submission arrangements for your organisation (which will vary depending on how the account is set up). **Select 'Document Actions' and then select 'Show Submission Path'**:

- If the screen shows '**With Owner'** and '**With Council',** then the proposal will be submitted directly by you (the PI).
- If the screen shows '**With Owner'** and '**Submitter Pool'** (there should be names listed against this section) and '**With Council',** then the proposal has to be approved and submitted by one of your RO's named submitters. You should allow at least 48 hours for them to do this, your RO may require longer, and we would strongly advise that you check this.

Please check that at least one of your organisation's named submitters will be available on the day you plan to submit. Please note that they will need to do this no later than 16:00 (GMT) UK time on 4th February 2021.

6. Review process and Assessment Criteria

General information on the MRC's approach to peer review is provided in the MRC Guidance for Applicants document.

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 topics 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

- 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?

Study design and feasibility

- The suitability of the investigator group including track record(s) of the individuals in their field(s) and whether they are best-placed to deliver the proposed research.
- How have team members from different disciplines been included and how has their variety of input been embedded in the approach to research?
- The management strategy proposed, including equitable access to any shared resources and sufficient capability and time commitments of senior staff to steer and oversee the research.
- Links with local research/health institutions and involvement of investigators from LMIC countries;
- Have opportunities for research capacity building been embedded into research plans?

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?
- 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

7. Contacts

Enquiries should be sent to JGHT@mrc.ukri.org.

8. Data Protection

Privacy Notice

All personal data provided to the MRC as part of UK Research and Innovation via the Je-S form will be processed in accordance with current UK data protection legislation. Please see Je-S Terms and Conditions for guidance on how personal data collected from applicants is used. Further information on how we use personal data can also be found in the UK Research and Innovation Privacy Notice.

Information on the terms and conditions that guide the general management of funded grants can be found in the MRC's Guidance for Applicants.

What will be shared and with whom?

As the Joint Global Health Trials scheme is a jointly funded scheme, information will be shared between the partners, the Foreign, Commonwealth and Development Office (FCDO), the Medical Research Council (MRC), the National Institute for Health Research (NIHR) and Wellcome.

Retention policy

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

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

12.2 Evaluation	Commissioned evaluation	Permanently

Further information can be found on the MRC Records Management Policy.

The retention periods cited are those in force at the time of writing and are subject to change due to periodic revision of the Medical Research Council's disposition schedule. Information about the retention periods currently in force may be obtained from the Medical Research Council by emailing Corporate@mrc.ukri.org. The data provided may also be aggregated and anonymised for the purposes of reporting and analysis.