

# MRC-AMED: ENGINEERING BIOLOGY CALL-SPECIFIC GUIDANCE FOR APPLICANTS

## UK based applicants

In 2023, the MRC will transition from the Joint Electronic Submissions (Je-S) system to the Funding Service. This means that all applicants, grant holders, research support staff, reviewers, and panel members must submit applications using the new Funding Service (TFS).

This guidance supplements the [standard MRC Guidance for Applicants](#). Please consult the [standard MRC Guidance for Applicants](#) for further information such as preparing the UK budget for your proposal.

This call-specific guidance document provides additional information specific to this call. Where guidance in the present document differs from that in the standard MRC Guidance for Applicants, it is important you follow the guidance in this present, scheme specific, document or the guidance within the new Funding Service.

## Japan based applicants

This call-specific guidance document provides information specific to this call. It is also important that Japanese researchers are aware of all relevant guidance provided by the Japan Agency for Medical Research and Development (AMED), which can be found on the [AMED website](#).

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## **Contents**

1. Important application information .....	3
1.1 Start Date and Duration .....	4
1.2 Key dates .....	5
2. Who can apply?.....	5
Project lead (previously principal investigator) .....	5
Project co-lead (previously co-investigator) .....	5
Project co-lead (international) (previously included under co-investigator).....	6
Researcher co-lead (previously researcher co-investigator).....	6
2.2 People named on the grant.....	6
3. Application process .....	7
3.1 Expression of Interest (EOI) .....	7
3.2 Full application: process overview.....	7



3.3 Full application: summary of components .....	8
3.6 Budgets .....	10
4. Assessment process and criteria .....	12
5. Agreements and ethics .....	14
5.1 Collaboration Agreement .....	14
5.2 Intellectual Property.....	15
5.3 Material Transfer Agreements .....	16
5.4 Ethics.....	16
5.5 Use of humans/human tissue .....	17
5.6 Use of animals.....	17
5.7 Use of Stem Cells .....	19
5.8 Responsible Research and Innovation (RRI).....	19
6. Terms and conditions for UK applicants .....	19
7. Contacts and Guidance .....	20
Annex 1: Review committee scoring system .....	21



## **1. Important application information**

The [Medical Research Council \(MRC\)](#) and the [Japan Agency for Medical Research and Development \(AMED\)](#) are pleased to invite proposals to the Engineering Biology for Novel Diagnostics and Therapeutics joint funding opportunity.

The main objective of this funding opportunity is to deliver joint research funding for internationally competitive and innovative collaborations between researchers from Japan and the UK in the field of engineering biology for novel therapies and diagnostics. This support will enable important synergy between researchers with shared or complementary interests.

A key aspect of the successful research programmes will be the establishment or enhancement of sustainable partnerships between the UK and Japan, supported through a strong mobility element to the available funding.

Specific objectives that underpin the UK-Japan research collaborative initiative are to support and promote:

- Joint academic research projects with the potential to further the field of engineering biology and enable progress towards novel therapies and diagnostics.
- Development of new and enhancement of existing partnerships to foster sustainable research links between the UK and Japan.
- the exchange of scientists between the two countries, particularly considering the development of the next generation of top researchers that will contribute to the promotion of international talent mobility.
- knowledge and/or methodology exchange between the two countries
- complementary access to facilities, resources, and equipment
- stronger opportunity for collaborative research and catalysis of further synergy.

Therefore, it is expected that jointly developed collaborative UK-Japan research applications will be submitted which detail an active research programme between UK and Japan-based researchers.

For further information on the background, scope and eligibility of this funding opportunity please see the Call Funding Finder page for UK applicants and [AMED website](#) for Japan based applicants.

Researchers will be responsible for developing their own collaborations and, once a research proposal is developed, UK and Japanese applicants must apply jointly for funding. For administrative purposes, all projects will have a Project Lead based at a UK Research Organisation (RO) and a Project Lead based at a Japanese RO.

**Note:** please see [section 2](#) Who Can Apply to clarify researchers' roles within the new UK Funding System.



Project co-leads will be responsible for leading the whole teams from their respective countries, and those teams may (but do not have to) comprise of several research groups from the same or different institutions, each with their own group leader.

UK and Japan based applicants must apply with jointly developed applications to both the Medical Research Council (MRC) and Japan Agency for Medical Research and Development (AMED). The application must be based around a common research plan and vision. Both partners must therefore submit identical joint project details and methodology document written in English to the MRC and AMED.

For UK applicants, this information will be supplied through the TFS Vision, Approach and International Partnership and Mobility Plan sections.

For Japan based applicants, this information should be completed within the project details and methodology document template and submitted to AMED.

As applicants will be submitting a common research plan and vision, it is vital that it provides full details of the work proposed for both the UK and Japanese components.

## 1.1 Start Date and Duration

We will fund projects lasting three years in duration.

In the UK projects are expected to begin within three months of funding confirmation.

In Japan, projects are expected to start in September 2024 and be completed by September 2027

### **Funding available for this call is as follows:**

AMED and the MRC will jointly provide bilateral support for up to 3 years to intensify productive collaboration in engineering biology research, with a strong focus on international talent mobility, between leading researchers in the UK and Japan.

In total, MRC will make up to £3 million available in support of the UK components.

Approximately 158 million JPY, in total for the three-year period per research project, will be provided by the AMED in support of the planned Japanese research. **33% of the requested budget must be allocated to talent circulation (Mobility) costs for both the UK and Japan budget.**

The size of the grants will vary according to the needs of each research project. UK and Japan based applicants do not need to request equal amounts from both sides. The difference in values should reflect the difference in costs covered and local prices. The agencies also expect the costs on each side to accurately reflect the research effort to be carried out. It is expected, however, that the research effort on both sides is comparable.

It is expected that this funding will support up to three projects subject to scientific quality.



The award of a UKRI-AMED Grant does not guarantee any further commitment to funding by the MRC or AMED.

## 1.2 Key dates

Stage	Date
<b>Deadline for Voluntary Expression of Interest (to be submitted to MRC only)</b>	19 March 2024
<b>Deadline for applicants to submit proposal (in both countries)</b>	16 April 2024
<b>Announcement of successful applications</b>	August 2024
<b>Funding start date</b>	From September 2024

## 2. Who can apply?

For support under this call, applicants and organisations must be eligible to apply for funding from their respective country’s funding agency. The expectation is that the UK PL and associated costs for UK-based research would be funded by the MRC, while the Japanese PL and associated costs for Japan-based research would be funded by AMED.

### **UK Applicants**

To be eligible to apply for this opportunity UK applicants must meet the [MRC eligibility criteria](#)

UK Research and Innovation (UKRI) has introduced new role types for funding opportunities being run on the new UKRI Funding Service.

These new role types include:

#### Project lead (previously principal investigator)

- The project lead is responsible for the intellectual leadership and overall management of the project. They are the main contact for UKRI.
- To be the project lead you must be affiliated with the ‘lead organisation’ on the application.
- The project lead should have an explicit agreement with the organisation that this will last for at least the duration of UKRI funding.
- By submitting an application, an organisation is confirming that named applicants can take part in a UKRI-funded project and will accept its relevant terms and conditions.

#### Project co-lead (previously co-investigator)

- A project co-lead UK is a member of the project leadership and management team. They may take over the leadership of the project, if required. Your team can have as many project co-leads as needed.
- To be a project co-lead you must be affiliated with one of the research organisations involved in submitting the application.



Project co-lead (international) (previously included under co-investigator)

- The Project co-lead (international) role is available when a funding opportunity is open to individuals based at an international research organisation.

Researcher co-lead (previously researcher co-investigator)

- A research and innovation associate who is not eligible to be a project lead or project co-lead, but has made a substantial contribution to the formulation and development of the application and will be closely involved with the project.

For further details, visit [Eligibility as an individual](#).

## Japan Applicants

The Japan-based Project Lead must be affiliated with a domestic university or research institution in Japan where the proposed project will be carried out. For further details, please refer to the AMED Call Supplemental guidance for Japanese researchers which can be found on the [AMED website](#).

## Third Country Applicants

The funders are not seeking to support applicants/partners outside of the UK and Japan through this initiative. Please contact [international@mrc.ukri.org](mailto:international@mrc.ukri.org) (for UK based PL's) and [amed-aspire@amed.go.jp](mailto:amed-aspire@amed.go.jp) (for Japan based PL's) if you are considering involving applicants/partners from a third country in your proposal.

## 2.2 People named on the grant

### ***The Project Leads (PL)***

The proposal should be jointly developed by a UK PL and a Japanese PL. They should develop a common research plan and vision and equally share leadership and project management for each project.

A Project Lead may only submit one application to this scheme as PL's but may be involved in more applications if listed as a Project co-lead.

The UK and Japan based PL are responsible for the intellectual leadership of the research project and for the overall management of the research. Each PL will be their respective funding agencies' main contact for the proposal.

### **UK based PL**

For administrative purposes when completing the UK TFS document, you will only be able to input one PL; this will need to be the UK PL. The Japan based PL will need to be listed as a project co-lead (international) on TFS. While it is essential that all Japan based PLs and PCLs are added to the TFS application, Japanese costs should be included only within the dedicated international resource section within the TFS form.



**Japan based PL:**

Please refer to the AMED Call Supplemental guidance for Japanese researchers which can be found on the [AMED website](#)

**Project co-leads (PCLs)**

The UK and Japan based PL's may be supported by a number of project co-leads named on the application. A PCL assists the PL in the management and leadership of the research project. They would provide intellectual and/or practical input into the research and whose participation may warrant inclusion of their name on any outputs (e.g. publications).

**Other support**

**UK based applicants**

For information on other parties involved in research, including project partners, please see section 1.3.4 in the standard [MRC Guidance for Applicants](#).

**If a UK project partner is from industry or if any Japanese investigators or project partners are from industry, then applicants must follow the [guidance](#) relating to the MRC Industrial Collaboration Framework (ICF).**

### **3. Application process**

#### **3.1 Expression of Interest (EOI)**

Researchers planning to submit to this scheme are encouraged to submit a short [Expression of Interest \(EOI\)](#) by 16:00 GMT on the 19 March 2024. It is the responsibility of the UK PL to submit the EOI on behalf of the UK/Japanese research collaboration.

Please note, this step is voluntary and does not form part of the review process, applicants who do not submit an EOI can still apply to the Call. MRC and AMED will not undertake eligibility checks at this point. Applicants should not await a response from the funders following the EOI submission, but simply continue with the development of the full proposal to be submitted by the deadline. The MRC and AMED will use the EOI to help prepare for the review process.

Applicants are not expected to submit an EOI to AMED as well, however, all details submitted to the MRC will be shared with AMED.

#### **3.2 Full application: process overview**

UK and Japanese applicants must apply separately to their respective funding agencies for the funding component requested within each country, but this must be based around a common research plan and vision. The application must be JOINTLY prepared by both UK and Japanese applicants.

UK applicants must submit through TFS by 16:00 UK time on 16 April 2024.

Japanese applicants must submit through the AMED online submission system, [e-Rad](#) by 18:00 JST on 16 April 2024.

**Please note, failure to submit a valid application to both the MRC and AMED by the respective deadlines will invalidate your submissions.**

The UK and Japan based applicants should jointly prepare a common research plan and the full application, including;

- a jointly prepared **Project Details and Methodology** and
- a jointly prepared **Justification of Resources**

Further guidance can be found within the Funding Service as well within the project details and methodology templates.

AMED and MRC will run a joint review process based on the jointly prepared proposals submitted to the respective systems (e-Rad and TFS).

The MRC and AMED will conduct a remit check/relevance review to identify applications that are in alignment with the scope of the call. Applications that are deemed not to be eligible or not to be relevant to the call will be withdrawn from the competition.

Before submitting their proposals, researchers should ensure they have fully considered all aspects of their collaboration, including ethics and IP.

### 3.3 Full application: summary of components

<b>Document</b>	<b>TFS for MRC</b>	<b>e-Rad for AMED</b>
Project details and methodology	X (within TFS)	X
Team details and track record	X (within TFS - <a href="#">R4RI</a> )	X
Justification of Resources	X (within TFS)	X
Data Management Plan	X (within TFS)	
Letter of supports (dated and signed)	X	X
<a href="#">Supplemental application form</a> (in Japanese)		X

- **Completed TFS application** .
  - All UK and Japan based Project Leads and Co-Project Leads MUST be included.
  - The costing part of the TFS form must reflect the UK costs. While the Japan based investigators should be included, hours charged on the TFS form for Japan based investigators should be 0. Japanese costs should be captured and justified in the dedicated international resource and cost justification section of the TFS application, as well as the AMED e-Rad site in addition to the Justification of Resources document.
- **A Completed e-Rad form**



- All Japan based PLs/PCLs MUST be included.
- UK Project Leads and Co-Project Leads are not required to obtain an e-Rad account nor be added to the list of participants in e-Rad. The costing part of the online e-Rad form must reflect only the Japanese component costs.
- On the proposal form, the Japan based Co-PL should be listed as the principal investigator and the UK Co-PL should be listed as the first named co-applicant.
- **A jointly prepared Project details and methodology document –**
  - The UK and Japan Project Leads MUST jointly prepare a project details and methodology document.
  - For the UK based PL, the information provided within the project details and methodology template will be captured within the vision and approach sections of the TFS application.
  - For the Japanese PL, the completed project details and methodology document should be submitted to AMED on e-Rad.
  - Please note, the project details and methodology document must reflect the details the UK based PL will have submitted to TFS.
- **Team details and track record**
  - MRC will be using R4RI, a flexible narrative CV template to capture each researchers contribution to the project. Further details can be found on TFS.
  - For AMED please follow the Call Supplemental guidance for Japanese researchers which can be found on the [AMED website](#).
- **Justification of Resources**
  - The UK PL should justify the UK resources within the “resources and cost justification” section of the TFS.
  - The UK PL should justify the Japan resources within the “international resources and cost justification” section of the TFS.
  - A jointly prepared MRC-AMED Engineering Biology justification of resources template should be completed, and submitted to AMED through e-Rad.
  - Please note, the JoR template must detail the total costs requested for the project and fully justify both the UK and Japanese costs. The submission on TFS and the submission on e-Rad should be a matching funding request.
- **Data Management Plan (only for UK based applicants) –** please see section 2.2.7 of the standard [MRC Guidance for Applicants](#).
- **MRC Industry Collaboration Framework (ICF) form –** This is needed if industry is involved in the UK and/or in Japan. Please see the [relevant MRC webpage](#) for further guidance.
- **UK National Health Service (NHS) costs (if required) –** please see section 3.5 of the standard [MRC Guidance for Applicants](#).
- **Use of animals overseas form(s) (if required)** please see section 4.4.6 of the standard [MRC Guidance for Applicants](#) and the [use of animals overseas section](#) of the National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs) website. This attachment should be uploaded within the Letters of Support section on the TFS.
- **Letters of support (dated and signed):**

- The UK PL should combine the Letters of Support into a single PDF and submit them to the TFS within the “Letters of Support” section.
- You should supply the following Letters of Support:
  - from the UK Research Organisation(s) demonstrating support for the proposed research project.
  - from the Japanese research organisation(s) demonstrating support for the proposed research project.
  - from any project partner where an in-kind payment is being contributed.
  - A human participation/human tissue letter signed by both the UK PL and Japanese PL when human/human tissue research is proposed and/or when the Japanese partner or another third party (ANY organisation other than the host UK RO) is responsible for recruitment of people as research participants and/or providing human tissue. Please see the ‘Research involving human tissues or biological samples’ section within TFS.
  - Use of Animals letter (if applicable, 2 sides of A4 max) – see section 4.4.6 of this Guide for Applicants for information. This should be signed by both the UK PL and Japanese PL.
- **Supplemental Application form for Japan based applicants.** The template is available on the [AMED call webpage](#).

### 3.6 Budgets

In total, MRC will make up to £3 million available in support of the UK components. Approximately 158 million JPY, in total for the three-year period per research project, will be provided by the AMED in support of the planned Japanese research. The funding agencies intend to use these available funds to support **up to three collaborative projects**, subject to quality.

Each grant will require a UK PL and a Japanese PL who will equally share leadership and project management for each project. Each PL will apply for funding to support the specific component of the grant from their respective funding agency.

#### Funding for international partnership and mobility activities

It is required that 33% of the total requested funding (from both UKRI and AMED) should be used for the purpose of building and expanding networks with the partner country and promoting mobility. These expenses can include the costs of organizing workshops/seminars etc, travel of researchers to the partner country and related expenses, personnel costs for staff involved in travel and exchanges, and research and other costs related to hosting researchers from the partner country. Please see table below for more detail.

Main Item	Definition
Research costs (equipment/supplies) when hosting researchers	Research facilities/equipment/prototypes, software (ready-made goods), purchasing costs for reagents/materials/consumables for use in research

Travel costs for personal exchanges and joint meetings	Travel costs of UK research participants, travel costs for invited participants such as external experts
Personnel costs/ services costs for expatriates	Personnel costs for those traveling: personnel costs for researchers, etc., employed to conduct the relevant contracted research (including personnel costs for PLs and Co-PLs) and related costs e.g. interpretation/translation
Other costs for international partnership and mobility activities	Costs for implementing the relevant contracted research other than the above. Examples: conference costs, equipment leasing costs, Equipment repair costs and subcontract costs.

### UK based applicants

MRC will make up to £3 million available to cover the UK components of three collaborative research projects selected for funding under this call. The MRC will provide funding under standard arrangements and at 80% FEC] **The UK element of funding will not cover UK PhD studentships or requests for capital items.** UK Projects must be three years in duration and start within three months of the funding announcement.

Please see section 3. Resources – Full Economic Costing in the standard [MRC Guidance for Applicants](#) for information on FEC.

### UK funding available

	<i>UK funding</i>
Research costs:	
Staff – directly incurred post (e.g. Researchers, Technicians)	Yes
Staff – directly allocated posts (PL and PCL time)	Yes
Equipment below £10,000: Costs should be claimed as 'Other Directly Incurred Costs'	Yes
Equipment above £10,000	No
Other Directly Incurred Costs Including (e.g. Consumables, Sub-Contracting costs)	Yes
Research studentships	No
Research assistants/postdoctoral researchers/research technicians	Yes
Studentships (degree programmes)	No
Travel and subsistence for exchange/mobility activities	Yes
Cost of workshops, meetings etc. Should be costed as 'Other Directly Incurred'.	Yes

### UK equipment:

**Capital costs above £10,000 cannot be funded via the MRC as part of this call and therefore any capital costs requested will not be accepted by the UK funders.**



Costs for 'small equipment' under £10,000 (such as consumables) are accepted by MRC from UK applicants. These should be listed within the 'Directly Incurred Costs' category within the TFS Resources and Cost table.

### **Japan based applicants**

Please refer to the AMED Call Supplemental guidance for Japanese researchers which can be found on the [AMED website](#).

### **Contract between Japan-based PL and AMED**

Support will be implemented in accordance with a contract for commissioned research which shall be entered into between AMED and the Japan-based PL's Institution. The contract for commissioned research will be signed once at the start of the project over the collaborative research period. Since the contract is agreed on condition that all administrative procedures related to the project in question shall be handled within the institution, the PL should consult with the department in charge at his/her institution.

## **4. Assessment process and criteria**

Following submission, both funding organisations will secure review committee members from their respective countries, collaborating to ensure an appropriate spread of expertise, organisations and EDI considerations. To be funded, proposals must be internationally competitive and at a standard equivalent to that normally expected to be supported by each funding organisation.

### **Assessment process**

#### Expert Review Committee

- We will invite experts to join an expert review committee. Your application will be independently assessed, against the specified criteria for this funding opportunity.
- As we will be utilising an expert review committee to conduct an initial assessment of applications, you will not be able to nominate reviewers for this opportunity.
- Following expert review, you will have 14 days to respond to reviewers' comments.

#### Shortlisting

- A shortlisting process may be conducted depending on the number of applications received. Shortlisted applications will go to a panel who will make a funding recommendation.

#### Panel

- Following expert review, and shortlisting, we will invite experts to use the evidence provided by reviewers and your applicant response to assess the quality of your application and rank it alongside other applications after which the panel will make a funding recommendation. The scoring system can be found in [annex 1](#).

It is envisaged that all eligible applications will go through the review committee process described above. However, the MRC/AMED reserve the right to adjust the process and introduce a shortlisting/streamlining step if a high number of proposals are submitted to the call.

## Assessment Criteria

Each proposal will be assessed against the following criteria;

Vision of the project: novelty, importance and timeliness of the proposed research, the impact of the research. The key points to consider include

- Does the proposed research have originality and novelty?
- Does the proposed research respond to social needs?
- Does the proposed research conform to the national policy on R&D in the medical field?
- Does the proposed research contribute to the advancement of research and development in the medical field?
- Is the research expected to produce internationally acclaimed research results?
- Can top-level international joint research be expected to continue after the completion of the research and development, thereby maintaining and improving scientific and technological capabilities for both countries?

Approach of the project: design and feasibility of the proposed methodology, the key points to consider include:

- Are the goals and plans of the overall plan clear? Are the annual plans specific and feasible?
- Is the research proposal of a high standard in the field of health and medical care, and can synergistic effects be expected through international joint research with the research team of the partner country?

Research partnership: including strength and clarity of the collaboration and opportunities provided, the sustainability of the partnership, the added value of the partnership and the appropriateness of the governance arrangements, the key considerations include;

- Does the proposal involve high-level international joint research aimed at enhancing scientific and technological capabilities for both countries?
- Is the target top international research community clearly defined and consistent with the project purpose?
- Is the division of roles between the Japanese and UK research teams clear and feasible throughout the research period?
- Is the plan for building and expanding the international collaboration appropriate?
- Is it expected to continue and expand as a global network after the completion of the research program?
- Are the research exchanges and collaborations planned on an equal footing and mutually beneficial for both countries? Is the relationship between the two countries such that one side is not subordinate to the other?

Plans for international partnership and mobility activities: a clear breakdown and justification of the proposed activities and costs (confirming 33%). The breakdown and justification should include;

- Are there appropriate plans for cultivating next-generation researchers based on past successes?
- Is the strategy for fostering the next generation of top researchers that will contribute to the promotion of international talent mobility appropriate?
- Can we expect human resource development to continue in the top research community after the completion of the research program?

Capability of the applicants and the project team to deliver the project, including strategies to foster knowledge and methodology exchange. Key questions to consider include:

- Does the Principal Investigator have long experience in top research communities with the co-investigators from foreign institution, and have experience in human resource development of young researchers, etc.?
- Is the composition of the research team organized with a view to achieving the project objectives and generating results?

Support for early career researchers and a clear strategy for fostering the next generation of top researchers that will contribute to the promotion of international talent mobility. Key questions to consider include:

- Are there appropriate plans for cultivating next-generation researchers based on past successes?
- Is the strategy for fostering the next generation of top researchers that will contribute to the promotion of international talent mobility appropriate?
- Can we expect human resource development to continue in the top research community after the completion of the research program?

Value for money and equity of the project. Key questions to consider include:

- Are the breakdown of expenses and the expenditure plan appropriate?
- Do you have sufficient research resources (research funds, human and material resources, etc.) to carry out the research activities in accordance with the purpose of the public offering?
- Is sufficient budget secured for human resource development of researchers dispatched overseas, and is an appropriate budget plan in place?
- Does the project include a budget plan for accepting excellent human resources from overseas under appropriate conditions?

Ethical and Responsible Research and Innovation (RRI) considerations of the project.

- Does the plan comply with bioethics and safety laws and regulations?

AMED and MRC will run a joint review process based on the jointly prepared proposals submitted to the respective systems (e-Rad and TFS).

## **5. Agreements and ethics**

### **5.1 Collaboration Agreement**

As the research projects will be carried out by multiple research organisations and project partners, the basis of collaboration between the organisations and project partners, including ownership of intellectual property (IP) generated during the project and rights to exploitation, and costs of IP management [this is not an eligible (direct) cost to MRC UKRI or AMED], is expected to be set out in a formal Collaboration Agreement between the research organisations involved. It is the responsibility of the research organisations to put such an





agreement in place before the research begins and within 6 months of the adoption of funding. **The terms of collaboration shall not conflict with MRC UKRI and AMED terms and conditions.**

The collaboration agreement should also include the allocation of resources throughout the project.

Arrangements for collaboration and/or exploitation must not prevent the future progression of academic research and the dissemination of research results in accordance with academic custom and practise and the requirements of the funding bodies. A temporary delay in publication is acceptable in order to allow commercial and collaborative arrangements to be established.

The collaboration Agreement does not need to be submitted to the funders however it must be made available if requested.

## 5.2 Intellectual Property

Intellectual Property Rights (IPR) means any copyright and related rights, patents, rights to inventions, registered designs, database rights, design rights, topography rights, trademarks, service marks, trade names and domain names, trade secrets, rights in unpatented know-how, rights of confidence and any other intellectual or industrial property rights of any nature including all applications (or rights to apply) for, and renewals or extensions of such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

Ownership of intellectual property (IP) generated during the project and rights to exploitation, as well as any costs regarding management of IP, are expected to be agreed between the collaborating research organisations before the research begins, unless otherwise stated. It is up to the respective UK and Japanese research teams to determine in advance how any exploited IP will be divided amongst the partners. Details of this agreement must be included in the Collaboration Agreement (as above).

Agreements must not conflict with MRC or AMED policies or terms and conditions. Any agreements in place between a research organisation and their respective funding organisation must be adhered to, including the sharing of IP costs or benefits. Any IP sharing agreements in place between a research organisation and their national funding body would be expected to apply only to the IP share of that research organisation.

The MRC will follow its standard rules/terms and conditions regarding IP, please see relevant sections of the [UKRI and MRC terms and conditions](#) for research grants.

### Japan based applicants

Japan based applicants should refer to the AMED Call Supplemental guidance for Japanese researchers which can be found on the [AMED website](#).

### 5.3 Material Transfer Agreements

Collection and exchange of material may occur between collaborating institutions, as necessary, in strict compliance with the relevant legislation in both countries.

### 5.4 Ethics

Any research involving humans/human tissue and/or animals (whether undertaken in the UK or Japan) must comply with legislation in both the UK and Japan. It must also comply with relevant policies and guidance of MRC and AMED. **All ethical information provided must cover all research activities taking place in both the UK and Japan.**

It is the absolute responsibility of the PL and the Ros to ensure that appropriate ethical approval is granted and adhered to, and that no research requiring ethical approval is initiated until it has been granted.

The ethical information sub-sections in TFS should be completed to give details of any human participation, research using animals, genetic and biological risk **in all countries** (stating clearly which country/countries the relevant research will be done in), and should state any UK and Japanese ethical committee approvals required. For further information please see Section 5 of the standard [MRC Guidance for Applicants](#).

#### **For Japanese based applicants**

Japan based applicants should refer to the AMED Call Supplemental guidance for Japanese researchers which can be found on the [AMED website](#).

#### **MRC ethics guidance**

Applicants must comply with all of the MRC's relevant policies and guidance regarding the use of humans/human tissue and/or animals in research. Further details are given below.

Approval(s) for the research detailed in an MRC grant proposal must be granted by the appropriate bodies before any work can commence. Institutions, applicants and grant holders have absolute responsibility for ensuring that the necessary approvals are granted for the research considered by the MRC and AMED.

The Project Leaders/ research organisation must be prepared to furnish the MRC with a copy of the ethical approval, and any correspondence with the committees, if requested. The Project Lead must notify the MRC if a regulator or a research ethics committee requires amendments that substantially affect the research question, methodology or costs to the extent that the project is no longer the same as that approved for funding by the MRC.

Please see [section 3.3](#) of this Call specific guidance for a summary of ethical documents required.



## 5.5 Use of humans/human tissue

### For Japanese based applicants

Japan based applicants should refer to the AMED Call Supplemental guidance for Japanese researchers which can be found on the [AMED website](#).

### For UK Based applicants

A signed and dated letter of support must be attached to the proposals when human/human tissue research is proposed (in either country). The letter should be titled 'Human participation/human tissue letter' and MUST be signed by both the UK PL and Japanese PL. It must be clear from the letter which human/tissue research is being proposed in which country.

The letter should state that all applicants will comply with the relevant MRC policies and guidance in the standard [MRC Guidance for Applicants](#) and call-specific Guidance for Applicants. The letter should also acknowledge that the UK PL and Japanese PL understand that MRC's current policy for research involving humans to take place overseas, is that **for research to be undertaken internationally, both local and UK ethical approval is required**. The letter should also state that the UK PL and Japanese PL understand that for clinical studies involving human participants and/or patients in the UK or overseas, appropriate consent must be obtained.

In addition, where the Japanese partner or another third party (ANY organisation other than the UK RO) is responsible for recruitment of people as research participants and/or providing human tissue, details should be included in the case for support and the 'Human participation/human tissue letter' MUST include confirmation of the following:

- which international partner is involved and that the partner has agreed to recruit the participants/provide tissue
- that what is being supplied is suitable for the research being undertaken
- that the quantity of tissue (where relevant) being supplied is suitable, but not excessive for achieving meaningful results.

The letter of support must be an integral part of the application (as an attachment within the Letters of Support section on the TFS) and must focus on the proposal it accompanies.

## 5.6 Use of animals

### For Japanese based applicants

Japan based applicants should refer to the AMED Call Supplemental guidance for Japanese researchers which can be found on the AMED website

### For UK based applicants

Applicants must ensure that all of the proposed research, both that in the UK and in Japan will comply with the principles of the MRC common guidance on [responsibility in the use of animals in bioscience research](#) and [NC3Rs Guidelines: Primate Accommodation, Care and Use](#).

In particular, UK institutions should be aware of the following aspect of the guidance relating to research or collaboration outside the UK:

*“When collaborating with other laboratories, or where animal facilities are provided by third parties, researchers and the local ethics committee in the UK should satisfy themselves that welfare standards consistent with the principles of UK legislation (e.g. the ASPA) and set out in this guidance are applied and maintained.*

*Where there are significant deviations, prior approval from the funding body should be sought and agreed. International research should also be compliant with all relevant national and local regulatory systems in the host country where the research is to be conducted.”*

Investigators proposing the use of animals (in either country) should read the guidance and:

- provide a signed and dated letter with the heading uploaded to the TFS which MUST be signed by both the UK PL and Japanese PL stating that:
  - all animal research (undertaken in either country) will adhere to all relevant national and local regulatory systems in the UK and Japan
  - they will follow the guidelines laid out in the [responsibility in the use of animals in bioscience research](#) document and ensure that work is carried out to UK and Japanese standards. If primates are used they should also confirm that they will follow the [NC3Rs Guidelines: Primate Accommodation, Care and Use](#)
  - before initiation of the proposed research work, appropriate approvals from institutional and/or central animal ethics committees will be obtained for experimental protocols to be adopted in their projects. Successful proposals may be expected to provide copies of these permissions before funding is released.
  - details on which animal research will take place in which country (UK, Japan or elsewhere) and through which funder the resources are being sought. Applicants should include confirmation that animal welfare standards at these institutions meet the requirements outlined above.
- If applicable, applicants should also submit the MRC ‘Use of Animals Overseas’ form(s) - please see section 4.4.6 of the standard [MRC Guidance for Applicants](#) and [the use of animals overseas section](#) of the National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs) website. This attachment should be uploaded and attached within the Letters of Support section of the TFS.

All applicants are required to comply with Section 4: ‘Proposals involving animal use’ of the standard [MRC Guidance for Applicants](#). Applicants should detail in the letter any additional information which was not included in the proposal document but which is pertinent to the animal research proposed and which the funders should be aware of.

In addition, researchers should be reminded that sufficient information and justification regarding any animal research proposed, regardless of country, must be provided in the proposal order to allow full peer review to take place.

## 5.7 Use of Stem Cells

### **For Japan based applicants**

Japan based applicants should refer to the AMED Call Supplemental guidance for Japanese researchers which can be found on the [AMED website](#).

### **For UK based applicants**

Please see section 5.8.1 of the standard [MRC Guidance for Applicants](#) for further information.

## 5.8 Responsible Research and Innovation (RRI)

### **For UK based applicants**

Both UKRI and AMED are committed to promoting effective international collaboration in research and innovation and ensuring that this takes place with integrity and strong ethical frameworks considering potential risks where relevant. Within your application you should detail the approaches you are going to take to manage responsible research and innovation, and regulation. This also includes identifying and managing the potential for unethical or dual-use of project outputs. You should ensure that your proposed activities align with UKRI and AMED's ethical and trusted research and innovation principles. Further guidance UKRI TRI principles and MRC policy on managing the risks of research can be found:

<https://www.ukri.org/who-we-are/mrc/our-policies-and-standards/research/managing-the-risks-of-research-misuse/> and <https://www.ukri.org/wp-content/uploads/2021/08/UKRI-170821-TrustedResearchandInnovationPrinciples.pdf>

### **For Japan-based applicants**

please see section 4.5 of [AMED Call Supplemental Guideline](#) for Japanese applicants.

## **6. Terms and conditions for UK applicants**

For the UK grant's terms and conditions please follow the link:

<https://www.ukri.org/funding/information-for-award-holders/grant-terms-and-conditions/>

### **UK grant starting procedures**

The UK side of the grant must start within three months of funding confirmation.

UK applicants should refer to the standard [MRC Guidance for Applicants](#) for information on what the starting procedure entails.

Please note that due to the requirement to start within three months of funding confirmation, the normal three months start period rules outlined in the UKRI Terms and Conditions RGC5, does not apply to this project.

### **Ethical requirements**

It is the responsibility of the PL and the research organisation to ensure that appropriate ethical approval is granted for this study and adhered to, and that no research requiring ethical approval is initiated until it has been granted.

MRC's [current policy for research involving humans](#) is that for research to be undertaken overseas, both local and UK ethical approval is required.

For clinical studies involving human participants and/or patients, appropriate consent must be obtained.

For grants that include the use of animals, the [responsibility in the use of animals](#) guidance should be adhered to, and in particular: 'When collaborating with other laboratories, or where animal facilities are provided by third parties, researchers and the local ethics committee in the UK should satisfy themselves that welfare standards consistent with the principals of UK legislation (such as the ASPA) and set out in this guidance are applied and maintained.'

The PL/RO must be prepared to furnish the Medical Research Council with a copy of the ethical approval, and any correspondence with the committees, if requested. The principal investigator must notify the Medical Research Council if a regulator or a research ethics committee requires amendments that substantially affect the research question, methodology or costs to the extent that the project is no longer the same as that approved for funding.

The grants must comply with the ethical sections within this call-specific Guide for Applicants and within the standard [MRC Guidance for Applicants](#).

### **UK government support**

This award is dependent on continuing government commitment for this initiative and continuing match from the partner funder. In the event that this support is withdrawn, the MRC reserve the right to terminate the award.

## **7. Contacts and Guidance**

Please read:

- the MRC call text
- the AMED open call webpage
- the current document, the call-specific Guidance for Applicants
- the standard MRC Guidance for Applicants

For further information, UK applicants should contact: [international@mrc.ukri.org](mailto:international@mrc.ukri.org)

For further information, relating to the call or the AMED application, Japanese applicants should contact: [amed-aspire\(AT\)amed.go.jp](mailto:amed-aspire(AT)amed.go.jp)

## Annex 1: Review committee scoring system

Score		Definition	Description
10	Fundable	Exceptional	Internationally of the highest class / R&D that is absolutely crucial in strategic terms for the health and medical field in the UK and Japan / a flawless proposal
9		Outstanding	Extremely internationally competitive / R&D that is very important in strategic terms for the health and medical field in the UK and Japan / an outstanding proposal and leading edge in most areas
8		Excellent	Internationally competitive and domestically of the highest class / R&D that is important in strategic terms for the health and medical field in the UK and Japan/ an excellent proposal with a few minor weak points
7		Very good	Domestically competitive / strategic R&D for the health and medical field in the UK and Japan / an excellent proposal but containing numerous minor weak points
6		Good	R&D in the health and medical field in the UK and Japan in which strategic investments should be made/an excellent proposal with moderate-level weak points
5	Non fundable	Fair	Proposal has several strong points but also moderate-level weak points
4		Potentially Useful	Proposal has several strong points but one major weak point
3		Poor	Proposal has hardly any strong points but several major weak points
2		Very poor	Proposal has hardly any strong points but many major weak points / poor quality science
1		Extremely poor	Proposal has no strong points whatsoever and many major weak points