MRC-AMED Regenerative Medicine and Stem Cell Research Initiative

CALL-SPECIFIC GUIDANCE FOR APPLICANTS

UK based applicants

This guidance supplements the standard MRC Guidance for Applicants. Please consult the standard MRC Guidance for Applicants for 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.

Japan based applicants

This call-specific guidance document provides additional 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), specifically the 2020 AMED Call Guideline for "The Program for Technological Innovation of Regenerative Medicine".

Contents

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 UKRI-Japan Regenerative Medicine and Stem Cell Research Initiative. For further information on the background, aim, objectives and scope, please see the Call webpage for UK applicants and MRC-AMED Call text 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 Principal Investigator (PI) based at a UK Research Organisation (RO) and a PI based at a Japanese RO.

UK and Japanese applicants must apply **separately** to their respective funding agencies by **20 Feb 2020** for the funding component requested within each country. The application must be based around a common research plan and vision and be JOINTLY prepared by both UK and Japanese applicants.

Both partners must therefore submit an identical joint Case for Support (including if applicable a one-page methodology annex) and separate optional one-page Gantt chart written in English to the MRC and AMED.

As there will be a single Case for Support, it is vital that it provides full details of the work proposed for both the UK and Japanese components.

An identical version (in English) of the call-specific Justification of Resources template should also be submitted to both MRC and AMED. Please note an identical version of the text provided in the Je-S 'Pathways to Impact' section must also be submitted to AMED via the e-Rad system

1.1 Start Date and Duration

In the UK projects must start on **1 October 2020**. Projects must be three years in duration and have completed by 30 September 2023.

In Japan projects must start on **15 September 2020** and complete in March 2023. The Japanese component of the projects will therefore be shorter than three years.

Funding available for this call is as follows:

- MRC - will make up to £5m available to cover the UK components of the collaborative research projects. UK based applicants may therefore request up to a maximum of £625k at 80% fEC per project.

- AMED - will make up to 12,500,000 yen (inclusive of 30% over heads) available to fund the Japanese components of the collaborative research projects per annum per project for 3 Japanese fiscal years. Japanese based applicants may therefore request up to a maximum of 37,500,000 yen (inclusive of 30% overheads) per project.

The size of the grants will vary according to the needs of each research project. UK and Japanese 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 approximately **eight projects** subject to scientific quality.

1.2 Key dates

Stage	Date
Pre-announcement	5 November 2019
Launch date	9 December 2019
Deadline for Intention to Submit (to be submitted to MRC only)	20 January 2020
Deadline for applicants to submit proposal (in both countries)	20 February 2020
External/remote peer review	March-June 2020
PI response to peer reviews	June 2020
Joint Panel Meeting	July 2020
Notice of decision date	July/August 2020
Funding start date	By 15 September on Japan side; 1 October 2020 on UK side

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 PI and associated costs for UK research would be funded by the MRC, while the Japanese PI and associated costs for Japanese research would be funded by AMED.

2.1 Types of research organisations (ROs)

The UK Principal Investigator (PI) MUST be based at one of the following, as per standard MRC eligibility criteria:

- Higher education institutions
- Independent research organisations

- Government funded organisations (other than MRC funded units and institutes)
- MRC units/institutes
- University units (former MRC units)

For the MRC participants, standard UK Research and Innovation (UKRI) eligibility criteria as described on the UKRI website will apply. Applications cannot be accepted from UK principal investigators in commercial organisations. **See section 1 of the standard MRC Guidance for Applicants for further details about eligible UK institutions. This call will follow standard MRC eligibility criteria.**

The Japan-based PI 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 2020 AMED Call Guideline for "The Program for Technological Innovation of Regenerative Medicine"

The funders are not seeking to support applicants/partners outside of the UK and Japan through this initiative. Please contact international@mrc.ukri.org (for UK based PI's) and rminnov"AT"amed.go.jp (replace "AT" with "@" (for Japan based PI's)) if you are considering involving applicants/partners from a third country in your proposal.

2.2 People named on the grant

The Principal Investigators

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

PIs may only submit one application to this scheme as PI but may be involved in more applications if listed as a Co-Investigator.

The UK PI and Japanese PI are responsible for the intellectual leadership of the research project and for the overall management of the research. The PI will be the funding agencies' main contact for the proposal.

UK based PI
For administrative purposes when completing the UK Je-S form, you will only be able to input one PI; this will need to be the UK PI. The Japanese PI will need to be listed as a co-investigator (Co-I) on Je-S.

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

UK:

- The MRC will consider proposals from any UK-based researcher who is based at an eligible research organisation and can demonstrate that they will direct the proposed

research and be actively engaged in carrying it through. See standard MRC Guidance for Applicants for further details about UK PI eligibility.

Japan:

- Please refer to 2020 AMED Call Guideline for "The Program for Technological Innovation of Regenerative Medicine" for roles and eligibility of the Japanese PI as well as further details on the e-Rad submission.

Co-investigators (Co-Is)

The UK PI and Japanese PI may be supported by a number of Co-Is named on the application. A Co-I assists the PI 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).

All UK and Japanese investigators MUST have verified Je-S accounts and must be added to the Je-S form under co-investigator. Please see section 3.5, below, 'Creating a Je-S application' for information on how to add an organisation on Je-S.

While, it is essential that all Japanese PIs and Co-Is are added to the Je-S form, Japanese costs should **not be** represented on the Je-S form.

Please note: The UK PI should liaise with the Japanese PI and any other non-UK based Co-investigators as early as possible in the application process to ensure that they set-up their verified Je-S account as a matter of priority. Co-Investigators without Je-S accounts should be encouraged to visit the Je-S website (https://je-s.rcuk.ac.uk) to gain access to the Je-S System.

Further information when creating a Je-S account can be found in section 3.5 of this document.

Other support

UK based applicants

For information on other parties involved in research including project partners, please see section 1 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 Agreement (MICA).

3. Application process

3.1 Intention to Submit (ItS)

Researchers planning to submit to this scheme should submit a short Intention to Submit (ItS) by 23:00 GMT on the 20 January 2020. It is the responsibility of the UK PI to submit the Intention to Submit on behalf of the UK/Japanese research collaboration.

Please note, this step does not form part of the review process. MRC and AMED will not undertake eligibility checks at this point. Applicants should not await a response from the funders following the ItS submission, but simply continue with the development of the full proposal to be submitted by the deadline. The MRC and AMED will use the ItS to help prepare for the review process.

Applicants are not expected to submit an ItS 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 the UK Joint electronic Submission (Je-S) System by 16:00 UK time on 20 February 2020.

Japanese applicants must submit through the AMED online submission system, e-Rad by 18:00 JST on 20 February 2020.

Please note the deadline to submit an application to each country differs, **failure to submit a valid application to the MRC and AMED by the respective deadlines will invalidate both submissions.**

The UK and Japanese applicants should jointly prepare a common research plan and jointly prepare the full application, including:

- a jointly prepared **'Case for Support'** (including, if applicable, a one-page methodology annex and optional one-page Gantt chart) providing full details of the work proposed for both the UK and Japanese components
- a jointly prepared **Justification of Resources** using the call-specific template.
- a jointly prepared Pathways to Impact. Please note an identical version of the text provided in the Je-S 'Pathways to Impact' section must be submitted to AMED via the e-Rad system

Further guidance can be found in the standard MRC Guidance for Applicants as well as in this present call-specific Guidance for Applicants document.

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

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 may be withdrawn from the competition.

UK and Japanese researchers should discuss ethics and Intellectual Property before fully developing their proposal.

3.3 Full application: summary of components

The following documents must be included in the jointly prepared full application submission on Je-S and e-Rad (with "X" indicating the relevant system):

Document	***Je-S for MRC***	***e-Rad for AMED***
Covering letter	X(optional)	X(optional)
A jointly prepared Case for Support	X	X
CVs	X	X
List of Publications	X	X
Justification of Resources	X	X
Pathways to Impact	X	X
Data Management Plan	X	
Letter of supports (dated and signed)	X	X
Supplemental application form (in Japanese)		X

- **A completed Je-S form**.
  - All UK and Japanese PIs/Co-Is MUST be included.
  - The costing part of the online Je-S form must reflect the UK costs, so while the Japanese investigators should be included, hours charged on the Je-S form for Japanese investigators should be 0. Japanese costs will instead be captured in the e-Rad site in addition to the Justification of Resources document.
- **A Completed e-Rad form**
  - All Japanese PIs/Co-Is MUST be included.
  - UK PIs/Co-Is 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.
- **A cover letter (optional)**. [UK based applicants] If you have submitted a similar or related proposal to any of the UK Research Councils in the last year, please provide

details in a cover letter including what has changed since the previous submission. [Both UK and Japan based applicants] The covering letter can be used to cover details such as conflicts of interest and names of conflicted experts that you request not to be used as peer reviewers by the MRC/AMED.

- **A jointly prepared Case for Support**, including an optional but recommended one-page annex detailing the methodology and experimental design aspects and a project Gantt Chart – please see section 3.4 for further guidance.
- **CVs and publication lists** (uploaded individually to Je-S and e-Rad) for each of the UK and Japanese Investigators and named research staff on the application. Please see section 2.2.1 and 2.2.2 of the standard MRC Guidance for Applicants.
- **Justification of Resources** (using the call-specific JoR template) for the total costs requested for the project (both UK and Japanese costs should be fully justified because this document will be provided to peer reviewers and panel members)
- **Pathways to Impact (jointly prepared)** – please see section 2.2.5 of the standard MRC Guidance for Applicants. Please note the text provided in the Je-S 'Pathways to Impact' section must also be submitted to AMED via the e-Rad system.
- **Data Management Plan (only for UK based applicants)** – please see section 2.2.8 of the standard MRC Guidance for Applicants.
- **MRC Industry Collaboration Agreement (MICA) form and Heads of Terms (if required)** – 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 as a 'Letter of Support'.
- **Letters of support (dated and signed):**
    - 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 PI and Japanese PI 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. See section 5.5.1 of this Guide for Applicants for further information.
    - **Use of Animals letter** (if applicable, 2 sides of A4 max) – see section 5.6.1 of this Guide for Applicants for information. This should be signed by both the UK PI and Japanese PI.
    - **Use of Stem cells letter** (if applicable, 2 sides of A4 max) – please see section 5 of the standard MRC Guidance for Applicants for further information.

- **Supplemental Application form for Japan based applicants**, this is for administrative use (in Japanese). The template is available on the AMED call webpage.

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.

Page lengths (A4 size):

Document	***Maximum length (Maximum)***
Covering letter	2 pages
A jointly prepared Case for Support	8 pages (including illustration, references and a project Gantt Chart) + optional additional 1 page for methodology annex
CV	2 pages per CV
List of Publications	1 page per List of Publications
Justification of Resources	Please refer to the call-specific template for information about page limits
Pathways to Impact	2 pages
Data Management Plan	3 pages
Letters of support (dated and signed)	2 pages each
Supplemental application form (in Japanese)	Please refer to the instructions in the template

Further guidance and details for all of the above content can be found in the standard MRC Guidance for Applicants.

3.4 The Case for Support and Justification of Resources

The Case for Support

A jointly prepared Case for Support must be uploaded as a PDF to the Je-S and e-Rad application. The case for support may be up to 8 A4 pages in length (including illustrations, references and a project **Gantt chart**) plus an optional additional one-page methodology annex, using Arial 11pt typeface with margins of 2cms on all sides.

In your case for support you should address each of the following headings

1 title
2 importance of the research (including synergistic effects of the collaboration)
3 scientific potential
  3.1 people and track record (including plans for the participation of early career researchers)
  3.2 research environment
  3.3 research plans and deliverables
4 ethics and research governance
5 exploitation and dissemination.

6 Project Partners

Further guidance on content under each of these headings can be found in Annex 2.

Details of key issues included in the Collaboration Agreement, for example management of Intellectual property, should be detailed in the 'consideration of ethical, governance and Intellectual Property issues around the project' section of the Case for Support.

A one-page annex may be included in addition to the case for support page limit providing additional detail of the methodology and experimental design aspects of the proposal. This information must be provided as a clearly marked annex at the end of the main Case for Support entitled '**Methodology and experimental design annex'**. Please note that you are not required to duplicate information presented elsewhere in the application.

The use of this annex is strongly advised where the proposal includes the use of animals and/or human participants, or where the methodology/experimental design proposed is practically novel. Please see annex 2 for further guidance.

Justification of Resources (JoR)

Please complete the call-specific JoR template available on both the MRC and AMED call webpage, it must be written in a minimum font size of Arial, 11 point, with margins of at least 2 cm, justifying that the resources requested are appropriate to undertake the research project. The call-specific template includes details of the page limits.

You must complete one Justification of Resources (JoR) document justifying both the UK costs and Japanese costs and attach it to your application under "Justification of Resources". The JoR must contain a breakdown and explanation of the costs requested for this funding scheme by each partner taking into account the requirements outlined under the 'Funding available' section of this document.

The JoR should explain why the resources requested are appropriate for the research proposed, taking into account the nature and complexity of the research proposal. It should not be simply a list of the resources required.

In addition to the standard content for the Justification of Resources, applicants should include:

- the GBP and Yen value of resources requested by the UK researchers.
- the GBP and Yen value of resources requested by the Japanese researchers.

Please note, for the purposes of the completing this section: GBP=135JPY

This is so that the value of the total funds requested for the research project can be assessed.

The costs on both the UK and Japanese side should be separate with a clear justification of each cost.

An identical version of the Justification of Resource should be submitted to both MRC and AMED via Je-S and e-Rad.

3.5 Creating a Je-S account and application

Japan based applicants
Registration on the Je-S system is needed in order to participate in this joint call. Please read through the instructions below and follow your UK PI's instructions. Japanese based PIs also need to make a submission through e-Rad. (refer to the 2020 AMED Call Guideline for "The Program for Technological Innovation of Regenerative Medicine".)

UK based applicants
To submit full proposals, please login to your Je-S account via https://je-s.rcuk.ac.uk, using the username and password you have chosen (if you do not have a Je-S account, or have forgotten your password, please see the guidance provided further below).

Please note that ONLY the UK Principal Investigator creates the Je-S application, any collaborating investigators from other research organisation (UK or Overseas) are added to the application depending on their involvement and responsibilities whilst working on the project.

New Je-S users: In order to gain access to the Je-S System, create an account.

Important information when creating a Je-S account:

- **All Investigators (from the UK, Japan and any third country) involved in a grant project will need to be registered on Je-S. It is important to register on Je-S at least two weeks before the deadline as the process takes time to complete.**
- It is recommended that overseas Co-Investigators should ensure that their Research Organisation (RO) has been added to the Je-S database before they commence the Je-S account creation process.
- The create account process will require the applicant to accept the terms and conditions using the Je-S System, before the applicant can proceed with the account creation.
- Applicants can choose to 'Skip the ORCID identifier' as this is NOT required for the purposes of being added to the proposal as an 'Investigator', priority is to create a verified Je-S account to enable the Investigator to be included within the Je-S application.
- Investigators should select the account type 'Applicant on a Standard or Outline Proposal' (within the Research Proposals section).

If an overseas Co-Investigators is unable to select their RO when attempting to create their Je-S account, MRC recommend that the Investigator emails the Je-S Helpdesk JeSHelp@je-s.ukri.org, with the full name and address details of the Overseas Organisation and they will contact you with further instructions.

Creating your Je-S application:

- 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

The '**Call/type/mode**' listed below can only be selected when the call opening date has been reached (until the advertised call closing date of **20 February 2020).**

All MRC funding calls close at **16:00 local UK time**, on the advertised closing date.

- Select council: **MRC**
- Select document type: **Standard Proposal**
- Select scheme: **Research Grant**
- Select call/type/mode (optional): **Japan (AMED) – Regenerative Medicine**
- Select **'create document'** option

Please telephone Je-S Helpdesk +44 (0)793 444164 should you require any assistance with the Je-S system.

Project details: UK Project start date ***must*** **be 1 October 2020.**

3.6 Budgets

In total, up to approximately £7m will be made available for this initiative. The funding agencies intend to use these available funds to support **approximately 8 collaborative projects**, subject to quality.

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

UK based applicants

- **UK Full Economic Costing (FEC)**

MRC will make up to £5m available to cover the UK components of the **collaborative research projects** selected for funding under this call. UK based applicants may therefore request up to a maximum of £625k at 80% fEC to cover the UK component of the research project. [The MRC will provide funding under standard arrangements and at 80% of the full Economic Cost (fEC).] **The UK element of funding will not cover UK PhD studentships or requests for capital items.**

Projects must be three years in duration and must start on 1 October 2020.

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

UK funding available

	UK funding
Research costs: Staff – directly incurred post (e.g. Researchers, Technicians) Staff – directly allocated posts (PI and Co-I time)	 Yes 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 'Other Directly Incurred Costs' section on Je-S.

Japan based applicants
AMED will make up to 12,500,000 yen (inclusive of 30% overheads) available per annum per project for 3 Japanese fiscal years.

The planned budget for research projects may vary each fiscal year, depending on the planned activities specific to each project. Funding for Japan-based applicants are allowable for:

	Main Item	**Definition**
Direct costs	Costs of goods (equipment/supplies)	Research facilities/equipment/prototypes, software (readymade goods), book purchasing costs, purchasing costs for reagents/materials/consumables for use in research
	Travel costs	Travel costs of R&D participants, travel costs for invited participants such as external experts

	Personnel costs/ services costs	Personnel costs: personnel costs for researchers, etc., employed to conduct the relevant contracted R&D Service costs: expenditure for services such as lecture requests, guidance/advice, test subjects, interpreters/translators, and unskilled labour.
	Other	Costs for implementing the relevant contracted R&D other than the above. Examples: R&D results publication costs (academic paper contribution costs, academic paper offprint costs, website production costs, etc.), conference costs, equipment leasing costs, Equipment repair costs, printing costs, subcontract costs, licensing fee, amount equivalent to consumption tax related to untaxed transactions, etc.
Indirect costs[1]	Expenditure used by research institutes and paid by AMED as necessary costs for managing the research institutes during implementation of the relevant R&D, paid at a fixed percentage of direct costs (within 30%) as an allowance.	

For details, please refer to the AMED's "Administration Manual for Contracted R&D Agreement".

Link from: https://www.amed.go.jp/keiri/index.html

[1] Implemented when AMED concludes a contracted R&D agreement with a national university corporation, inter-university research institute corporation, independent administrative corporation, special corporation, special private corporation, general incorporated association, general incorporated foundation, public interest incorporated association, public interest incorporated foundation or private university, etc., and does not apply in the case that the researcher is affiliated with a national facility or other institution (excluding the National Institute for Educational Policy Research). The fixed percentage will not exceed 30%. With regard to Subsidiary Institutions (excluding national facilities or other institutions) also, indirect costs are allocated in accordance with direct costs.

Contract between Japan-based PI 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 PI's Institution. The contract for commissioned research will be signed each fiscal year 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 PI should consult with the department in charge at his/her institution.

Spending obligations

UK: Due to the tight time scales of this call, successful UK research organisations will need to adhere to strict spending requirements. For this call, the end date of the proposed research

should be no later than 30 September 2023. The UK payment profiles are likely to be slightly irregular for this scheme. If you have any questions about the payment profiles, please contact international@mrc.ukri.org

Japan: Projects must start by 15 September 2020 and complete in March 2023. The Japanese component of the projects will therefore be shorter than three years.

4. Assessment process and criteria

Following submission, peer-review will be undertaken by the funding agencies. To be funded, proposals must be internationally competitive and at a standard equivalent to that normally expected to be supported by each funding organisation. Applicants will be given the opportunity to provide a written response to peer review comments, in June, prior to the panel meeting.

Key assessment criteria and perspectives for the submissions will be:

- compatibility with the objectives and scope of the call
- significance and impact of the research
- scientific rationale: novelty, innovativeness, importance and timeliness of the research
- design and feasibility of the project plan
- partnership: including strength and clarity of collaborations and opportunities provided, and quality of the project management structure proposed; the added value of the UK-Japanese collaboration; engagement of early career researchers
- quality and suitability of the research environment and of the facilities
- value for money for Japanese and UK science
- ethical considerations and governance arrangements.

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

Peer review process

- Eligible applications will be externally peer reviewed, including written reviews by reviewers selected by MRC. In parallel the eligible applications will be reviewed by the evaluation committee members selected by AMED.
- The PIs will be offered the opportunity to provide a written response to both sets of reviews on behalf of all applicants.
- Following this process, applications will be assessed by a joint MRC-AMED Evaluation Meeting of academics selected by the funders.
- Applications will be given one overall score. The proposals with the highest scores will be funded in rank order subject to them meeting the minimum quality threshold.

It is envisaged that all applications will go through the full peer review 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.

Peer review assessment and scoring

The UK external peer reviewers will be asked to comment on all of the points listed in the table below in their written review. External reviewers will also be asked to give the proposal an overall score from 1-6. Further information on the scoring system is included in Annex 1.

The Japanese evaluation committee members will be asked to comment on the proposals. They will not be asked to give the proposal an overall score. The queries to PIs from the Japanese evaluation committee members will be provided together with the comments and scores of UK external peer reviewers.

The Joint evaluation committee will then be asked to consider the unified points and scoring system. Their assessment will be based on the proposal, the written reviews and the PI response to reviewer comments. The joint evaluation committee members will be asked to give the proposal an overall score from 1-10. The committee will consist of academic experts selected by both the UK and Japan, and will make a funding recommendation.

For further information on the UK peer review process, please see the **MRC peer review** page.

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. **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.

Details of key issues included in the Collaboration Agreement, for example management of Intellectual property, should be detailed in the 'consideration of ethical, governance and Intellectual Property issues around the project' section of the Case for Support.

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 at https://mrc.ukri.org/funding/guidance-for-mrc-award-holders/information-for-award-holders .

Japan based applicants
Japanese based applicants should refer to VII - Handling of R&D Accomplishments in the 2020 AMED Call Guideline for "The Program for Technological Innovation of Regenerative Medicine".

5.3 Material Transfer Agreements

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

It is the absolute responsibility of the PI 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 the Je-S proposal form 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. Section 5 of the standard MRC Guidance for Applicants has recently been updated to reflect amendments to this section of the Je-S form.

Applicants must be clear in their applications in which country the proposed research involving humans and/or animals will take place and must fully complete the ethical information section for research taking place in either country.

For Japanese based applicants
Japanese based applicants should refer to V.1.4. - Obligations of Research Institutes in implementing this Program in the 2020 AMED Call Guideline for "The Program for Technological Innovation of Regenerative Medicine"

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, although it is unlikely that proposals for this call will include animal research.

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 principal investigator/ research organisation must be prepared to furnish the MRC with a copy of the ethical approval, and any correspondence with the committees, if requested by the UK council. The principal investigator 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 Guidance for Applicants for a summary of ethical documents required.

5.5 Use of humans/human tissue

For Japanese based applicants
Please refer to V.4. (4) Compliance with Laws/Ordinances and Ethical guidelines in the related laws and guidance stated in the 2020 AMED Call Guideline for "The Program for Technological Innovation of Regenerative Medicine" (written in Japanese).

5.5.1 MRC guidance

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 PI and Japanese PI. 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 PI and Japanese PI 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 PI and Japanese PI 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) and must focus on the proposal it accompanies.

5.6 Use of animals

For Japanese based applicants
Please refer to V.4. (4) Compliance with Laws/Ordinances and Ethical guidelines to the related laws and guidance in the 2020 AMED Call Guideline for "The Program for Technological Innovation of Regenerative Medicine" (written in Japanese).

5.6.1 MRC guidance

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 Animals (Scientific Procedures) Act 1986), 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 'Use of Animals letter' (uploaded as a Letter of Support to the Je-S application) which MUST be signed by both the UK PI and Japanese PI 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 as a 'Letter of Support'.

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 Japanese based applicants
Please refer V.4. (4) Compliance with Laws/Ordinances and Ethical guidelines to the related lows and guidance in the 2020 AMED Call Guideline for "The Program for Technological Innovation of Regenerative Medicine (written in Japanese)

5.7.1 MRC guidance

Please see section 5 of the standard MRC Guidance for Applicants for further information.

If applicable, a signed and dated letter with the heading 'Use of Stem Cells letter' (uploaded as a Letter of Support to the Je-S application) should be submitted and MUST be signed by both the UK PI and Japanese PI.

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 on **1 October 2020**. The start of the grant may NOT be delayed beyond this date.

UK applicants should refer to the standard MRC Guidance for Applicants for information on what the starting procedure entails. Please inform the relevant support staff in your organisation of this requirement to ensure the project starts on time.

Please note that due to the requirement to start by 1 October 2020, the normal three months start period rules outlined in the UKRI Terms and Conditions RGC4, does not apply to this project.

Ethical requirements

It is the responsibility of the PI 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 PI/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.

UK requests for extensions to awards

Due to financial restraints of the Fund for International Collaboration, grant extensions will only be considered under exceptional circumstances (in line with the Equality Act 2010) and will require MRC agreement on a case-by-case basis. The Research Organisation remains responsible for compliance with the terms of the Equality Act 2010 including any subsequent amendments introduced while work is in progress; and for ensuring that the expectations set out in the Medical Research Councils' statement of expectations for equality and diversity are met.

7. Contacts and Guidance

Please read:

- the MRC call text (for UK based) and the MRC-AMED call text (for Japan based applicants)
- the AMED open call webpage (Japan based applicants)
- the current document, the call-specific Guidance for Applicants (both UK and Japan based applicants)
- the standard MRC Guidance for Applicants (for UK and reference for Japan based applicants)
- the 2020 AMED Call Guideline for "The Program for Technological Innovation of Regenerative Medicine (For Japan based applicants)

An identical version of the call-specific Justification of Resources document should be submitted to both the MRC and AMED.

For further information, UK applicants should contact: international@mrc.ukri.org

For further information, relating to the call or the AMED application Japanese applicants should contact: rminnov"AT"amed.go.jp（Replace "AT" with "@"）

Annex 1: External peer review scoring system

Proposals will be evaluated and rated overall on a scale ranging between 1 and 6 by scientific reviewers who will utilise the following score indicators.

Categories 1-2 are not worthy of funding.

Categories 3-6 are worthy of funding, subject to the availability of resources.

Score Indicators	Score
Exceptional - Top international programme, or of exceptional national strategic importance Scientific quality and impact - Crucial scientific question or knowledge gap or area of strategic importance - Original and innovative; novel methodology and design - Potential for high health and/or socioeconomic impact Scientific leadership - Excellent leadership *(track record, team, environment, and collaborators)* Justification of resources - Potential for high return on investment *(resources requested, likelihood of project delivery, anticipated knowledge generation)* - Appropriate staff time allocated to deliver project (*Principal investigators and co-investigators*) Other - Ethical and/ or governance issues are fully considered	**6**
Excellent - Internationally competitive and leading edge nationally, or of national strategic importance Scientific quality and impact - Crucial scientific question or knowledge gap or area of strategic importance - Original and innovative; novel methodology and design - Potential for high health and/or socioeconomic impact Scientific leadership - Excellent leadership *(track record, team, environment, and collaborators)* Justification of resources - Potential for high return on investment *(resources requested, likelihood of project delivery, anticipated knowledge generation)* - Appropriate staff time allocated to deliver project (*Principal investigators and co-investigators*) Other: - Ethical and/ or governance issues are fully considered	**5**
Very High Quality - Internationally competitive in parts Scientific quality and impact - Crucial scientific question or knowledge gap or area of strategic importance - Robust methodology and design *(innovative in parts*) - Potential for high health and/or socioeconomic impact Scientific leadership - Excellent leadership *(track record, team, environment, and collaborators)* Justification of resources	**4**

- Potential for significant return on investment - Appropriate staff time allocated to deliver project (*Principal investigators and co-investigators*) Other: - Ethical and/ or governance issues are fully considered	
High Quality Scientific quality and impact - Worthwhile scientific question or knowledge gap or a valuable scientific resource - Methodologically sound study - Potential for significant health and/or socioeconomic impact Scientific leadership - Strong leadership *(track record, team, environment, and collaborators)* Justification of resources - Potential for significant return on investment *(resources requested, likelihood of projected delivery, anticipated knowledge generation)* - Appropriate staff time allocated to deliver project (*may be scope strengthen management of the project)* Other: - Ethical and/ or governance issues are well considered	**3**
Good Quality Scientific quality and impact - Worthwhile scientific question with potentially useful outcomes - Methodologically sound study but areas require revision - Likelihood of successful delivery Scientific leadership - Appropriate leadership *(scope to strengthen team; environment; collaborators)* Justification of resources - Potentially more limited return on investment *(resources requested, likelihood of project delivery, and anticipated knowledge generation)* - Resources broadly appropriate to deliver the proposal Other: - Ethical and/or governance issues are adequately considered	**2**
Poor Quality Scientific quality and impact - Poorly defined question - Methodologically weak study - Limited likelihood of new knowledge generation Scientific potential - Poor leadership Justification of resources - Potentially poor return on investment Other: - Ethical and/ or governance issues are not adequately considered	**1**

Annex 2: MRC-AMED Case for Support Guidance

General guidance

The case for support should be a self-contained description of the proposed work with relevant background and should not depend on additional information. MRC and AMED reserve the right to withdraw proposals that contain links to additional information which extends the case for support.

Please note justification of resources is not required in the case for support. This is a separate document which should be attached to the Je-S and e-Rad application.

The guidelines below list general points that should be addressed when writing the case for support. However, each proposal is unique, and it is the responsibility of the applicant to ensure that all the reasonable questions that the reviewers need to address are answered in the proposal – especially if the plan or resources are unusual or complex.

The scientific case should be set out under each of the headings specified in the guidance notes for the specific funding scheme.

This guidance should be read in conjunction with the information on the assessment criteria, which provides detailed information on what reviewers are looking for. All information that the applicants wish to be considered as part of their research proposal (within the page limits stipulated) must be attached with their proposal form. **The proposal cannot be supplemented by further information beyond the deadline for submissions.**

The proposal and case for support will be sent out to a number of reviewers to read. Feedback from reviewers has shown that they are keen to see clarity, succinctness and accessibility.

Proposals which do not meet the following requirements will be returned unprocessed:

- Use sans-serif typeface (Arial or equivalent), font size of 11pt (this includes any references listed within the case for support) and margins of 2cm on all sides.
- Only include one PDF document for the case for support, which must be within the page limit stipulated.
- The only acceptable annex is the: Reproducibility and statistical design (see below)
- Any unpublished data must be included in the case for support. Preprints may be included in publication lists. Manuscripts in press or submitted to journals should not be included.

Case for support content

1. Title	**The title of of the proposed project** This should be no more than 150 characters and reflect the aim of the project.
2.Importance of the research	Explain the need for research in this area, and the rationale for the particular lines of research planned. • Justify the research, either through its importance for human health, or its contribution to relevant areas of basic biomedical science. • Give sufficient details of other past and current research to show that the aims are scientifically justified, and to show that the work will add distinct value to what is already known, or in progress. • Where relevant, explain how plans benefit, fulfill unmet needs or contribute to current plans in the health service or industry. • Where the research plans involve creating resources or facilities, or forming consortia, networks or centres of excellence, the case will need to address the potential added value, as well as issues of ownership, direction and sustainability. • Explain the synergistic effects of the collaboration
3.Scientific potential	*3.1People and track record* • Each of the CVs will be uploaded separately as attachments in both Je-S and e-Rad. If it is not obvious, the applicant may elaborate on why the group is well qualified to do this research in the case for support. • Explain plans for the participation of early career researchers. • Explain how each of the investigators named in the proposal will work together and outline other major collaborations important for the research. • The applicant should acknowledge any previous or current MRC/AMED funding and describe progress-to-date on delivery of this research. The quality and productivity of the recent work will be a factor in assessing the likely quality of future work. • If the applicant has not been active in research recently, simply state this. • Describe any other factors which the applicant considers may promote delivery of the proposal. *3.2Research Environment* • Describe how the scientific or clinical environment(s) in which the research will be done will promote delivery of the proposed research. • Explain how the research will benefit from facilities provided by the host Research Organisations. • Describe any clinical, commercial, or organisational dependencies necessary to support the research, or to help translate it into practice. *3.3Research plans and deliverables* • Describe the research plan and deliverables clarifying the Japanese and UK components. Please describe: ○ the goal(s) to be achieved at the completion of the research, concisely and quantitatively.

	○ how the research results may contribute to overcoming current challenges, from a long-term perspective, and how they may contribute to the field of stem cells/regenerative medicine or, for example, new drug design (which might include the expected number of years to accomplish the expected results and the degree of lowering costs (if this is the focus) etc.). • Give details of the general experimental approaches, study designs, and techniques that will be used (the one-page 'Reproducibility and statistical design' annex should be used to supplement information in this section, where necessary and as appropriate. It is not necessary to describe each experiment, but give enough detail to show why the research is likely to be competitive in its field. For example: ○ Highlight plans which are particularly original or unique ○ Describe all foreseeable human studies and animal experiments (in as much detail as possible at this stage) ○ Explain in greater detail how new techniques, or particularly difficult or risky studies, will be tackled, and alternative approaches should these fail ○ Identify facilities or resources you will need to access ○ Give sufficient detail to justify the resources requested • If this is a pilot work or proof of principle proposal, give a brief description of likely subsequent proposals if the work is successful. • Explain opportunities or plans for pursuing commercial exploitation
4.Ethics and research governance	• Describe briefly the ethical issues arising from any involvement of people, human samples or personal data in the research proposal. Please give details of how any specific risks to human participants will be controlled, and of any new animal research the MRC and AMED would be supporting. • Describe the ethical review and research governance arrangements that would apply to the work done.
5.Exploitation and dissemination	• Is the proposed research likely to generate commercially exploitable results? • What arrangements and experience does the research group or the host research organisation have to take forward the commercial exploitation of research in this area? • Other than publication in peer reviewed journals, indicate how any results arising from the research will be disseminated so as to promote or facilitate take up by users in the health services.
6.Project partners	• All partner contributions, whether in cash or in-kind, should be explained in detail, including the equivalent value of any in-kind contributions • In-kind contributions can include staff time, access to equipment, sites or facilities, the provision of data, software or materials.

Reproducibility and statistical design (recommended annex)

The purpose of this annex is to provide important additional information on reproducibility, and to explain the steps taken to ensure the reliability and robustness of the chosen methodology and experimental design. Please note in this context, methodology refers to the rationale for choosing which method to use and not the provision of detailed descriptions of the methods to be used.

It is **strongly advised** that a one-page annex to the case for support is included, to provide additional information specifically relating to the statistical analyses, methodology and experimental design aspects of the proposal (beyond that contained in the main case for support). Please note that you should not duplicate information presented elsewhere in the application.

This information must be provided as a clearly marked annex at the end of the main case for support, entitled 'Reproducibility and statistical design annex' and should not be added as a separate attachment. Standard formatting guidance applies. Applications not adhering to these conditions will be returned unprocessed.

Applications that do not provide sufficient detail to convince reviewers that the proposed experiments will be carried out appropriately to produce robust and reproducible research will be rejected for funding on these grounds and subject to the usual limits on resubmission.

To see worked examples of experimental design: https://mrc.ukri.org/documents/pdf/worked-examples-experimental-design/.

The NC3Rs have developed a free online tool to guide researchers through the design of their experiments, helping to ensure that they use the minimum number of animals consistent with their scientific objectives, methods to reduce subjective bias, and appropriate statistical analysis. The NC3R's Experimental Design Assistant can be found on the NC3R's website. Applicants may wish to embed the summary output figure of this tool into their one-page annex.

What to include in the annex

It is expected that professional statistical (or other relevant) advice would be sought in putting this section together. Each experiment does not need to be described in detail, but sufficient information must be included that reviewers are readily able to understand the experimental plan. Where appropriate, the use of figures, tables and/or diagrams is encouraged.

The following table highlights the key points you should include in the annex.

Experimental approach to address objectives. This information may be provided in diagrammatic or tabular form if appropriate.	• Primary and secondary experimental outcomes to be assessed (e.g. cell death, molecular markers, behaviour change) and how these relate to experimental objectives • Number of experimental and control groups • A clear definition of the 'experimental unit' in the analysis and the implications thereof (i.e. there is a difference between N samples from one animal, as distinct from one sample from each of N animals, or combining samples from multiple animals) • Number of 'experimental units' in each experimental group. • Total number of 'experimental units' to be measured • Number of times each 'experimental unit' will be measured • Number of independent replications of each experiment. • Steps taken to minimise the effects of bias (e.g. blinding, randomisation) or an explanation of why this would not be appropriate • Breeding strategies may be included here, if applicable.
Justification of model(s) chosen (e.g. animal model, cell line etc.	• How and why the models and/or methods are appropriate to address the scientific objectives
Sample sizes	• Show clearly how effect sizes have been calculated and justify how they are biologically relevant • Demonstrate that statistical power calculations are grounded in justifiable and explicit assumptions about both anticipated effect size and variability of the experimental effects • If statistical power calculations cannot reasonably be applied, applicants should provide a principled explanation of the choice of numbers • Explanations based solely in terms of 'usual practice' or with reference solely to previously published data will not be considered adequate.
Planned statistical analyses and their relation to the choice of sample size	• Overview of the planned statistical analyses in relation to the sample size • Details of any statistical/methodological design advice sought (you may cost a relevant expert, e.g. statistician, into your proposal if necessary and justified). A letter of support from the expert involved is permitted, but not mandatory

What not to include in the annex

The annex should not to be used as a simple continuation of the methods set out in the case for support; please do not include detailed descriptions of the methods. Applications misusing the annex in this way will be returned. The case for support should be a self-contained description of the proposed work with relevant background and should not depend on additional information.