FY2019
Advanced Research and Development Programs for Medical Innovation (AMED-CREST, PRIME) Application Q&A

Q&A information can also be found on the Calls for Proposals website.
URL: https://www.amed.go.jp/koubo/04/02/0402B_00022.html

Please refer to the following website for information about operation of the Cross-ministerial R&D Management System (e-Rad) and registration of affiliated research institutions and researchers, as well as how to use e-Rad:
URL：https://www.e-rad.go.jp/

1. Matters common to both AMED-CREST and PRIME

(1) Eligible applicants

Q. Are part-time researchers (visiting scholars, etc.) eligible to apply? Also, am I eligible even if I will be retiring during the R&D period?

A. You are eligible to apply if you are able to establish an R&D project organization at a research institution in Japan during the R&D period, and AMED is able to conclude a contracted R&D agreement with this research institution. With regard to principal institutions and subsidiary institutions that are national facilities or other institutions (general term for national facilities or other institutions or public research institutes), only in the case that the relevant institution and the R&D PI or Co-Investigator affiliated with the relevant institution makes a request based on reasonable grounds and following discussion with AMED shall the method of payment of the R&D grant being paid by AMED to the R&D PI or Co-Investigator of the relevant institution be adopted.

(2) Approval by affiliated institutions

Q. When making an application, is the approval of the affiliated institution required?

A. Yes. Please note that procedures to obtain approval for submission of the R&D project from your affiliated research institution have been added to the e-Rad application process for the Advanced Research and Development Programs for Medical Innovation, beginning with applications for FY 2017. If an R&D proposal is selected for the program, a contracted R&D agreement shall be concluded between AMED and the research institution where the R&D PI conducts research. Furthermore, in the case of AMED-CREST, the subsidiary institution with which the R&D Co-Investigator is affiliated shall conclude a subcontracted R&D agreement with the principal institution to conduct R&D subcontracted by the principal institution to the subsidiary institution. When submitting an application via e-Rad, please ensure that the R&D PI confirms that the proposal also has the approval of the subsidiary institution(s) before obtaining the approval of the principal institution, and this should be conveyed to affiliated research institutions.

However, with regard to principal institutions and subsidiary institutions that are national facilities or other institutions (general term for national facilities or other institutions or public research institutes), only in the case that the R&D PI or Co-Investigator affiliated with the relevant institution makes a request based on reasonable grounds and following discussion with AMED shall the method of payment of the R&D grant being paid by AMED to the R&D PI or Co-Investigator of the relevant institution be adopted.

In the case of subcontracted R&D agreements, as a general rule the subcontracted institution shall perform institution accounting on the condition that they respond to requests by AMED to conduct audits, etc.

(3) Simultaneous applications for JST Strategic Basic Research Programs and AMED Advanced Research & Development Programs for Medical Innovation

Q. Is it possible to apply simultaneously to both JST CREST/PRESTO and AMED-CREST/PRIME programs included under these Application Guidelines?

A. Yes. There are no restrictions on doing this. However, please note that, as explained in "V. 9. (5) Elimination of Unreasonable Duplication or Excessive Concentration of Research Funds" in the Application Guidelines, selection is also performed from the viewpoint of "unreasonable duplication" and "excessive concentration" of R&D funds.

(4) When a JST Strategic Basic Research Programs project is currently underway

Q. Is it possible to apply to AMED-CREST or PRIME even when currently carrying out a JST CREST or PRESTO project?

A. Applications are not accepted from R&D PI who were selected for JST programs up to FY2014 and are now executing projects in transferred R&D areas under AMED, with the exception of projects that will finish in FY2019. However, applications can be submitted for other research areas in which JST programs are currently underway since these are not subject to any restrictions.
Please note that, as explained in "V. 9. (5) Elimination of Unreasonable Duplication or Excessive Concentration of Research Funds" in the Application Guidelines, selection is also performed from the viewpoint of "unreasonable duplication" and "excessive concentration" of R&D funds.

(5) Submitting an application when affiliated with an overseas research institution and securing a place to conduct research in Japan

Q. I am currently affiliated with an overseas research institution; can I apply to the program?

A. In the case of PRIME, it is possible to submit an application on the condition that you are able to establish a system for conducting R&D at a research institution in Japan by the date that R&D is due to commence (October 1, 2019). In the case of AMED-CREST, it is possible to submit an application on the condition that you have been accepted by a research institution in Japan and have obtained the approval of the research institution to carry out the R&D project. Please also refer to the Q&A section of "(10) Applying via the e-Rad system".

(6) Continuation of R&D projects following transfer of the R&D PI

Q. If the R&D PI is transferred (promotion, transfer to a different research institution, etc.) while carrying out the R&D project, will the R&D PI be permitted to continue the R&D project?

A. Provided it is possible for the R&D PI to continue working on the R&D project unhindered following the transfer, the R&D project may be continued. Having another person take over as R&D PI of the project as the result of a personnel transfer, however, is not permitted.

(7) Transfer of equipment, etc. following a change in affiliated institutions

Q. If the research institution affiliation changes because of a personnel transfer or other reason while the R&D project is being carried out, is it possible to move the equipment, etc., purchased with R&D funds to the new research institution?

A. Equipment, etc., purchased with contracted R&D funds (direct costs) must, in principle, be transferred (via transfer of ownership, etc.) to the new research institution.

(8) Use of R&D costs

Q. Is it possible to outsource work such as program preparation to an external company, etc.?

A. If it is required for the R&D, outsourcing is accepted. However, this is based on the premise that subcontracting of work to outside parties is in accordance with subcontracting agreements that exclude R&D elements.

(9) Proposal document format

Q. Can I submit an application using forms other than the specified proposal forms?

A. When submitting an application, be sure to use the proposal forms for this round of solicitation that have been specified for each R&D area and type of research. Your application may not be accepted if you use proposal forms for previous fiscal years or that are otherwise different from those specified. For further information, please refer to “IV. 2. (1) Proposal Document Format” in the Application Guidelines.

Q. How should I fill in the “R&D area,” “R&D discipline,” “R&D field,” and “Key words of R&D field sections of the R&D Proposal?
A. For this application, you do not need to fill in the “R&D area,” “R&D discipline,” “R&D field,” or “Key words ofR&D field sections of the R&D Proposal.

Q. Is it possible to use color for text or figures and tables in R&D proposals? Do evaluators read R&D proposals in color when assessing R&D proposals?
A. Evaluators do read R&D proposals in color when assessing them. However, proposals may be printed out from PDF files, so we ask that you take care to use figures and tables that are easy to read, even at low resolutions.

Q. Can I delete the notes in blue and black text, as well as the out of text parts in green text on the R&D Proposal form?
A. The notes in blue text are examples showing how to fill out the proposal form, and the out of text parts in green text are supplementary explanations, so these may be deleted. However, you should not delete the notes in black text.

Q. I expect to be transferred after the acceptance period for application documents, so what should I write on the application form for information regarding my affiliated institution and the person in charge of accounting work during the application period?
A. In your application documents, please provide information about your current affiliated institution (your affiliated institution at the time of submission), and if necessary, provide an explanation of your situation in the “References and Additional Statement” on the R&D proposal forms (Annex E5, Annex J5, Annex P4). Carry out procedures via the e-Rad system to obtain approval of the submission of the R&D proposal from the affiliated institution at your institution at the time of submission. Please also obtain the approval of your new affiliated institution before your transfer.

Q. What is the “researcher number” referred to on the R&D Proposal form?
A. The “researcher number” is an 8-digit researcher identification number assigned when researcher information is registered on the e-Rad system (cross-ministerial R&D Management system [http://www.e-rad.go.jp/]). For details regarding registration of researcher information, please refer to “III. 2. (3) Submission of Proposal Documents” in the Application Guidelines.

Q. At present, I am affiliated with an overseas research institution and have no researcher number. What should I do?
A. Please apply for your own researcher number by sending (by postal mail) a completed Researcher Number Issuance Request Form, a copy of your ID, and other required documents directly to the e-Rad system administrator. For further information, please refer to “How to Register” in “For Researchers (not affiliated with a research institution)” under “Registration and Procedures” on the e-Rad portal site. If you are affiliated with a research institution located outside Japan, it will not be possible for you to submit your application via e-Rad, so please be sure to contact the AMED staff in charge of applications via e-mail (kenkyuk-kobo”AT”amed.go.jp) a minimum of two (2) weeks before the end of the acceptance period (Please change “AT” to @ when inputting the address).

(10) Applying via the e-Rad system
Q. Can I revise the application documents after I have submitted the application via e-Rad?
A. To revise the application documents after you have submitted them, if it is within the acceptance period (or before the deadline for submission), you will need to carry out the “Withdraw” procedures on the e-Rad system and submit the application again after you have revised it. Be sure not to carry out the “Withdraw” procedures on the day that is the deadline for submission. If the

deadline for submission of applications has already passed, you will not be permitted to replace submitted application documents under any circumstances. For further information, please refer to "III. 2. (3) Submission of Proposal Documents" in the Application Guidelines.

Q. When applying via e-Rad, is it necessary to convert all of the application documents into PDF format?
A. If you are applying for the AMED-CREST R&D areas of "Molecular understanding of the biological phenomena and responses at the early life stages to improve the quality of health and medical care" and "Understanding of pathophysiological processes and discovery of medical technology seeds through spatiotemporal research of tissue adaptation and repair mechanisms", please submit the "R&D PI and R&D Co-Investigators List" in Excel format. All other application documents must be converted into PDF format for submission. If you are applying for the AMED-CREST R&D area "Clarification of the mechanism of individual's functional impairment over the entire life course" or PRIME, all application documents must be converted into PDF format for submission. For details, please refer to section "IV. 2. Proposal Document Format and Notes for Preparation" of the Application Guidelines.

Q. My affiliated institution registered on e-Rad is not the same as my actual (current) affiliated institution. Will there be any problems for me submitting an application?
A. If your registered affiliated institution is a previous affiliated institution or otherwise differs from your actual affiliated institution, your application information will be sent to the clerical affairs supervisor for e-Rad matters of your previous affiliated institution, the process of approval by your affiliated institution may not be carried out, leaving your application submission uncompleted. **In this case, AMED will not accept your application for any reason.** Please contact the clerical affairs supervisors for e-Rad matters of both your previous and your current affiliated institution and request that they correct your affiliated institution information. Please refer to the e-Rad portal site for the necessary procedures.

Q. I am currently not affiliated with a research institution; is it possible to apply via e-Rad?
A. It is not possible for you to apply via e-Rad. In cases such as this, you need to undertake proxy registration procedures with AMED, so please be sure to contact AMED staff via e-mail (kenkyuk-kobo"AT"amed.go.jp) a minimum of two (2) weeks prior to the end of the acceptance period (Please change "AT" to @ when inputting the address).
Please note that there have been cases in which submission of an application could not be completed because the applicant had not changed their e-Rad affiliated institution information from their previous institution to their current affiliated institution. **In this case, AMED will not accept your application for any reason.**

Q. Currently I am affiliated with a research institution that is located outside Japan, Is it possible for me to submit my application via e-Rad?
A. It is not possible for you to apply via e-Rad. In cases such as this, you need to undertake proxy registration procedures with AMED, so please be sure to contact AMED staff via e-mail (kenkyuk-kobo"AT"amed.go.jp) a minimum of two (2) weeks prior to the end of the acceptance period (Please change "AT" to @ when inputting the address).

(11) Possibility of having a representative interviewed in the interview screening

Q. If the date of the interview screening is inconvenient, is it possible to have someone else (a representative) interviewed in my place? Alternatively, is it possible to set a different interview date?
A. It is not possible to have someone else interviewed in your place. In addition, since interview dates were set after coordinating the schedules of numerous evaluators, setting a different interview date is also not possible. Please check the interview schedule shown in "III. 2. (4) Schedule for Review" in the Application Guidelines. Interview schedules for individual R&D areas will be posted to the Calls for Proposals website (https://www.amed.go.jp/koubo/04/02/0402B_00022.html).

(12) Roles of the PS and PO

Q. Who is the Program Supervisor (PS) and the Program Officer (PO) for the program? What roles do they perform?

A. The PS and PO are responsible for determining policies for managing R&D areas, selecting R&D projects, adjusting and approving R&D plans (including R&D funds and R&D unit organization), as well as exchanging opinions with the R&D PI by visiting their research facilities and providing advice and instructions regarding R&D projects, evaluation of R&D projects, and management of R&D areas.

(13) Conflicts of interest involving applicants and PS/PO

Q. Can I submit an application if I have a conflict of interest with a PS and/or PO?

A. Yes. The restrictions on applicant eligibility due to conflicts of interest involving applicants and the PS/PO that were in effect up to FY 2017 are no longer in effect, beginning with solicitations for FY 2018.

Q. Can the PS and PO be involved in the review of an application by a researcher if they have a conflict of interest with that researcher?

A. In the process of selecting R&D projects for this program, projects are evaluated by a Project Evaluation Panel comprising Project Evaluation Panel members (PS, PO, advisors, etc). From the standpoint of conducting fair and transparent evaluations, COI management is carried out for Project Evaluation Panel members in accordance with AMED regulations, and in principle Project Evaluation Panel members who have a conflict of interest are not involved in the evaluation of that project. For more information, refer to “III.3. Method for Reviewing Proposal Documents” in the Application Guidelines.

(14) Information on the applications submitted for the previous fiscal year

Q. Please provide information on the R&D projects selected and applications submitted for the previous fiscal year.

A. Please refer to the following website for information on the R&D projects selected and applications submitted for the previous fiscal year.
https://www.amed.go.jp/koubo/04/02/0402C_00009.html

(15) Supportive measures for life events during the R&D period

Q. Is it possible to suspend and then resume R&D projects in response to life events (childbirth, child care, and nursing care)?

A. If the R&D PI experiences a life event, it is possible, upon consultation with the PS/PO, to suspend the R&D project for periods of time designated for individual life events and then resume their research. In this case, the R&D plan, including R&D costs, will be reviewed taking the effects of suspension on the project into consideration.

2. Matters regarding AMED-CREST

(1) R&D unit organization

Q. Is it possible for multiple research institutions to form a single group? Is it necessary for groups to always be divided by research institution?

A. If there is a need for multiple institutions (laboratories, departments, research institutions, etc.) to be engaged in research in the same R&D items, these institutions may form a single group. However, if expenditure needs to be calculated for institutions on an individual basis, the group must be separated into a principal institution that has concluded a contracted R&D agreement with AMED and subsidiary institutions that have concluded subcontracted R&D agreements with the principal institution. For details, please make inquiries after your proposal has been adopted.

Q. Is it possible to include a researcher affiliated with an overseas research institution in an R&D unit as an R&D Co-Investigator?

A. It is possible if the required conditions are fulfilled. For example, participation of the relevant researcher is essential for realization of the proposed R&D initiative; it is possible to conclude a subcontracted R&D agreement with the principal institution; and intellectual property is transferred to the principal institution. Please refer to the conditions stipulated in "II. 2. Requirements for Organizing an R&D Project" in the Application Guidelines.

Q. What criteria is used to determine whether the implementation of research would be difficult if it were not carried out at a foreign institution?

A. The criteria for conducting research at a foreign institution are shown below.

1. Required facilities do not exist in Japan and are only available at a foreign institution.
2. Field studies that can only be performed overseas are required.
3. Research materials can be obtained only at a foreign research institution or foreign location and cannot be brought to Japan.

(2) R&D implementation system and budget allocation

Q. Please cite R&D Co-Investigator group organizational approaches for the R&D implementation system and R&D Co-Investigator group budget allocations that are unacceptable.

A. Unacceptable organizational approaches include (but are not limited to) those in which: 1) The R&D PI does not play the central role in the R&D organization for pursuing the proposed R&D initiative; 2) A substantial portion of the R&D is subcontracted to one or more external part(ies); 3) The role and position of the R&D Co-Investigator group within the R&D initiative is unclear; and 4) The budget is allocated equally to the R&D Co-Investigator group without considering its role and position.

Q. Is it possible to change the R&D project organization and total budget included in the R&D Proposal during the interview screening?

A. Selections will be made based on the content of the R&D Proposal, so please carefully consider the content at the time of application so that no alterations are subsequently required. Please note that at the time the project is adopted, changes may be requested in accordance with instructions from the PS.

Q. Is it necessary to distribute funding from the start of the R&D period to R&D Co-Investigators who join the project after the R&D has progressed?

A. It is not possible to distribute R&D funding to R&D Co-Investigators who have joined the project part-way through the R&D period for the period in which they have not been involved in the R&D. At the time of application submission, the overall R&D plan will be screened regarding whether or not the necessary system for realizing the R&D concept has been put in place, so please include in your R&D proposal information about any R&D Co-Investigators who it is planned will join the project part-way through.

(3) R&D budget

Q. Should the basis for estimation and the yearly budget be included in the R&D proposal?

A. It is not necessary to include the basis for estimation, but it is necessary to include the R&D budget plans by item and research group in the R&D proposal. In addition, those selected for participation in the interview screening will be asked to prepare supplementary information covering matters such as R&D expenditure details.

Q. After an R&D proposal is selected, how should the R&D funds be allocated within the R&D unit (R&D project)?
A. The allocation of R&D funds within the R&D unit is determined based on the overall R&D plan that was formulated immediately after the project was adopted and the annual R&D plan that is prepared each fiscal year. For further information on R&D plans, please refer to "VI. 1. Project Management" in the Application Guidelines.

(4) Contracted R&D Agreement

Q. Is the contracted R&D agreement of the research institution with which a R&D Co-Investigator is affiliated concluded in the form of a subcontracted R&D agreement with the research institution with which the R&D PI is affiliated and not directly with AMED?
A. Yes. Under this program, beginning with projects selected for FY2017, R&D conducted by subsidiary institutions takes the form of R&D subcontracted by the principal institution. Accordingly, AMED only concludes a contracted R&D agreement with the principal institution, and each subsidiary institution concludes a subcontracted R&D agreement with the principal institution. Even though the agreement is in the form of a subcontracted R&D agreement, please ensure that R&D obligations are fully met. For details regarding subcontracting, please refer to the "Administration Manual for Contracted R&D Agreements with the Japan Agency for Medical Research and Development" on the AMED website (only in Japanese).

(5) Duplicate applications

Q. Is it possible to submit an AMED-CREST R&D proposal as the R&D PI and participate in another R&D proposal as an R&D Co-Investigator?
A. It is possible, but if both proposals are short-listed, R&D funding may be reduced or the researcher in question may be asked to participate in only one of the R&D projects, depending on factors such as the content and scale of the R&D to be carried out. Please note that having another researcher change places with the R&D PI or a R&D Co-Investigator in order to submit an application is not permitted. For further details, please refer to "II. 3. Limitations on Duplicate Applications within the Program" in the Application Guidelines.

(6) Applications in the R&D areas "Understanding of the biological phenomena and responses at the early life stagesto improve the quality of health and medical care" and "Understanding of pathophysiological processes and discovery of medical technology seeds through spatiotemporal research of tissue adaptation and repair mechanisms"

Q. Who are the AMED reviewers?
A. AMED reviewers are researchers affiliated with overseas research institutions who have deep insight into the research fields that comprise the target R&D area.

Q. Why will AMED reviewers be participating in the review process?
A. AMED has decided that AMED reviewers should participate in the ex-ante evaluation process, in order to further improve the quality of project evaluations and help internationalize the R&D environment. For this reason, since FY2018, AMED reviewers have also been participating in newly established R&D areas for this program.

Q. Are the interviews (hearings) also conducted in English?
A. As a rule, the hearings are conducted in Japanese. Hearings can also be conducted in English if it would be difficult to conduct them in Japanese.

Q. Can I submit the application documents in Japanese?

A. Of the items in the application documents to be submitted, “1. Research objectives,” “2. Research Plan and Approaches,” “3. Research Achievements (Form E1),” and “Summary of Proposal (Appendix E2)” should be submitted in English. The application will not be accepted if these items are written in Japanese.

Q. Why do I need to submit a “Security Trade Control Checklist (Appendix E2)?
A. With the addition of AMED reviewers to the review process, it was necessary for AMED to take steps to ensure security trade control.

Q. How is the “Security Trade Control Checklist (Appendix E2)” (in Japanese only) used?
A. The content of the form will be used only as needed for the purpose of ensuring security export control and will not affect the review in any way. For further information, please refer to “II. 5. (4) Security Trade Control (Countermeasures to Technology Leakage Overseas)” and “IV. 2 (1) Proposal Document Format” in the Application Guidelines.

Q. Will AMED reviewers participate in the review process for proposed projects in other R&D areas or PRIME?
A. AMED reviewers will not participate in the review process for the R&D area “Clarification of the mechanisms of individual’s functional impairment over the entire life course” and projects proposed for PRIME.

Q. Under security trade control regulations, are there cases in which AMED reviewers do not participate in reviews? In such cases, how is the fairness of reviews ensured?
A. There are cases in which AMED reviewers do not take part in reviews due to security trade control regulations. In such cases, to ensure that the presence or absence of AMED reviewers does not create significant unfairness, the Project Evaluation Panel discusses applications after carefully examining the evaluations and comments of AMED reviewers.

(7) R&D evaluations

Q. How is the selected R&D project evaluated?
A. In principle, the R&D project undergoes:
1) a mid-term review, conducted approximately three years after the start of R&D; and
2) an ex-post evaluation, conducted just before the conclusion of the R&D period.
For details, please refer to “VI. 2. Evaluation” in the Application Guidelines.

3. Matters regarding PRIME

(1) Requirements for applicants

Q. Is there an age limit for PRIME applicants (R&D PI)?

A. There is no definitive age limit. However, it is hoped that PRIME can help to boost the careers of young researchers.

Q. Is it possible to submit a PRIME R&D proposal as the R&D PI and participate in an AMED-CREST R&D proposal as an R&D Co-Investigator?

A. It is possible to submit a PRIME R&D proposal. However, if the applicant is already participating in an AMED-CREST R&D project as an R&D Co-Investigator and his/her PRIME R&D proposal is short-listed, or if both the applicant's PRIME R&D proposal and the AMED-CREST R&D proposal in which the applicant is to participate as a R&D Co-Investigator are short-listed, adjustments such as revising the applicant's position in the proposed R&D project under AMED-CREST or choosing either participating in the AMED-CREST R&D project or pursuing the PRIME R&D project may be required (excluding projects ending in FY2019). It is advisable, therefore, to carefully consult with the person who is or who is to be the AMED-CREST R&D PI before submitting a PRIME R&D proposal.

Q. Can fellowship researchers at the Japan Society for the Promotion of Science apply for the PRIME program?

A. There are no restrictions on the applicant's position at the time of application. Researchers who are currently performing R&D under the program of an institution other than AMED, or who intend to apply to do so, should ask the relevant institution whether it is appropriate to conduct R&D concurrently under its program and the PRIME program.

(2) R&D budget

Q. Should the basis for estimation and the yearly budget be included or noted in the R&D Proposal?

A. A basis for estimation is not required, but the budget for each fiscal year should be included. However, those selected to participate in the interview screening will be asked to prepare supplementary information covering matters including R&D budget details, etc.

(3) R&D participants to be included on the R&D Proposal form

Q. Is it necessary to include R&D participants in Annex P2 "R&D Implementation System" on the R&D Proposal form?

A. If there are any laboratory assistants or other R&D participants who are not the R&D PI, please include those who are expected to participate in the project at the time that the application is submitted.

(4) Personnel costs

Q. Can the personnel costs for the R&D PI be paid out of the R&D funds? Are there any cases in which the personnel costs for the R&D PI are provided separately in addition to R&D funds?

A. As explained in "II. 1. Eligible Applicants" in the Application Guidelines, applicants must be affiliated with a domestic Japanese research institution, and in general, a system for carrying out the proposed R&D is organized at this institution. Therefore, in principle, the personnel costs should be paid by the affiliated institution. However, please inquire individually in cases such as when, under the employment conditions of your affiliated research institution, your personnel costs are paid from external funds that you have been awarded.

(5) R&D Collaborators

Q. Is it possible to include R&D Collaborators in the project? Also, is it possible to include researchers at other institutions in the project as R&D Collaborators?

A. If their participation is essential to the realization of the R&D concept for the project for which you are submitting an application, it is possible to include R&D Collaborators in the project. It is also possible to include researchers at other institutions in the project as R&D Collaborators, but it is not possible to distribute R&D funding to them.

Reference: Matters regarding the R&D areas (from the Q&A at the Briefing of Solicitation)

R&D area: Investigations into life phenomena and the discovery of medical technology seeds based on spatiotemporal insights into biological tissue adaptation and repair mechanisms

Q. Emphasis is placed on integrating different fields of research, but under PRIME, is it also possible to submit proposals in this R&D area that include the potential for future collaborations with researchers in other fields?
A. Yes, it is possible. We also accept proposals that incorporate technologies from researchers in other fields in order to develop the research further.

Q. It may be difficult to generate results during the R&D period from the analysis of all cell-cell interactions between organs and within each organ—which should be prioritized in a proposal?
A. It depends on the circumstances in each case. Even for a single organ, if it is possible to clarify the cells and factors derived from various sites at the time of repair, we will probably obtain sufficient clarification on the processes of repair. Therefore, from the outset, there is probably no need to analyze every single cell-cell interaction between organs and within each organ.

Q. Does the best approach include verification in human tissues once detailed analysis at the molecular and cell level has been done using animal models?
A. It all depends on the content of the proposal, so I cannot give one overall answer. However, even with analysis using mice, we see sufficient value in research that clarifies new cells or factors and features a pathway through to applications in humans.

Q. Are the research subjects limited to mammals? Is it also possible to submit proposals that use model animals as materials for technology development?
A: We welcome proposals as long as they have appealing research content, particularly for PRIME.

Q. MEXT's specific research examples of Research and Development Objectives include "Apply genome editing, single cell analysis, or organoid technologies." Is my understanding correct that the research should aim to clarify the pathophysiology and that these technologies should be used for this purpose if they are suitable, rather than research to originate such technologies?
A. That is correct. Proposals can be submitted even on well-established technologies if their use leads to new discoveries or new perspectives.

Q. Does this R&D area include research into the molecular mechanisms of cell death?
A. This R&D area prioritizes an understanding of the adaptation and repair mechanisms found in tissues in response to stress or injury. If the research proposal discusses the impact on the surrounding tissues of a failure in repair that leads to the death of certain cells, the research content would be consistent with this R&D area. However, if the research proposal focuses on the mechanism by which stress leads to death of a single population of cells, then it would not be consistent with the direction of this R&D area.

R&D area: Clarification of the mechanism of individual functional impairment over the entire life course

Q. PRIME covers a wide range of subjects for research, but would this area include research into how an individual is affected by disease in a particular organ?
A. If the applicant thinks that the proposal is consistent with individual functional impairment, then please submit it.

Q. Is it acceptable if disease is the cause of the functional impairment?
A. This R&D area includes functional impairment caused by disease, or environmental factors, or even an autonomous decline.

Q. There are two items (points 1 and 2) for the Goals to be achieved in the MEXT's Research and Development Objective (page 60 of the Application Guidelines). Is it possible to submit a proposal for research that meets either one of these goals?
A. Yes.

Q. Individual functional impairment is different from aging, but does this area include research into the markers of aging?
A. It may include some parts of this theme.

Q. The R&D area stresses the entire life course rather than separating out a specific life stage, but I have the image that functional impairment accompanies aging. I think this theme could also link with projects on aging—could you describe the image for research in this area?
A. For example, recent research has started to show that events at the developmental stages can impact functional impairment in the future, so we are interested in research that, for example, looks into the links between events occurring at the developmental stages and this functional impairment in the future. Previous research into development just investigated that specific point in time, but this R&D area should investigate from the perspective of how this is linked to future functional impairment. For this reason, we are interested in proposals for research that include a perspective across the entire life course.

Q. Does this area also target functional impairment occurring after disease during the developmental stage or infancy? This could possibly also include delayed mental development or functional impairment in infancy?
A. That is correct.

Q. The R&D area specifies individual functional impairment, so are proposals not acceptable if the research does not target individuals? Does it include research at the cell level that links to functional impairment in the individual?
A. This area includes research that has a perspective on functional impairment in the individual or if it clarifies how functional impairment in the individual links to the cell or molecular level even without research at the individual level.

Q. Does individual functional impairment include a decline in cognitive abilities etc.?
A. A decline in brain function is included. However, research targeting a specific disease is not included. Even if the research relates to a particular disease, we expect the research content to further our understanding of the mechanisms of functional decline in an individual.

Q. You stress basic research, so does this not include research using clinical samples for example?
A. We stress basic research simply to indicate that it is not vital to have medical or clinical applications. However, research using human clinical samples is included in this area.