

FY2018  
Advanced Research and Development Programs for Medical Innovation  
(AMED-CREST, PRIME)  
Application Q&A

Q&A information can also be found on the website for research proposal solicitations below. For contents that draws frequent inquiries, we intend to update the information as required.

URL : [https://www.amed.go.jp/koubo/04/02/0402B\\_00007.html](https://www.amed.go.jp/koubo/04/02/0402B_00007.html)

Refer to the following website for the operation of the Cross-ministerial R&D Management System (e-Rad), registration of affiliated research institutions and researchers, as well as how to use e-Rad:

URL : <http://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 for application? Also, am I eligible even if I will retire during the R&D period?

A. You are eligible for application, when you are able to establish an R&D project organization at a research institution in Japan during the R&D period, and if AMED is able to conclude a contracted R&D agreement with the 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 R&D PI or Co-Investigator affiliated with the relevant institution makes a request based on reasonable grounds and following discussion with AMED shall a payment method 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 by the affiliated institution required?

A. Yes. Please note that procedures to obtain approval of the submission of the R&D project from your affiliated research institute have been added to the e-Rad application process in 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 the research institution where the R&D PI conducts research and AMED. 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 from 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 subsidiary institutions 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 a payment method 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 under the condition that they respond to requests by AMED to conduct audits, etc.

- (3) Simultaneous application 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?
- A. Yes. There are no restrictions on doing this. However, as described in “V 9. (4) Elimination of Unreasonable Duplication or Excessive Concentration of Research Funds” in the Application Guidelines, please note that selection is also performed with 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, although now executing a JST CREST or PRESTO project?
- A. Applications are not allowed for R&D PI who were selected for JST programs by FY2014 and are now executing projects in the transferred R&D areas in AMED, with the exception that the projects are going to finish in FY2018. However, applications can be made for other research areas in which JST programs are currently underway since they are not subject to any restrictions.  
As described in “V 9. (4) Elimination of Unreasonable Duplication or Excessive Concentration of Research Funds” in the Application Guidelines, please note that selection is also performed with 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, 2018). 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.
- (6) Continuation of R&D following a personnel transfer
- Q. If the R&D PI experiences a personnel transfer (promotion, transfer to a different research institution, etc.) while conducting R&D, will the R&D PI be permitted to continue R&D projects?
- A. Provided it is possible to continue R&D projects unhindered following the personnel transfer, R&D projects may be continued. Having another person take over as R&D PI as a 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 R&D is being conducted, 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 cost) 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 R&D work, it is possible. However, this is based on the premise that subcontracting work to outside parties is based on 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 that have been specified for each R&D area and type of research. Your application may not be accepted if you use proposal forms that

are different from those specified. For more information, refer to “IV. 2. (1) Proposal Document Format” in the Application Guidelines.

Q. What 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 (Form E1-1/J1/P1)?

A. For this application, you do not need to 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 (Form 1).

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 in the R&D Proposal?

A. The notes in blue text are examples showing how to fill out the proposal, so these may be deleted. However, you should not delete the notes in black text.

Q. What is the researcher number referred to on R&D Proposals?

A. 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 the registration of researcher information, 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 a researcher registration by yourself by sending a completed Researcher Number Issuance Request Form, a copy of ID and other required documents directly (by postal mail) to the e-Rad system administrator. For more information, refer to “How to Register” in “For Researchers (not affiliated with a research institution) under “Registration and Procedures” on the e-Rad portal site.

(10) Replacing application documents

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 conduct the “Withdraw” operation on e-Rad and submit the application again after you have revised it. Be sure not to conduct the “Withdraw” operation 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 documents and so on under any circumstances. For more information, refer to “III. 2. Preparation and Submission of R&D Proposals” in the Application Guidelines.

(11) Possibility of having someone else be interviewed in the interview screening

Q. If the date of the interview screening is inconvenient, is it possible to have someone else be 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 by 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” of 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\\_00009.html](https://www.amed.go.jp/koubo/04/02/0402B_00009.html)).

(12) The roles of PS and PO

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

A. The Program Supervisor (PS) is a Research Supervisor and the Program Officer (PO) a Deputy Research Supervisor. The PS and PO are responsible for determining the policy of operating R&D areas,

selecting R&D projects, adjusting and approving R&D plans (including R&D funds, R&D unit organization), as well as exchanging opinions with R&D PI by visiting their research facilities, providing advice and instructions on R&D projects, evaluating R&D projects and operating R&D areas with other required means.

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

Q. Can I submit an application even 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 through the previous fiscal year are no longer in effect beginning with solicitations for this fiscal year.

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

A. In the process of selecting R&D projects in this program, projects are evaluated by a Project Evaluation Panel made up of Project Evaluation Panel members (PS, PO, advisors, etc). From the standpoint of conducting fair and transparent evaluations, COI management is conducted 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. 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\\_00179.html](https://www.amed.go.jp/koubo/04/02/0402C_00179.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 R&D projects for periods of time designated for individual life events and then resume their research work. 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 subjects, these institutions may form a single group. However, if the expenditures need to be made 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 inquire 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 the R&D Co-Investigator?

A. It is possible in the case that 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 a R&D Project” in the Application Guidelines.

Q. What criteria will be used to determine whether the implementation of research would be difficult if not done at a foreign institution?

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

1. Required facilities do not exist in Japan and have been installed only at a foreign institution.
2. Field studies that can be performed only 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 the 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 when in the interview?

A. Selections will be made according to the content contained in the R&D Proposal, so please carefully consider the content at the time of applications so that no alterations subsequently arise. It should be noted that at the time of adoption of the project, changes can be requested in accordance with instructions from the PS.

### (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 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 details of R&D expenditure.

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 more information on R&D plans, please refer to “VI. 1. Project Management” of the Application Guidelines.

(4) Contracted R&D Agreement

Q. Is the contracted R&D agreement of the research institution to which the 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 awarded projects for FY2017, R&D conducted by the subsidiary institution takes the form of R&D subcontracted from the principal institution. Accordingly, AMED only concludes a contracted R&D agreement with the principal institution, and the 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 Agreement in Japan Agency for Medical Research and Development” on the AMED website.

(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 the 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 details and scale of the R&D to be performed. It should be noted that applications made by changing places with the R&D PI and the R&D Co-Investigator are not permitted. For more details, please refer to “II. 3. Limitations on Duplicate Applications within the Program” of the Application Guidelines.

(6) Applications in the R&D area “Understanding of pathophysiological processes and discovery of medical technology seeds through spatiotemporal research of tissue adaptation and repair mechanisms”

Q. What type of people are the AMED reviewers?

A. AMED reviewers are researchers affiliated with overseas research institutions who have deep insights into the research fields that make up the target R&D area.

Q. Why will new AMED reviewers participate 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, it was decided that AMED reviewers should participate in the AMED-CREST project evaluations in newly established R&D areas for this program as well, beginning from this fiscal year.

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 (Form E1-1),” “2. Research plan and research methods (Form E1-2),” “3. Research achievements (Form E1-3)” and “Summary of Proposal (Appendix E)” 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 “外国為替及び外国貿易法に基づく輸出規制対象物品の有無について” checklist (in Japanese only) (Appendix E2, which is in page 5 of Appendix E) ?

A. With the addition of AMED reviewers to the review process, there was a need to take steps required for security trade control.

Q. How is the“外国為替及び外国貿易法に基づく輸出規制対象物品の有無について” checklist (in Japanese only) (Appendix E2, which is in page 5 of Appendix E) used?

A. The content of the form will be used only as needed for security export control purposes and will not affect the review in any way. For more information, 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 of proposed projects for other R&D areas or PRIME?

A. AMED reviewers will not participate in the review process for the R&D areas “Clarification of the mechanisms of individual’s functional impairment over the entire life course” and “Understanding the interactions and symbiosis between the microbiome and the host organism, leading to an understanding of the mechanisms of disease onset” and PRIME proposed projects.

#### (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
- 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 the R&D Co-Investigator?

A. It is possible to submit a PRIME R&D proposal. However, if the applicant has been already participating in a AMED-CREST R&D project as the 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, where participating as the 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 participation in the AMED-CREST R&D project or pursuing the PRIME R&D project, may be required (excluding projects ending in FY2018). It is advisable, therefore, to consult in detail with the person who is or would 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 work under the system of an institution other than AMED, or who are going to apply to do so, should ask the relevant institution whether it is appropriate to perform work concurrently under its system and the PRIME program.

#### (2) R&D Budget

Q. Should the basis for estimation and the yearly budget be included in noted on 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 details of R&D budget 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" of R&D Proposal?

A. If there are any laboratory assistants or other R&D participants who are not R&D PI, please include those who are anticipated 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? Is there any case where the personnel costs for an R&D PI will be provided separately in addition to R&D funds?

A. As described in "II. 1. Eligible Applicants" in the Application Guidelines, applicants must be affiliated with a domestic Japanese research institution, and in general, they will organize a system for carrying out the proposed R&D at this institution. Therefore, in principle, the personnel cost 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.