FY2018

Research Program on the challenges of Global Health issues

Application Guidelines

April 2018

Division of International Collaboration
Department of International Affairs
Japan Agency for Medical Research and Development (AMED)

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Ⅰ. Introduction

The R&D projects being solicited in accordance with these Application Guidelines are R&D projects being solicited under [Grant program title], which is administered by the Japan Agency for Medical Research and Development (hereinafter referred to as "AMED").

1. Program Outline

(1) Program Background

Global-scale health issues include not only maternal and child health and infectious disease-related health issues, but also new issues faced by vulnerable countries, such as lifestyle diseases and aging of society, that have recently emerged, and there is a growing needs to respond to the increase in and diversification of health needs. The important of these issues within the international community is also growing more and more, with not only the World Health Organization (WHO) but also major international assemblies such as the United Nations General Assembly and G7 frequently addressing health issues as major agenda topics. Furthermore, the "2030 Agenda for Sustainable Development" and "Sustainable Development Goals (SDGs)"—adopted by the United Nations General Assembly in September 2015 with the aim of building on the Millennium Development Goals—set new goals in the health field, further strengthening international initiatives.
In Japan, in recent years government policies and strategies related to international health have been formulated one after another. These include the "Healthcare Policy", "Development Cooperation Charter", "Big-Boned Policy" ("Basic Policies for the Economic and Fiscal Management and Reform"), "Japan Revitalization Strategy 2016", "Basic Guidelines for Strengthening Measures on Emerging Infectious Diseases", "Basic Design for Peace and Health", and "National Action Plan on Antimicrobial Resistance(AMR)". The policy objective of these policies and strategies is for Japan to contribute to measures related to global-scale health issues, and they purport to purport to promote universal health coverage (UHC) and health security through collaboration with international organizations, as well as advance healthcare-related international development.
In May 2016, Japan was the host country for the G7 Ise-Shima Summit, and the G7 Kobe Health Ministers' Meeting was held and the Kobe Communiqué adopted in September of the same year. Within limited financial resources, Japan is contributing effectively and efficiently to global health by spearheading international policies in the health field and strengthening international technological cooperation, and it is required to maintain and strengthen its presence within the international community.

(2) Program Direction

Keeping in mind the mission of AMED, which is the innovation and practical implementation of technology, the aims of "the research program on the challenges of Global Health issues" are to optimize scientific technology and techniques applying this technology so that they can be implemented by even countries with limited resources; promote field work investigation research and empirical research aimed at spreading health services, so that they reach people; and generate research accomplishments that contribute to the setting of standards by international organizations such as the WHO.

2. Program Structure

(1) Program Implementation System

In accordance with the "Plan for Promotion of Medical Research and Development*", a Program Supervisor (hereinafter referred to as "PS") and Program Officer (hereinafter referred to as "PO") are assigned to the Program to ensure efficient utilization of competitive research funds and generation of excellent research accomplishments.

The PS and PO have complete knowledge and understanding of the progress status of the program overall and provide the necessary guidance and advice to ensure that the program runs smoothly. Furthermore, research institutes and researchers are obligated to cooperate with the PS and PO. Based on the guidance and advice provided by the PS and PO, researchers may be required to revise, change, or suspend their R&D project plans or change their project implementation system if this is deemed necessary.

*http://www.kantei.go.jp/jp/singi/kenkouiryou/suisin/ketteisiryou/dai2/siryou2.pdf

(2) Roles of Principal Institutions and Subsidiary Institutions

Under this program, R&D projects shall be implemented by Principal Institutions or, if necessary, Subsidiary Institutions

(a) "Principal Institution" refers to the research institute* with which the R&D Principal Investigator (PI) is affiliated and which has concluded a direct contracted R&D agreement with AMED.

(b) “Subsidiary Institution” refers to a research institute* other than the Principal Institution with which a Co-Investigator is affiliated and which has concluded a subcontracted R&D agreement with the Principal Institution.

*For details regarding contracted R&D agreements with institutions under this program, please refer to Chapter V.

Ⅱ. Application Requirements

1. Eligible Applicants

Eligible Applicants for this program shall be researchers affiliated with a research institute in Japan that fulfills the conditions shown in (1)–(5) below and who have the capability to take responsibility for formulating an R&D implementation plan and compiling the research accomplishments for the R&D project for which the application is being submitted (hereinafter referred to as "R&D Principal Investigator" (PI)).

(1) "Research Institute" refers to institution with the characteristics shown in (a)–(h) below.
- (a) National facility or other organization[1] (limited to institutions/facilities where the PI is employed in an educational position, research position, medical care position[2], welfare service position[2], or designated position[2], or as a fixed-term contract researcher).
- (b) Research institute, etc., affiliated with a local public body.
- (c) University as prescribed under the School Education Act (Law No. 26 of 1947) or university affiliated research institute, etc. (including inter-university research institute corporations).
- (d) R&D division or research laboratory, etc. of a private enterprise
- (e) A special private corporation, general incorporated association, general incorporated foundation, public interest incorporated association, or public interest incorporated foundation (hereinafter referred to as a "special private corporation, etc.") whose main activity purpose is research.
- (f) An independent administrative corporation as prescribed under Article 2 of the Act on General Rules for Incorporated Administrative Agencies (Act No. 103 of 1999) or local incorporated administrative agency as prescribed under Article 2 of the Act on Local Incorporated Administrative Agencies (Act No. 118 of 2003) whose main activity purpose is research.
- (g) Non-profit, charitable technology research associations[3]
- (h) Other institution deemed appropriate by the President of AMED.

[1]Refers to a research institute, inspection and certification institute, educational and training facility, medical and rehabilitation facility, reformatory and internment facility, or work facility affiliated with a government organization as prescribed by the Cabinet Office and under Article 3 Paragraph 2 of the National Government Organization Act

[2]Limited to persons affiliated with a hospital or institution that conducts research.

[3]With regard to technologies used in industrial activities, mutual associations providing finance, human resources, and facilities in which the association members autonomously conduct joint research.

(2) In the case that the project is selected, the research institute's facilities and equipment can be used for carrying out the project.

(3) In the case that the project is selected, the research institute is able to carry out administrative procedures such as contract procedures.

(4) In the case that the project is selected, the research institute is capable of responsibly handling any intellectual property (IP) rights (including patents and copyright, etc.) generated through implementation of this program.

(5) The research institute is capable of continuing to promote R&D even after this program has concluded, and can support researchers in relation to this program.

In the case that a researcher who is not affiliated with a designated research institute or is affiliated with a research institute outside of Japan is selected as the PI, the researcher may apply for this program if they are able to become affiliated with a research institution in Japan and create a system for conducting research by concluding a contract with AMED. However, in the case that the above conditions are not met, as a general rule the decision to adopt the R&D project shall be cancelled.

Furthermore, in order to confirm the research institute's ability to fulfill the contracted R&D agreement, at the time of the application review, the Principal Institution or Subsidiary Institution may be required to submit materials regarding the content of major projects undertaken by the institution and its finances (assets, debts, etc.).

2. Important Items Regarding Application

(1) Contracted R&D Agreements

In implementing selected R&D projects, as a general rule* a contracted R&D agreement shall be concluded between the research institute carrying out the R&D project and AMED.

*For details, please refer to Chapter V.

(2) Cross-ministerial Research and Development Management System (e-Rad)

For contracted R&D funds, applications shall be accepted via the Cross-ministerial Research and Development Management System (hereinafter referred to as "e-Rad"), which places certain processes related to R&D management centered on competitive research funding systems. In submitting an application, please be sure to carefully read the program outline, the outline of R&D projects for which applications are being solicited, and other information provided and thoroughly consider the kinds of results your proposed R&D project can produce before completing the proposal documents. For details, please refer to Chapter IV.

(3) Registration with a Clinical Trial Registration System

In the case that an intervention study is to be conducted, in accordance with the "Ethical Guidelines for Medical and Health Research Involving Human Subjects", please register the project with one of the three clinical study registration systems listed below prior to commencement of the relevant clinical study (you may be required to submit a report indicating whether or not the project has been registered (free format) at the time that you submit your contracted R&D accomplishments report). Please note that investigations shall be carried out to ensure that there are no discrepancies between the registered project content and the content of the research being conducted.

1) University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN-CTR)
   http://www.umin.ac.jp/ctr/index-j.htm
2) Japan Pharmaceutical Information Center (JAPIC) Clinical Trial Information
   http://www.clinicaltrials.jp/user/cte_main.jsp
3) Center for Clinical Trials, Japan Medical Association (JAMACCT) Clinical Trial Registry
   https://dbcentre3.jmacct.med.or.jp/jmactr/

(4) Security Trade Control (Countermeasures to Technology Leakage Overseas)

At research institutes, a large quantity of cutting-edge research is carried out. At universities in particular, with the increase in international students and foreign researchers due to internationalization, there is an increasing risk of cutting-edge research and/or research materials/equipment flowing out of Japan and being misused for the development/production of weapons of mass destruction or for other improper uses. For this reason, it is imperative that in carrying out various type of research activities—including contracted R&D under this program—research institutes implement systematic measures to ensure that research accomplishments that could be used for military purposes do not fall into the hands of persons suspected of being involved in the development of weapons of mass destruction or with terrorist organizations or other concerning activities.

In Japan, export regulations* are enforced in accordance with the Foreign Exchange and Foreign Trade Act (Law No. 228 of 1949) (hereinafter referred to as the "Foreign Exchange Act"). Accordingly, in the case that a person wishes to export (provide) goods or technology prescribed under the Foreign Exchange Act, as a general rule they are required to obtain the permission of the Minister of Economy, Trade and Industry. Please be sure to comply strictly with all laws, ministerial ordinances, and directives, etc., issued by various Japanese government ministries and agencies, beginning with the Foreign Exchange Act. IN the case that R&D is carried out in infringement of relevant laws or guidelines, allocation of R&D funds may be suspended and the decision to allocate R&D funds may be cancelled.

*Currently, under Japan's security export control system, there are two types of regulations based on international agreements: (1) a system under which the permission of the Minister of Economy, Trade and Industry must generally be obtained in the case that a person wishes to export (provide) goods (technology) with specifications or functions above a certain level—mainly carbon-fiber and numerically controlled machine tools, etc.—("List Control"), and (2) a system under which the permission of the Minister of Economy, Trade and Industry must generally be obtained in the case that a person wishes to export (provide) goods (technology) to which List Control do not apply and which fulfill certain conditions (use, demand, inform conditions) (Catch-all Regulations).

Not only the export of goods but also the provision of information is subject to regulations under the Foreign Exchange Act. When providing List Control technology to a foreign national (non-resident of Japan), permission must be received in advance. "Provision of technology" includes not only the provision of blueprints/designs, specifications, manuals, samples, prototypes, and other technological information via paper, e-mail, CD, USB flash drive, or other storage medium but also the provision of operational knowledge through technological guidance or skills training and technological support at seminars, etc. There are cases in which large amounts of technological exchange that could be subject to regulation under the Foreign Exchange Act may be included in joint research activities or when international students are involved.

On the Ministry of Economy, Trade and Industry website, details regarding security trade control are provided. Please refer to the following for further details (in Japanese).

- Ministry of Economy, Trade and Industry: Security Trade Control (general)
  http://www.meti.go.jp/policy/anpo/
- Ministry of Economy, Trade and Industry: Handbook for Security Trade Control (8th edition, 2014)
  http://www.meti.go.jp/policy/anpo/seminer/shiryo/handbook.pdf
- Center for Information on Security Trade Control
  http://www.cistec.or.jp/

- Guidance for Management of Sensible Nuclear Technology (SNT) in Relation to Security Trade Control (for universities/research institutes)
  http://www.meti.go.jp/policy/anpo/law_document/tutatu/t07sonota/t07sonota_jishukanri03.pdf

Ⅲ. Application/Selection Implementation Methods

1. Outline of R&D Projects for which Applications Are Being Solicited

The outline of the R&D projects for which applications are being solicited included in these Application Guidelines is as follows. For details regarding individual R&D projects being solicited, please refer to Chapter XI.

#	Name of Field/R&D Projects Being Solicited	Scale of R&D funds	Period in which R&D is Scheduled to be Implemented	Planned Number of New Awarded Projects
1	Study on implementation of prevention of onset and progression of chronic diseases in low and middle income countries	Around 3.850.000yen per year for each project (excluding indirect costs)	Max. of 1 year FY2018	Around 0～4 projects
2	GACD collaborative call: Scaling-up of evidence-based interventions at the population level for the prevention or management of hypertension and/or diabetes	Around 15.400.000yen（～30.800.000yen） per year for each project (excluding indirect costs) (Only 1.540.000yen for JFY 2018)	Max. of 5 years FY2018 – FY2022	Around 0～2 projects

- "Scale of R&D Funds" is an approximate estimate guide.
- "Scale of R&D Funds" and "Planned Number of New Awarded Projects" may change depending on the situation regarding budget appropriation following the commencement of applications. In the event that there is a significant change, it is possible that acceptance of applications submitted for some of all of the R&D projects being solicited or adoption of projects may be cancelled.
- Although applicants may submit applications for multiple R&D projects being solicited, in order to show that there is no unreasonable duplication or excessive concentration of research funds (for details refer to Chapter V. 9 (4)), they must be sure to list information for all the other R&D projects for which applications are being submitted simultaneously in the relevant R&D Proposal column.

2. Preparation and Submission of R&D Proposals

(1) Methods for Obtaining Proposal Forms, Etc.

Please download forms for proposal documents and other materials necessary for application from the "Calls for Applications" page on the AMED website.

https://www.amed.go.jp/koubo/

(2) Period of Acceptance of Proposals

■ **Solicitation Theme#1:** Study on implementation of prevention of onset and progression of chronic diseases in low and middle income countries
April 20, 2018 (Fri.) – May 31, 2018 (Thu) [12:00] (Japanese Standard Time) (Observe strictly.)

■ **Solicitation Theme#2::** GACD collaborative call: Scaling-up of evidence-based interventions at the population level for the prevention or management of hypertension and/or diabetes
Submission to **e-Rad:** April 20, 2018 (Fri.) – September 10, 2018 (Mon) [12:00] (Japanese Standard Time) (Observe strictly.)

Submission to **GACD common submission portal:** April 20, 2018 (Fri.) – September 10, 2018 (Mon) [16:00] (English Summer Time) (Observe strictly.)

Note 1: Procedures for registering with e-Rad can only be carried out during e-Rad system operating hours.
Note 2: For all R&D proposals, applications received after the deadline will not be accepted

(3) Submission of Proposal Documents via **e-Rad** **(Solicitation Theme#1 & #2)**

Please submit proposal documents via e-Rad by the deadline. Applications will not be accepted if the proposal documents are not submitted by the deadline. When completing (inputting) the R&D proposal documents, please following the guidelines provided in this item and on the R&D Proposal (Form 1) and be sure that all the information

you are required to provide is correct. Please note that submitted proposal documents cannot be replaced after the application deadline.

(a) Points to note in using the system

An e-Rad operating manual is available for reference or downloading from the e-Rad portal site (http://www.e-rad.go.jp/). Please read and agree to the system usage regulations before submitting your application.

1) System operating hours

The e-Rad system is available for use between 00:00 and 24:00 on weekdays and public holidays.

Note: During the above system operating hours, the e-Rad system by be temporarily shut down for maintenance or inspection. In the event that e-Rad is to be temporarily shut down, notice will be posted in advance on the e-Rad portal site.

2) Registration of research institute

In the case that researchers are applying for the program through a research institute, the "Principal Institution" (the research institute with which the PI is affiliated) and "Subsidiary Institution" (a research institute other than the Principal Institution with which a Co-Investigator is affiliated) must be registered with e-Rad prior to the time of application as a general rule.

For information regarding how to register research institutes, please refer to the e-Rad portal site. Registration procedures may require several days, so please allow leeway of two weeks or more for carrying out registration procedures. Please note that once you have registered with e-Rad, there is no need for you to register again for another R&D program or project. Moreover, if you have already registered with e-Rad for another R&D program or project, there is no need for you to register again. In the case that you are not affiliated with a specific research institute at the time of application or are affiliated with a research institute outside of Japan, please separately contact the department responsible for the relevant project as early as possible before submitting your application.

3) Registration of researcher information

The PI for the R&D project for which the application is to be submitted and the Co-Investigator participating in the research must register their researcher information and obtain a system login ID and password. The research institute should register information for researchers who are affiliated with it. Please note that researcher information registered previously for a scientific research grant is already registered in the e-Rad system. Please check your researcher number and input additional information regarding your affiliated research institution. Information for researchers who are not affiliated with a research institute shall be registered by e-Rad system operation managers at the Ministry of Education, Culture, Sports, Science and Technology (MEXT). Please refer to the e-Rad portal site for the necessary procedures

(b) Points to note regarding submission of documents via the e-Rad system

1) File type

The electronic media format needs to be converted into PDF format before uploading to the e-Rad system. Please select PDF conversion from the menu that appears after you login to the system. It is also possible to download conversion software from this menu and install it on your computer for your use. (In order to ease the burden on the system and realize stable operations, the option of submitting files in Word format, etc., as is, which was available under the old system, is no longer available.) If you use foreign-language letters or special characters, the text may be garbled, and so please be sure to check the content of the converted PDF file on the system. Please refer to the User's manual (quick guide for researchers) with regard to letters/characters/symbols that may be used.

2) Image file format

Image files for insertion in proposal documents should be submitted in "GIF", "BMP", "JPEG", or "PNG" format. If image files in other formats (e.g. images created with different applications such as CAD, Scanner, PostScript, or DIP software) are inserted in the proposal documents, the documents cannot be converted to PDF format correctly. For information on how to insert image data into proposal documents, please refer to the Researchers' Operation Manual.

3) File capacity

The maximum size of single files that can be uploaded to the e-Rad system is 10MB.

4) Uploading proposal documents

Please convert proposal documents to PDF format before uploading.

5) Consent of affiliated institute

Application to the program is not complete at the point that the PI submits the application to their affiliated research institute via e-Rad. Be sure to undergo procedures to obtain approval of the submission of the R&D project from your affiliated research institute.

6) Checking acceptance status

Verifying the acceptance of proposal documents can be done by viewing the Applied Project Information Management Screen (応募課題情報管理). If the acceptance status upon the end of the acceptance period does not display the message "being processed by funding agency (配分機関処理中)" the submitted documents can be assumed to be invalid.

7) Amendment of proposal documents after submission

In order to amend proposal documents that have already been submitted, you need to carry out "Retrieval" procedures before the application deadline and then re-submit the amended documents. For details regarding retrieval procedures, please refer to the Researchers' Operation Manual.

8) Other

Details about points to note and content other than that shown above are posted as required on the e-Rad portal site (Researchers' Page), so please check this information.

(c) Contact for inquiries regarding e-Rad system operation

For inquiries regarding how to operate the e-Rad system, please contact the e-Rad portal site's Help Desk. (Please refer to Chapter X.) Please be sure to check the portal site and see the "Frequently Asked Questions" page before contacting the Help Desk. Please note that the Help Desk cannot answer any inquires whatsoever regarding the content of the Call for Applications, application review status, or acceptance/rejection of applications.

(4) Methods for Obtaining, Preparing, and Submitting Proposal Forms Prescribed by GACD (Project#2)

Proposal documents are to be prepared in English using uniform methods and formats prescribed by GACD. Please refer to the GACD website for the necessary application documents as well as information on how to prepare proposal documents.

https://www.gacd.org/funding/calls-for-proposals/gacd-scale-up-call

Please submit the proposal documents before the application deadline via the GACD Common Submission Portal. Applications will not be accepted if the proposal documents are not submitted by the deadline. Please note that submitted proposal documents cannot be replaced after the application deadline.

(5) Schedule

The schedule from application to selection of projects for the program shown below is current as at the time that the call for applications opens. For details on how reviews are carried out, refer to Chapter III. 3.

<table>
<tr><th>#</th><th>Name of Field/R&D Projects Being Solicited</th><th>Solicitation Period</th><th colspan="2">Document Review / Interview (hearing)</th><th>Notification of selection</th><th>Commencement of R&D</th></tr>
<tr><td rowspan="2">1</td><td rowspan="2">Study on implementation of prevention of onset and progression of chronic diseases in low and middle income countries</td><td rowspan="2">April 20, 2018 (Fri.) – May 31, 2018 (Thu)</td><td colspan="2">(a) Review by the Evaluation Panel on "the research program on the challenges of Global Health issues".</td><td rowspan="2">End of June, 2018</td><td rowspan="2">Early July, 2018</td></tr>
<tr><td>June, 2018</td><td>Middle of June, 2018</td></tr>
<tr><td rowspan="4">2</td><td rowspan="4">GACD collaborative call: Scaling-up of evidence-based interventions at the population level for the prevention or management of hypertension and/or diabetes</td><td rowspan="4">April 20, 2018 (Fri.) – September 10, 2018 (Mon)</td><td colspan="2">(a) Review by the Evaluation Panel on "the research program on the challenges of Global Health issues".</td><td rowspan="4">End of December, 2018</td><td rowspan="4">January, 2019</td></tr>
<tr><td>September-October, 2018</td><td>October, 2018</td></tr>
<tr><td colspan="2">(b) Review by GACD Joint International Peer Review</td></tr>
<tr><td>September-November 2018</td><td>None</td></tr>
</table>

■ **Solicitation Theme#1:** Study on implementation of prevention of onset and progression of chronic diseases in low and middle income countries

Document review: Early June – Midlle of June 2018 (tentative)

Interview (hearing): Midlle of June 2018 (tentative)

Note 1: In the case that a hearing is conducted, the PI for the relevant project shall as a general rule be contact by e-mail no later than one week before the hearing is to take place. (In the case that the project is not eligible for a hearing or hearings themselves are not being conducted, the PI will not be contacted. Please wait to receive your Notification of Selection/Rejection.) In the case that there is a change in information regarding the implementation or scheduling of hearings, this will be posted on the Application Information page on the AMED website listed in Chapter III.2. (1), so please refer to this page for details. Note that we cannot answer questions regarding the eligibility of individual projects for hearings.
Note 2: The PI of a project for which a hearing is to be conducted may be sent via e-mail a list of "Matters of Inquiry" that have arisen through the document review process. Please e-mail answers to these questions to the Secretariat by the deadline specified by AMED ahead of the hearing.
Note 3: As a general rule, the hearing shall be attended by the PI. The date and time of the hearing cannot be changed.
Note 4: Following the hearing, administrative matters may be confirmed with the PI as necessary. Please respond swiftly to the relevant checks via the method specified by AMED.

Notification of Selection/Rejection End of June, 2018

Note: The PI of a project that has been selected as a candidate project for adoption may be required to revise the project's objectives, implementation plan, and/or implementation system in accordance with the review results, and conditions for adoption, including changes to the total R&D funding amount may be added. In such cases, the appropriateness of the plan may be reconsidered.

Commencement of R&D Project (Contracting, Etc.) (tentative date) Early July, 2018

Note: The "Tentative Date" has been set in consideration of the time period required for formulating an optimal R&D plan at the time of submitting the proposal with a view to the timing of the commencement of R&D, and to enabling researchers to make the preparations they can between the time of the decision to adopt the project and the time the contracted R&D agreement is concluded so that R&D can commence as swiftly as possible after conclusion of the agreement, and **does not guarantee conclusion of a contracted R&D agreement**. In order to conclude the contracted R&D agreement on the "Tentative Date", the cooperation and efforts of research institutes, etc. regarding the formulation and/or revision of R&D plans (including R&D funds and R&D systems) are required. AMED will also endeavor to coordinate with the PS/PO of a project as swiftly as possible to ensure that the contracted R&D agreement can be concluded as early as possible.

■ **Solicitation Theme#2:** GACD collaborative call: Scaling-up of evidence-based interventions at the population level for the prevention or management of hypertension and/or diabetes

Document review by the Evaluation Panel on "the research program on the challenges of Global Health issues". Middle of September- Middle of October, 2018

Interview (hearing)by the Evaluation Panel on "the research program on the challenges of Global Health issues". End of October, 2018

Document review by the GACD Joint International Peer Review Middle of September- Middle of November 2018

Note 1: In the case that a hearing is conducted, the PI for the relevant project shall as a general rule be contact by e-mail no later than one week before the hearing is to take place. (In the case that the project is not eligible for a hearing or hearings themselves are not being conducted, the PI will not be contacted. Please wait to receive your Notification of Selection/Rejection.) In the case that there is a change in information regarding the implementation or scheduling of hearings, this will be posted on the Application Information page on the AMED website listed in Chapter III.2. (1), so please refer to this page for details. Note that we cannot answer questions regarding the eligibility of individual projects for hearings.
Note 2: The PI of a project for which a hearing is to be conducted may be sent via e-mail a list of "Matters of Inquiry" that have arisen through the document review process. Please e-mail answers to these questions to the Secretariat by the deadline specified by AMED ahead of the hearing.
Note 3: As a general rule, the hearing shall be attended by the PI. The date and time of the hearing cannot be changed.
Note 4: Following the hearing, administrative matters may be confirmed with the PI as necessary. Please respond swiftly to the relevant checks via the method specified by AMED.

Notification of Selection/Rejection End of December, 2018

Note: The PI of a project that has been selected as a candidate project for adoption may be required to revise the project's objectives, implementation plan, and/or implementation system in accordance with the review results, and conditions for adoption, including changes to the total R&D funding amount may be added. In such cases, the appropriateness of the plan may be reconsidered.

Commencement of R&D Project (Contracting, Etc.) (tentative date) Early January, 2019

Note: The "Tentative Date" has been set in consideration of the time period required for formulating an optimal R&D plan at the time of submitting the proposal with a view to the timing of the commencement of R&D, and to enabling researchers to make the preparations they can between the time of the decision to adopt the project and the time the contracted R&D agreement is concluded so that R&D can commence as swiftly as possible after conclusion of the agreement, and **does not guarantee conclusion of a contracted R&D agreement**. In order to conclude the contracted R&D agreement on the "Tentative Date", the cooperation and efforts of research institutes, etc. regarding the formulation and/or revision of R&D plans (including R&D funds and R&D systems) are required. AMED will also endeavor to coordinate with the PS/PO of a project as swiftly as possible to ensure that the contracted R&D agreement can be concluded as early as possible.

3. Method for Reviewing Proposal Documents

(1) Review Method

In selecting R&D projects under this program, ex-ante evaluations (reviews) shall be conducted by evaluators (reviewers) comprising external experts appointed by the President of AMED in order to determine the necessity of the R&D project, appropriateness of project objectives and plans, and budget allocation.

(a) Reviews shall be conducted in private by a Project Evaluation Panel established by AMED.

(b) The Project Evaluation Panel shall evaluate project proposals by conducting a document review of the content of the submitted proposal documents and conducting interviews (hearings) as necessary* and deliberating on the project content.

*During the review process, the PI may be required to provide additional materials, etc.

(c) In deciding projects for adoption, the PI of a project may be required to revise* the project's objectives, implementation plan, and/or implementation system in accordance with the review results, and conditions for adoption, including changes to the total R&D funding amount may be added. In such cases, the appropriateness of the plan may be reconsidered.

*In the case that the project is adopted, the objectives, etc., revised at this stage shall be used as evaluation indicators when a Mid-term Review and an Ex-Post Evaluation are carried out. Please refer to Chapter VI. for information regarding the management and evaluation of awarded projects.

(d) Following completion of reviews, AMED will send notification of selection/rejection to the PI of the project. Note that we cannot answer questions regarding the progress status of the selection process.

(e) Evaluation Panel members are obligated to maintain confidentiality regarding any secret information learned during the course of performing their evaluation duties, including after these duties have concluded, in order to prohibit leakage or misappropriation of this information.

(f) The names of the R&D projects adopted for the program (awarded projects) and the name of the PI will be published at a later date on the AMED website. Furthermore, as a general rule, the names of all evaluators (reviewers) shall be published by AMED once each year.

(g) From the standpoint of conducting fair and transparent evaluations, management of conflict of interest for Project Evaluation Panel members shall be implemented in accordance with AMED regulations. In the case that any of the following items apply to a Project Evaluation Panel member, they are required to report to AMED that they are subject to management of conflict of interest and as a general rule shall not be involved in evaluation of the relevant project. However, in the case that the Project Evaluation Panel Chair recognizes that participation by the Project Evaluation Panel member in question is especially necessary for ensuring the scientific validity of the evaluation and that their ability to make appropriate and transparent decisions as part of the evaluation is not impaired, the Project Evaluation Panel member may participate in the evaluation of the relevant project.

1) The evaluatee is a family member/relative of the Project Evaluation Panel member.
2) The evaluatee is affiliated with the same department at a university, the National Research and Development Agency, or a national research institution or other research institute or business enterprise as the Project Evaluation Panel member.
3) The evaluatee has worked closely with the evaluator on a joint research project within the past three years including the fiscal year in which the Project Evaluation Panel evaluation is conducted.

4) The Project Evaluation Panel member and evaluatee have a close teacher-disciple relationship wherein one provided guidance and instruction regarding the other's doctoral thesis.
5) The evaluatee has received economic benefits from the Project Evaluation Panel member within the past three years, including the fiscal year in which the Project Evaluation Panel evaluation is conducted, of more than one million yen.
6) The Project Evaluation Panel member is in a direct competitive relationship with the evaluatee.
7) Other serious conflicts of interest are recognized to exist.

(h) Program applicants and persons intending to apply for the program are prohibited from lobbying AMED executive officers, Program Director (PD), PS, PO, or evaluators regarding evaluations or project selection.

(2) Review Criteria and Perspectives in Evaluating Projects on "the research program on the chellenges of Global Health issues"

In selecting projects for this program, reviews of proposal documents shall be carried out from the following perspectives. In the case that a proposal is submitted for an R&D project that designates a subsidiary institution, evaluations shall also examine the necessity of the subsidiary institution for carrying out the R&D and the competency of the subsidiary institution to carry out the R&D.

(a) Compatibility with the program's purpose
- Is the project compatible with the program's purpose and aims, etc.?
- Can the project be expected to make proposals/recommendations for governments of developing countries and international organizations to promote the resolution of health issues?
- Can the project contribute to efforts by the Japanese Government to promote the resolution of global-scale health issues?

(b) Appropriateness of the plan
- Are the overall content and aims of the plan clear?
- As the plans for each fiscal year detailed and realizable?

(c) Technological significance and predominance
- Are the current technological level and previous performance of the research institute sufficient?
- Does the project proposal have originality and novelty?
- Does the project respond to needs in the field of global-scale health issues?
- Does the project contribute to the generation of new technologies or the utilization of new technologies in addressing global-scale health issues?
- Does the project contribute to progress in the field of global-scale health issues?

(d) Implementation system
- Has an R&D system centered on the applicant been organized appropriately?
- Has a sufficient collaboration network within Japan been constructed?

Has a sufficient collaboration network been constructed with overseas researchers/research organizations, supporters/support organizations, and government officials/government organizations, including persons/organizations related to the target developing country?

(e) Costs
- Are the breakdown of costs and spending plan appropriate?

(f) Items stipulated under other programs
- With regard to global-scale health issues, is the project proposal based on worldwide trends?
- With regard to global-scale health issues, is the project compatible with global guidelines and strategies, etc., formulated by the World Health Organization or other organizations, and does it contribute to constructive reforms?
- Is the project appropriate for the current situation in the target developing country?
- Does the project have appropriate strategies for publishing research achievements?

(g) Overall evaluations

Overall evaluations will be carried out in consideration of (a) – (f) above and the following items.
- Is the project plan in compliance with laws and ordinances related to bioethics or safety measures?
- Are the efforts of the applicant appropriate?

(3) GACD Joint International Peer Review

Based on uniform evaluation standards prescribed by GACD, the Joint International Peer Review shall evaluate the quality, appropriateness, feasibility, and impact, etc., of the proposal content.

(a) Reviews shall be conducted in private by a Joint International Peer Review Panel comprising reviewers selected by GACD.

(b) The Joint International Peer Review Panel shall evaluate project proposals by conducting a document review of the content of the submitted proposal documents and deliberating on the content in the panel meeting.

(c) GACD Joint International Peer Review Criteria

Please refer to the GACD application website.

https://www.gacd.org/perch/resources/gacd-scale-up-call-text-2.pdf

4. Promotion of Selection of Young Researchers

In common with the purport of other programs providing public research funds, this program aims to broadly nurture researchers who will lead Japan's future and return research accomplishments to society through the human resources who have been nurtured by the program. From this perspective, this program can be expected to engage young researchers.

Ⅳ. Preparation of Proposal Documents and Cautions

1. Handling of Information Contained in Proposal Documents

(1) Purpose of Use of Information

In addition to reviewing R&D project proposals as part of the selection proves, information included in proposal documents, etc., shall also be used by contracted R&D fund administration organizations and for research support purposes as described in IX.

Furthermore, information included in proposal summaries shall also be used in analysis of research trends that contributes to the operation of the AMED program, such as the creation of new programs. In accordance with laws related to the protection of personal information possessed by independent administrative corporations and other organizations, the confidentiality of secret information included in proposal documents shall be strictly maintained to ensure that the rights and interests of the applicant are in no way unfairly infringed. For details, please refer to the Ministry of Internal Affairs and Communications website.*

* "Introduction of legal systems for the protection of personal information by government organizations/independent administrative corporations, etc." (Ministry of Internal Affairs and Communications)
http://www.soumu.go.jp/main_sosiki/gyoukan/kanri/horei_kihon.html

(2) Necessary Disclosure/Provision of Information

(a) Information related to each adopted project (name of program, name of R&D project, researcher's affiliated research institutions, position, researcher's name, budget amount and implementation period) may be sorted, classified, made public on AMED's website, the information required for macro-analysis analyzed by AMED, provided to the Cabinet Office via e-Rad, and the analysis results published. Applicants are therefore requested to input into e-Rad the R&D accomplishment information for the year (academic papers and patents etc.) and accounting performance information even after selection of project.

(b) Within the scope necessary for eliminating unreasonable duplication/excessive concentration, some information included in proposal documents, etc., may be provided via e-Rad to divisions in charge of other competitive research funding programs, including other government ministries or agencies (including the provision of personal information used when computerized data processing and management is contracted out to an external private enterprise). Similarly, information may also be provided in the event that it is necessary to check for duplicate applications to other competitive research funding systems, etc.

2. Proposal Document Format and Notes for Preparation

(1) Proposal Document Format

The proposal document form shall be the "R&D Proposal". Please complete each item simply and clearly. With regard to the acceptance period for proposal documents and submissions, please refer to Chapter III.

(2) Preparation of proposal documents

Applications are to be submitted via e-Rad. In preparing proposal documents, please also refer to the Points to Note shown in (3). If not completed correctly, proposal documents may not be accepted.

Please be careful with regard to the following items when inputting information into the Proposal Form.

(a) As a general rule, the Research Proposal (Form 1) is to be prepared in Japanese (or English), but the abstract must be prepared in both Japanese and English. In the case that information required on the Research Proposal is missing, the application may be ineligible for review.

(b) With regard to formats prescribing word limits or page limits, please be sure to comply with the set limits.

(c) With regard to letter/character size when inputting information, please use 10.5 point as a general rule.

(d) As a general rule, please use half-width letters when inputting alphanumeric characters. (E.g. post codes, telephone numbers, and numbers of people.)

(e) Please number the pages of proposal documents with numbers placed centrally at the bottom of each page in the form of (-1-).

(f) Proposal documents may be prepared in color, but please ensure that the documents' content can be understood even when the documents are photocopied in black-and-white.

(3) Notes on Preparing Proposals

(a) Compliance with laws and ordinances/ethical guidelines, etc.

In preparing R&D proposals, be sure to comply with relevant laws and ministerial ordinances/ethical guidelines prescribed by government ministries and agencies. For details, please refer to Chapter V. 4 (4).

(b) Approval of R&D Project Proposals by Organizations

In submitting proposal documents, the PI must obtain the approval of the Principal Institution (research institute with which the PI is affiliated and which is to conclude a direct contracted agreement with AMED). Furthermore, in the case that multiple research institutes jointly submit an R&D proposal for carrying out research, the approval of the heads of all the research institutes must be obtained.

(c) Revision of Proposal Content

In selecting R&D projects for adoption, due to budget restrictions and other reasons, it may be necessary to request applicants to revise their submitted research proposal plans. Furthermore, in implementing awarded R&D projects, please note that the expenditure/implementation period allocated to the project may need to be changed due to budget restrictions in the future.

(d) Ineligible Project Proposals

The following R&D projects are ineligible for funding under this program.

1) Proposals that aim simply to purchase ready-made facilities and equipment.
2) Proposals that envision covering the costs necessary for procuring equipment with funding from this program when covering these procurement costs with funding from another source would be appropriate.

(4) Required Documents Apart from R&D Proposals

(a) Records of ex-ante interviews/face-to-face advice with PMDA

In the case that the applicant has already undergone ex-ante interviews with PMDA under their "regulatory science consultation" program, a summary of the interview must be submitted with the R&D proposal (free format; summary may be provided by the academic institution), and if the applicant has already undergone face-to-face advice, a record of the face-to-face advice or separate sheet (consultation content) such be submitted with the R&D proposal. For details, please refer to the Points to Note provided for projects being solicited under Chapter XI.

Note: R&D projects that progress to the practical application stage (R&D projects within the scope of the "Regulatory science strategy consultation" program) must as a general rule undergo face-to-face advice within one to two years of the project being adopted as a condition of the contracted R&D agreement (please refer to Chapter IV. 1. for details regarding the period in which the consultation should be undertaken). Although is it not compulsory for the applicant to have undergone face-to-face advice at the time of application, it is desirable that face-to face consultation is undertaken and the consultation results are reflected in the R&D plan.

(b) Materials related to clinical study, etc.

For research undertaking investigator-initiated trials or clinical studies with a view to creating innovative drugs or medical devices, or nonclinical studies aimed at conducting such trials/studies,* applicants are required to submit materials related to the clinical study such as a trial plan and protocol (including information such as aims, subjects, selection criteria, exclusion criteria, number of cases, observation content, intervention content, statistical methods, and research system) (free format; a draft may be submitted if the trials have not been implemented at the time of application). For details, please refer to the Points to Note provided for projects being solicited under Chapter XI.

*Note: Does not include clinical research that is not aimed at creating new drugs or medical devices or that differ from normal processes for evaluating/approving new medical technology.

(c) Self-monitoring/self-evaluation results related to animal experiments

With regard to research institutes conducting animal experiments using animal species specified under the Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Academic Research Institutions (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) No. 71 of 2006) and Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Implementing Agencies under the Ministry of Health, Labour and Welfare (Notification by Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare on June 1, 2006), based on these fundamental guidelines, research institutes may be required to submit a copy of the results of their most recently implemented self-monitoring/self-evaluation related to the research institute's conformance with these fundamental guidelines.

(d) Documents etc. regarding management of R&D

From the perspective of verifying the appropriateness of R&D management, from now on there may be requests to submit the indicated documents relating to pharmaceuticals. In addition, where necessary inquiries regarding content may be made.

Ⅴ. Conclusion of Contracted R&D Agreements

1. Conclusion of Contracted R&D Agreements

(1) Agreement Conditions

With regard to awarded R&D projects, R&D projects a one-fiscal-year contracted R&D agreement shall be concluded between the research institution implementing the R&D project* and AMED in accordance with the principle of the accounting period of the national government. Successful applicants shall receive detailed information from AMED following project selection.

In concluding contracted R&D agreements, in the case that the conditions decided at the time the project was adopted have not been fulfilled based on the opinions of the Project Evaluation Panel, PS, and PO, etc., and agreement is not reached regarding both the content of the agreement (including expenditure estimates) and method, an agreement will not be concluded even for an awarded R&D project.

Even after the contracted R&D agreement has been concluded, in the case that unavoidable circumstances arise due to budget restrictions, the R&D project may need to be revised or suspended.

The PS or PO, etc., shall check on the R&D progress status, and the contracted R&D agreement may be changed or cancelled part-way through the fiscal year due to revisions to the R&D plan or other reasons.

*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 or the 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 PI or Co-Investigator of the relevant institution be adopted. (In such cases, payment will be in accordance with the Guidelines for Handling of R&D Grants prescribed by AMED.) If this is the case, administration related to R&D grant accounting shall be entrusted to the head of the relevant institution.

Furthermore, in the case that the need to carry out the research content at the Principal Institution and the Subsidiary Institution in an integrated manner under the R&D plan is recognized and the Subsidiary Institution is not a national facility or other institution, approval may be given under the program for the R&D to be subcontracted. However, even in the case that the R&D is subcontracted, as a general rule project accounting shall be performed by the subcontracted institution and the subcontracted institution shall be required to undergo auditing in response to requests from AMED.

(2) Preparations for Concluding Agreement

Following the adoption of an R&D project, the research institution implementing the R&D project shall be required to carry out the following to enable procedures for concluding the contracted R&D agreement to proceed quickly and smoothly.

(a) Preparation of an Overall R&D Plan and R&D Plan*

(b) Obtain an estimate for the expenditure needed under the administrative plan

(c) Organize accounting regulations rules for employee inventions, etc.

*One Overall R&D Plan is to be prepared for each R&D project based on the R&D proposal at the time of adoption of the project. Centered on the proposed R&D concept for the entire project implementation period, please include the basic plan, R&D content, R&D system, and budget plan. This plan shall be used as a base material for considering budget allocation each fiscal year, conducting a Mid-term Review and an Ex-Post Evaluation, and managing project progress.

One R&D Plan is to be prepared for each agreement when contracted R&D agreements for each fiscal year are concluded.

Plan forms shall be provided separately after projects have been adopted.

(3) Administrative Procedures Regarding Conclusion of Agreements

Please carry out the necessary administrative procedures based on the AMED "Administration Manual for Contracted R&D Agreement".*

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

(4) Determination of Contracted R&D Funding Amount

Contracted R&D funding amounts are determined based on examination of the Contracted R&D Accomplishments Report which is required to be submitted in accordance with the Contracted R&D Agreement following the conclusion of the Contracted R&D Agreement period for the relevant fiscal year. During this examination, in the case that expenditure for research purposes is found to have been used fraudulently or for purposes not recognized as contracted R&D activities under the Contracted R&D Agreement, all or part of the expenditure may be required to be returned. Furthermore, the person(s) conducting the research who used the funds fraudulently may be excluded from any agreements with AMED for a certain period of time, depending on the extent of the fraud. (Please refer to Ⅴ. 8. (2).)

2. Scope and Payment of Contracted R&D Funds

(1) Scope of Contracted R&D Funds

In accordance with the governmental ministries' and agencies' expenditure table used in common for the competitive funds, items of expenditure have been set as follows for the program. For details, please refer to the AMED "Administration Manual for Contracted R&D Agreement".[1]

	Main item	Definition
Direct costs	Costs of goods (equipment/supplies)	Research facilities/equipment/prototypes, software (ready-made 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, interpretation/translation, and unskilled labor.
	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, amount equivalent to consumption tax related to untaxed transactions, etc.
Indirect costs[2]	Expenditure used by research institutes as necessary costs for managing the research institutes during implementation of the relevant R&D, paid at a fixed percentage of direct costs (with a 30% rule of thumb) as an allowance.	

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

[2]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, private enterprise, 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.

(2) Appropriation of Contracted R&D Funds

Please calculate costs required for conducting the R&D and record the total amount. As a general rule, calculation and recording of costs should be performed in accordance with the AMED "Administration Manual for Contracted R&D Agreement".*

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

Note: Contracted R&D agreements for researcher-initiated trials or clinical studies under AMED shall employ "Contract management method using value per procedure (VPP) charts in researcher-initiated trials or clinical studies".* In the case that an awarded R&D project is recognized as being subject to this management method, if the research institute has created a system for registering cases for trials/clinical research in accordance with newly prescribed internal consignment regulations ("Regulations for Handling Contracted R&D in Researcher-initiated Trials and Clinical Studies" (tentative title), the head of the research institute can request case registration from other medical institutions in a kind of outsourcing method. For details, please refer to AMED "Operation of Research Funds: Management of Medical Institution Expenditure for Researcher-initiated Trials and Clinical Studies" (link from: https://www.amed.go.jp/program/kenkyu_unyo.html).

*Facilities where there is a sufficient administrative support system for trials/clinical research may continue using their current management method for the foreseeable future.

(3) Payment of Contracted R&D Funds

As a general rule payment of contracted R&D funds shall be made each quarter in even (one-quarter) installments of the total amount for direct and indirect costs for the entire fiscal year.

(4) Provision of Documentary Evidence (Receipts, Etc.) for Indirect Costs

Please check in the AMED "Administration Manual for Contracted R&D Agreement".*

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

3. Carryover of Contracted R&D Funds

In the course of the program, in the case that it becomes difficult to ensure completion of contracted R&D fund payments within the relevant fiscal year due to difficulty deciding preliminary surveys or research methods for the R&D, various conditions related to the R&D plan, weather-related issues, difficulty in procuring materials, or other unavoidable reasons, the contracted R&D funds may be carried-over to the end of the next fiscal year maximum with the approval of the Minister of Finance.

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

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

4. Obligations of Research Institutes in Implementing this Program

(1) Compliance with Laws and Ordinances

In implementing this program, research institutes must be observant of the fact that their research is being funded with public funds and strictly comply with related national government laws and ordinances, endeavoring to ensure that the program is implemented fairly and efficiently. In particular, research institutes shall be required to take measures to prevent misconduct,[1] fraudulent use,[2] and fraudulent receipt[3] (hereinafter referred to collectively as "Misconduct, etc.").

[1]"Misconduct" refers to the fabrication, falsification, or plagiarism of data or survey results, etc. included in research accomplishments published through submission to a journal, etc. (hereinafter referred to as an "Academic paper, etc.") by a researcher, either willfully or through gross negligence of the fundamental duty of diligence that researchers bear in carrying out their research activities. The definitions of each of the above terms is as follows.

(i) Fabrication: creation of data or research accomplishments that do not exist.

(ii) Falsification: manipulation of research materials, equipment, or processes and changing results obtained from data or research activities to results that are untrue.

(iii) Plagiarism: appropriation of the ideas, analysis methods, data, research accomplishments, academic papers, or terminology of another researcher without the approval of the relevant researcher or appropriate acknowledgement.

[2]"Fraudulent use" refers to the use of public R&D funds, either willfully or through gross negligence, for a purpose other than that for which it was intended, or in a manner that infringes the content of the grant decision or conditions for use of the public R&D funds (including, but not limited to, purposes or uses other than those stated in the R&D plan, or use of R&D funds that infringes laws, ordinances, regulations, notifications, or guidelines, etc.)

[3]"Fraudulent receipt" refers to a researchers receiving public R&D funds through falsehoods or other unfair means.

*Under the above definitions, "researcher" refers to a researcher, technician, research assistant, or other person conducting research activities using public R&D funds, or a person engaged in work subsidiary to these research activities.

(2) Participation in/Completion of Research Ethics Education Program

As part of measures to prevent misconduct from occurring, AMED requires all researchers participating in this program to take and complete a research ethics education program. Research institutes shall implement research ethics education for researchers and report to AMED on the status of participation. (For details, please refer to Chapter V. 6. and the AMED website.)

Furthermore, in the case that a researcher does not fulfill their obligation to undergo the research ethics education despite AMED's urging, the research institute may be directed by AMED to suspend all or part of the contracted R&D funding. In this case, research institutes must suspend contracted R&D funding as directed by AMED and not recommence funding until directed to do so.

(3) Conflict of Interest Management

In order to ensure the fairness and reliability of research, in accordance with AMED's "Regulations for Managing COI in Research Activities" (revised on June 30, 2017; Regulation No. 90), the situation regarding conflict of interest for researchers involved in R&D projects shall be managed appropriately and reported.

In the case of research institutes conducting R&D under the AMED program, in the case that AMED determines that the conflict of interest of the PI or Co-Investigator of a project is not being managed appropriately, AMED may instruct the research institute to improve the situation or suspend provision of R&D funds, as well as require the research institute to return all or part of the R&D funds already paid. For details, please refer to Chapter V. 7. and the AMED website.

(4) Compliance with Laws/Ordinances and Ethical Guidelines

In the case that implementation of the proposed R&D concept involves research requiring procedures based on laws/ordinances and/or ethical guidelines (such as R&D requiring the consent/cooperation of another party; R&D requiring care in handling personal information; and R&D requiring measures regarding bioethics/safety measures), research institutions must undertake the necessary procedures for obtaining the approval of both internal and external ethics committees.

Please note that, in the case that R&D is carried out in infringement of related laws/ordinances and policies that must be complied with, the R&D may be suspended, the contracted R&D agreement cancelled, and/or the decision to adopt the R&D project cancelled.

Furthermore, in the case that the R&D plan includes R&D or surveys requiring the consent/cooperation of another party or social consensus, research institutes must take appropriate measures with regard to the handling of the guarantee of human rights and interests.

Within 61 days after the end of each fiscal year or the conclusion of the contracted R&D project, research institutions shall report to AMED regarding the status of ethical reviews by research institutes concerning related laws/ordinances and policies, as well as the status of conflict of interest management.

With regard to R&D related to life sciences in particular, the main laws and ordinances prescribed by government ministries and agencies are as follows. In addition, there are also laws and ordinances that pertain to certain R&D content, so please check the latest revision of laws/ordinances, etc.

- Act on Regulation of Human Cloning Techniques (Act No. 146 of 2000)
- Act on Prevention of Infectious Diseases and Medical Care for Patients Suffering from Infectious Diseases (Act No. 106 of 2006)
- Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003)
- Act on the Safety of Regenerative Medicine (Act No. 85 of 2013)
- Clinical Research Act (Act No. 16 of 2017)
- Guidelines on the Handling of Specified Embryos (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) No. 173)
- Guidelines on the Derivation of Human Embryonic Stem Cells (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Health, Labour and Welfare (MHLW) No. 2 of 2014)
- Guidelines on the Distribution and Utilization of Human Embryonic Stem Cells (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) No. 174 of 2014)
- Guidelines on the Research on Producing Germ Cells from Human iPS Cells or Human Tissue Stem Cells (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) No. 88 of 2010)
- Ethical Guidelines for Human Genome/Gene Analysis Research (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) , the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Economy, Trade and Industry (METI) No. 1 of 2013)
- Ministerial Ordinance on Good Clinical Practice for Drugs (Ordinance of the Ministry of Health and Welfare No. 28 of March 27, 1997)
- Ministerial Ordinance on Good Clinical Practice for Medical Devices (Ordinance of the Ministry of Health, Labour and Welfare (MHLW) No. 36 of 2005)
- Ministerial Ordinance on Good Clinical Practice for Regenerative Medical Products (Ordinance of the Ministry of Health, Labour and Welfare (MHLW) No. 89 of 2014)
- Ministerial Ordinance on Good Laboratory Practice for Nonclinical Safety Studies of Drugs (Ordinance of the Ministry of Health, Labour and Welfare (MHLW) No.21 of 1997)
- Ministerial Ordinance on Good Laboratory Practice for Nonclinical Safety Studies of Medical Devices (Ordinance of the Ministry of Health, Labour and Welfare (MHLW) No.37 of 2005)
- Ministerial Ordinance on Good Laboratory Practice for Nonclinical Safety Studies of Regenerative Medical Products (Ordinance of the Ministry of Health, Labour and Welfare (MHLW) No.88 of 2014)
- On the Approach of Research and Development Using Human Tissues Obtained from Surgery (Report of the Health Science Council, the Ministry of Health and Welfare, 1998)
- Ethical Guidelines for Medical and Health Research Involving Human Subjects (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT), and Ministry of Health, Labour and Welfare (MHLW) No. 1 of 2017)
- Policies on Clinical Research Involving Gene Therapy (Public Notice of the Ministry of Health, Labour and Welfare (MHLW) No. 344 of 2015)
- Ethical Guidelines for Assisted Reproductive Technology Studies Involving Production of Human Fertilized Embryos (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Health, Labour and Welfare (MHLW) No. 2 of 2010)
- Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Academic Research Institutions (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) No. 71 of 2006); Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Implementing Agencies under the Ministry of Health, Labour and Welfare (Notification by Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW) on June 1, 2006; partially revised on February 20, 2015); and Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Implementing Agencies under the Ministry of Agriculture, Forestry and Fisheries

(Notification by the Director-General of the Secretariat, Agriculture, Forestry and Fisheries Research Council, Ministry of Agriculture, Forestry and Fisheries (MAFF) on June 1, 2006)

*Please refer to the following websites for details regarding bioethics and ensuring safety.
・MEXT's Life Sciences Forum "Initiative on Bioethics and Biosafety"
http://www.lifescience.mext.go.jp/bioethics/index.html
・Regarding Guidelines on Research (Ministry of Health, Labour and Welfare (MHLW))
http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/hokabunya/kenkyujigyou/i-kenkyu/index.html

(5) Management Responsibility for Executing Contracted R&D Funds

The contracted R&D funds shall be executed by the research institute in accordance with the contracted R&D agreement. For this reason, research institutes shall abide by the principles stipulated under "Competitive research funding should be managed at the responsibility of the research institution", and research funds shall be managed under the responsibility of research institutes.

(6) Response Obligations Regarding System Maintenance, etc.

(a) Obligation to take action with regard to system maintenance

All research institutes must strictly comply with the items required to be implemented by research institutes in accordance with the Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards) (formulated on March 31, 2014; finally revised on February 23, 2017; decided by Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW)) and the Guidelines for Responding to Misconduct in Research Activities in the Field of Health, Labour and Welfare (formulated on January 16, 2015; finally revised on February 23, 2017)

5. Obligations of Researchers Participating in Research Activities under this Program

(1) Fair and Appropriate Execution of Contracted R&D Funds

Researchers participating in this program should be fully aware of the fact that AMED contracted R&D funds are provided by precious tax paid by the general public, and are obligated to execute funds fairly, appropriately, and efficiently.

(2) Application Procedures

When lodging an application for this program, the researcher who is to participate in this program must make the appropriate arrangements, such as explaining the research to and receiving approval for the research from the research institute that is to conduct the R&D project in advance.

(3) Participation in/Completion of Research Ethics Education Program

In order to prevent fraudulent use, fraudulent receipt, and misconduct, researchers participating in this program are required to complete a research ethics education program. (Please refer to Chapter V. 6. for details.) Please note that in the case that a researcher does not complete a research ethics education program, execution of contracted R&D funds may be suspended until completion of the research ethics education program is confirmed.

6. Participation in Research Ethics Program

(1) Program(s) to be Undertaken/Educational Materials

Persons required to undergo research ethics training as listed in (2) below shall undergo training using one of the following programs/materials.

- APRIN e-Learning Program (CITI Japan)
- "For the Sound Development of Science: The Attitude of a Conscientious Scientist" (Japan Society for the Promotion of Science Editing Committee "For the Sound Development of Science")
- Programs implemented by research institutes whose content is deemed to be equivalent to the that of the above programs

(2) Persons Required to Undergo Research Ethics Training

Persons required to undergo research ethics training shall be researchers whom research institutes determine to be participating substantially in research activities being conducted with research funds provided by AMED.

(3) Research Ethics Training Period

As a general rule, persons required to undergo research ethics training shall undertake this training within the first fiscal year of the R&D period, and should continue to undertake ethics training as appropriate thereafter. (Training undertaken previously may also be valid.)

(4) Role of Research Institutes

Research institutes shall ensure that persons required to undergo research ethics training as listed in (2) above who are affiliated with their institution (included a contracted institution) undergo the R&D ethics education using one of the programs/materials listed in (1) above, and shall report on their training status to AMED.

(5) Reporting Research Ethics Training Status

Research institutes shall compile information on researchers' R&D ethics education status and submit a report on the status of training on the form prescribed by AMED by e-mail to AMED (Department of Research Integrity and Legal Affairs). (Seal need not be affixed.)

Subject of report: Persons required to undergo research ethics training in programs commencing in/after FY2018
Deadline for submission: May 31, 2019
Documents to be submitted: "Report on the Status of Participation in R&D Ethics Education Programs" (Please download the form from the AMED website)
URL: https://www.amed.go.jp/kenkyu_kousei/
Where/how to submit report: Please e-mail the report to kenkyuukousei"AT"amed.go.jp
(Change "AT" to @ when inputting the address.)
Subject line: "FY2018 R&D Ethics Education Status Report XXX" (Replace XXX with the name of the research institute.)

(6) Inquiries

For inquiries related to R&D ethics education programs, please send an e-mail to [kenkyuukousei"AT"amed.go.jp] (Change "AT" to @ when inputting the address.)

7. COI Management

(1) Target Persons

PI or Co-Investigator of R&D projects
Projects on the List of Non-R&D Projects on the AMED websites Research Integrity page's "COI Management in R&D" are excluded as targets.

(2) Requests for COI Reviews

Prior to the conclusion of a contracted R&D agreement for the relevant R&D project each fiscal year, target persons shall report to the COI Committee regarding matters related to economic interests and then comment regarding reviews concerning conflict of interest in the R&D project.

(3) Submission of Ethics Review and COI Status Reports

The PI and Co-investigator affiliated with each research institute shall prepare an ethics review and conflict of interest status report for each project in which they are involved; have the head of the affiliated research institute affix his/her seal to the documents, and then submit the documents to the program department responsible for the relevant project by postal mail. (The research institute should also compile and submit a report by the Co-Investigator at contracted institutions.) The deadline for submission of reports is within 61 days after the end of each fiscal year or the conclusion of the contracted R&D project.

(4) Inquiries

For inquiries related to conflict of interest management, please send an e-mail to [kenkyuukousei"AT"amed.go.jp] (Change "AT" to @ when inputting the address.)

*For details, please refer to the following websites
- Regulations for Managing COI in Research Activities
- Regulations Q&A
- Reports on the State of Ethical Reviews and COI Management
  https://www.amed.go.jp/kenkyu_kousei/riekisohan_kanri.html

8. Countermeasures to Misconduct, Fraudulent Use, and Fraudulent Receipt

(1) Reporting of and Cooperation in Investigations of Misconduct, Fraudulent Use, and Fraudulent Receipt

- In the case that a complaint (including criticism from external organizations such as the media or the Board of Audit) related to misconduct, fraudulent use, or fraudulent receipt (hereinafter collectively referred to as "misconduct") by a research institute in relation to this program, the research institute shall swiftly report to AMED that it will be commencing a preliminary investigation into the matter in accordance with the Guidelines for Responding to Misconduct in Research Activities in the Field of Health, Labour and Welfare (No. 0116-1, decided by Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW) on January 16, 2015; finally revised on February 23, 2017) ; Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards) (decided by Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW) on March 31, 2014; finally revised on February 23, 2017); and AMED Regulations for Responding to Misconduct in Research Activities (formulated on April 1, 2015; revised on February 19 and November 2, 2016).
  In the event that it is deemed necessary for the research institute to conduct such an investigation, an investigative committee must be established and the policy, targets, and methods of the investigation discussed with AMED.
  Note that in this case, AMED may order the complainee and/or the research institute to suspend use of research funds under this program as a temporary measure during the investigation if necessary.
  Furthermore, the research institute must submit to AMED a final report including the investigation outcome, cause of the misconduct, status of management/auditing of other competitive research funding in which the people involved in the misconduct are also involved, and plan for preventing recurrence by the deadline prescribed under the AMED Regulations for Responding to Misconduct in Research Activities (formulated on April 1, 2015; revised on February 19 and November 2, 2016).
  In the case that it is confirmed that misconduct has occurred even partially and even before the investigation has been completed, the research institute must swiftly recognize this fact and report it to AMED, as well as submit an investigation progress report and/or interim investigation report, even if the investigation has not yet concluded.
  Please note that, except in the case that there is a legitimate reason, such as hindering the investigation, the research institute must submit materials pertaining to the relevant case to AMED and respond to AMED's perusal of these materials and on-site investigations.
  In the case that that research institute extends the deadline for submission of the final report, AMED may take measures against the research institute such as reducing indirect costs by a certain percentage or suspending execution of contracted R&D funds. In addition, for details regarding items that should be incorporated into the final report, please refer to Guidelines for Responding to Misconduct in Research Activities in the Field of Health, Labour and Welfare (No. 0116-1, decided by Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW) on January 16, 2015; finally revised on February 23, 2017) ; Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards) (decided by Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW) on March 31, 2014; finally revised on February 23, 2017); and AMED Regulations for Responding to Misconduct in Research Activities (formulated on April 1, 2015; revised on February 19 and November 2, 2016).

(2) In the Event that Misconduct, Fraudulent Use, or Fraudulent Receipt is Discovered

In the case that misconduct takes place under this program, the following measures will be taken against the relevant research institute and researcher(s) in accordance with Guidelines for Responding to Misconduct in Research Activities in the Field of Health, Labour and Welfare (No. 0116-1, decided by Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW) on January 16, 2015; finally revised on February 23, 2017) ; Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards) (decided by Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW) on March 31, 2014; finally revised on February 23, 2017); and AMED Regulations for Responding to Misconduct in Research Activities (formulated on April 1, 2015; revised on February 19 and November 2, 2016).

(a) Cancellation of contracted R&D agreement

In the case that AMED recognizes that misconduct has taken place under this program, AMED shall cancel the contracted R&D agreement with the relevant research institute and demand the return of all or part of the contracted R&D funds from the research institute. Furthermore, AMED may not provide contracted R&D funds to the relevant research institute for the next fiscal year or thereafter.

(b) Restrictions on applications and participation

Researchers who are found to have carried out misconduct under this program or who are recognized as having been involved in or responsible for the misconduct shall have their application to and participation in AMED programs restricted in accordance with the degree of misconduct as shown in the table below.

[In the case of misconduct]

*The period of restriction deemed appropriate in consideration of the category of misconduct according to the person's involvement in the misconduct, between one year and ten years from the fiscal year in which the day the misconduct is recognized occurs or the next fiscal year.

<table>
<tr><th colspan="3">Category of misconduct according to involvement</th><th>Degree of misconduct</th><th>Period deemed appropriate</th></tr>
<tr><td rowspan="5">Person Involved in the Misconduct</td><td colspan="2">1. Especially malicious individual who intentionally engages in misconduct from the outset of the research</td><td></td><td>10 years</td></tr>
<tr><td rowspan="3">2. Author of academic paper, etc. related to research in which there has been misconduct</td><td>The author responsible for the academic paper in question (supervisor, first author, or other position of responsibility deemed equivalent)</td><td>The impact on the advancement of research in the relevant field or society is large, and the maliciousness of the misconduct is deemed to be high.</td><td>5–7 years</td></tr>
<tr><td>The impact on the advancement of research in the relevant field or society is small, and the maliciousness of the misconduct is deemed to be low.</td><td>3–5 years</td></tr>
<tr><td>Author other than that listed above</td><td></td><td>2–3 years</td></tr>
<tr><td colspan="2">3. An individual involved in misconduct other than that stipulated in 1 or 2</td><td></td><td>2–3 years</td></tr>
<tr><td colspan="3" rowspan="2">An author responsible for academic papers, etc. related to research in which there has been misconduct but who was not involved in the misconduct (supervisor, first author, or other position of responsibility deemed equivalent)</td><td>The impact on the advancement of research in the relevant field or society is large, and the maliciousness of the misconduct is deemed to be high.</td><td>2–3 years</td></tr>
<tr><td>The impact on the advancement of research in the relevant field or society is small, and the maliciousness of the misconduct is deemed to be low.</td><td>1–2 years</td></tr>
</table>

[In the case of fraudulent use/fraudulent receipt]

*The period of restriction deemed appropriate in consideration of the content of the fraudulent use/fraudulent receipt, between one year and ten years from the fiscal year in which the day on which execution of the research funds is suspended or the next fiscal year.

Content of usage of research funds	Period deemed appropriate
1. The degree of fraudulent use of research funds is deemed to have a small social impact and be slightly pernicious	1 year
2. The degree of fraudulent use of research funds is deemed to have a large social impact and be highly pernicious	5 years
3. Cases other than 1 or 2 that are deemed to have a social impact or be pernicious	2–4 years
4. Cases in which research funds were used for personal economic gain, regardless of 1 through 3	10 years

5.	Cases in which the relevant project was adopted as an R&D project through falsehoods or other dishonest means	5 years
6.	Cases in which the person is not directly involved in fraudulent use of research funds but uses the research funds in a manner that infringes duty of diligence	1–2 years

**In the following cases, the offender shall be given a reprimand without imposing restrictions on application.

- In 1–4, the person's actions are deemed to have a small social impact and be slightly pernicious, and the funding amount used fraudulently is small.
- In 6, researchers whose actions are deemed to have a small social impact and be slightly pernicious, and who neglected duty of diligence.

Furthermore, in the case that misconduct is recognized to have taken place under this program and restrictions are place on the researcher's application to and participation in AMED programs, the researcher's application to and eligibility for participation in research funding programs provided by related government ministries/agencies may similarly be restricted as information regarding the misconduct shall be provided to those in charge of programs under which competitive research funds are allocated by related government ministries/agencies or independent administrative corporations under the jurisdiction of related government ministries/agencies.

(c) Restrictions on researchers whose application to and participation in other R&D funding programs has been restricted

With regard to researchers who have been found to have carried out misconduct under R&D funding programs other than this program that are under the jurisdiction of the national government or an independent administrative corporation and are government-financed either wholly or in part, and whose application to and participation in these programs has been restricted, application to and participation in this program shall also be restricted for the duration of the restrictions imposed. In the case that the relevant researcher's application to or participation in this program becomes known after adoption by another program, adoption by the relevant program may be cancelled. Furthermore, in the case that the relevant researcher's participation in the program becomes known after the conclusion of the contracted R&D agreement, the relevant agreement may be cancelled.

(d) Cases in which it is suspected that misconduct has occurred under another R&D funding program

In the case that there is a complaint, etc., that a researcher participating in this program is suspected of perpetrating misconduct under another R&D funding program, the research institute with which the relevant researcher is affiliated is obligated to report to AMED that an investigation of the relevant misconduct allegations has been implemented.

Please note that, on receipt of this report, AMED may order the temporary suspension of usage of contracted R&D funds if deemed necessary.

Furthermore, in the case that the research institute to which the relevant researcher is affiliated fails to make the above report, the contracted R&D agreement may be cancelled.

(e) Disclosure of misconduct

In the case that the measures and/or restrictions prescribed in (a) and (b) above are implemented under this program, the content of the relevant measures shall be publicly disclosed in accordance with [Guideline name] (month, day, year); [Guideline name] (month, day, year); and AMED Regulations for Responding to Misconduct in Research Activities (formulated on April 1, 2015; revised on February 19 and November 2, 2016).

(3) Admission to the AMED RIO Network

AMED constructed a network called the "RIO Network"1 in FY2017. Research institutes that have concluded contracts with AMED shall register the officers in charge of R&D ethics education, the officers in charge of promoting compliance, and the officers in charge of R&D misconduct and research funding misconduct with AMED and participate in RIO Network activities.

Please refer to the following website[2] for more details about the RIO network.

1 A network comprising Research Integrity Officers (RIO) (officers in charge of R&D ethics education and officers in charge of promoting compliance) and officers responsible for research integrity at research institutes conducting R&D with AMED funds.
2 https://www.amed.go.jp/kenkyu_kousei/rionetwork.html

9. Points to Note between Selection and Conclusion of Agreement

(1) Cancellation of Decision to Adopt R&D Project

Following adoption of the R&D project, the decision to adopt the R&D project may be cancelled in the following cases.

- Documents required by AMED to be submitted are not submitted by the submission deadline

- A researcher/researchers involved in the relevant R&D project have had their application to/participation in AMED R&D programs restricted
- An investigation has been opened into allegations of misconduct

(2) Researchers Undergoing Investigation/Researchers Discovered to Have Undertaken Misconduct

Please note that in concluding contracted R&D agreements, AMED requires research institutes to provide representation and warranty with regard to items (a) through (c) below.

(a) The "PI" or person in an equivalent position (as the person in charge of the R&D for the project), and the "Co-Investigator" or person in an equivalent position (as the person sharing R&D items with the PI for the project) designated in an R&D plan have not been found by the research institute to have carried out misconduct in accordance with Japanese Government guidelines for responding to misconduct* (including cases in line with the regulations in response to misconduct of AMED, but excluding, however, persons regarding whom restrictions have not been placed regarding application to/participation in competitive research funding programs implemented by the national government or independent administrative corporations based on the findings of the research institute, or whose period of restriction on application to/participation in competitive research funding programs implemented by the national government or independent administrative corporations has ended).

(b) In the case that persons who are the subject of an investigation (hereinafter referred to as the "Investigation") being conducted by the research institute in accordance with Japanese Government guidelines for responding to misconduct (including cases in line with the regulations in response to misconduct of AMED) are either the PI or Co-Investigator for the R&D Plan, AMED has been notified of the relevant target persons by the day before the contracted R&D agreement will be concluded and AMED's consent has been obtained with regard to handling of the relevant target persons.

(c) The research institute is strictly complying with and implementing each of the items that research institutes are required to implement as research institute system improvements as prescribed under Japanese Government guidelines for responding to misconduct.

*In the case that a research institute with which AMED has concluded a contracted R&D agreement also concludes a contracted agreement with a third party institute (from AMED's perspective, a subcontracted agreement. Hereinafter, the third party institute shall be referred to as the "subcontracted institute"), please note that of the researchers affiliated with the Subcontractor, the relevant research institute is also required to provide representation and warranty for the "Co-Investigator" (or person in an equivalent position).

* The "Japanese Government guidelines for responding to misconduct" referred to in this section is a blanket term for all of the various policies and guidelines concerning response to misconduct formulated by all the government's ministries and agencies.

(3) Submission of R&D Plans and Reports

With regard to awarded projects, please note that some parts of the R&D Plan and reports may be required to be submitted in English.

(4) Elimination of Unreasonable Duplication or Excessive Concentration of Research Funds

(a) Measures to prevent unreasonable duplication

In the case that a researcher is unnecessarily being allocated competitive research funds from the national government and/or multiple independent administrative corporations for the same research project (name or content of the research receiving R&D funds) being conducted by the same researchers and any of the following applies, the R&D project may be eliminated from eligibility for review, the decision to adopt the R&D project may be cancelled, or the amount of funds reduced (hereinafter referred to as "Cancellation of decision to adopt, etc.").

- Applications are submitted simultaneously for multiple competitive research funding programs that are essentially the same (including if the projects overlap to a considerable degree; the same shall apply hereinafter) and multiple R&D projects are adopted on an overlapping basis.
- Applications are repeatedly submitted for R&D projects that are essentially the same as an R&D project that has already been adopted and been allocated competitive research funds
- There is duplication regarding the use of research funds amongst multiple R&D projects
- Other equivalent cases

Although there are no restrictions on submitting applications for other competitive research funds at the stage of applying for this program, please notify AMED staff in charge of this program promptly in the case that your R&D project is adopted by another competitive research funding program. If this is not reported, there is the possibility that the decision to adopt the R&D project under this program will be cancelled.

(b) Measures to prevent excessive concentration

Even if the content of the R&D proposal submitted for this program differs from the content of R&D being implemented under another competitive research funding program, in the case that the overall research funds allocated to the relevant researcher or research group (hereinafter referred in this item as "Researchers, etc.") in the relevant fiscal year exceeds the limit that can be used effectively and efficiently and cannot be used completely within the research period, and any of the following apply, the decision to adopt the R&D project under this program may be cancelled.

- Excessive research funds are allocated in comparison to the researcher's abilities or research methods
- Excessive research funds are allocated in comparison to the effort allocated to the relevant R&D project (percentage of the researcher's overall work time* that is needed for implementing the relevant research)
- Unnecessarily expensive research equipment is purchased
- Other equivalent cases

*Based on the Council for Science, Technology and Innovation's definition of "effort": the percentage of researchers' time exclusively spent for the R&D activities concerned against the researcher's annual working hours. Researchers' total working hours refer to not only the time spent in research activities but also total substantive working hours, including educational/clinical activities and administrative duties.

Accordingly, in the case that an application for an R&D project is submitted to and adopted by another competitive research funding program after an application documents for the R&D project has been submitted to this program, or if changes are made to the information provided on the application documents, please report this promptly to the AMED staff in charge of this program. If this is not reported, there is the possibility that the decision to adopt the R&D project under this program will be cancelled.

(c) Provision of information related to application content in order to eliminate unreasonable duplication/excessive concentration

In order to eliminate unreasonable duplication/excessive concentration, information related to parts of the application content (or awarded project/program content) may be provided within the necessary extent, to the persons in charge of other competitive research funding programs, including other government ministry/agency programs, via e-Rad. Furthermore, in the case that information is requested for checks being conducted under other competitive research funding programs, information may be provided in this way.

(d) Status of application and/or acceptance under other competitive research funding programs, including other government ministry/agency programs

Applicants may be required to provide information in proposal documents regarding the status of application and/or acceptance under other competitive research funding programs, including other government ministry/agency programs (name of program, name of R&D project, project implementation period, budget amount, effort, etc.) In the case that the information provided is factually inaccurate, the R&D project application may be rejected, the decision to adopt the R&D project may be cancelled, or the amount of funds allocated to the R&D project may be reduced.

Ⅵ. Management and Evaluation of Awarded Projects

1. Project Management

A Contracted R&D Accomplishments Report is required to be submitted each fiscal year for all awarded projects. Furthermore, the PS and PO shall manage progress of the project.

In implementing progress management, exit strategies shall be realized through the implementation of project progress meetings, questionnaires (documents to be completed with details on R&D progress status), hearings (interviews for individual projects), and site visits (confirming the actual status of R&D at the facility carrying out the research), so please cooperate in these activities. Please note that, depending on the progress status, review of the project plan or cancelation (early conclusion) of the project may be required.

In addition, R&D projects moving into the practical application stage (R&D projects that are within the target scope of the "regulatory science strategy consultation" program conducted by the Pharmaceuticals and Medical Devices Agency (PMDA)), as required to undergo face-to-face advice as a general rule in the first or second year[1, 2] after adoption of the R&D project under this program as a condition of adoption. Furthermore, based on appropriate information management, the research institute shall consent to AMED attending various kinds of consultation interviews under the "regulatory science strategy consultation" program during the R&D period and share face-to-face advice records and related information with AMED.

[1]Regarding R&D projects involving clinical studies (trials), face-to-face advice must be undergone prior to the commencement of the clinical trials. R&D that have already undergone face-to-face advice prior to adoption of the R&D project may undergo face-to-face advice again during the R&D period as necessary.

[2]Although it is not compulsory for the R&D project to have undergone face-to-face advice at the time of application to this program, it is desirable that face-to-face advice be undergone and the results of the consultation reflected in the R&D plan.

For research undertaking investigator-initiated trials or clinical studies with a view to creating innovative drugs or medical devices, or nonclinical studies aimed at conducting such trials/studies* during the R&D period, research institutes are required to submit materials related to clinical studies such as a protocol (including information such as aims, subjects, selection criteria, exclusion criteria, number of cases, observation content, intervention content, statistical methods, and research system).

*Note: Does not include clinical research that is not aimed at developing new drugs or medical devices or that differs from normal processes for evaluating/approving new medical technology.

2. Evaluation

Under this program, awarded projects whose planned project period is five years or longer shall undergo a Mid-term Review by the "Project Evaluation Panel" at around the third year after the R&D commences to rigorously evaluate the degree to which the R&D plan is being achieved and R&D accomplishments, etc.* Awarded projects whose planned project period is less than five years are not required to undergo a Mid-term Review as a general rule, but in the case that it becomes necessary to conduct a Mid-term Review in the course of implementing the program, a Mid-term Review shall be conducted by the "Project Evaluation Panel".

Furthermore, in the case that it is deemed necessary, R&D projects under this program shall undergo a Mid-term Review, regardless of the timing. Based on evaluation results, AMED may decide to cancel (conclude early) or extend a project in accordance with the overall decision of the PS and PO, etc.

In addition, all awarded projects are to undergo Ex-Post Evaluations at an appropriate time following the conclusion of the R&D project. Based on the evaluation results, it may be decided to extend for one year the R&D period of projects that can be expected to lead to practical application and that should be continued developmentally. Moreover, a follow-up evaluation may be carried out after a certain period of time after conclusion of the project if deemed necessary.

*"Five years" refers to five fiscal years.

3. Presentations at Accomplishments Report Meeting

As part of achievements reporting under this program, the PI of an awarded project shall be required to make a public or closed-door presentation at an Accomplishments Report Meeting held by AMED. In addition, as part of follow-up evaluations and examinations of further development of project accomplishments, the PI of an awarded project may be requested, if necessary, to make a presentation in or after the fiscal year in which the project was completed, so please cooperate with this request.

Ⅶ. Handling of R&D Accomplishments

With regard to the handling of R&D accomplishments, research institutes (contractors) are obligated under contracted R&D agreements to strictly comply with items regarding R&D accomplishment reportings, intellectual property (IP) and usage of R&D accomplishments.

1. Submission and Publication of R&D Accomplishments Reports

Contractors shall submit a R&D accomplishments report summarizing the research accomplishments of the R&D project. Please note that the deadline for submission of reports is within 61 days from the end of the term of the contracted R&D agreement or from the conclusion/cancellation/discontinuance of the contracted R&D, whichever comes first. In the case that the R&D accomplishments report is not submitted by the deadline, it shall be deemed that the contracted R&D agreement has not been fulfilled, so please be sure to strictly comply with the submission deadline.

A part of the items in the R&D accomplishment reports and outline of accomplishments will be treated as publicly open information. As it will be published at appropriate times on the AMED website please be careful to indicate parts that are not to be made public in the section “Non-Disclosure Items” in the reporting form with regard to information about patents that are pending but have not been published in an official gazette, knowhow and other confidential sales information and any other undisclosed information. Moreover, with regard to final accomplishment reports produced at the end of research projects that have lasted for several years, the content under the section of “Items for Disclosure” in the reporting form compiled by the PI upon Ex-Post Evaluation will be published at appropriate times on the AMED website.

2. Attribution of R&D Accomplishments

With regard to patent rights, copyrights and other intellectual property (IP) relating to R&D accomplishments, these can revert to the contractor under the condition that the requirements provided for in Article 19 of the Industrial Technology Enhancement Act (Act No.44 of 2000, the Bayh-Dole Act. The Japanese version of the Bayh-Dole Act) are satisfied. The purpose of the Bayh-Dole Act is to invigorate R&D activities through the reversion of IP rights to contractors so that the results of these R&D activities can be used efficiently in business activities. Under this program, it is expected that contractors themselves will make the maximum effort to achieve practical application of their research accomplishments, and for this reason the Bayh–Dole Act has been applied. For details regarding conditions, please refer to contracted items prescribed under the contracted R&D agreement at the time the agreement is concluded.

3. Measures towards the practical application of R&D accomplishments

Contractors are requested to maintain a strong sense of awareness that they are in a position in which they must try their best to use the accomplishments of the R&D entrusted to them by AMED in order to make a contribution to society, implement them and put them to practical use, and take the requisite measures towards this goal. In particular, they are requested to make the maximum use of inventions, knowhow, data and other IP, while in accordance with AMED's IP policy* ensuring that appropriate measures have been implemented within the contractor’s funding sources such as appropriating indirect costs, and costs for obtaining IP rights in order to ensure appropriate protection and utilization of patent rights and other IP rights on a global scale.

AMED’s Department of Intellectual Property provides consistent support for maximizing and achieving the practical application of R&D accomplishments that have reverted to the contractors, so do not hesitate to contact the Medical IP Desk (details of which are found below in Chapter IX. 7.).

* https://www.amed.go.jp/chitekizaisan/chizai_policy.html

4. IP Educational Materials for Medical Researchers

IP educational materials for medical researchers are provided on the AMED website* as a reference for considering strategies for submitting applications for, obtaining patent/IP rights for, and utilizing R&D accomplishments that have reverted to contractors. Researchers are strongly recommended to peruse these IP educational materials prior to carrying out research.

In addition, AMED has prepared e-learning IP educational materials for researchers selected for the AMED program with the objective of deepening understanding of strategies for the IP applications peculiar to the field of medicine, utilization strategy and Bayh-Dole reports obligated according to agreements. It is a requisite that these IP educational materials are studied by researchers in the case of some programs. Details will be provided later about how to access these e-learning IP educational materials

* https://www.amed.go.jp/chitekizaisan/chizai_kyouzai.html

5. Securing Open Access to R&D Accomplishments

Having secured the necessary IP rights, contractors are requested to cooperate in ensuring open access to research accomplishments as far as possible.

Ⅷ. Handling of Acquired Goods

1. Ownership

Ownership of goods, etc. acquired by Universities and Research Institutions,[1] through direct costs (hereinafter referred to as "Acquired Goods") shall revert to the university, etc.

Ownership of acquired goods by Companies, etc.,[2] shall revert to AMED in the case of goods with an acquisition cost of 500,000 yen or more (consumption tax included) and has a service life of one year or more, but the relevant acquired goods may be used free-of-charge for the purpose of contracted R&D by the contractor until the conclusion of the contracted R&D period. The contractor shall manage the relevant acquired goods properly with the due diligence of a prudent manager.

[1]"Universities and research institutions" include:
(i) Incorporated educational institutions such as national university corporations, public university corporations, and private universities
(ii) Public research institutions such as national research institutes, public research institutes, and independent administrative corporations
(iii) Organizations with a public nature, such as public-service corporations, that are recognized by AMED.

[2]"Companies, etc." is a general term for research institutes other than "universities, etc."

2. Handling of Acquired Goods after Completion of R&D Period

For the purpose of continued application of the relevant R&D, as a general rule Companies etc., may continue to borrow free-of-charge tangible property acquired in or after FY2015 and whose ownership has reverted to AMED for the duration of its service life and the tangible property may be transferred to the Companies etc., for a fee after its service life has passed, provided that this shall not apply in either case in the event that AMED uses or disposes of the relevant acquired goods.*

With regard to acquired goods that are treated as consumables, no specific leasing agreement or other procedures will be implemented, but the contractor shall manage the relevant acquired goods properly with the due diligence of a prudent manager until their use is finished (resale of acquired goods for profit is not permitted).

*The above are the general rules for handling of acquired goods, but changes may be made. Formation regarding handling of acquired goods will be provided again at the time of leasing agreement, sales agreement, and/or transfer procedures following the conclusion of the R&D project.

3. Disposal of Radioactive Waste

It is the responsibility of the contractor to dispose of contaminated property and/or radioactive waste generated through implementation of the R&D project.

Ⅸ. Other

1. Two-way Communication with the General Public

In accordance with the “Promotion of the 'Dialogue on Science and Technology with Citizens' (A Basic Course of Action)” (decided by the Minister of State for Science and Technology Policy and the Executive Members of the Council for Science and Technology Policy on June 19, 2010), the Council for Science and Technology Policy (now the Council for Science, Technology and Innovation) requires not only that science and technology results are returned to the general public, but also that the content and results of R&D activities be explained to society and the general public in an easy-to-understand manner from the standpoint that it is imperative to take the stance of obtaining the general public’s understanding and support as well as promoting science and technology in order to generate outstanding science and technology results without pause, further advancing Japan’s science and technology. Furthermore, the 5th Science and Technology Basic Plan (decided by a Cabinet Decision on January 22, 2016) demands that science and technology and society, which have traditionally worked at cross purposes, need to have a deeper relationship in order to facilitate dialogue and cooperation, or “co-creation,” between a diverse range of stakeholders, including researchers, citizens, media, industry, and policymakers. From this perspective, there is a need for initiatives to explain research activity contents and their results and accomplishments in a comprehensible manner to society and the general public, and to promote dialog and cooperation with many stakeholders. In response to this, research institutions are requested to hold public meetings and symposia, about their R&D accomplishments and continuously post their R&D accomplishments on the Internet, and eagerly involve themselves in round table meetings etc. that include the participation of a wide spectrum of stakeholders.

Reference: Regarding the Promotion of Dialog with Citizens on Science and Technology (basic initiative guidelines)
http://www8.cao.go.jp/cstp/output/20100619taiwa.pdf

2. Health Risk Information

In accordance with requests from the Ministry of Health, Labour and Welfare, AMED requires researchers to report information obtained in the process of conducting research that could seriously threaten the lives and/health of members of the general public (hereinafter referred to as “Health risk Information”) to the Ministry of Health, Labour and Welfare using the prescribed form. For details such as contact information, please refer to the AMED Administration Manual for Contracted R&D Agreement in Japan Agency for Medical Research and Development.[2]

The health risk information provided is evaluated together with other information by the Ministry of Health, Labour and Welfare and used in considering necessary responses to the relevant health risk. Providing this information does not place responsibility on the researcher, so please provide a broad range of information.

[1]http://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/kenkoukiken.doc
[2]Link from https://www.amed.go.jp/keiri/index.html

3. Registration of researcher information on researchmap

Researchmap is the largest database in Japan serving as a list of researchers in the nation. It enables researchers to publicize their registered accomplishments over the Internet. In addition, researchmap links in with e-Rad and many university databases of researchers, and since the information registered on it can be used on other systems it makes it unnecessary for researchers to repeatedly input information in multiple application forms about accomplishments and applications on various databases. The information registered on researchmap is effectively used in governmental and other science and technology policy making research and for statistical purposes, and those carrying out projects under this program are therefore requested to cooperate by registering with researchmap.

* http://researchmap.jp/

4. Smoothing Utilization of Research Tool Patents

With regard to research tool patents, please endeavor to handle research tool patents appropriately in accordance with the Guidelines for Facilitating the Use of Research Tool Patents in the Field of Life Sciences (Council for Science and Technology Policy (now the Council for Science, Technology and Innovation), March 1, 2007.

5. Measures Related to the IP Strategic Program

The “IP Strategic Program” is a program formulated every year by Intellectual Property Strategy Headquarters in accordance with the Intellectual Property Basic Act (Act No. 122 of 2002) with the aim of promoting strengthening of IP strategies. Under the Intellectual Property Strategic Program 2014 (Intellectual Property Strategy Headquarters on July 4, 2014),[1] strategic utilization of certification is to be promoted in order to further invigorate international standardization activities, and AMED is also to promote R&D with a view to international standardization/certification.

Accordingly, in the case that a public research institute under this program carries out R&D with the potential to lead to international standardization/certification, the research institute is requested to undertake R&D with a view to international

standardization, such as considering support when instigating certification activities for incorporating formulation of standards for certification into individual R&D plans and including the participation of certification organizations in R&D activities.

[1]Intellectual Property Strategic Program 2014 (excerpt)
http://www.kantei.go.jp/jp/singi/titeki2/kettei/chizaikeikaku20140704.pdf
First pillar: Building up a global IP system for enhancing industrial competitiveness
4. Efforts for international standardization and certification
(2) Measures to be taken in the future
(Promoting international standardization strategies in specific strategic fields[2])

・With regard to international standardization strategies in specific strategic fields (with the fields selected based on market scale and growth potential, expandability of the field, Japan's superiority in the field, and the significance of international standardization), the Government of Japan will take the lead in international discussions and facilitate voluntary efforts made by interested parties (short term and medium term) (Cabinet Secretariat, Cabinet Office, MIC, MEXT, Ministry of Health, Labor and Welfare [MHLW], MAFF, METI, Ministry of Land, Infrastructure, Transport and Tourism [MLIT], Ministry of the Environment [MOE]).

[2]"Specific strategic fields": (1) Advanced medical technology, (2) Water, (3) Next generation vehicles, (4) Railways, (5) Energy management, (6) Digital content, (7) Robots

6. IP consultation support through AMED IP Consultants and AMED IP Liaisons

In order to encourage the practical application of R&D accomplishments obtained from AMED projects implemented, AMED provides a free-of-charge IP consultation service run by AMED IP Consultants covering IP strategy and licensing strategies. Furthermore, as one facet of this IP consultation service, when requested we also provide a free service to formulate precise IP strategies for R&D accomplishments through 1) investigating the available literature, 2) market research, and 3) sharing information on investigations into the application of R&D accomplishments.

In addition, the AMED IP Liaison visits research institutions throughout the nation and in conjunction with the AMED IP Consultants help to create a system enabling consultation at an early stage regarding appropriate out-licensing of R&D accomplishments obtained. Specifically, the AMED Liaison provides 1) IP strategy advice aimed at appropriate out-licensing at the early stages of R&D, 2) investigations of the available literature, markets research and support for technical seeds evaluation, and 3) guidance for the creation of appropriate PR sheets on R&D accomplishments for exhibitions and business negotiations.

If you wish to receive the support mentioned above, please contact AMED's Medical IP Desk. Please refer to the website[2] below for information regarding the Medical IP Desk.

1 AMED IP Liaisons: https://www.amed.go.jp/chitekizaisan/chizai_riezon.html

2 Medical IP Desk: https://www.amed.go.jp/chitekizaisan/medical_ip_desk.html

7. Seeds/needs matching support system

The creation of an undisclosed information network is underway, with the goal of matching at the earliest possible stage the R&D seeds of university and academia with the needs of corporations. The network is scheduled to be ready for use in April 2018. It is hoped that those in charge of R&D seeds in the medical field will actively register those seeds with the network when it is ready as it will enable them to introduce excellent R&D seeds to the personnel in-charge of in-licensing at multiple companies, and help create alliances with a company at an early stage

8. Support from the AMED Drug Discovery Support Network/Department of Innovative Drug Discovery and Development

In order to link the results of outstanding basic research by universities to the practical application of drugs, AMED's Department of Innovative Drug Discovery and Development (hereinafter referred to as the "Drug Development Department") functions as headquarters for constructing a nationwide "Drug Discovery Support Network" comprising the Institute of Physical and Chemical Research (RIKEN), National Institutes of Biomedical Innovation, Health and Nutrition (NIBIOHN), National Institute of Advanced Industrial Science and Technology (AIST), and other institutions. Network activities include providing continuous support for practical application related to drug discovery research, mainly from the applied study stage through to the preclinical development stage, as well as business derivation.

The Drug Development Department provides a wide range of consultation services for researchers undertaking drug discovery research as part of programs implemented by the Department, as well as gathers, examines, and evaluates information regarding promising R&D seeds; formulates R&D plans (including exit strategies) aimed at IP strategies for individual R&D seeds and collaboration with drug companies; provides technological support for applied research (exploratory study, optimization study, etc.) and nonclinical studies (conforming to GLP (Good Laboratory Practice)); introduction and contracted support of CROs (Contract Research Organizations) and CMOs (Contract Manufacturing Organizations), etc.; and procedures for collaboration with drug companies.

In this way, the Drug Development Department is a department that specializes in providing advice on technological projects related to practical application to researchers at universities, etc., engaged in drug discovery research, as well as support for formulating R&D strategies aimed at collaboration with drug companies. For this reason, R&D projects that are related to drug development may receive active support from the Drug Development Department in coordination with the relevant departments/offices.

Accordingly, information regarding applications for R&D projects related to drug development shall be provided to the Drug Development Department, regardless of whether or not the project is adopted under this program (please refer to Chapter IV. 1.). Furthermore, the Drug Development Department provides the above-mentioned support based on requests by researchers on the premise of maintaining confidentiality and protecting IP rights that have reverted to the researcher.

In the same way, with regards to the applied R&D projects related to drug development that is or was supported by the Drug Development Department, AMED provides the information on the support content to the department in charge of the program.

Please refer to Chapter X. for references related to support provided by the AMED Drug Discovery Support Network and the Drug Development Department.

9. Enhancement of AMED Project Evaluations

With the aim of enhancing the Project Evaluation Panel and conducting even more appropriate evaluations, AMED is endeavoring to secure panel members with a high degree of knowledge in specialized fields and pace careful attention to membership diversity from the perspectives of age, gender, and affiliated institution.

For this reason, in the case that a R&D project is adopted under this program, AMED may request that researchers provide their cooperation as AMED Project Evaluation Panel members.

10. Cooperation with Databases

(1) National Bioscience Database Center

The Japan Science and Technology Agency National Bioscience Database Center (NBDC)* provides the Life Science Database Archive (http://dbarchive.biosciencedbc.jp/) from which complete sets of data generated by researchers in the life science field in Japan can be downloaded. The Center also provides data related to human bioscience through the NBDC Human Database (http://humandbs.biosciencedbc.jp/), a platform for sharing various data generated from the human genome and other human-derived specimens.

To enable research accomplishments data in the bioscience field to be used widely and for a long time, please cooperate in contributing data to the NBDC “Life Science Database Archive” and/or “NBDC Human Database”.

* National Bioscience Database Center (http://biosciencedbc.jp/) provides R&D and services for making it easier to integrate and use Japanese bioscience-related databases with the aim of invigorating research and development through widespread sharing and utilization of research data.

(2) Deposit of Developed Resources to the National Bioresource Project (NBRP)[1]

So that the persons implementing this program contribute to research in the life science field, after using bioresources developed under this program and publishing the research accomplishments obtained via academic papers, etc., as a general rule researchers are to deposit the relevant bioresources to institutions participating in the NBRP Core Facility Upgrading Program[2] (limited to bioresources targeted by the NBRP), making these resources broadly available for researchers’ use.

[1] NBRP: https://www.amed.go.jp/program/list/04/01/002.html

[2] “Deposit”: Procedure for permitting the use of resources in resource programs (storage/provision) without transferring various rights related to the relevant resources. By prescribing conditions for provision within the deposit consent form, it is possible to add conditions regarding restrictions on use of resources and use of extracts from academic papers, etc., for users receiving the relevant resources.

(3) Other

With regard to specimen storage and genome analysis, R&D projects are required to actively use existing research bases, and AMED may in some cases provide guidance regarding/matching with the most suitable research bases. Accordingly, please cooperate in the event that AMED requests that the R&D project provides data to various databases designated by AMED, including in response to the above.

11. Responding to the Implementation of the Clinical Research Act

Notices about future ordinances and notifications will be published on the AMED website so please take the appropriate measures.

* With regard to clinical researches that have been continuously conducted since before the implementation of the Act, procedures need to be completed within the transitional period after its implementation and in line with its stipulations.

X. References

If you should have any questions regarding the content of these application guidelines, please make inquiries via the contact addresses provided in the table below.[1, 2] In addition, in the case that any information provided here changes, these changes shall be posted in the AMED website under "Collaborative Calls Information",[3] so please check the website for updates.

[1]Please make inquiries by e-mail as far as possible (Change "AT" to @ when inputting the address.)

[2]Be careful to dial the correct telephone number. Unless otherwise stated, telephone inquiry services are available 10:00–12:00 and 13:00–17:00 weekdays.

[3]https://www.amed.go.jp/koubo/

Content of inquiry	Contact address
R&D projects being solicited; review; how to fill in proposal documents	AMED Division of International Collaboration, Department of International Affairs Tel: +81-3-6870-2215 E-mail: chikyukibo"AT"amed.go.jp
Misconduct/fraudulent use/fraudulent receipt	AMED Department of Research Integrity and Legal Affairs E-mail: kouseisoudan "AT"amed.go.jp
Management of conflict of interest/research ethics education programs	AMED Department of Research Integrity and Legal Affairs E-mail: kenkyuukousei"AT"amed.go.jp
RIO Network	AMED Department of Research Integrity and Legal Affairs E-mail: rionetwork"AT"amed.go.jp
Medical IP Desk (Contact point for medical IP consultation)	AMED Department of Research Integrity and Legal Affairs E-mail: medicalip"AT"amed.go.jp
Support provided by the AMED Drug Discovery Support Network/Department of Innovative Drug Discovery and Development	AMED Department of Innovative Drug Discovery and Development East Japan Office 8F Muromachi Chibagin Mitsui Bldg, 1-5-5 Nihonbashi-Muromachi, Chuo-ku, Tokyo 103-0022, Japan Tel: +81-3-3516-6181 E-mail: id3navi"AT"amed.go.jp
How to use the e-Rad system	e-Rad Portal Site Help Desk Before telephoning, please check the "Frequently Asked Questions (FAQ)" page. Link from: https://www.e-rad.go.jp/contact/ →After checking the FAQ page, log in to e-Rad so that you can check the operation manual, then dial: Tel: 0570-066-877 (NAVI-DIAL) or +81-3-6631-0622 (direct line) if the NAVI-DIAL service is unavailable. Operating hours: 9:00–18:00 (weekdays) *Excludes Saturdays, Sundays, public holidays, or Year-end/New Year holidays (December 29 – January 3)
Bioscience Database Life Science Database Archive	Japan Science and Technology Agency (JST) National Bioscience Database Center (NBDC) E-mail: dbarchive"AT"biosciencedbc.jp http://dbarchive.biosciencedbc.jp/
Bioscience Database NBDC Human Database	Japan Science and Technology Agency (JST) National Bioscience Database Center (NBDC) E-mail: humandbs"AT"biosciencedbc.jp http://humandbs.biosciencedbc.jp/

XI. R&D Projects Being Solicited

The R&D project for which applications are being solicited is as follows. For an overview of this entire program, please refer to Chapter I; for application/selection implementation methods, please refer to Chapter III.

Solicitation Theme #1 is call for research project of a formative study to investigate a value of research theme toward applying for future GACD（※1）collaborative awards. Applicants are able to apply for both of Solicitation Theme #1 and #2.

（※1）About GACD: http://www.gacd.org/
GACD was established in 2009 with the purpose of supporting research organized on a global scale targeting non-communicable diseases (chronic diseases) in low- and middle-income countries. Currently, membership comprises 14 major research funding organizations in 14 countries (AMED joined GACD in June 2016).

1. Solicitation Theme #1.

(1) Name of project
Study on implementation（※2）of prevention of onset and progression of chronic diseases in low and middle income countries（※3）

（※2）*Implementation Research*：
Implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care (Eccles/Mittman 2006).

（※3）World Bank definitions of low and middle income economies can be found at DAC List of ODA Recipients
http://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/daclist.htm

(2) Background
Reflecting population aging throughout the world, the global burden of non-communicable diseases constitutes a major public health challenge, which undermines social and economic development. In low- and middle-income countries (LMICs), as well as in high-income countries, chronic diseases including cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes are responsible for onset of disabilities, and are responsible for a considerable part of mortality. There is a growing concern that chronic diseases are risk factors for dementia too. It is expected for Japan to contribute to the global health by taking advantage of advanced science and technology, and knowledge and experiences which have been accumulated in our country toward preventing and managing chronic diseases.
AMED's membership in GACD enables AMED to promote collaborative, global health research research in implementation science.

(3) Aims and Content
This call encourages investigators to submit research application of formative study to implement evidence-based intervention (※4) for prevention of onset and progression of chronic diseases into clinical practice and/or community settings in a target country. Research plan should include baseline survey and pilot intervention study for small groups. An intervention should built on an implementation strategy which includes implementation outcomes (※5).

(※4) e.g. behavioral interventions, prevention, early detection, diagnostic, treatment and disease management interventions, quality improvement programs

(※5) It is encouraged to include implementation outcomes in addition to clinical outcomes.(e.g. feasibility, fidelity and/or adaptation, spread and/or penetration, acceptability, sustainability, uptake, and cost effectiveness etc..）

(4) Expected outcomes

Investigators must submit documents which scientifically show the study result and are expected to develop a research proposal to expand study result in English. Investigators are encouraged to apply to up-coming GACD collaborative call based on the study result.

(5) Scale of R&D funding

#	Name of Field/R&D Projects Being Solicited	Scale of R&D funds	Period in which R&D is Scheduled to be Implemented	Planned Number of New Awarded Projects
1	Study on implementation of prevention of onset and progression of chronic diseases in low and middle income countries	Around 3.850.000yen per year for each project (excluding indirect costs)	Max. of 1 year FY2018	Around 0～4 projects

Note: The R&D funding amount to be implemented shall be assessed based on evaluation results.

(6) Notes for development of research application

(a) Research plan must include following components; name of a target disease and its prevalence and disease burden in a country where the research is conducted, research objectives, research methods, research outcome, characteristics and originality of the research, etc..
(b) An implementation system diagram which clearly shows inter-relationship and collaboration among principle investigator, co-investigator and collaborating companies and so on. Research team must be comprised with one or more collaborating researcher (s) and/or co-investigator(s) who belong to a collaborating research institute (s) of the LMICs. The diagram should also show the roles of these collaborating researcher who belong to a collaborating research institute (s) of the LMICs.
(c) For conducting a clinical study or epidemiological study, it is desirable to involve an epidemiologist or biostatistician from developing a research plan.
(d) For conducting a clinical study or epidemiological study, a format which describes research protocol should be attached to research application. Research protocol may include followings; objective, subject, inclusion/exclusion criteria, numbers of study subjects, content of observation, contents of intervention and intervention method, method of analysis, statistical method, outcome/endpoint, research implementing systems etc). Even if submission of a detail of research protocol is difficult, a tentative study outline must be submitted.
(e) In regard to past research achievements which are related to applying study proposal, major and recent academic papers, clinical guidelines, journals etc. must be submitted as an attachment.

2. Solicitation Theme #2.

(1) Name of project
GACD collaborative call: Scaling-up of evidence-based interventions at the population level for the prevention or management of hypertension and/or diabetes

(2) Background/Aims/Content
This call for applications is an international cooperative call for proposals with shared principles, purposes, scope of the call and review under GACD and seeks proposals for implementation research in the field of the prevention or management of hypertension and/or diabetes in low- and middle-income countries. For details regarding the R&D projects being solicited, please refer to the following websites.

GACD hypertension and/or diabetes scale up call, call for proposals
https://www.gacd.org/funding/calls-for-proposals/gacd-scale-up-call

Please note that the countries targeted for this research are low- and middle-income countries, and so R&D projects concerning the vulnerable populations of high income countries are excluded from this call for applications.

(3) Scale of R&D funding

#	Name of Field/R&D Projects Being Solicited	Scale of R&D funds	Period in which R&D is Scheduled to be Implemented	Planned Number of New Awarded Projects
2	GACD collaborative call: Scaling-up of evidence-based interventions at the population level for the prevention or management of hypertension and/or diabetes	Around 15.400.000yen（～30.800.000yen） per year for each project (excluding indirect costs) (1.540.000yen for JFY 2018 only)	Max. of 5 years FY2018 – FY2022	Around 0～2 projects

Note: The R&D funding amount to be implemented shall be assessed based on evaluation results.

(4) Notes for development of research application

(a) An implementation system diagram which clearly shows inter-relationship and collaboration among principle investigator, co-investigator and collaborating companies and so on. Research team must be comprised with one or more collaborating researcher (s) and/or co-investigator(s) who belong to a collaborating research institute (s) of the LMICs. The diagram should also show the roles of these collaborating researcher who belong to a collaborating research institute (s) of the LMICs.
(b) For conducting a clinical study or epidemiological study, it is desirable to involve an epidemiologist or biostatistician from developing a research plan.
(c) For conducting a clinical study or epidemiological study, a format which describes research protocol should be attached to research application. Resreach protocol may include followings; objective, subject, inclusion/exclusion criteria, numbers of study subjects, content of observation, contents of intervention and intervention method, method of analysis, statistical method, outcome/endpoint, research implementing systems etc). Even if submission of a detail of research protocol is difficult, a tentative study outline must be submitted.
(d) In ragard to past research achievements which are related to applying study proposal, major and recent academic papers, clinical guidelines, journals etc. must be submitted as an attachment.

(5) Expected outcomes

Please refer to “Expected Impact” of the GACD Call Text. Documents which scientifically show the result of intervention study in a target country must be submitted.

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