FY2018

International Collaborative Research Program:
Strategic International Collaborative Research Program
(SICORP)

Japan-Spain Joint Funding "Nanomedicine Call for Collaborative Research Proposals Driven by Early Stage Researchers"

Notes for Japan-based co-applicants

- Supplemental guideline -

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

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TABLE OF CONTENTS

Ⅰ. Introduction

This Supplemental Guideline provides important points to note to Japan-based co-applicants in addition to Application Guideline regarding Japan-Spain Joint Funding "Nanomedicine Call for Collaborative Research Proposals Driven by Early Stage Researchers" under International Collaborative Research Program: Strategic International Collaborative Research Program (SICORP), which is administered by the Japan Agency for Medical Research and Development (hereinafter referred to as "AMED").

1. Program Outline

SICORP, with a view to disseminating excellent research results of our country to the world, aimes to create synergies by collaborating with foreign countries and regions, and develop mutually in science and technology that can be a source of our competitiveness.

This program liaises with funding agencies in counterpart countries and regions that have been designated as being particularly important by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) under intergovernmental agreements, and provides support to international joint research projects on the basis of equal partnership.

The aim of this program is to contribute solutions to challenges facing world today and to bolster Japan's scientific and technological capabilities through collaboration with a broad range of countries.

2. Program Structure

(1) Program Implementation System

In accordance with the "Plan for Promotion of Medical Research and Development"*, 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 (in Japanese)

(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 early stage 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)). For requirements of young researchers, please refer to Application Guideline

(1) "Research Institute" refers to institution with the characteristics shown in (a)–(g) 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) 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.
- (e) 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.
- (f) 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.

(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 carry out the necessary procedures, etc., for supporting 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 the contract start date, which scheduled for January 1, 2019. However, in the case that the above conditions are not met by the date, 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 head of the research institute in Japan carrying out the R&D project and the President of AMED. (The research institute in Spain shall conclude a contracted R&D agreement with AEI-MINECO.)

*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 Research 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 research registration systems listed below prior to commencement of the relevant clinical research (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/

* In the case that Clinical Research Registration System changes in accordance with the enforcement of the clinical research law, please respond appropriately pursuant to the law and regulations.

(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 in addition to punishments and penalties under relevant laws and regulations.

*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 Regulations", 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 Regulations 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 Regulation technology to a non-resident of Japan or in foreign countries, 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, DVD, 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 Project for which Applications Is Being Solicited

The outline of the R&D project for which applications is being solicited included in Application Guideline is as follows. For details regarding the project being solicited, please refer to Application Guideline.

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
Nanomedicine	Around 5.38 million yen per year for each project as direct costs* *Indirect costs are allocated separately up to 30% of direct costs.	Max. of 3 years (FY2018 –FY2021)	0- 3 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 competitive research funds (please refer to Chapter V.9.(4)), they must be sure to list information for all the other R&D projects for which Additional application form 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/en/news/program/0301B_00004.html

(2) Period of Acceptance of Proposals

- Japan-based co-applicants

Application start date: March 28, 2018
Application deadline: 19:00 pm on Tuesday June 12th, 2018 (Japan Time) (No exceptions)

- Spain-based co-applicants

Application start date: April, 2018 (To be announced)
Application deadline: noon on Tuesday June 12th, 2018 (Spain Time) (No exceptions)

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

Japan-based co-applicants should submit proposal documents to AMED via e-Rad by the deadline. Spain-based co-applicants should also submit proposal documents to AEI-MINECO by the deadline. Applications will not be accepted if both proposal documents are not submitted by respective deadlines. When completing (inputting) the R&D proposal documents, please following the guidelines provided in this item and on the R&D Proposal 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.

[For Japan-based co-applicants]

Form No.	Proposal Documents	File format
1	R&D Proposal (Application form (in English))	PDF
2	Additional application form* (in Japanese)	PDF

* Japan-based co applicants only

(a) Points to note in using the system

e-Rad was renewed on February 28, 2018. Screen design, menu composition, etc. have been completely revamped for improving usability. The Researchers' Operation Manual is available from the e-Rad portal site (http://www.e-rad.go.jp/). Please check tha main changes 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 affiliated with a research institute shall be registered by e-Rad system operation managers. 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

Please refer to the Researchers' Operation Manual before submitting proposal documents via e-Rad.

1) File type
The electronic media format needs to be converted into PDF format before uploading. For your information, you can convert the files made in Microsoft Word or Ichitaro into PDF format via PDF conversion function on e-Rad. It is also possible to download conversion software from e-Rad and install it on your computer for your use. Please refer to the Researchers' Operation Manual with regard to letters/characters/symbols that may be used.

2) File capacity
The maximum capacity of files than can be uploaded is 10 MB.

3) Uploading proposal documents
Please convert proposal documents to PDF format before uploading.

4) 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. Please make sure to undergo procedures to obtain approval of the R&D project from your affiliated research institute.

5) Checking acceptance status

At the time of the deadline, if the acceptance status of your application shown on the system's "Application Acceptance Status Listing Screen" is not "Being processed by funding agency", the proposal documents are invalid. In the case that the message "Being processed by funding agency" does not appear by the application deadline, please contact your affiliated institute urgently. It is possible to check the acceptance status of proposal documents from the "Application Acceptance Status Listing Screen"

6) 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.

(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) Schedule

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

Document review Early June 2018 to early August (tentative)

Interview (hearing) *Implemented as necessary.

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 Early September 2018 (Tentative)

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 (Contracting, Etc.) January 1, 2019 (Tentative)

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 contacted 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.

The awardees of this joint call are going to participate the kick-off meeting in Spain which is scheduled to be held in fall of 2018.

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 a joint evaluation committee consisting of evaluators (reviewers) on Japan side comprising external experts appointed by the President of AMED and evaluators (reviewers) on Spain side appointed by AEI-MINECO 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 the Joint Evaluation Committee established by AMED and AEI-MINECO.

(b) The Joint Evaluation Committee shall evaluate project proposals by conducting a document review of the content of the submitted proposal documents and conduct 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 interim and ex-post evaluations 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 Japan-based co-PI of the project. Note that we cannot answer questions regarding the progress status of the selection process.

(e) The Joint Evaluation Committee 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. Furthermore, from the standpoint of conducting fair and transparent evaluations, interested parties must not be involved in the evaluation process.

(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 the Joint Evaluation Committee members on Japan side shall be implemented in accordance with AMED regulations. In the case that any of the following items apply to a Joint Evaluation Committee member on Japan side, 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 Joint Evaluation Committee co-Chairs recognizes that participation by the Joint Evaluation Committee 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 Joint Evaluation Committee member may participate in the evaluation of the relevant project.

1) The evaluatee is a family member/relative of the Joint Evaluation Committee 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 Joint Evaluation Committee 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 Joint Evaluation Committee evaluation is conducted.
4) The Joint Evaluation Committee 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 Joint Evaluation Committee member within the past three years, including the fiscal year in which the Joint Evaluation Committee evaluation is conducted, of more than one million yen.
6) The Joint Evaluation Committee 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, PD, PS, PO, or evaluators regarding evaluations or project selection.

(2) Review Criteria and Perspectives in Evaluating Projects

In selecting projects for this program, reviews of proposal documents shall be carried out from the evaluation criteria and perspectives described in Application Guideline. 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. There is a possibility of considering duplicates with the countries and diseases targeted by the project adopted so far. Please refer to Chapter IV. of Application Guideline for details.

4. Promotion of Young Researchers' appointment

Since AMED supports research projects by public research funding, we are expected to foster young researchers to become future leaders in our country, and proactively return research outcomes to society by such researchers nurtured under the projects as our common significance.

Therefore, it is desirable to positively appoint young researchers in the projects of AMED. Also, after adopting the projects, we may consider whether the appointment and development of young researchers are well-planned and are properly done in determining the go/no-go of projects and the allocation amounts of research expense at mid-term evaluation etc.

Furthermore, we have some projects with a special category for young researchers, which require a R & D representatives to be a young researcher, so we hope that young researchers will actively apply for such projects.

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 Chapter IX.

Furthermore, information included in proposal summaries in Additional application form 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 applicant is not disadvantaged unnecessarily. 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 regarding individual awarded projects (name of program, name of R&D project, names of researchers, researchers' affiliated research institutes, budget amount, and implementation period) falls under "Information that is made public, or information that is scheduled to be made public, as provided for by law or by custom" as prescribed in Article 5 Paragraph (1) Item (a) of the Act on Access to Information Held by Independent Administrative Agencies, and therefore may be publicly disclosed. In addition, information necessary for macro analysis may be provided to the Cabinet Office via e-Rad for the purpose of evidence-based policy-making and analysis results may be publicly disclosed.

For this reason, please input e-Rad about research result information / accounting performance information of each year concerning the adopted subject matter and indirect expenses execution result information concerning competitive funds.

(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 forms shall be the "Application form" and "Additional application form". 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 from Japan-based co-applicants 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 onto the Proposal Form.

(a) As a general rule, the Application Form (Form 1) is to be prepared in English, but the Additional Application Form (Form2) must be prepared in Japanese. 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 Japanese 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, Arial and font size of 10 when inputting English. (E.g. post codes, telephone numbers, and numbers of people.)

(e) Please number the pages of proposal documents as it is set .

(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 R&D Proposals

(a) Compliance with ministerial 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 head 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 R&D 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 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 Proposal Documents

(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 strategy 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 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 VI. 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 research, etc.

For research undertaking investigator-initiated trials or clinical trials with a view to creating innovative drugs or medical devices, or nonclinical studies aimed at conducting such trials,* applicants are required to submit materials related to the clinical research 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/studies 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 (MHLW) on June 1, 2006), based on these fundamental guidelines, research institutes are 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.

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 head of the research institution in Japan implementing the R&D project* and the President of AMED in accordance with the principle of the accounting period of the national government. Successful Japan-based co-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 Joint Evaluation Committee, 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 contracted institution in Japan 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 (Application Form) 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 interim and ex-post evaluations, 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

Under this program, items of expenditure have been set as follows. 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, interpreters/translators, 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, testing costs, amount equivalent to consumption tax related to untaxed transactions, etc.
Indirect costs[2]	Expenditure used by research institutes and paid by AMED as necessary costs for managing the research institutes during implementation of the relevant R&D, paid at a fixed percentage of direct costs (within 30%) as an allowance.	

[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). With regard to Subsidiary Institutions (excluding national facilities or other institutions) also, indirect costs are allocated in accordance with direct costs.

[3]Certain amount of an item of Direct Costs may be appropriated to another item of Direct Costs if such treatment is necessary for the performance of the Contracted Research and Development; provided, however, that the prior approval of AMED shall be obtained if the amount per item of such treatment exceeds fifty percent (50%) of Direct Costs (or five million yen (JPY 5,000,000), if an amount equal to fifty percent (50%) of Direct Costs is less than five million yen (JPY 5,000,000)).

[4]Even if the amount of funds transferred is under the limitation, if there is a significant change in the R&D plan, Confirmation of AMED is necessary beforehand regardless of the amount transferred. Also, a person in charge in AMED may confirm the content of the transfer at a later date.

(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 in future incorporate "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 Trials" (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 Trials" (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 prescribed 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" (March 17, 2016; Regulation No. 35 of 2016), 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 preservation 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.

(a) 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. 3 of 2014)
- 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

(b) Regulations concerning the use of biological/genetic resources.

In addition to access to genetic resources in the partner country, when transferring samples, information, or materials* out of or into the partner country, consideration must be given to international rules (Convention on Biological Diversity, foreign exchange laws, security trade control laws, etc.) and to comply with the laws of the partner country and other countries involved. If you plan to use biological/genetic resources of foreign countries for your research, you must sufficiently know in advance about their ratification and compliance status regarding relevant treaties such as the Cartagena Protocol on Biosafety, the Bonn convention, the Washington Convention, the Ramsar Convention, the Convention on Biological Diversity and so on. Also consider signing a material transfer agreement (MTA). Refer to the following websites for detailed information on the access to biological/genetic resources and the Convention on Biological Diversity.

Further information: ABS Task Force Team for Academia http://nig-chizai.sakura.ne.jp/abs_tft/
Further information: Japan Bioindustry Association http://www.mabs.jp/index.html
Further information: Convention on Biological Diversity http://www.cbd.int/

* This restriction is not limited to items related to the research. Care must be taken with all genetic resources (materials) including commercial goods.

* Handling of materials resulting from research
Regarding research materials created or acquired through the international joint research, in addition to conducting appropriate management based on the institution's own internal regulations, and taking into

account the fact that the joint research is international, or in the case of transfer to a third party, in order to ensure that research outcomes can be smoothly applied, it is necessary to take measures such as signing an MTA between each of the institutions participating in the research.
Materials are tangible materials (which excludes copyrightable items such as academic papers, presentations, or other items that are copyright, etc.) having an academic value, asset value, or other value that fall into the following categories
(i)Items created or acquired during research that demonstrate that the aims of the research have been achieved.
(ii) Items created or acquired during research that are used to obtain (i).
(iii) Items created or acquired as derivatives when creating or acquiring (i) or (ii).
Examples: materials, reagents, samples (microorganisms, soil, rock, plants, etc.), laboratory animals, prototypes, models, chemical substances, strains

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

The entire amount of 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" in the Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards)* (decided by the Minister of Education, Culture, Sports, Science and Technology (MEXT) on February 15, 2007), and research funds shall be managed under the responsibility of research institutes in accordance with "Items required to be implemented by institutions" as prescribed in the above guidelines.

(6) Response Obligations Regarding System Maintenance

(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 (including establishing systems related to the management/auditing of public research funds) in accordance with the Guidelines for Responding to Misconduct in Research Activities (decided by the Minister of Education, Culture, Sports, Science and Technology on August 26, 2014) and the Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards) (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014) .

(b) Confirmation of system maintenance

Under the contracted R&D agreement for this program, research institutes may be requested to report the implementation status of system maintenance concerning the management and monitoring of public research funds to the MEXT using a Self-evaluation (Including System Maintenance) Checklist (hereinafter referred to as "Checklist"), as well as conduct various surveys regarding system improvement, etc.
For this reason, all research institutes must submit checklists based on the formats provided on the both websites shown below to the MEXT via e-Rad by a deadline to be stipulated separately by AMED.
i) Checklist for system maintenance
Basis: Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards)
Submission method: http://www.mext.go.jp/a_menu/kansa/houkoku/1301688.htm
ii) Checklist regarding misconduct in research activity
Basis: Guidelines for Responding to Misconduct in Research Activities
Submission method: http://www.mext.go.jp/a_menu/jinzai/fusei/1374697.htm

* The forms of Checklist is scheduled to be revised on April 1, 2018. Therefore, for submission after the date, it is necessary to submit in the revised forms.

(c) Necessity of submitting a checklist

In the case that you have already submitted checklists since April 1, 2018 when applying for a MEXT program, it is not necessary to newly submit checklists when applying for another the MEXT program or concluding a contracted R&D agreement in the same fiscal year.

Under public research funding management and monitoring guidelines, it is required that a checklist be submitted around once each fiscal year, and so research institutes that are continuing implementation in the following year and beyond must also submit a checklist to the MEXT once each fiscal year.

*Registration with e-Rad
In order to submit a checklist, it is essential to create an environment that enables use of e-Rad, and so research institutes that have not yet implemented e-Rad registration procedures should do so immediately. Please note that registration usually takes around two weeks to complete.
For details regarding registration procedures, please refer to the "Preliminary Preparations for Using the System" section on the following websites provided for research institutes affiliated with e-Rad.
http://www.e-rad.go.jp/

(d) Cooperation with surveys

After submitting the checklist, research institutes may be requested to cooperate as necessary in surveys related to system improvement status conducted by the MEXT.

(e) Issue of conditions for managing public research funds and measures for reducing indirect costs

In the case that it is determined based, on reports/ surveys of public research funding management/ monitoring system improvement, that a research institute's system improvement is inadequate, management conditions stating the items requiring improvement and the deadline for implementing these improvements (one year), shall be issued by the MEXT in accordance with the Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards)" (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014).
Please note that, in the case that it is subsequently deemed that the research institution has not fulfilled these conditions, measures against the research institute will be implemented such as reducing indirect expenses for all competitive funds allocated from the MEXT and the independent administrative agencies under the jurisdiction of MEXT, and suspending the allocation of competitive funds.

*Please refer to the following website.
Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards)" (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014)
http://www.mext.go.jp/component/a_menu/science/detail/__icsFiles/afieldfile/2014/03/18/1343906_02.pdf

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

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

Researchers participating in research activities under 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 be responsible for R&D 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.

・CITI Japan e-Learning Program

・"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 FY2016
Deadline for submission: End of May of the year following training
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: "FY2016 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 and Co-Investigator of R&D projects

(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 Related to this Program

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 (decided by the Minister of Education, Culture, Sports, Science and Technology on August 26, 2014); Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards)” (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014); and AMED Regulations for Responding to Misconduct in Research Activities (formulated on April 1, 2015; revised on February 19, 2016; Regulation No. 34 of 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, 2016; Regulation No. 34 of 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 (decided by the Minister of Education, Culture, Sports, Science and Technology on August 26, 2014); Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards)” (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014); and AMED Regulations for Responding to Misconduct in Research Activities (formulated on April 1, 2015; revised on February 19, 2016; Regulation No. 34 of 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 (decided by the Minister of Education, Culture, Sports, Science and Technology on August 26,

2014); Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards)" (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014); and AMED Regulations for Responding to Misconduct in Research Activities (formulated on April 1, 2015; revised on February 19, 2016; Regulation No. 34 of 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 rowspan="2">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 slightly 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 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

With regard to researchers who restricted application and participation to this program out of researchers who have been found to have carried out misconduct or infringed duty of diligence in this program, the outline of the

relevant misconducts (name of program, name of institute, project implementation period, content of misconduct and content of measures) shall be publicly disclosed. Moreover, in case of finding misconduct, the research institute should promptly disclose the investigation outcome in accordance with Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards)" (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014); Guidelines for Responding to Misconduct in Research Activities (decided by the Minister of Education, Culture, Sports, Science and Technology on August 26, 2014); and AMED Regulations for Responding to Misconduct in Research Activities (formulated on April 1, 2015; revised on February 19, 2016; Regulation No. 34 of 2016).

(3) Admission to the AMED RIO Network

AMED constructed a network called the "RIO Network"*. 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 administrative activities related to R&D misconduct and research funding misconduct with AMED and participate in RIO Network activities.

*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 related administrative activities for research institutes conducting R&D with AMED funds.
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 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) have not been found by the research institute to have carried out misconduct in accordance with Japanese Government guidelines for responding to misconduct* (excluding, however, persons who have not has restrictions on 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 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 was 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 (from AMED's perspective, a subcontracted agreement. Hereinafter, the third party shall be referred to as the "Subcontractor"), 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 item are the following guidelines.

- 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)
- 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)
- Guidelines for Responding to Misconduct in Research Activities (decided by the Minister of Education, Culture, Sports, Science and Technology on August 26, 2014)
- Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards)" (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014)
- Guidelines for Responding to Misconduct in Research Activities (the Ministry of Economy, Trade and Industry (METI) on December 26, 2007; finally revised on January 15, 2015)
- Guidelines for Responding to the Misuse of Public Research Funds (the Ministry of Economy, Trade and Industry (METI) on December 3, 2008; finally revised on January 15, 2015)

(3) Submission of R&D Plans and Reports

With regard to awarded projects, please note that the R&D Plan and some 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 R&D projects 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
- 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
- The 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 researcher's time exclusively spent for the R&D activities concerned against the researcher's annual working hours. Research's total working

hours refer to not only the time spent in research activities but also total substantive working hours, including educational/medical 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 the Cross-ministerial Research and Development Management System (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 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 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 carefully 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 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 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 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 trials with a view to creating innovative drugs or medical devices, or nonclinical studies aimed at conducting such trials* during the R&D period, research institutes are required to submit materials related to the clinical research 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 creating 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 an interim evaluation by the "Project Evaluation Panel" at round 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 an interim evaluation as a general rule, but in the case that it becomes necessary to conduct an interim investigation in the course of implementing the program, an interim evaluation 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 an interim evaluation, regardless of the timing. Based on evaluation results, AMED may decide to cancel (prematurely conclude) 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 fiscal years.

3. Presentations at Accomplishments Report Meeting

As part of achievements reporting under this program, the co-PIs of an awarded project shall be required to make a public or closed-door presentation at an Accomplishments Report Meeting held by AMED and/or AEI. In addition, as part of follow-up examinations 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 IP rights and usage of research accomplishments.

1. Submission and Publication of Contracted R&D Accomplishments Reports

Contractors shall submit a contracted 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 contracted R&D accomplishments report is not submitted by the deadline, it shall be deemed that the contracted R&D agreement has not been fulfilled and payment of contracted R&D funds cannot be made, so please be sure to strictly comply with the submission deadline.

In addition, the content of some items in the contracted R&D accomplishments report and the content of general research reports comprise information for public disclosure and shall be published on the AMED website at an appropriate time.

2. Attribution of R&D Accomplishments

Patent rights, copyright, and other IP rights obtained through implementation of the R&D project can revert to the contractor under certain conditions in accordance with the Japanese version of the Bayh-Dole Act under the Industrial Technology Enhancement Act (Law No. 44 of 2000). The purpose of the Japanese version 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 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 Japanese version of 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 for practical application of R&D Accomplishments

In owning IP rights related to the results of R&D contracted by the Japanese Government, contractors are in a position whereby they should make maximum efforts to achieve practical application of their R&D accomplishments themselves and be deeply conscious of the expectations being held for the realization of research accomplishments' practical application. In particular, in accordance with AMED's IP policy,* contractors should ensure that appropriate measures have been implemented amongst the contractor's funding sources, such as appropriating indirect costs, in obtaining IP rights in order to ensure appropriate protection and utilization of IP rights on a global scale.

AMED's Department of Intellectual Property provides consistent support for maximizing and achieving practical application of R&D accomplishments that have reverted to contractors.

Support provided by AMED's Department of Intellectual Property includes (1) support for strengthening intellectual propertization of research accomplishments, (2) advice for business collaboration strategies, and (3) support for activities leading to businesses or licensing (please refer to Chapter IX, 6.).

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

4. IP Educational Materials for Medical Researchers

IP educational materials for medical researchers is 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.

* 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 universities, 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 that "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 an enterprise, etc., may continue to use 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 enterprise, 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.

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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. Accordingly, research institutes are requested to proactively undertake measures to continuously disseminate information about research activities, such as holding public lectures or symposiums on research accomplishments and/or continually posting research accomplishments on the Internet.

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. Regarding Registration with “researchmap”

As the largest directory of researchers in Japan, “researchmap” (formerly called "ReaD&Researchmap"*) is a researcher information database of approximately 240,000 registered researchers as of March 2015. The information registered by the researcher on his/her research track record can optionally be made accessible to the Internet. Additionally, the compatibility of “researchmap” with other systems, which enables seamless access to its registered information, allows it to link with e-Rad and many university faculty databases, thereby saving researchers from repetitiously entering the same research record information on multiple applications and databases.

The information registered at “researchmap” is put to use in national and other academic and science and technology policy formulation research, as well as being used for statistical objectives, so those implementing the program are requested to be sure to register with “researchmap”.

* https://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 is using contracted R&D funds to carry 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. Support for Formulation of IP Strategies by AMED IP Consultants

AMED shall provide consistent support in order to promote the practical application of research accomplishments obtained through programs implemented by AMED. Specifically, AMED provides (1) support for strengthening related to intellectual propertization of R&D results such as consultation for improving written descriptions and advice for addition data; (2) advice regarding business collaboration strategies connected to IP for moving R&D to the developmental stage; and (3) support for detailed investigation and proposal formulation of IP strategies/exit strategies under R&D plans through collaboration with AMED IP consultants[*1] and the relevant AMED departments/offices, beginning with support for activities leading to businesses or licensing. AMED therefore provides information necessary for achieving practical application of research accomplishments (information on IP and R&D plans) (please refer to Chapter IV. 1.). In addition, AMED plans to implement hearings as necessary.

If you wish to receive support for formulating proposals for IP strategies/exit strategies, please contact AMED's Medical IP Desk. Please refer to the website below for information regarding the Medical IP Desk[*2].

[*1]https://www.amed.go.jp/chitekizaisan/chizai_riezon.html
[*2]Medical IP Desk: https://www.amed.go.jp/chitekizaisan/medical_ip_desk.html

7. Matching support system for seeds and needs

AMED are currently constructing a nonpublic information network system to support matching of research seeds information and corporate needs information from academia of universities etc. at an early stage with the aim of realizing the research and development results in the medical field at an early stage. It will be available from April 2018. By using this system, Academia can appeal the acquired research seeds (including research plan) to the staff in charge of introduction of multiple companies, and can work together with companies at an early stage. Please register positively.

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 commissioned by AMED 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.

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”.
- Contact: The Japan Science and Technology Agency National Bioscience Database Center (NBDC)
  Inquiries regarding the Archive: dbarchive“AT”biosciencedbc.jp
  Inquiries regarding the Human Database: humandbs“AT”biosciencedbc.jp
  (Change “at” to @ when inputting the address.)
  * 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]National Bio Resource Project (NBRP): https://www.amed.go.jp/program/list/04/01/002.html

[2]“Contribute”: 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 contribution 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. Research implementation until the last day of the fiscal year

To enable to conduct the research until the last day of the fiscal year, we have taken the following measures.

(1) The deadline for submitting the "Actual Performance Report (and Settlement of Balance) for Contract Research" will be May 31 of the next fiscal year.

(2)The deadline for submitting the "Actual Performance Report," the report on research results for this fiscal year, will be May 31 of the next fiscal year.

Research institutions should keep in mind that the measures above have been made to enable research to be conducted until the very last day of the fiscal year; thus, they should make efforts to prepare whatever necessary by that time.

12. Promotion of the sharing of research equipment and apparatuses

"Introduction of New Research Equipment and Apparatuses Operating Integrally with Research Organization Management" (Advance Research Fundamentals Working Group, Scholarship Commission, November 2015) requests that "Research Equipment and Apparatus Sharing Systems by Research Organization Units" (hereinafter, referred to as "apparatus sharing systems") for universities, national research institutes, etc. be implemented. Moreover, "Reformation of Competitive Research Funds for Producing Sustainable Research Results (Interim Report)" (Investigative Commission for the Reformation of Competitive Research Funds, June 24, 2015) states that "Large equipment and apparatuses from competitive funds in principle shall be shared."

Given these intentions, at research institutes such as universities, national research institutes, etc., with respect to research equipment and apparatuses purchased for this program, ―in particular, large and versatile systems―it is recommended that purchasing and sharing by aggregating multiple research funds, sharing equipment and apparatuses with other researchers in related fields in a way that does not obstruct the proposed research project, and further utilizing equipment and apparatuses purchased by other research funds, etc., occur.

It is also recommended that the sharing of research equipment and apparatuses across research organizations and institutions is promoted by actively partnering with the "Inter-University Network for Common Utilization of Research Equipments" operated by the Institute for Molecular Science, National Institutes of Natural Sciences, Inter-University Research Institute Corporation with the aim of facilitating the mutual use of equipment nationwide, as well as with the national university-wide sharing system that has been established through the "Equipment Support Center Development Project," etc. at all national universities.

- "Introduction of New Research Equipment and Apparatuses Operating Integrally with Research Organization Management" (Advance Research Fundamentals Working Group, Scholarship Commission, November 2015) http://www.mext.go.jp/component/b_menu/shingi/toushin/__icsFiles/afieldfile/2016/01/21/1366216_01_1.pdf (Japanese)
- "Reformation of Competitive Research Funds for Producing Sustainable Research Results (Interim Report)" (Investigative Commission for the Reformation of Competitive Research Funds, June 24, 2015) http://www.mext.go.jp/b_menu/shingi/chousa/shinkou/039/gaiyou/1359306.htm (Japanese)
- Unification of Rules on Use of Competitive Funds (Agreement of Liaison Conference among Relevant Ministries on Competitive Funds, March 31, 2015) http://www8.cao.go.jp/cstp/compefund/shishin3_siyouruuru.pdf
- " Inter-University Network for Common Utilization of Research Equipments" https://chem-eqnet.ims.ac.jp/

13. Employment of research assistants (RA)

The 3rd, 4th, and 5th Science and Technology Basic Plan set a numerical target that "enabling 20 percent of doctorate course students to receive an amount equivalent to their living expenses" in order to attract quality students and business persons from Japan and overseas by increasing economic supports.

In “Reformation of Education in Graduated School Leading Future (Deliberation Summary)” (Work Group on Universities, Central Council for Education, September 15, 2015), it was requested that research assistant (RA) employment for (latter-stage) doctoral students be enhanced by various financial resources and that payment for employed (latter-stage) doctoral student RAs and TAs be standardized at a level approximating living expenses.

14. Helping young post-doctoral researchers to secure varied career paths

The Ministry of Education, Culture, Sports, Science and Technology’s basic policy for supporting diverse career paths for young research staff who have doctoral qualifications and are being employed with public research funds (December 20, 2011 Council for Science and Technology, Committee on Human Resources) (www.mext.go.jp/b_menu/shingi/gijyutu/gijyutu10/toushin/1317945.htm) states that it is necessary to actively support public research institutions and research directors who are using public research funds to employ young research staff with doctoral qualifications in their efforts to secure diverse domestic and overseas career paths for these young research staff members. Given these intentions, when public research funds (i.e., competitive funds, other project research funds, and project-type education research funds) are used to employ junior doctoral researchers, when projects are adopted, active assistance to ensure that students can pursue various research career paths will be appreciated.

Further, considering the utilization of indirect costs for relevant initiatives will be appreciated.

15. Responding to enforcement of Clinical Research Law

Based on future ministerial ordinances / notifications regarding Clinical Research Law, we will notify you at AMED website etc.

* Regarding clinical researches that have been continuing from before the enforcement of the law, it is necessary to carry out procedures based on the law within the transitional period after the enforcement.

X. References

If you should have any questions regarding the content of Application Guideline and this Supplemental Guideline, 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; how to fill in review/proposal documents	Division of International Collaboration, Department of International Affairs, AMED E-mail: sicorp"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
Support provided by the AMED Drug Discovery Support Network/Department of Innovative Drug Discovery and Development	AMED Department of Innovative Drug Discovery and Development West Japan Office Tower B, Grand Front Osaka, 1 3-chome Ofuka-cho, Kita-ku, Osaka City, Osaka Prefecture, Japan. 530-0011 Tel: +81-6-6372-1771 (Extension 120) 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 +81-3-5625-3961 (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/
AMED's IP policy and handling of IP in contracted R&D projects	AMED Department of Intellectual Property Tel: 03-6870-2237 Email: medicalip"AT"amed.go.jp

XI. R&D Projects Being Solicited

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

Japan Agency for Medical Research and Development (AMED)

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