



**FY2018**

**Science and Technology Research Partnership for  
Sustainable Development (SATREPS)**

**Application Guidelines**

September 2017

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

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## Notes for FY2017 Research Proposals

This invitation for research proposals is for proposals that will be implemented under the government's FY2018 budget, but submitted and selected before the budget is finalized. Moreover, the SATREPS (Science and Technology Research Partnership for Sustainable Development) program is linked with the official development assistance (ODA) program, and requires time for coordination with institutions in the counterpart country. For these reasons, in order to start the research projects as soon as possible, the process needs to start before the budget is approved. In consequence, when the budget is finally approved, details and amounts may change, which could potentially affect the fields of research, contract research expenses, and number of projects selected. It may also be necessary to request additional documentation following budget approval. Changes in budget-related information will be posted on the following website, which should be checked occasionally. After proposals have been submitted, applicants can be notified by email when necessary.

<http://www.amed.go.jp/en/news/proposals.html>

### 1. How to Apply

FY2018 Research Proposals must be submitted via e-Rad, the Cross-ministerial R&D Management System. To use e-Rad, researchers who are affiliated with a research institution need to check that their institution has been registered on e-Rad, and that the researcher's information has also been registered on e-Rad by the institution's administrative contact. Researchers who are not affiliated with a research institution need to register their researcher information on e-Rad in advance. Cross-ministerial R&D Management System (e-Rad) Portal Site <http://www.e-rad.go.jp/> (Japanese)

Deadline for submission of research proposals: 12:00 noon (Japan time) on Monday October 30, 2017

### 2. Submission of request for ODA technical cooperation

The SATREPS program is linked with ODA projects, and therefore, must also assume the role of technical cooperation project. The portion of the expenses attributable to ODA projects is covered not by contract research expenses but under the technical cooperation project framework. In submitting a research proposal to AMED, please carefully read “XI. 2. Outline of technical cooperation through ODA” and subsequent pages and check that the principal investigator's institution can implement the project in accordance with the Agreement with JICA. In addition, please liaise sufficiently with the researchers in the counterpart country on the details of the joint research. It is also necessary that the counterpart research institute submits an official request for ODA technical cooperation to Japan's Ministry of Foreign Affairs (MOFA) via the ministry or agency in the recipient country responsible for ODA and the local Japanese embassy. The deadline for submitting the official request for ODA technical cooperation is on Monday October 16, 2017. The internal deadline used by the counterpart ministry or agency is normally set earlier than the submission deadline, so please take that into account when liaising with the counterpart research institute.

If the counterpart government does not request a technical cooperation project, a research proposal submitted in Japan will be considered incomplete and not go through the selection process.

## I. Introduction

The R&D projects being solicited in accordance with these Application Guidelines are R&D projects being solicited\* under Science and Technology Research Partnership for Sustainable Development (SATREPS), which is administered by the Japan Agency for Medical Research and Development (hereinafter referred to as “AMED”).

\*Because implementation of these R&D projects being solicited is premised on the Diet’s adoption of the FY2017 Budget, agreement details shall be discussed separately in the case that the government budget is not adopted by April 1, 2017.

### 1. Program Outline

#### (1) Program Objectives

The SATREPS program is a collaboration between two Japanese government agencies: the Japan Agency for Medical Research and Development (AMED) and the Japan International Cooperation Agency (JICA). Based on the needs of developing countries, AMED and JICA cooperate to promote international joint research targeting global issues<sup>1</sup> with an objective of future utilization of research outcomes<sup>2</sup>. Implemented through collaboration with Official Development Assistance (ODA), the aim of the program is to acquire new knowledge and technology that lead to the resolution of global issues and the advance of science and technology, and through this process, to create innovations. International joint research under this program also aims to enhance the research and development capabilities of developing countries, and helps create sustainable research systems able to address and resolve issues.

The SATREPS program constitutes an important component of the science and technology diplomacy promoted by the Japanese government. The program does not merely provide supports for basic and applied research. It ensures that research outcomes on science and technologies suited to the issues and needs of the counterpart country benefit society, and contributes to science and technology innovations in the country. Accordingly, the program aims to facilitate the strengthening of diplomatic relations between Japan and the counterpart country while also contributing to the national interests of Japan.

<sup>1</sup> Global issues: Issues that are difficult to resolve by a single country or region acting on its own and that need to be handled by the international community as a whole.

<sup>2</sup> Utilization of research outcomes: The research projects should lead to future social and economic benefits, achieved by using newly obtained knowledge and technology to enhance government services or to develop products that can be deployed in the market.

#### (2) Program Direction

##### (a) Background to the program

There is a need for joint research and capacity building of research institutions based on the requirements of developing countries, as a means by which the promotion of science & technology and the training and development of human resources can boost each other. Japan recognized this need, and has given it the status of a key part in one of its major policies. ("Toward the Reinforcement of Science and Technology Diplomacy," May 19, 2008)

In this context, Japan's Ministry of Education, Culture, Sports, Science and Technology (MEXT) and Ministry of Foreign Affairs (MOFA) implemented the SATREPS program in 2008 by creating a close tie between science & technology and official development aid, enabling the research institutions of Japan and developing countries to take part in international joint research that can contribute to the resolution of global issues.

(b) Program status

Japan's Fifth Science and Technology Basic Plan (approved by the Japanese Cabinet in January 2016) enshrines that Japan will proactively leverage its science and technology potential to help combat global issues, including climate change, declining biodiversity, food and water resource issues, and infectious diseases, and improve the quality of life in developing countries, in order to actively contribute to the sustainable development of the world.

To this end, specifically, Japan needs to partner and cooperate with universities, public research institutions, the business community, as well as other countries and international organizations to carry out research and development to find solutions to global issues. In addition, it needs to promote a wider application and adoption of research outcomes in and outside of Japan, and take a lead in achieving an international consensus. At "United Nations Sustainable Development Summit" held in September 2015, Outcome Document "Transforming our world: the 2030 Agenda for Sustainable Development" with **"the Sustainable Development Goals"**<sup>3</sup> as a core component was adopted as a new and more comprehensive world action agenda for people, planet and prosperity. Based on this agenda, **SATREPS program will actively correspond to SDGs and contribute to the international community.**

In scientific and technological cooperation with emerging and developing countries, it is important to break away from the aid-driven forms of cooperation that have prevailed up to now, and move instead towards strategically establishing frameworks for more equitable partnerships with such countries in order to facilitate the generation of socially inclusive and sustainable innovation ("inclusive innovation"). It is also important to strengthen international professional networks. Therefore, in our science and technology cooperation with emerging and developing countries, Japan needs to develop systems to promote inclusive innovation by pursuing collaborations with the counterpart country's government, universities, public research institutions, funding bodies, and companies, and help to foster young researchers and industry professionals in the country.

Additionally, the Basic Plan presents that to reinforce the foundation of science and technology innovations, Japan will train and secure highly trained personnel who will generate new knowledge and values, and a diversified workforce that will accelerate the creation of innovation. At the same time, Japan will create environments that enable each and every individual to maximize his or her contributions in the most appropriate settings, according to their own capabilities and motivations. It is expected that international joint research projects will also lead to fostering Japanese talents tailored to globalization.

Industry-academia-government partnerships are critical for implementing the Basic Plan. The Basic Plan states that to advance science and technology innovations effectively, the key elements are fleshing out initiatives aimed at strengthening the functions of the diverse implementers of science and technology innovation activities, such as universities, public research institutions, and companies, and expanding industry-academia-government partnerships.

The FY2018 invitation for research proposals seeks projects that reflect these policies while meeting the aims of the SATREPS program.

3 <http://www.un.org/sustainabledevelopment/>

### (3) SATREPS Program Structure

The SATREPS program structure is shown in Figure 1. Launched by AMED in cooperation with JICA, SATREPS promotes international joint research between Japan and developing countries. Through collaboration with research institutions in developing countries, it aims to facilitate the acquisition of new knowledge and technology that can lead to the resolution of global issues and the advancement of science and technology. Under this program, AMED (which possesses expertise in funding research projects in Japan) provides support for research expenses in Japan and elsewhere (but not in the partner country), while JICA bears expenses necessary for the implementation of ODA technical cooperation (including dispatch of experts from Japan, acceptance of foreign researchers, and provision of machinery and equipment).

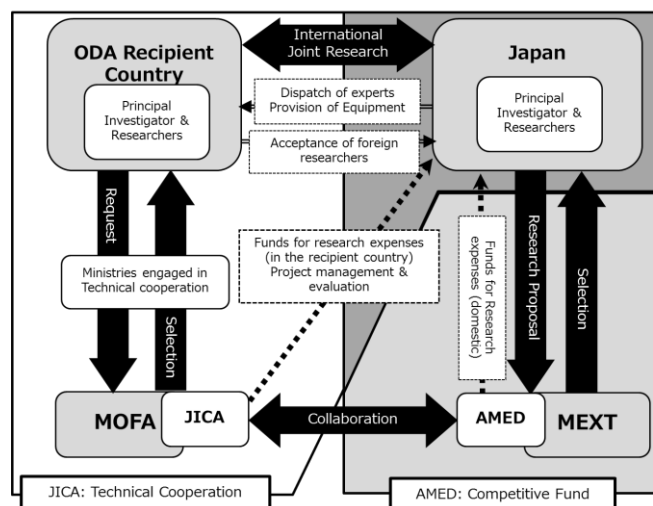


Figure 1. SATREPS Program Structure

Management of R&D for international joint research as a whole is conducted cooperatively between JICA and AMED. It is expected that the promotion of international joint research activities under this program will enable Japanese research institutions to conduct research more effectively in fields and targets where it is advantageous to implement the research in developing countries. Meanwhile, it is hoped that for research institutions in the developing countries (primarily universities and research institutions focusing on activities for public benefit, but excluding those related to military affairs), the establishment of research center facilities and the development of human resources through joint research activities will make it possible to develop self-reliant, sustainable research systems.

### (3) SATREPS Program Main Flow

#### (a) Setting research areas, and inviting proposals and applications

The Japanese government (MEXT and MOFA) identifies fields of particular importance in resolving



global issues and designates them as targets for research promotion under this program. Based on this, AMED appoints a program director (PD) with overall responsibility for all research fields and management of the program, and program supervisor (PS) each with responsibility for a single, more specific research area in which they have expertise.

AMED invites researchers at universities and research institutes in Japan to submit research proposals in each research area. Decisions on which research projects are to be selected are made by a screening committee comprising POs and external reviewers.

While AMED selects proposals, requests are received from developing countries for ODA technical cooperation for international joint research, and MOFA reviews these requests in conjunction with JICA in Japan. Therefore, it is essential for the principal investigator in Japan to coordinate with researchers in the ODA recipient country in order to confirm the details of the joint research when making an application to AMED. It is a requirement that official requests for ODA technical cooperation be submitted by the research institution in the recipient country to MOFA in Japan by the specified deadline, via the ministry or agency in the recipient country responsible for ODA and the Japanese embassy that handles affairs for the recipient country.

(b) Research project selection by AMED in Japan and ODA technical cooperation decisions by MOFA/JICA

The selection process for research projects at AMED and the screening process for ODA technical cooperation at MOFA/JICA are interlinked. Both applications, one to AMED by the Japanese principal investigator and one for ODA technical cooperation, have to be approved in order for the research project to be provisionally selected for the program. MOFA notifies the prospective recipient country of this decision. (See Figure 2.)

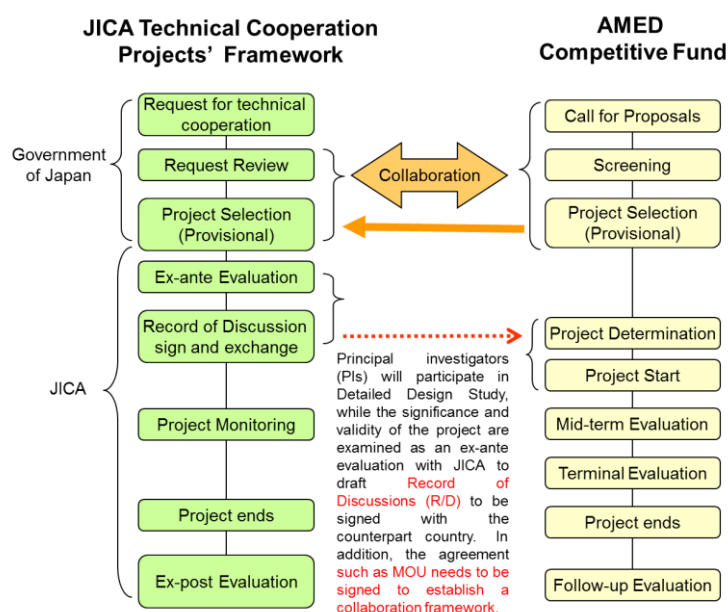


Figure 2. SATREPS Program Flow

(c) Preparations for implementing selected projects

To implement the international joint research, a Record of Discussions (R/D) must be signed by the ODA recipient country and JICA to confirm that they agree on the details of the ODA technical cooperation. In

addition, a Memorandum of Understanding (MOU) or similar document about the joint research, of which details shall match the R/D and JST's Contract Research Agreement, must also be signed between the research institutions (parties concerned). Because of this requirement, after receiving notification of provisional selection, the principal investigator and other researchers are requested to work towards the prompt signing of these documents.

After giving notification that a research project has been provisionally approved, AMED firstly concludes a Provisional Research Expenses Contract with the principal investigator's institution in Japan. This enables JST to make research funds available to Japanese researchers even before the R/D is signed, in order for international joint research to start as soon as possible after the R/D is signed. Such expenses shall be limited to research expenses incurred in Japan when making preparations for the joint research.

In order to confirm the background and details of the ODA technical cooperation application and discuss details of the joint research, JICA sends an investigation team, comprising of the principal investigator in Japan and other members, to the prospective recipient country. The investigation team performs a Detailed Design (D/D) study and summarizes the results of discussions in a Minutes of Meeting (M/M) document, signed by JICA and the recipient country. JICA shall then create an R/D based on the details of the M/M. Once the R/D is signed by the director of the JICA overseas office and a representative in the developing country, the ODA technical cooperation project can begin.

However, the signing of the R/D can take a long time, and may not even be completed before the end of the year in which the project would be implemented (the end of FY2018). Even if a research project has been selected, if the R/D is not likely to be signed in the near future, or if there are other reasons<sup>4</sup> such as deteriorating public security, preparations for implementing the project may be halted part way through, and circumstances may make it impossible for the research to be implemented. Please note that if it becomes impossible for the R/D to be signed, the selected research project cannot be implemented, and from that point, AMED shall no longer provide research funding.

<sup>4</sup> Potential reasons include unavoidable circumstances such as natural disasters or decisions made by the government of the prospective recipient, and circumstances such as improper use of research funds or improper research activities.

#### (d) Implementation of the international joint research

In order to implement the international joint research as a formal SATREPS project, the principal investigator and other researchers shall act in accordance with a contract (Contract Research Agreement) signed with AMED and contracts signed with JICA (Agreement and project contract<sup>5</sup>). The principal investigator shall be responsible for the research project and for coordinating the running and management of the project as a whole. It is not essential for the Japanese principal investigator to be permanently stationed in the partner country for the period of the joint research, but to ensure that the research proceeds smoothly, it is desirable that at least one member of the Japanese research team be stationed there as permanently as possible as an expert (designated under this program as a "dispatch of overseas researchers (Japanese researchers) for overseas research")<sup>6,7</sup>.

<sup>5</sup> The Agreement (Agreement regarding the implementation of technical cooperation under the framework of SATREPS) is a

comprehensive document stipulating the rights and obligations of JICA and the principal investigator's institution. JICA and the principal investigator's institution shall conclude the Agreement when the R/D for the institute's first project is signed. In addition, JICA and the principal investigator's institution shall clarify the expenses that JICA will bear, and shall sign an Agreement and project contract containing an estimate of these expenses and details of accounting procedures, for reference by either party.

(JICA will only conclude an Agreement with the principal investigator's institution, not with other research institutions involved in the research project.)

<sup>6</sup> An overseas researcher dispatched to the developing country does not necessarily have to be the principal investigator. Other members of the Japanese research team necessary for the joint development are eligible. However, postgraduate and other students are not eligible to be sent under the "dispatch of overseas researchers (Japanese researchers) for overseas research" designation.

<sup>7</sup> In technical cooperation projects, JICA recruits project coordinators through a transparent recruiting process and stations them in the ODA recipient country to provide support to experts and manage local operating expenses or to support procurement of machinery and equipment by the local JICA office. JICA similarly stations local project coordinators for SATREPS projects. Such staff cannot simultaneously participate in research work.

#### (e) Human resource development

##### - Human resource development through the Japanese Government (MEXT) Scholarship Program

Since FY2010, MEXT has a "SATREPS Section" within its Japanese government scholarship program (University Recommendation) for SATREPS projects. The aim of the SATREPS Section is to facilitate the development of young researchers with the potential to be future key players in relevant research in their own countries by studying or conducting research as a research student and taking a doctorate at a Japanese institution. Invitation for this Japanese government scholarship program is implemented by MEXT, and scholarship is budgeted separately from SATREPS. For more details, please refer to the Japanese government (MEXT) scholarship program website. Please note that this scholarship program may be altered depending on the final budget.

Japanese government (MEXT/Monbukagakusho) scholarship program

[http://www.mext.go.jp/a\\_menu/koutou/ryugaku/06032818.htm](http://www.mext.go.jp/a_menu/koutou/ryugaku/06032818.htm) (Japanese)

<http://www.studyjapan.go.jp/en/toj/toj0302e.html> (English)

##### - Acceptance of foreign researchers

There is also the "acceptance of trainees" system (which is called "acceptance of foreign researchers" in the SATREPS program) for inviting researchers from the ODA recipient country to Japan using the ODA budget. The researchers are invited from the research institution carrying out the international joint research in the developing country to Japan, where they carry out research. It is hoped that such researchers will play a long-term key role at their research institution after their return from Japan. They are considered as indispensable for promoting the joint research. Please note that the acceptance of foreign researchers under this system is normally conditional on the researcher's period of research in Japan terminating within the period for joint research specified in the R/D.

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

When a proposal is selected as a SATREPS project, if young post-doctoral researchers are employed to participate in the project using public funds (competitive funding and other project research funding, education and research funding through open funding schemes for universities), there is a requirement to provide active assistance to such researchers to help them to secure varied career paths. This requirement is based on a policy document issued on December 20, 2011 by the Council for Science and Technology's Committee on Human Resources concerning basic policy for securing varied career paths for young post-doctoral researchers employed using public funds from MEXT.

\* Employment of research assistants (RA)

The 4th Science and Technology Basic Plan aims to provide more comprehensive economic support in the form of funding fellowships, teaching assistants (TA), and research assistants (RA) so that bright students can feel secure in aiming for graduate school. This is an attempt to accelerate the 3rd Science and Technology Basic Plan's aim to "enable 20 percent of doctoral students (latter stage) to receive an amount equivalent to their living expenses."

Based on this principle, the SATREPS program recommends that when latter stage doctoral students are employed as research assistants on a SATREPS project, they are paid a salary level equivalent to living costs to ensure that they do not need to be concerned about the economic cost of participating. The following considerations apply when employing a research assistant:

- Assumed to be a doctoral student (latter stage).

- Recommended payment is in the order of 2 million yen per year or 170,000 yen per month. Payments of this level can be handled as research expenses. Take care, however to avoid situations that could be interpreted as the payment being charged to SATREPS but used for simply studying or for research work other than that of the SATREPS program, which would be regarded as inappropriate (fraudulent) use of funds.

- Decisions regarding actual payment amounts and payment periods, etc. should be made by the research institution. AMED does not place restrictions on payments above or below the recommended level.

- When research assistants are receiving payments from scholarship loans or other systems, there should be no impediment to the objectives of the scholarship or the research institution that the assistant is affiliated to. AMED does not, however, place any systematic restriction on overlapping payments.

It is desirable that the effective use of all of these programs will have a synergistic effect, in terms of developing the skills of key personnel and young researchers promoting research in the developing country and enhancing systems for ongoing international joint research with Japan.

References: Major science & technology policy and other documents concerning SATREPS

Toward the Reinforcement of S&T Diplomacy (May 19, 2008)

[http://www8.cao.go.jp/cstp/english/doc/s\\_and\\_t\\_diplomacy/20080519\\_tow\\_the\\_reinforcement\\_of.pdf](http://www8.cao.go.jp/cstp/english/doc/s_and_t_diplomacy/20080519_tow_the_reinforcement_of.pdf)

Task Force Report on Science and Technology Diplomacy (February 2010, Council for Science and

Technology Policy; in Japanese)

<http://www8.cao.go.jp/cstp/sonota/kagigaiko/8kai/siryo1-1.pdf>

The 5th Science and Technology Basic Plan (January 22, 2016, Cabinet decision; in Japanese)

<http://www8.cao.go.jp/cstp/kihonkeikaku/5honbun.pdf>

Policy for the Allocation of Resources, Including the Science and Technology Budget (July 17, 2014, Council for Science and Technology Policy; in Japanese)

<http://www8.cao.go.jp/cstp/budget/houshin.html>

Comprehensive Strategy on Science, Technology and Innovation (May 24, 2015, Cabinet Decision)

<http://www8.cao.go.jp/cstp/sogosenryaku/2016/honbun2016.pdf> (Japanese)

<http://www8.cao.go.jp/cstp/english/> (English; may not include the latest Japanese version)

Sustainable Development Goals (SDGs) (September 2015, UN Sustainable Development Summit)

<http://www.un.org/sustainabledevelopment/>

Basic Plan on Ocean Policy (April 26, 2013, Cabinet decision, in Japanese and English)

[http://www.kantei.go.jp/jp/singi/kaiyou/kihonkeikaku/130426kihonkeikaku\\_je.pdf](http://www.kantei.go.jp/jp/singi/kaiyou/kihonkeikaku/130426kihonkeikaku_je.pdf)

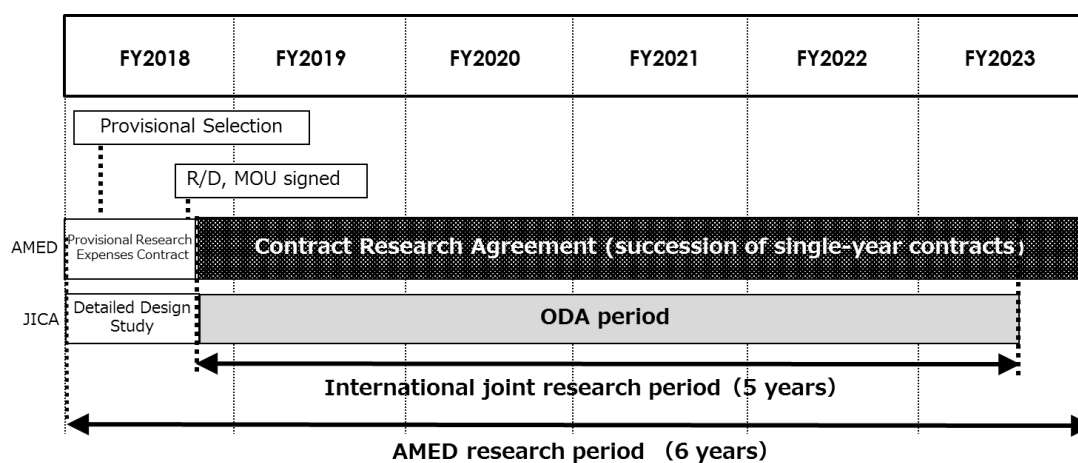
Basic Plan on Space Policy (January 25, 2013, Strategic Headquarters for Space Policy)

<http://www8.cao.go.jp/space/plan/plan-eng.pdf>

#### (4) Research Period and Expense

##### (a) Research period/Duration of research

The period of international joint research (period to conduct the technical cooperation project set out in the R/D) is three to five years.



Completion date for contract research may be extended up to the end of the fiscal year in the final year of joint international research implementation prescribed under the R/D.

Figure 3. Extent of Research Period (5-year project)

As shown in Figure 3, within the limits of the budget for AMED contract research expenses determined at the time of provisional selection, it may be possible to extend the completion date for research activities in Japan funded by AMED contract research expenses up to the end of the fiscal year in the final year of joint international research implementation prescribed under the R/D (in such cases, payment of expenses incurred by the ODA side extending past the period stated in the R/D will not be made).

Following provisional selection of research projects, AMED contract research expenses are available to Japanese research institutions before the signing of R/D and other agreements (MOU, etc.) to ensure swift implementation of the international joint research project after the R/D and other agreements are signed. This coverage only extends to research expenses incurred by the Japanese team for the purpose of preparation for the international joint research activities.

(b) Outline of the application and project selection process

1) Research fields and areas

Research proposals are currently invited in the Infectious Diseases Control field. See the AMED website for details regarding the invitation for research proposals in the Infectious Diseases Control field:

<http://www.amed.go.jp/en/news/program/030120160620.html>

The research budget from AMED is tentative, and may change due to budgetary considerations.

2) Application requirements

The applicant must be affiliated with a research institution in Japan, must be able to take responsibility as principal investigator for the international joint research, and must be able to be engaged in the international joint research from beginning to end.

3) Applications deadline (Deadline for ODA applications to reach MOFA is the same)

12:00 noon (Japan time) on Monday October 30, 2017 (applications received after the deadline will not be accepted)

(c) Expenses covered by AMED and JICA

As a rule, research expenses are categorized into those covered by AMED as contract research expenses and those covered by JICA as project expenses, as described below: (See also Table 2.)

A. Research expenses incurred in Japan and other locations outside the developing country will be supported by AMED as contract research expenses.

B. Costs incurred within the developing country (on-site machinery and equipment procurement, etc.) are shouldered by JICA (travel expenses to invite researchers to Japan from the developing country shall also be the responsibility of the JICA).

C. As a rule, travel costs and on-ground expenses for researchers from Japan dispatched to the counterpart institutes on official business shall be borne by AMED (for those who are dispatched for more than one year, travel cost for dispatch and return, transfer allowance, other allowances, etc.)<sup>8</sup>. Activities relating to the international joint research undertaken by researchers from Japan within the developing country will be governed by the provisions on tax immunity and permission for activities prescribed in the R/D concluded between JICA and the counterpart institutes.

When SATREPS project team members are dispatched to the ODA recipient country, JICA does not cover supplementary labor costs and overhead costs or in-country salary (paid directly as a fixed monthly amount when the team member is affiliated with an institution but not paid during the dispatch period)

incurred by the researcher's institution.

As JICA supports that country with ODA under the technical cooperation framework, the country is required to depend on its own efforts. Consequently, the local institution's costs incurred for the project (labor costs, rent, consumables used by local researchers, operation and maintenance of machinery and equipment supplied, domestic transportation fees for local researchers, daily allowance for attending a meeting, and other miscellaneous costs) should in principle be covered by its own country.

<sup>8</sup> In some exceptional cases, it may be possible for costs relating to official trips to the developing country to be covered by AMED research expenses (For example, researchers of the developing country institute employed in Japan as post-doctoral researchers). However, trips covered by AMED funds will not be considered activities as prescribed by the R/D for the international joint research in question: tax immunity provisions may not apply, and permission for on-ground activities may not be granted. Consult with JICA in advance.

When a private-sector corporation or similar entity submits an application as the research institution, coverage of expenses may differ from the description given above. Consult AMED/JICA in advance for details.

| Expenses   | AMED                      | JICA            |
|--|---------------------------|-----------------|
| A; Research expenses incurred in Japan   | YES                       |                 |
| A: Research expenses incurred outside of partner countries<br>(Travel expenses to third countries, on-site expenses, etc.) | YES<br>(Note 1)           |                 |
| B: Costs incurred in partner countries   | Exceptionally<br>(Note 2) | YES<br>(Note 3) |
| B: Travel expenses to invite researchers to Japan from partner countries   | Exceptionally<br>(Note 4) | YES             |
| C: Travel expenses between Japan and partner countries   | Exceptionally<br>(Note 5) | YES             |

Table 2. Categories of expenses covered by AMED and JICA

Note 1: Joint projects with research institutions in a third country are not covered.

Note 2: In principle, financial support from AMED is limited to costs that can be covered as research expenses in the partner country, and that cannot be covered by JICA, such as travel costs and on-ground expenses incurred through activities considered to be an extension of research in Japan.\*

Note 3: Research expenses incurred in the ODA recipient country include equipment, research supplies, and consumables required for the Japanese researchers to conduct international joint research in the partner country. (As JICA supports that country with ODA under the technical cooperation framework, the country is required to depend on its own efforts. Consequently, the local institution's costs incurred for the project (labor costs, rent, consumables used by local researchers, operation and maintenance of machinery and equipment supplied, domestic transportation fees for local researchers, daily allowance for attending a meeting, and other miscellaneous costs) should in principle be covered by its own

country.)

Note 4: Limited to external experts, etc. who are not part of the partner country's research team.

Note 5: Limited to students, external experts, etc., and other cases where dispatched to the partner country as JICA experts is not possible.

\* In some exceptional cases, it may be possible for costs relating to official trips to the developing country to be covered by AMED research expenses (For example, researchers of the developing country institute employed in Japan as post-doctoral researchers, who are not accepted as JICA experts). However, trips covered by AMED funds will not be considered activities as prescribed by the R/D for the international joint research in question: tax immunity provisions may not apply, and permission for on-ground activities may not be granted. Consult with JICA in advance.

## 2. Program Structure

### (1) Program Implementation System

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

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

### (2) Roles of Principal Institutions and Subsidiary Institutions

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

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

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



## II. Application Requirements

### 1. Eligible Applicants

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

(1) “Research Institute” refers to institution with the characteristics shown in (a)–(g) below.

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

<sup>1</sup>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

<sup>2</sup>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 either contract start date or June 1, 2018. However, in the case that the above conditions are not met by these dates, 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 carrying out the R&D project and the President of AMED.

\*For details, please refer to Chapter V.

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

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

### (3) Security Trade Control (Countermeasures to Technology Leakage Overseas)

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

In Japan, export regulations\* are enforced in accordance with the Foreign Exchange and Foreign Trade Act (Law No. 228 of 1949) (hereinafter referred to as the "Foreign Exchange Act"). Accordingly, in the case that a person wishes to export (provide) goods or technology prescribed under the Foreign Exchange Act, as a general rule they are required to obtain the permission of the Minister of Economy, Trade and Industry. Please

be sure to comply strictly with all laws, ministerial ordinances, and directives, etc., issued by various Japanese government ministries and agencies, beginning with the Foreign Exchange Act. IN the case that R&D is carried out in infringement of relevant laws or guidelines, allocation of R&D funds may be suspended and the decision to allocate R&D funds may be cancelled.

\*Currently, under Japan's security export control system, there are two types of regulations based on international agreements: (1) a system under which the permission of the Minister of Economy, Trade and Industry must generally be obtained in the case that a person wishes to export (provide) goods (technology) with specifications or functions above a certain level—mainly carbon-fiber and numerically controlled machine tools, etc.—("List 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 foreign national (non-resident of Japan), permission must be received in advance. "Provision of technology" includes not only the provision of blueprints/designs, specifications, manuals, samples, prototypes, and other technological information via paper, e-mail, CD, USB flash drive, or other storage medium but also the provision of operational knowledge through technological guidance or skills training and technological support at seminars, etc. There are cases in which large amounts of technological exchange that could be subject to regulation under the Foreign Exchange Act may be included in joint research activities or when international students are involved.

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

- Ministry of Economy, Trade and Industry: Security Trade Control (general)  
<http://www.meti.go.jp/policy/anpo/>
- Ministry of Economy, Trade and Industry: Handbook for Security Trade Control (8<sup>th</sup> 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](http://www.meti.go.jp/policy/anpo/law_document/tutatu/t07sonota/t07sonota_jishukanri03.pdf)

### III. Application/Selection Implementation Methods

#### 1. Outline of the SATREPS Project for which Applications Is Being Solicited

The outline of the SATREPS project for which applications is being solicited included in these Application Guidelines is as follows. For details regarding the project being solicited, please refer to Chapter XI.

| Name of field/R&D projects being solicited   | Scale of R&D funds   | Period in which R&D is scheduled to be implemented | Planned number of new awarded projects |
|--|--|--|--|
| Infectious disease field<br>“Research on measures to address infectious diseases control attuned to the needs of developing countries” | Around 100 million yen per year for each project (including indirect costs)<br><br>Funding slit:<br>AMED (Contract research expenses):<br>Approx. 35 million yen per year (Approx. 175 million yen over 5 years)<br>JICA (ODA project expenses under the technical cooperation framework): Approx. 60 million yen per year (Max. 300 million yen over 5 years) | Max. of 5 years<br>(FY2019 –FY2024)                | Around 2 projects                      |

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

An applicant can file only one research proposal as principal investigator for this program across all the research areas (including Infectious Diseases Control field handled by AMED).

#### (a) Research field

Infectious disease field “Research on measures to address infectious diseases control attuned to the needs of developing countries”

#### (b) Research content

HIV/AIDS, malaria, dengue fever, tuberculosis, highly-pathogenic avian influenza, bacteria resistant to antibiotics like carbapenem and colistin, and other emerging and re-emerging infectious diseases not only pose a threat to health in developing countries, but act as a major impediment to social and economic development. The frequency with which people and goods are now moving across national borders means that these problems are not confined to developing countries. Japan is consequently keen to boost international cooperation regarding infectious diseases that spread quickly and widely across the border. Several examples are given below of potential research and development projects that target solutions for global issues in the area of infectious diseases control.

- Research and development on Zoonosis such as avian influenza, rabies and others
- Research and development for technology related to epidemiology, diagnostics, vaccines and therapeutics for the detection and control of emerging and re-emerging infectious diseases including HIV/AIDS, malaria, Dengue fever, tuberculosis and bacteria resistant to antibiotics like carbapenem and colistin.

## 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.

<http://www.amed.go.jp/koubo.html>

### (2) Period of Acceptance of Proposals

Application start date: September 12, 2017

Application deadline: 12:00 noon (Japan time) on Monday October 30, 2017

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

Note 3: The deadline for submitting the official request for ODA technical cooperation is on Monday October 16, 2017. If the counterpart government does not request a technical cooperation project, a research proposal submitted in Japan will be considered incomplete and not go through the selection process.

### (3) Submission of Proposal Documents

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

(a) Points to note in using the system

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

1) System operating hours

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

Note: During the above system operating hours, the e-Rad system may 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

1) Downloading of proposal forms

Please download the prescribed form file after first checking the system/program information

2) File type

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

3) Image file format

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

4) File capacity

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

5) Uploading proposal documents

Please convert proposal documents to PDF format before uploading.

6) Consent of affiliated institute

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

7) 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"

8) 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.

9) Other

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

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

For inquiries regarding how to operate the e-Rad system, please contact the e-Rad portal site’s Help Desk. (Please refer to Chapter X.) Please be sure to check the portal site and see the “Frequently Asked Questions” page before contacting the Help Desk. Please note that the Help Desk cannot answer any inquiries 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     | Mid February 2018 (tentative)                     |
| Interview (hearing) | February 2018 or later *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.3. (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      Mid May 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.) (tentative date)      Mid June 2018 (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.

### 3. Method for Reviewing Proposal Documents

#### (1) Review Method

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

- (a) Reviews shall be conducted in private by a Project Evaluation Panel established by AMED.
- (b) The Project Evaluation Panel shall evaluate project proposals by conducting a document review of the content of the submitted proposal documents and 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 the PI of the project. Note that we cannot answer questions regarding the progress status of the selection process.
- (e) Evaluation Panel members are obligated to maintain confidentiality regarding any secret information learned during the course of performing their evaluation duties, including after these duties have concluded, in order to prohibit leakage or misappropriation of this information. 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 Project Evaluation Panel members shall be implemented in accordance with AMED regulations. In the case that any of the following items apply to a Project Evaluation Panel member, they are required to

report to AMED that they are subject to management of conflict of interest and as a general rule shall not be involved in evaluation of the relevant project. However, in the case that the Project Evaluation Panel Chair recognizes that participation by the Project Evaluation Panel member in question is especially necessary for ensuring the scientific validity of the evaluation and that their ability to make appropriate and transparent decisions as part of the evaluation is not impaired, the Project Evaluation Panel member may participate in the evaluation of the relevant project.

- 1) The evaluatee is a family member/relative of the Project Evaluation Panel member.
  - 2) The evaluatee is affiliated with the same department at a university, the National Research and Development Agency, or a national research institution or other research institute or business enterprise as the Project Evaluation Panel member.
  - 3) The evaluatee has worked closely with the evaluator on a joint research project within the past three years including the fiscal year in which the Project Evaluation Panel evaluation is conducted.
  - 4) The Project Evaluation Panel member and evaluatee have a close teacher-disciple relationship wherein one provided guidance and instruction regarding the other's doctoral thesis.
  - 5) The evaluatee has received economic benefits from the Project Evaluation Panel member within the past three years, including the fiscal year in which the Project Evaluation Panel evaluation is conducted, of more than one million yen.
  - 6) The Project Evaluation Panel member is in a direct competitive relationship with the evaluatee.
  - 7) Other serious conflicts of interest are recognized to exist.
- (h) Program applicants and persons intending to apply for the program are prohibited from lobbying AMED executive officers, 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 following perspectives. In the case that a proposal is submitted for an R&D project that designates a subsidiary institution, evaluations shall also examine the necessity of the subsidiary institution for carrying out the R&D and the competency of the subsidiary institution to carry out the R&D.

- ① Compatibility with the program's purpose
  - Is the project compatible with the program's purpose and objectives, etc.?
- ② Scientific/technological significance and advantage
  - Is the current technological level and previous performance sufficient?
  - Does the project proposal have originality, novelty, and innovativeness?
  - Does the project contribute to the advancement of the field of medicine?
  - Does the project contribute to the generation of new technologies?
  - Does the project respond to social needs?

- Is the project compatible with national policies regarding R&D in the field of medicine?
- ③ Appropriateness of the plan
- Are the overall content and objectives of the plan clear?
  - As the plans for each fiscal year detailed and realizable?
  - Is the project plan in compliance with laws and ordinances related to bioethics or safety measures?
- ④ Implementation system
- Has an R&D system centered on the applicant been organized appropriately?
  - Has a sufficient collaboration network been constructed?
  - Are the efforts of the applicant appropriate?
  - Is there unreasonable duplication/excessive concentration?
- ⑤ Costs
- Are the breakdown of costs and spending plan appropriate?
- ⑥ Items prescribed under the program and items that should be considered comprehensively
- Is the direction and feasibility of utilization of research outcomes clearly defined?
  - Is the proposal based a clear need for the ODA recipient country to address a global issue and in line with Japan's ODA policy with regard to that country?
  - Does the developing country have prospects for continuing to manage and maintain the machinery and equipment provided and continue the research after the end of the joint research period?
- ⑦ Needs of counterpart country and application to ODA purpose
- Is there critical needs in counterpart country to the project concerning global problems?
  - Is the purpose of counterpart country focused on the Japanese ODA proposal?
- ⑧ Capability of sustainable development
- Do the counterpart country have enough possibility to proceed their research after finishing the project?
  - Is there personnel capability for young Japanese and counterpart country's researchers?

## IV. Preparation of Proposal Documents and Cautions

### 1. Handling of Information Contained in Proposal Documents

#### (1) Purpose of Use of Information

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

Furthermore, information included in proposal summaries shall also be used in analysis of research trends that contributes to the operation of the AMED program, such as the creation of new programs. In accordance with laws related to the protection of personal information possessed by independent administrative corporations and other organizations, the confidentiality of secret information included in proposal documents shall be strictly maintained to ensure that the 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/gyoukan/kanri/horei\\_kihon.html#7\\_2](http://www.soumu.go.jp/gyoukan/kanri/horei_kihon.html#7_2)

#### (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 inputting the information into the Government Research and Development Database (please refer to Chapter IX. 3.), and analysis results may be publicly disclosed.

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

### 2. Proposal Document Format and Notes for Preparation

#### (1) Proposal Document Format

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

(2) Preparation of proposal documents

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

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

- (a) As a general rule, the Research Proposal (Form 1) is to be prepared in Japanese, but the abstract must be prepared in both Japanese and English. In the case that information required on the Research Proposal is missing, the application may be ineligible for review.
- (b) With regard to formats prescribing word limits or page limits, please be sure to comply with the set limits.
- (c) With regard to letter/character size when inputting information, please use 10.5 point as a general rule.
- (d) As a general rule, please use half-width letters when inputting English. (E.g. post codes, telephone numbers, numbers of people.)
- (e) Please number the pages of proposal documents with numbers placed centrally at the bottom of each page in the form of (-1-).
- (f) Proposal documents may be prepared in color, but please ensure that the documents’ content can be understood even when the documents are photocopied in black-and-white.

(3) Notes on Preparing 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.

## 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 implementing the R&D project\* and the President of AMED in accordance with the principle of the accounting period of the national government. Successful applicants shall receive detailed information from AMED following project selection.

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

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

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

\*With regard to Principal Institutions and Subsidiary Institutions that are national facilities or other institutions (general term for national facilities or other institutions or public research institutes), only in the case that the relevant institution or the PI or Co-Investigator affiliated with the relevant institution makes a request based on reasonable grounds and following discussion with AMED shall a payment method of the R&D grant being paid By AMED to the PI or Co-Investigator of the relevant institution be adopted. (In such cases, payment will be in accordance with the Guidelines for Handling of R&D Grants prescribed by AMED.) If this is the case, administration related to R&D grant accounting shall be entrusted to the head of the relevant institution.

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

#### (2) Preparations for Concluding Agreement $\tau$

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

- (a) Preparation of an Overall R&D Plan and R&D Plan\*
- (b) Obtain an estimate for the expenditure needed under the administrative plan
- (c) Organize accounting regulations rules for employee inventions, etc.

\*One Overall R&D Plan is to be prepared for each R&D project based on the R&D proposal at the time of adoption of the project. Centered on the proposed R&D concept for the entire project implementation period, please include the basic plan, R&D content, R&D system, and budget plan. This plan shall be used as a base material for considering budget allocation each fiscal year, conducting 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: <http://www.amed.go.jp/program/youshiki.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”.<sup>1</sup>

|              | 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<br>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.<br>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 <sup>2</sup> | 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. |   |

<sup>1</sup>Link from: <http://www.amed.go.jp/program/youshiki.html>

<sup>2</sup>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.

## (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: <http://www.amed.go.jp/program/youshiki.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: [http://www.amed.go.jp/program/kenkyu\\_unyo.html](http://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: <http://www.amed.go.jp/program/youshiki.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: <http://www.amed.go.jp/program/youshiki.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,<sup>1</sup> fraudulent use,<sup>2</sup> and fraudulent receipt<sup>3</sup> (hereinafter referred to collectively as “Misconduct, etc.”).

<sup>1</sup>“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.

<sup>2</sup>“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.)

<sup>3</sup>“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.

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)
- 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>

#### (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 Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW) on March 31, 2014), 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

Research institutes must strictly comply with items required to be implemented by research institutions under the Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards)<sup>1</sup> (decided by Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW), Guidelines for Responding to Misconduct in Research Activities in the Field of Health, Labour and Welfare<sup>2</sup> (No. 0116-1, decided by Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare (MHLW) on January 16, 2015), and other guidelines (including establishing systems related to the management/auditing of public research funds).

\* Please check the following websites for information about guidelines.

1 “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)

<http://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/0000043065.pdf>

2 “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)

<http://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/husei2.pdf>

(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 a checklist based on the format provided on the website shown below to the MEXT via e-Rad by a deadline to be stipulated separately by AMED.

[http://www.mext.go.jp/a\\_menu/kansa/houkoku/1324571.htm](http://www.mext.go.jp/a_menu/kansa/houkoku/1324571.htm)

(c) Necessity of submitting a checklist

In the case that you have already submitted a checklist this fiscal year when applying for a MEXT program, it is not necessary to newly submit a checklist 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/shozoku/system/index.html>

[http://www.mext.go.jp/a\\_menu/kansa/houkoku/1324571.htm](http://www.mext.go.jp/a_menu/kansa/houkoku/1324571.htm)

[http://www.mext.go.jp/a\\_menu/kansa/houkoku/1301688.htm](http://www.mext.go.jp/a_menu/kansa/houkoku/1301688.htm)

(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 shall be issued management conditions 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) stating the items requiring improvement and the deadline for implementing these improvements (one year).

Please note that, in the case that it is subsequently deemed that the research institution has not fulfilled these conditions, AMED shall implement measures against the research institute such as reducing indirect costs with regard to R&D funding and/or suspending allocation of competitive research funding.

\*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/afeldfile/2014/03/18/1343906\\_02.pdf](http://www.mext.go.jp/component/a_menu/science/detail/_icsFiles/afeldfile/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: [http://www.amed.go.jp/kenkyu\\_kousei/](http://www.amed.go.jp/kenkyu_kousei/)

Where/how to submit report: Please e-mail the report to [kenkyuukousei@amed.go.jp](mailto:kenkyuukousei@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 [\[kenkyuukousei@amed.go.jp\]](mailto:kenkyuukousei@amed.go.jp) (Change "at" to @ when inputting the address.)

7. COI Management

(1) Target Programs/Projects

(a) All R&D projects commencing in or after FY2016

- Excludes all activities unrelated to R&D (infrastructure improvement, human resources training, etc.)
- Research institutes that have not completed preparation of conflict of interest regulations or a conflict of interest committee as at April 2016 shall be exempted from application of AMED Regulations for Managing COI in Research Activities until March 31, 2018. However, such research institutes must also endeavor to implement appropriate management of conflict of interest regarding researchers participating in AMED programs.

(b) R&D projects commencing in or before FY2015 that are projects under programs listed in the appendix of the regulations

- However, such projects commencing in or before FY2015 under programs other than those listed in the appendix of the regulations must also endeavor to implement appropriate management of conflict of interest regarding researchers participating in AMED programs.

(2) Target Persons

## PI or Co-Investigator of R&D projects

### (3) 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.

### (4) 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.

### (5) Inquiries

For inquiries related to conflict of interest management, please send an e-mail to [kenkyukousei“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  
[http://www.amed.go.jp/content/files/jp/kenkyukousei/riekisohan\\_kisoku.pdf](http://www.amed.go.jp/content/files/jp/kenkyukousei/riekisohan_kisoku.pdf)
- Regulations Q&A  
[http://www.amed.go.jp/content/files/jp/kenkyukousei/riekisohan\\_kisoku-qa.pdf](http://www.amed.go.jp/content/files/jp/kenkyukousei/riekisohan_kisoku-qa.pdf)
- Reports on the State of Ethical Reviews and COI Management  
[http://www.amed.go.jp/content/files/jp/kenkyukousei/riekisohan\\_houkokuyoshiki.docx](http://www.amed.go.jp/content/files/jp/kenkyukousei/riekisohan_houkokuyoshiki.docx)

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

(MEXT programs)

- 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)

(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 complaine 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.

| Category of misconduct according to involvement |  | Degree of misconduct  | Period deemed appropriate   |
|---|--|---|---|
| Person Involved in the Misconduct               | 1. Especially malicious individual who intentionally engages in misconduct from the outset of the research |   | 10 years  |
|   | 2. Author of academic paper, etc. related to research in which there has been misconduct                   | The author responsible for the academic paper in question (supervisor, first author, or other position of responsibility deemed equivalent) | 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.<br>5–7 years |
|   |  |   | 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.<br>3–5 years  |
|   | Author other than that   |   | 2–3 years   |

|   |  |  |           |
|---|--|--|-----------|
|   | listed above   |  |           |
|   | 3. An individual involved in misconduct other than that stipulated in 1 or 2 |  | 2–3 years |
| 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) |  | 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. | 2–3 years |
|   |  | 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.  | 1–2 years |

[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 placed 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

In the case that the measures and/or restrictions prescribed in 1) and 2) above are implemented under this program, the content of the relevant measures shall be publicly disclosed 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).

- (3) Admission to the AMED RIO Network

AMED plans to construct a network called the “RIO Network”<sup>\*</sup> in FY2017. Research institutes that have concluded contracts with AMED shall register the officers in charge of R&D ethics education, the officers in charge of promoting compliance, and the officers in charge of administrative activities related to R&D misconduct and research funding misconduct with AMED and participate in RIO Network activities.

<sup>\*</sup>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.

## 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<sup>\*</sup> (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
- There is duplication regarding the use of research funds amongst multiple R&D projects
- Other equivalent cases

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

(b) Measures to prevent excessive concentration

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

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

\*Based on the Council for Science, Technology and Innovation’s definition of “effort”: the percentage of researcher’s time exclusively spent for the R&D activities concerned against the researcher’s annual working hours. Researcher’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<sup>1,2</sup> 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.

<sup>1</sup>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.

<sup>2</sup>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 PI of an awarded project shall be required to make a public or closed-door presentation at an Accomplishments Report Meeting held by AMED. In addition, as part of follow-up 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.

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.

\*[http://www.amed.go.jp/chitekizaisan/chizai\\_policy.html](http://www.amed.go.jp/chitekizaisan/chizai_policy.html)

### 3. 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.

\*[http://www.amed.go.jp/chitekizaisan/chizai\\_kyouzai.html](http://www.amed.go.jp/chitekizaisan/chizai_kyouzai.html)

### 4. 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,<sup>1</sup> through direct costs (hereinafter referred to as “Acquired Goods”) shall revert to the university, etc.

Ownership of acquired goods by Companies, etc.,<sup>2</sup> 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.

<sup>1</sup>“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.

<sup>2</sup>“Companies, etc.” is a general term for research institutes other than “universities, etc.”

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

For the purpose of continued application of the relevant R&D, as a general rule 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.<sup>2</sup>

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.

<sup>1</sup><http://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/kenkoukiken.doc>

<sup>2</sup>Link from <http://www.amed.go.jp/program/youshiki.html>

### 3. Information for inputting data into the Government Research and Development Database

Research carried out using contracted R&D funds is targeted for input into the Government Research and Development Database (Council for Science, Technology and Innovation, Cabinet Office), which is a cross-ministerial R&D database. Please submit the following information to the Government Research and Development Database via e-Rad.

- (1) Researcher ID number (8 digits)



The unique number issued by e-Rad to individual researchers is called the “Researcher ID number”. Under the e-Rad system, individual researchers are issued with a “Researcher Number” for handling basic information for the relevant R&D program/project such as the name of the research project, names of researchers, research implementation period, and budget amount in order to ensure the uniqueness of each researcher.

Note: The “Researcher Number” differs from “Researcher ID”.

## (2) Effort

The PI should provide figures for the number of hours a researcher requires to carry out the relevant research that comprise the total number of working hours of that researcher (including hours worked outside regular working hours) (so-called “Effort”) expressed as a percentage (rounded off the two decimal places).

Because researchers on the relevant project do not bear a certain percentage of total “effort”, please make sure there are no mistakes in your calculations.

$$\text{Effort rate for Researcher A (\%)} = \frac{\text{Hours required for Researcher A to perform the relevant research}}{\text{Researcher A's total annual working hours}} \times 100$$

## (3) Research fields on the “Research Field Particulars and Key Words List”

With regard to research fields that are related to the principal field of research (“Research Field (Principal)” (“Research Field (Secondary)”), selected the research field from the “Research Field Particulars and Key Words List” and input the research field, research category, research field, particulars number, and particulars name. In addition, with regard to key words for the content of the relevant research, please select key words from the “Research Field Particulars and Key Words List” and input the key word number and key word (minimum of one, maximum of five).

When inputting key words, you must select a minimum of one key word from the “Research Field Particulars and Key Words List”; however, when you wish to input key words that are not on the “Research Field Particulars and Key Words List”, please input a maximum of two key words in 50 letters/characters or less in the “Other Key Words” column. Accordingly, it is possible to input a maximum of seven key words.

## (4) Nature of the R&D

Please indicate whether the relevant R&D is basic research, applied research, or developmental research.

## 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),<sup>1</sup> 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.

<sup>1</sup>Intellectual Property Strategic Program 2014 (excerpt)

<http://www.kantei.go.jp/jp/singi/titeki2/kettei/chizaikaku20140704.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<sup>2</sup>)

- 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]).

<sup>2</sup>“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 property 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 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.

#### 7. 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.

#### 8. 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 pay 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.

## 9. 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@biosciencedbc.jp](mailto:dbarchive@biosciencedbc.jp)  
Inquiries regarding the Human Database: [humandbs@biosciencedbc.jp](mailto:humandbs@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)<sup>1</sup>

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<sup>2</sup> (limited to bioresources targeted by the NBRP), making these resources broadly available for researchers’ use.

<sup>1</sup>National Bio Resource Project (NBRP): <http://www.amed.go.jp/program/list/04/01/043.html>

<sup>2</sup>“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.

## X. References

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

<sup>1</sup>Please make inquiries by e-mail as far as possible (Change “at” to @ when inputting the address.)

<sup>2</sup>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.

<sup>3</sup><http://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<br>Tel: +81-3-6870-2216<br>E-mail: <a href="mailto:amed-satreps@amed.go.jp">amed-satreps@amed.go.jp</a>  |
| Misconduct/fraudulent use/fraudulent receipt  | AMED Department of Research Integrity and Legal Affairs<br>E-mail: <a href="mailto:kouseisoudan@amed.go.jp">kouseisoudan@amed.go.jp</a>   |
| Management of conflict of interest/research ethics education programs   | AMED Department of Research Integrity and Legal Affairs<br>E-mail: <a href="mailto:kenyuukousei@amed.go.jp">kenyuukousei@amed.go.jp</a>   |
| 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<br>Tower B, Grand Front Osaka, 1 3-chome Ofuka-cho, Kita-ku, Osaka City, Osaka Prefecture, Japan. 530-0011<br>Tel: +81-6-6372-1771 (Extension 120)<br>E-mail: <a href="mailto:id3navi@amed.go.jp">id3navi@amed.go.jp</a>   |
| How to use the e-Rad system   | e-Rad Portal Site Help Desk<br>Before telephoning, please check the “Frequently Asked Questions (FAQ)” page.<br>Link from: <a href="https://www.e-rad.go.jp/contact/">https://www.e-rad.go.jp/contact/</a><br>→After checking the FAQ page, log in to e-Rad so that you can check the operation manual, then dial:<br>Tel: 0570-066-877 (NAVI-DIAL) or +81-3-5625-3961 (direct line) if the NAVI-DIAL service is unavailable.<br>Operating hours: 9:00–18:00 (weekdays)<br>*Excludes Saturdays, Sundays, public holidays, or Year-end/New Year holidays (December 29 – January 3) |

|   |   |
|---|---|
| <p>Bioscience Database<br/>Life Science Database Archive</p>                  | <p>Japan Science and Technology Agency (JST)<br/>National Bioscience Database Center (NBDC)<br/>E-mail: dbarchive“AT”biosciencedbc.jp<br/><a href="http://dbarchive.biosciencedbc.jp/">http://dbarchive.biosciencedbc.jp/</a></p> |
| <p>Bioscience Database<br/>NBDC Human Database</p>                            | <p>Japan Science and Technology Agency (JST)<br/>National Bioscience Database Center (NBDC)<br/>E-mail: humandbs“AT”biosciencedbc.jp<br/><a href="http://humandbs.biosciencedbc.jp/">http://humandbs.biosciencedbc.jp/</a></p>    |
| <p>AMED’s IP policy and handling of IP in<br/>contracted R&amp;D projects</p> | <p>AMED Department of Intellectual Property<br/>Tel: 03-6870-2237<br/>Email: medicalip“AT”amed.go.jp</p>  |

## XI. R&D Projects Being Solicited

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

### 1. R&D progression after selection (provisional selection)

#### (1) Responsibilities of research institutions after selection (provisional selection)

The responsibilities of Japanese research institutions (institutions to which the principal investigator and main research collaborators in research projects that have been selected or provisionally selected are affiliated) are as described below.

(a) The research institution must secure a structure for conducting the research. Also, the director of the institution must give maximum consideration to the status of the principal investigator during the term of the research. The director of the institution is considered to be the president or chair of the board or other person with responsibility for the whole of the institution, or in the case of entities such as private-sector corporations, it should be a person in a position of responsibility to ensure the required support and setup throughout the period of research. It does not normally include executives or management at a lower level in the organization, such as general managers, directors of divisions or centers, or heads of departments).

(b) In order for the research to proceed effectively, it is necessary to ensure the smooth progress of procedures for signing agreements with JST/JICA, submission of required reports to JST/JICA, and the facilitation of surveys of accounting processes by JST/JICA or government accounting audits. Details are given in Japanese in V. (Considerations when submitting an application). Make sure that these requirements are fully understood before submitting an application. Concerning the Agreement with JICA, project operations and accounting operations must be handled appropriately in accordance with the project contract and "SATREPS Project Jisshino Tebiki (only in Japanese)" stipulated by JICA (including reporting to JICA as required).

(c) Research institutions, as the bodies which implement ODA technical cooperation, shall be required to provide support for activities (e.g. procedures to request payment of funds that have been awarded to the principal investigator's institution) in accordance with the Agreement, project contract, and R/D, etc. with JICA. Only the principal investigator's institution will sign the Agreement with JICA; however, other research institutions involved in the research project are required to provide support for activities in accordance with the R/D, etc. The principal investigator's institution, acting as the principal investigator's institution for the Japan side, must oversee the activities of Japan side researchers in the partner country to ensure that they are conducted appropriately, and in addition, concerning the Agreement with JICA, must handle project operations and accounting operations appropriately in accordance with the project contract and "SATREPS Project Jisshino Tebiki (only in Japanese)" stipulated by JICA (including reporting to JICA as required).

(d) Necessary reports must be made to JST and JICA when applying for and after obtaining intellectual property rights vested in the research institutions in accordance with Article 19 of the Industrial Technology Enhancement Act (Japanese version of the Bayh-Dole Act).

(e) Apart from the R/D, the principal investigator's institution must sign a Collaborative Research Agreement (CRA) with the research institution in the partner country regarding the international research collaboration. The CRA should include the treatment of intellectual property rights, handling of confidential information,



publication of research results, warranty and indemnification, and access to and transfer of the partner country's bio-resources.<sup>12</sup> A draft of the document should be checked by JST before signing. It is best to sign and exchange CRA simultaneously with the signing and exchange of R/D between JICA and the institution(s) of the ODA recipient country in order to match the content with the R/D. All researchers and members in the research team in Japan shall observe the CRA signed by the principal investigator's institution.

(f) A research institution entering a Contract Research Agreement with JST wishing to include researcher(s) not affiliated with that institution must exchange appropriate documents between the two institutions in order to ensure compliance with the JST Contract Research Agreement, Joint Research Agreement and content of R/D (e.g. When a researcher affiliated with University B is to participate on a research team at University A which has entered a Contract Research Agreement with JST).

## (2) Requirements for principal investigator (applicant) and research participants

The principal investigator (PI; applicant) must be affiliated with a Japanese research institution<sup>11</sup>, be able to fulfill the duties as principal investigator for the international joint research project, and be able to engage in the international joint research from start to finish. The application should be written by the principal investigator in person.

Japan side research participants are required to be affiliated with a research institution in Japan.

- If a researcher has posts at both a Japanese research institution and a research institution in the partner country, he or she cannot be included in both institutions' lists of members, so has to choose which one.

The principal investigator has to be a Japan side member.

- If a researcher not affiliated with the research institution is required to participate in the project, appropriate procedures need to be taken.

- An institution in a third country (neither Japan nor the partner country) cannot participate in the joint research. Moreover, a researcher whose only affiliation is an institution in a third country cannot participate in the joint research. See the Q&A for details.

- International agencies can participate, but with certain limitations. See the Q&A for details.

- The lists of members should be shared between the Japan side and the partner country side.

## (3) Responsibilities of principal investigators after selection (provisional selection)

The following responsibilities will take effect for the principal investigator (etc.) upon provisional selection.

### (a) Leading and managing the research

- The principal investigator must assume responsibility for the entire international joint research for the full duration of its implementation. The principal investigator, based on his or her own research concept, must be able to form a research team best suited to the implementation of the research subject, and exercise leadership while engaging directly in the research subject. Under this program, research teams may be formed including researchers affiliated with other research institutions in Japan (including private enterprises, etc.) and researchers specializing in other research fields, including the humanities and social sciences, and conduct joint research with research institutions in developing countries.

- The principal investigator must act as the leader of the project under JICA technical cooperation to oversee

and liaise with the counterpart and others to coordinate the planning and implementation of Japan's inputs (including experts dispatch, provision of machinery and equipment, acceptance of trainees), reporting regularly to JST/JICA, submitting to JST/JICA's project appraisal, and appropriately managing the execution of the project, and must manage and control the SATREPS project as a whole. As a rule, unilateral termination of the research activity at the principal investigator's wishes midway through the implementation period will not be allowed.

- After provisional selection, the principal investigator must be able to attend meetings in Japan with JST/JICA (three to five times) and to visit the prospective ODA recipient country in a part of JICA's Detailed Design Study (approx. 10 to 14 days during the period between August and October 2017).
- The principal investigator shall be responsible for research, for planning and implementation of inputs, and in the case of a research team being formed in Japan, for that research team. In planning and implementing the dispatch of joint researchers and provision of machinery and equipment, the principal investigator shall take particular care to ensure full communication with the counterpart country, and to secure roles for young researchers from both Japan and the partner country. The principal investigator shall also attend meetings of the Joint Coordinating Committee (JCC) held in the developing country to report on progress of the research and discuss operation and management.
- The principal investigator shall submit reports and other materials required by JST/JICA and submit to project appraisal by JST/JICA. The principal investigator shall also report on the progress of research whenever requested by the JST/JICA.
- The principal investigator shall be responsible for consensus-building, communication and coordination with administrative offices and other entities within the research institution.
- This fund is supported by the Government of Japan. Therefore, the principal investigators are encouraged to actively publicize research outcomes both domestically and internationally while taking into consideration the handling of intellectual property rights.
- If any result achieved through the research project is to be publicized in a paper or other form or presented at a conference or other venue, it should be indicated that the outcome has been achieved with support of the JST/JICA Science and Technology Research Partnership for Sustainable Development (SATREPS).
- Taking into account that this is an international joint research initiative, the principal investigators are required to actively acquire intellectual property rights where that is not to the disadvantage of the partner. In principle, applications for intellectual property rights shall be conducted by the institution on the basis of the Contract Research Agreement.
- When the principal investigator participates in workshops or symposia organized by JST/JICA, he or she is expected to make a presentation of research outcomes.

(b) Compliance with research agreement etc.

Each principal investigator shall comply with the research agreement between JST and research institutions, other JST rules and regulations, JICA's Agreement for Technical Cooperation and project contract, the R/D concluded between JICA and counterpart research institutions, and CRA related to the joint research concluded between research institutions.

(c) Submission of documentation confirming compliance

After a project proposal has been selected, the principal investigator will, via an explanatory meeting held by

JST, confirm compliance with the following items, and notify JST in writing that compliance has been confirmed.

a. Compliance with the requirements of the Application Guideline

b. The research funding provided by JST is paid for from national taxes. The principal investigator must promise not to act in an illicit manner or make illicit use of anything in the course of the research.

c. In order to prevent misconduct by researchers and others participating in the project, the principal investigator shall commit to publicizing the obligation to study the research ethics course stipulated by JST (CITI JAPAN e-learning) and ensuring that the content of the course is understood.

If researchers do not study the research ethics course described in c. above, payment of research expenses may be suspended until the researchers are in compliance.

Note: The obligation to study the research ethics materials and the submission of documents confirming compliance are applicable to research topics selected in FY2013 onwards.

(d) Obligation to study research ethics learning course

In order to prevent misconduct (fabrication, falsification, or plagiarism of research reports, etc.), researchers and others participating in the project are obliged to study the research ethics course stipulated by JST (CITI JAPAN e-learning).

For more details, please refer to the following website:

<http://www.jst.go.jp/researchintegrity/education.html#M2> (Japanese)

## 2. Outline of technical cooperation through ODA

Before you apply for this program, please ensure that you fully understand the following since this program is implemented using the ODA framework.

### (1) What is official development assistance?

Official Development Assistance (ODA) is development cooperation using public funds in the forms of financial support and technical cooperation provided by donor governments or their implementing agencies to recipient countries, aiming to contribute to the promotion of the economic development and welfare of developing countries as well as the stabilization of people's livelihood. Japan joined the Colombo Plan in 1954<sup>12</sup> and at the same time started providing development aids. Japan has been providing economic and technical cooperation to developing countries ever since.

The Japanese government sets forth its philosophy on ODA, the principle of ODA implementation and the framework for planning and implementing its ODA policy in its "Development Cooperation Charter". In the Development Cooperation Charter, having asserted that "global challenges cannot be dealt with by a single country and require united efforts at the regional level or by the international community as a whole," Japan states, "Japan will take the lead in addressing these challenges... Through these efforts, Japan will seek to contribute to building a sustainable and resilient international community."

<sup>12</sup> The Colombo Plan is a regional organization established in January 1950 in a cooperative attempt to strengthen economic and social development of member countries in South Asia, Southeast Asia and the Asia-Pacific region.

### (2) What is technical cooperation?

JICA aims to contribute to the promotion of international development cooperation and sound economic growth of Japan and the international community by contributing to the socioeconomic development, recovery and economic stability of developing countries. JICA's activities include: technical cooperation (acceptance of trainees, expert dispatch, provision of machinery and equipment, etc.), loans and grant aid, the promotion of cooperation activities by Japanese nationals (dispatch of Japan Overseas Cooperation Volunteers, etc.) and international disaster relief.

Technical cooperation provides technical assistance in order for developing countries to develop capacity to address development issues independently and comprehensively through institution building, capacity and institutional development.

A form of technical cooperation is a technical cooperation project, which is key activity to be conducted by choosing the best combination of "acceptance of trainees" "expert dispatch" and "provision of machinery and equipment". JICA pursues best outcomes by engaging in technical cooperation in a planned and comprehensive way from planning through implementation to the assessment of outcomes and by working together with relevant institutions in recipient countries.

The current Science and Technology Research Partnership for Sustainable Development (SATREPS) program promotes international joint research between research institutes in Japan and research institutes in ODA recipient countries using the technical cooperation project framework. It is expected to produce promote international joint research projects in the form of ODA projects that aim to utilize research outcomes for the benefit of society.

### (3) Technical cooperation project flow

#### 1) From the submission of a request for cooperation to the examination and adoption of a project

JICA's technical cooperation is initiated at the receipt of requests from developing countries.

Japan's ODA involves a process called "request survey", in which a research institute in a developing country wishing to obtain technical cooperation from JICA for a new project to be launched in and after the following fiscal year is invited to submit a request. The actual procedures are as follows: a research institute that wishes to launch a new project under the framework of JICA's technical cooperation prepares a request form, gains approval from competent authority and submits the form through the country's ministry responsible for ODA to the Embassy of Japan in the country. Then, the Embassy of Japan forwards the request form with other documents to the Ministry of Foreign Affairs (MOFA) in Japan.

Upon the receipt of the request, the government of Japan screens the requested project and when it is deemed that the project should proceed, a project selection notice is sent to the recipient country's government and international agreement is made between Japanese government and the recipient country's government (The Embassy of Japan in the recipient country and the recipient country's responsible authority issue a verbal note, etc.)

All requests for cooperation regarding the SATREPS program for fiscal year 2018 must be received by Japan's Ministry of Foreign Affairs (MOFA) in Tokyo no later than 12:00 noon (Japan Time) on Monday October 16, 2017.

**Please note that requesting countries' governments usually set an application deadline before the above-mentioned deadline.** So please bear that in mind when you coordinate schedules with research institutes in requesting countries. As in the deadline for research proposal through e-Rad system, requests received after the deadline will not be considered.

Regardless of requests submitted for projects up to FY2017, a country wishing to apply for project selection for FY2018 is required to submit a request form again.

Please note that requests not received by the deadline will not be considered even if the research proposal has been submitted.

In applying (i.e. submitting a request form), you should share the information before hand with the Embassy of Japan and JICA office in partner country.

## 2) Preparing for a Detailed Design study

Based on the above-mentioned international agreement, JICA conducts a Detailed Design (D/D) study. The D/D study is to examine the current status of possible cooperation field and the background to a request for cooperation. During the process, JICA discusses with the requesting country's related parties on basic project plans, implementation structure and responsibilities of donor and recipient countries, and what was discussed during the meetings is summarized in a Minutes of Meeting (M/M) to be signed by the both parties. The principal investigator who manages the Japan research team (i.e. the project leader) is required to participate in the D/D study. In addition, in the D/D study, the expected outcomes from the planned project are more clearly identified and ex-ante evaluation is performed to examine the appropriateness of the project comprehensively.

If the study discovers significant issues concerning the requesting country's implementation structure or responsibilities, etc. and it is judged that they would make it difficult to implement the project as planned, significant revisions to the plans are required and it may be necessary to consider abandoning the plan altogether.

## 3) Signing a Record of Discussions (R/D)

After completing the D/D study, JICA prepares a Record of Discussions (R/D) to be signed by JICA and an implementing agency of the recipient country, while going through the approval process. The R/D is an official agreement on the implementation of a project, specifying the details of project activities and necessary measures.

## 4) From the commencement to the end of a project

In accordance with a cooperation period stipulated in the R/D, a project is launched. Based on the R/D, inputs including expert dispatch are provided to meet project objectives.

Furthermore, during the project implementation period, the project is monitored on a regular basis to check progress on expected outcomes.

The flow of the above-mentioned processes from 1) to 4) is summarized in Figure 2 on page 3.

#### 5) Points of note regarding project implementation

A project provisionally accepted may take time before the R/D is signed (please refer to Table 3 for a typical timeframe between the provisional selection of a project and the signing of the R/D). JICA's expenses may be incurred only after a project contract is signed between JICA and the principal investigator's institution after the signing of the R/D. In addition, please note that JICA's spending shall be based on the R/D signed between JICA and the research institute in the recipient SATREPS Application Guideline (Provisional Translation by JST) country concerned and JICA cannot fund any expenses associated with a project under this program before an R/D is signed and after the cooperation period specified in the R/D is over.\*

\* See (c) "Preparations for implementing selected projects" on page 3.

#### 6) Miscellaneous

For details on project implementation, please refer to the following:

JICA "Science and Technology Research Partnership for Sustainable Development (SATREPS) Project Jisshino Tebiki (only in Japanese)"

|   | Typical timeframe*  |
|---|---|
| Prepares for a Detailed Design study (meetings, contract with consultant (members responsible for evaluation analysis), formalities for dispatching research group)   | About 2.5 months  |
| Conducts the Detailed Design study (local survey), signs M/M and reports on the study in Japan  | About 0.5-1 month   |
| JICA performs ex-ante evaluation  | About 1.5-2 months  |
| The R/D is signed (between the head (Resident Representative) of JICA overseas office and competent authority or the head of research institution in the recipient country)   | About 0.5-2 months  |
| Prepares for launching a project, including procedures for approving project implementation, the Agreement and project contract are signed between JICA and the principal investigator's institution, selection and dispatch of project coordinators**. | About 2-3 months  |
| Project commencement  | About 7-10 months after the project is provisionally accepted |

\* Actual time period differs depending on projects.

\*\* Project coordinator is explained in detail in Section 6.

[http://www.jica.go.jp/activities/schemes/science/form/ku57pq00000nj5mf-att/general\\_01.pdf](http://www.jica.go.jp/activities/schemes/science/form/ku57pq00000nj5mf-att/general_01.pdf)

Table 3. Timeframe from the provisional selection of projects through the signing of an R/D to the launch of the project

#### (4) Framework for implementing a technical cooperation project

##### 1) Japan's implementation structure

The Embassy of Japan, JICA overseas office and a Japanese research team work together in the recipient country. A research team consists of the project leader (i.e. the principal investigator and the representative of the researchers who leads the research team) and a project coordinator\* who supports the research team and researchers responsible for their respective research fields.

(\* See Section 6 for a project coordinator.)

## 2) Recipient country's implementation structure

Participants from the recipient country will be: ministry and agency responsible for ODA (the ministry of foreign affairs, the ministry of finance, the ministry of planning, etc.), ministry and agency controlling research institutes (the ministry of higher education, the ministry of agriculture, the ministry of health, the ministry of industry, etc.) and research institutes (university, research institute, etc.). The recipient country's team consists of: project director who bears the ultimate responsibility for the project, project manager who has the overall responsibility for managing on-site works and essentially serves as the head of the counterparts, and counterparts, i.e. staff who conduct project activities together with the Japanese team.

## 3) Joint implementation structure between Japanese team and recipient country's team

JICA's technical cooperation project is conducted jointly with recipient countries. Recipient country ownership is important in promoting the country's independence and development. Recipient country's principal investigator's responsibility as project manager is as serious as the Japanese principal investigator's responsibility as project leader. (See Figure 5.) Furthermore, Joint Coordinating Committee (JCC) is established and meets on a regular basis to discuss and solve issues so that joint research is conducted smoothly. JCC, as a general rule, consists of related parties from the Japan and recipient country's sides (the Japan side: the Embassy of Japan, the head (Resident Representative) of JICA overseas office, the principal investigator, researchers, project coordinators, etc.; the recipient country's side: ministry and agency responsible for international assistance, ministry and agency controlling research institutes, related authorities, research institutes, etc.). Given that this program is international joint research, JCC shall be operated jointly by the Japan and recipient country's sides.

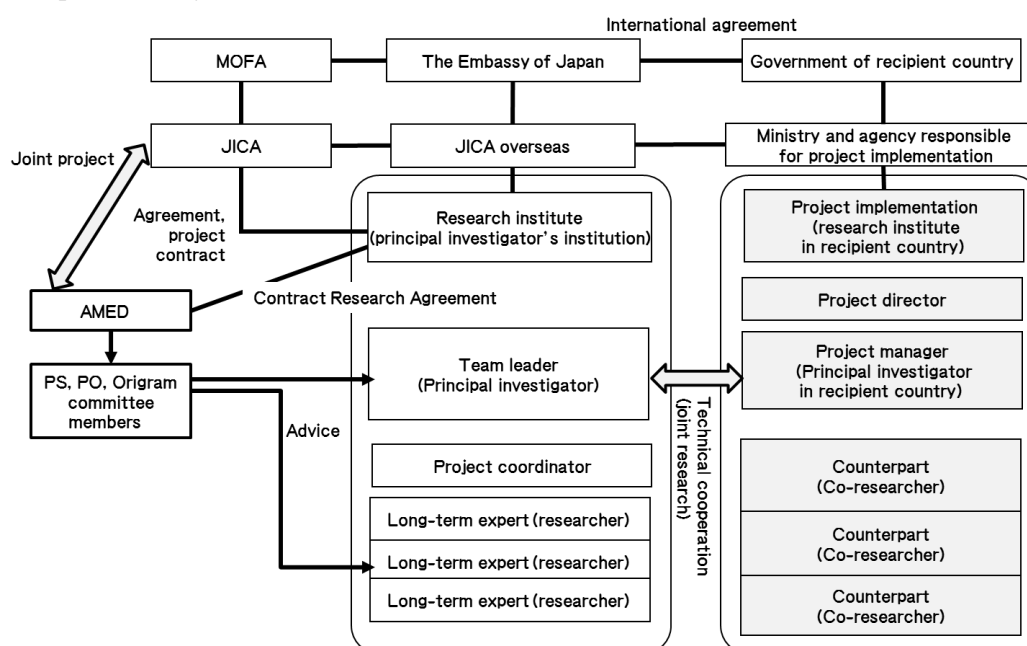


Figure 5. The framework for implementing a technical cooperation project (example)

(5) Contract between JICA and the principal investigator's institution

The research institute the principal investigator of the selected project is affiliated with signs a Contract Research Agreement with JST and is also required to sign an “agreement regarding the implementation of technical cooperation under the framework of SATREPS” (hereinafter referred to as “the Agreement”) and a project contract with JICA. The Agreement specifies duties and responsibilities of JICA, the principal investigator and the principal investigator's institution regarding the selected project. The Agreement is intended to help clarify the research institute's roles and responsibilities in conducting joint research in developing countries.

Please note that the Agreement has to be signed per research institute that the principal investigator is affiliated with. The research institute that has already signed the Agreement for other SATREPS project is not required to newly sign the main part of the Agreement, but is required to prepare an appendix that defines the scope of application.

For the forms of the Agreement (the main part), the appendix and project contract, please refer to the following websites (only in Japanese):

The main part of the Agreement:

[http://www.jica.go.jp/activities/schemes/science/form/ku57pq0000nj5mf-att/arrangements\\_01.pdf](http://www.jica.go.jp/activities/schemes/science/form/ku57pq0000nj5mf-att/arrangements_01.pdf)

Appendix:

[http://www.jica.go.jp/activities/schemes/science/form/ku57pq0000nj5mf-att/arrangements\\_02.pdf](http://www.jica.go.jp/activities/schemes/science/form/ku57pq0000nj5mf-att/arrangements_02.pdf)

Project contract:

[http://www.jica.go.jp/activities/schemes/science/form/ku57pq0000nj5mf-att/contract\\_01.pdf](http://www.jica.go.jp/activities/schemes/science/form/ku57pq0000nj5mf-att/contract_01.pdf)

Here explains the Agreement and project contract.

1) The Agreement

The Agreement is signed between the principal investigator's institution and JICA to stipulate the both parties' duties and responsibilities, etc. The responsibilities of the principal investigator's institution include: dispatch of Japanese researchers to the recipient country, invitation of the recipient country's researchers to Japan, procurement of machinery and equipment and workplace health and safety promotion. In practice, although consideration is given to the investigator's institution' rules and regulations including those on accounting, where the principal investigator's institution carries out its responsibilities, the organization's rules and regulations apply to such activities. Any intellectual property rights arising from the project shall belong not to JICA but to the research institute concerned.

2) Preparing a project plan

In launching a project, the both parties discuss to prepare a comprehensive project plan and terminal project plans including budgets of the terms. Based on the terminal plans, a review is performed to ascertain the progress of the project in the middle of the project and to revise the plans accordingly. Although it is called “a terminal” plan, a period covered in the plan is not necessarily limited to one fiscal year and can enter in the next fiscal years. Where a project contract includes the procurement of machinery and equipment, ensure that a proposed delivery date falls within the project period covered in the terminal plan.

3) Project contract

The project contract stipulates the content of a project and who is responsible for expenses and accounting,



and is signed for every terminal plan between JICA and the principal investigator's institution. Expenses shall be incurred only after the project contract is signed. The period to be described in a terminal plan is not necessarily limited to one fiscal year and the project contract can be signed for a period of several fiscal years.

Based on the Agreement and project contract signed, the principal investigator's institution shall incur expenses and settle them within the project contract period in accordance with their organization's rules and regulations. The research institute can receive advance payments for its estimated expenses from JICA two times through the contract period (The first advance payment may be up to the half of the contract amount). For rules and regulations concerning administration, such as expenditure items, estimation, advance payment based on the estimate, settlement, etc., see "SATREPS Project Jisshino Tebiki (only in Japanese)" on the JICA's website:

[http://www.jica.go.jp/activities/schemes/science/form/ku57pq0000nj5mf-att/general\\_01.pdf](http://www.jica.go.jp/activities/schemes/science/form/ku57pq0000nj5mf-att/general_01.pdf)

#### 4) Project budget limits

**ODA project expenses are approximately JPY 60 million per project per year**, and are limited to a maximum of JPY 300 million yen over a 5-year project. This includes spending regarding the dispatch of overseas researchers (short and long term), acceptance of foreign researchers, costs associated with the provision of machinery and equipment (e.g. purchase cost, transportation to destination, insurance premium, the procurement of machinery and equipment in the recipient country, etc.), direct administrative cost and costs of local research activities which are managed by project coordinators. Consequently, the total amount managed by the principal investigator's institution under the project contract will be less than JPY 300 million yen (for a 5-year project).

However, costs concerning the dispatches of project coordinators and research supervising groups (for the D/D study, operation guidance, etc.) are not included in the above-mentioned amount, and JICA directly bears the expenditures as need be. (\*For project coordinator, see Section 6)

#### 5) Expenses that may be incurred

JICA project expenses are in principle used to cover expenditures for joint research in accordance with the JICA's Technical Cooperation scheme. Of such expenses, the contract amount as agreed in the project contract may only be used to cover the following costs of activities for the purpose of successful joint research as described in the R/D agreed between JICA and the research institute in the recipient country and the R/D-based comprehensive plan or terminal plans: (1) costs of the dispatch of Japanese side researchers to the recipient country\*, (2) costs of acceptance of the recipient country side researchers\* in Japan, (3) costs of supplying machinery and equipment needed for joint research in the recipient country, and (4) direct administrative cost in Japan (Table 3).

|  |   |
|--|---|
| 1. Costs of the dispatch of Japanese researchers for overseas research from Japan to recipient country | Air fare, daily allowance, accommodation cost, sundry expenses, etc. (For those who are dispatched for more than one year, travel cost for dispatch and return, transfer allowance, other allowances, etc.)       |
| 2. Costs of acceptance of foreign researchers (researchers in the recipient country)                   | Air fare, daily allowance, accommodation cost, training expenses, etc. Acceptance period is classified into two: short-term (less than one year) and long term (one year and over).**                             |
| 3. Costs of supplying machinery and equipment needed for joint research                                | Purchase cost, transportation cost and cost for set-up and adjustment. Machinery and equipment to be used in Japan are not included, and the costs are covered under the AMED's Contract Research Agreement, etc. |
| 4. Administrative cost in Japan  | Labor costs of part-time administrative workers, the cost of office supplies, etc. (excluding expenditures on research supplies).   |

Table3. Expenditures to be shouldered by JICA

\* Undergraduates and postgraduates cannot be dispatched as overseas researchers to a beneficiary country even if he or she is a member of Japanese research team.

\*\* Since foreign researchers (on short- and long-term dispatch) shall not be accepted beyond the joint research period (i.e. project implementation period as described in the R/D), the principal investigator's institution is kindly requested to carefully prepare acceptance of foreign researchers from the planning phase.

#### 6) The principles of the recipient country's responsibility to shoulder expenses

With focus on the recipient country's self-help efforts and sustainable development after the project is completed, ODA projects generally require the recipient country to shoulder certain expenditures. Please note that, in line with these practices, JICA does not offer financial support for all expenses in this program, which is conducted as part of international cooperation through ODA, but requires the recipient country to shoulder some expenses to promote its self-help efforts. Examples of expenditures to be shouldered by the recipient country are as follows:

- (a) Labor costs of the researchers at research institute(s) in the recipient country and the related parties, and staff employed directly by the research institute(s).
- (b) Rent and utility cost of project office.
- (c) Transportation fees, travel expenses (daily allowance and accommodation cost) and daily allowances for attending meetings arising from the domestic business trips required for regular works or researches by researchers at the research institute(s) and the related parties in the recipient country.
- (d) Costs of equipment, office supplies and facilities used for research activities, and costs of the operation and maintenance of machinery and equipment supplied when they are used for researches by the recipient researchers only.

Note that JICA requests the recipient country that it should shoulder expenses for facilities and equipment needed for research and utilize existing facilities and equipment, in order to inject resources on key focus areas.

#### 7) Expense management

With regard to ODA project expenses, except for expenses in the recipient country that JICA directly shoulders, in accordance with the Agreement signed between the Japanese research institute and JICA, costs of execution of the project contract to be shouldered by the Japanese research institute are managed by the principal investigator's institution.

In JICA's ODA technical cooperation projects, no fund is directly given to the recipient country, and no financial assistance is given to such activities by research institutes in the recipient country.

Especially, since there has been some misunderstanding of JICA's policy of not directly giving project funds to research institutes in the recipient country, please ensure that the partner country is given an explanation beforehand.

(6) Project coordinator

JICA generally invites the public to apply for the position of a project coordinator, and ensure that the selected project coordinator will start working at the earliest possible date after the R/D is signed. Project coordinator's responsibilities include: expense management (including budget implementation) in the recipient country as described earlier, arrangements with governmental institutions in the recipient country regarding the dispatch of Japanese side researchers to the recipient country and acceptance of the recipient country side researchers in Japan and communication with the local JICA office regarding the procurement of machinery and equipment. The project coordinator is a member of the Japanese project team working together with researchers and those engaged in joint research, although the project coordinator won't be involved in research activities. JICA requires the project coordinator to share information with a representative of researchers and other team members to ensure that the project is conducted smoothly and properly.

JICA may not dispatch a project coordinator and instead ask a principal investigator's institution to include the jobs of a project coordinator in its project contract with an administrative indirect expense when it is deemed necessary and appropriate for the recipient county.

(7) Project monitoring

As shown in Figure 2 on page 7, the technical cooperation project is monitored on a regular basis to check the progress and is reviewed jointly with the recipient country's related parties during the project. As the monitoring during the period of a technical cooperation project is performed as part of the overall management of the project, the Japanese research institutions and the recipient country research institutions etc. are expected to be active participants in its process.

For the details of monitoring for JICA technical cooperation projects, see "SATREPS Project Jisshino Tebiki (only in Japanese)" on the JICA's website:

[http://www.jica.go.jp/activities/schemes/science/form/ku57pq00000nj5mf-att/general\\_01.pdf](http://www.jica.go.jp/activities/schemes/science/form/ku57pq00000nj5mf-att/general_01.pdf)

(8) Contact concerning ODA

1) JICA headquarters

Office for Science and Technology Cooperation of the JICA headquarters acts as a point of contact for inquiries concerning this project. For inquiries on framework of ODA technical cooperation, please contact:

Office for Science and Technology Cooperation, Japan International Cooperation Agency (JICA)

E-mail: eigst@jica.go.jp

## 2) JICA: domestic and overseas offices

A list of domestic offices

<http://www.jica.go.jp/about/structure/domestic/index.html> (Japanese)

<http://www.jica.go.jp/english/about/organization/domestic/index.html> (English)

A list of overseas offices

<http://www.jica.go.jp/about/structure/overseas/index.html> (Japanese)

<http://www.jica.go.jp/english/about/organization/overseas/index.html> (English)

Before contacting us, it will be helpful for you to clarify your research concept and plan through discussions with researchers in the beneficiary country, so that we can deal with your query promptly and efficiently. Please note that JICA domestic and overseas offices do not respond to inquiries on the content of public invitations.

## 3) Useful websites on ODA and technical cooperation

Ministry of Foreign Affairs of Japan - ODA

<http://www.mofa.go.jp/mofaj/gaiko/oda/index.html>

“ODA Kunibetsu Chiikibetsu Seisaku/Joho” (policy and information on ODA by country and region) (Only in Japanese)(The website offers information for you to check whether or not your research field is in line with Japan’s ODA policy in the beneficiary country and related region.)

<http://www.mofa.go.jp/mofaj/gaiko/oda/region/index.html>

“JICA “Technical cooperation project”” (the website explains JICA ODA technical cooperation projects in general.)

<http://www.jica.go.jp/project/index.html>

“JICA Science and Technology Cooperation on Global Issues” (including SATREPS)

<http://www.jica.go.jp/activities/schemes/science/index.html>

“JICA Toshokan Zousho Kensaku” (JICA Library search)(When you search by project name, Adobe PDF documents on SATREPS report publications are returned in the search result.)

<http://libopac.jica.go.jp/>

The partner/requesting country's ministry and agency responsible for international assistance. The ministry and agency responsible for ODA differ depending on country, - for instance, the ministry of foreign affairs, the ministry of finance, the ministry of planning, etc.-

**Request for technical cooperation:**

A request from the government wishing to obtain technical cooperation from JICA (the ministry and agency responsible for ODA) to the government of Japan. The ministry of foreign affairs of Japan and JICA receive requests for technical projects expected to be launched for the next fiscal year onwards. The request for technical cooperation from the requesting country's government is submitted to the ministry of foreign affairs in Japan through the Embassy of Japan in the requesting country.

**International agreement:**

An agreement that is entered under international law by country or international organization as actor, establishing the respective parties' rights and obligations. The international agreement is classified into two: "a treaty" that has to be ratified by the national Diet and "an administrative arrangement" that is closed only by the government to "manage foreign affairs". In general, the international agreement has to be approved by the cabinet. In addition to the official international agreement mentioned above, those agreed by the ministry of foreign affairs without the cabinet's approval are also considered as a kind of the international agreement in practice, and this type of agreement is included in the international agreement referred to in this program.

**Technical cooperation project:**

Activities that aims to address issues in developing countries and are conducted by combining three cooperation tools, i.e. "expert dispatch", "acceptance of trainees" and "provision of machinery and equipment", as a project within a certain timeframe to achieve objectives set.

**Expert dispatch:**

Dispatch of personnel from Japan to the recipient country to guide counterparts (administrators, management and so forth). In this program, Japanese researchers who conduct research in the recipient country as JICA experts are referred to as "overseas researchers", and those who are dispatched for a period exceeding one year per dispatch (i.e. From departure date to return date) are referred to as "long-term overseas researchers" and those who are dispatched for a period not exceeding one year as "short-term overseas researchers". Procedures concerning the dispatch of short-term overseas researchers are taken by the principal investigator's institution (Expenses for dispatching short-term overseas researcher are included in the contract amount described in the project contract signed between JICA and the research institute). However, procedures for dispatching long-term overseas researchers are taken directly by JICA (and expenses for their dispatch are not included in the contract amount described in the project contract signed between the parties concerned).

**Acceptance of trainees:**

A form of capacity development initiative on the transfer of expertise and technology in various fields through acceptance of counterparts from developing countries as trainees in Japan or a third country. In this SATREPS program, researchers invited for joint research from recipient countries are referred to as "foreign

researchers”, who are accepted as JICA trainees.

**Ex-ante evaluation:**

Evaluation on the appropriateness of the proposed cooperation, which is conducted to examine priorities and necessities prior to the commencement of cooperation and to specify the content of cooperation and clarify expected outcome. Evaluation indicators set in ex-ante evaluation are used as criteria to measure the progress and effects of the cooperation throughout the life of a project.

**Local cost:**

Costs to be shouldered by the recipient country in implementing and managing the cooperation project. Specifically, local cost includes, but not limited to, personnel expenses, land acquisition cost, transportation cost concerning machinery and equipment provided, recurrent cost (i.e. the regular cost incurred repeatedly, - for instance, costs of the operation and management of facilities built or machinery and equipment provided in the course of cooperation, or employment costs.)

**Capacity development (CD):**

Developing countries’ efforts to strengthen their abilities (capacity) to address their respective development issues. JICA serves as a facilitator that supports developing countries’ capacity development.

<http://libopac.jica.go.jp/>

For instance, type in “capacity” in the above-mentioned JICA library search, you will get results containing the word, including the “Capacity Assessment handbook” (only in Japanese) as shown below.

<http://libopac.jica.go.jp/images/report/P0000245021.html>

### 3. Q&A

For questions about the Cross-ministerial R&D Management System (e-Rad), including registration of affiliated research institutions or researchers, and instructions for use of e-Rad, visit the e-Rad portal site:

<http://www.e-rad.go.jp/> (Japanese)

#### (1) Q&A about the SATREPS program objectives and purposes

Q: How many projects have been selected so far, and what sort of projects are they?

A: 12 projects were selected in FY2008, 20 in FY2009, 17 in FY2010, 10 in FY2011, 8 in FY2012, 10 in FY2013, 10 in FY2014, 14 in FY2015, and 14 in FY2016, giving a total of 115 international joint research projects (including projects in Infectious Diseases Control field). Details of these projects are given in the SATREPS brochure and at the following website:

<http://www.jst.go.jp/global/english/kadai/index.html>

Q: What are the main changes in the FY2017 Invitation for Research Proposals compared to the previous FY?

A: The main changes in the FY2017 Invitation for Research Proposals are listed at the following website:

<http://www.jst.go.jp/global/koubo.html> (Japanese)

Q: How should I gain an understanding of the developing country's needs?

A: Under the SATREPS program, one of the key perspectives applied when selecting projects is whether a research proposal is in line with the needs of the developing country. Proposals are expected to show a proper understanding of the partner country needs, obtained through means such as prior contact and interaction in a research context. One useful reference is the Country Assistance Policy (an ODA policy that MOFA establishes by comprehensively taking into account factors such as the local political, economic, and social situations, development plan, and development challenges) which has been formulated for some countries. Country Assistance Policies are published on the MOFA website:

<http://www.mofa.go.jp/policy/oda/assistance/index2.html>

For some countries, the website below also lists themes on which JICA considers research is needed, based on the circumstances of the countries:

<http://www.jst.go.jp/global/pdf/researchneeds.pdf> (Japanese)

Furthermore, in order to conduct international joint research with the aim of application of outcomes, a systematic approach is expected in the partner country, bringing in partner country government agencies, etc. The selection process takes into account whether the structure is adequate for that purpose. When setting up a project, we also recommend liaising in advance with the Japanese embassy in the partner country and with the local JICA office.

Q: Does having the project linked to ODA mean that the principal investigator needs to be stationed in the partner country (long term overseas dispatch)?

A: The principal investigator does not necessarily need to be stationed in the partner country, but it is considered important for the principal investigator to visit the partner country and manage the project on the ground. Technical cooperation projects allow for flexibility, including dispatch on a short-term shuttle basis. Nevertheless, in order to ensure that the activities in the partner country proceed smoothly and to enhance the effectiveness of the project, it is of course desirable for Japan-side researchers to be either be stationed in the partner country full time or close to full time. When planning the dispatch of researchers to the partner

country, take into consideration that the Japan-side researchers are required to contribute through the joint research to developing the partner country's self-reliant research and capacity development, and that as project director the principal investigator is responsible for the dispatch of researchers overseas as part of the international joint research.

Q: Is it necessary to station Japan-side research participants other than the principal investigator in the partner country?

A: It is not necessarily the case that Japan-side researchers have to be stationed in the partner country, but an appropriate strategy is essential. In order for the joint research to proceed smoothly in the partner country (a developing country), and because the purpose of the project is capacity development of the developing country through joint research, if researchers are not stationed overseas, it is necessary for them to be regularly dispatched to the partner country and that their emphasis is on their research overseas, such as by spending three months in the partner country followed by one month back in Japan. Projects are selected through an overall evaluation that includes consideration of the Japan-side implementation structure described in the proposal.

Q: Can a researcher affiliated with a research institution in a third country (not the partner country) participate in the project?

A: In principle, a researcher affiliated with a research institution located in a third country cannot participate in the project. However, such researchers can be invited to workshops, etc. Moreover it is possible for such a researcher to become affiliated (as a visiting researcher, etc.) with an institution participating in the joint research (including the principal investigator's institution), and participate in the research under the auspices of that institution.

Q: Is there a restriction on the number of SATREPS program applications that can be made per institution?

A: There is no restriction on the number of applications that can be made per institution. If multiple applications are made from a single institution, each set of research proposal documents is required to include a separate written approval from the director of the institution (president or chair of the board, etc.).

(2) Q&A about operation of the parts of the program handled mainly by JST (Q&A mainly about selection and implementation of research within Japan)

1) Application requirements

Q: What requirements do private-sector companies need to satisfy to apply for the program?

A: The requirements include the company being incorporated in Japan.

Q: Can a private-sector company be a principal investigator's institution?

A: Yes, it can. However, the following point needs to be taken into account.

- A company conducting activities with a public nature can become the principal investigator's institution for a project. Even if the company is not conducting activities with a public nature, it can still become the principal investigator's institution if it makes a joint proposal with a university or similar institution.

Q: What points need to be borne in mind when a private-sector company participates?

A: The following points need to be borne in mind.

- Before JST can conclude a Contract Research Agreement with a company or similar entity, it screens the



company to determine whether the contract is possible and what sort of form the contract should take. As a result of this screening, JST may require compliance with a particular form of contractual relationship. If the company's state of finances is markedly unstable, the contract may be judged unfeasible, preventing the research project from being conducted at the proposed research institution. In such a case, the proposer may be required to take action such as reviewing the implementation structure.

- The SATREPS program is based on the premise of joint research with a partner country. In addition to implementing the research, there are requirements for publication of outcomes and sharing of intellectual assets, and for outgoing transfer of samples and information, etc. The company is requested to confirm in advance with the partner country side that entering into such a relationship with private-sector affiliated researchers is not a problem.
- Salary etc. for the person in charge of the research (principal investigator/lead joint researcher) cannot be covered as direct expenses.
- If certain conditions are satisfied, it is possible to cover salary etc. for other research participants (members involved with a specific research item).
- When using ODA costs to procure goods, in principle a competitive procurement process should be used (either bidding or comparative quotes), based on specifications that do not require specific brands.

Details are available at the following website under Contract Research Agreement Administrative Procedures (for private-sector companies).

<http://www.jst.go.jp/global/itaku.html> (Japanese)

Q: Can a post-doc submit an application as principal investigator?

A: A Post-doc cannot apply as principal investigator or lead joint researcher.

Q: Can post-doc students or graduate school or similar students participate in the research project?

A: Postdoctoral research fellows and graduate students can take on specific roles in the research project, and by being listed as research participants in the research plan documents, can participate as members in the project. Undergraduate students can also participate under similar conditions as part of the process of nurturing excellent researchers in Japan. Because of their status as students, graduate students and undergraduates cannot be dispatched to the partner country as overseas researchers using ODA costs, but if certain conditions are satisfied (concluding an employment contract with the affiliated institution, traveling together with an overseas researcher, etc.), it is possible to cover travel and the costs of employment of students as research assistants under JST contract research expenses. See the Contract Research Agreement Administrative Procedures etc. for details.

Q: Can a researcher who is not a Japanese national submit an application as principal investigator?

A: As long as he or she is affiliated with a research institution in Japan, a non-Japanese national researcher can apply as principal investigator.

Q: Can a researcher who is not a Japanese national apply as an overseas researcher?

A: The SATREPS is based on Japan providing technical cooperation and building relationships with the partner country, so in principle, it assumes the dispatch of researchers who are Japanese nationals. Nevertheless, if there are no other researchers with specific skills required and a non-Japanese national is irreplaceable for the project, then that researcher may be dispatched as an overseas researcher as long as the partner country government accepts the dispatch. In such cases, the researcher can be dispatched under ODA

costs (and in cases where dispatch as an overseas researcher is not possible, traveling to the partner country under JST contract research expenses is in principle possible, although the researcher may not be eligible for rights and exemptions applied under agreements with the partner country, including tax exemptions and legal immunity).

Q: Can researchers without a specific affiliation participate?

A: In principle, researchers without a specific affiliation cannot participate in the joint research. However it is possible for a participating institution (including the principal investigator's institution) to give affiliation status (visiting researcher, etc.) to the researcher so that he or she can participate in the research with that institution providing coverage and taking responsibility.

Q: On the premise that research will be implemented at the counterpart institution, can a Japanese national resident outside Japan submit an application as principal investigator?

A: In principle, this is not permitted. The program envisages a principal investigator based in Japan and the institution he or she is affiliated with conducting joint research with a principal investigator based in the partner country and the institution he or she is affiliated with.

Q: Can a part-time staff member (visiting researcher, etc.) submit an application as principal investigator?

A: This is possible if the researcher can provide an implementation structure at a research institution in Japan for the duration of the research period. Whether it is possible to make an agreement and sign a contract with the research institution for the part-time staff member to be principal investigator depends on the contractual relationship between the research institution and the part-time staff member.

Q: If the principal investigator moves to a different institution partway through the project term, can the research still continue?

Q: Do Forms 1-10 have to be completed in Japanese?

A: In principle, Forms 1-10 should be completed in Japanese. However, if that is problematic, English is acceptable. English-language copies of the application forms are posted on the English-language SATREPS website.

<http://www.jst.go.jp/global/english/koubo.html>

The research proposal forms must be submitted via e-Rad, the Cross-ministerial R&D Management System. This system has some sections that require entry in Japanese. For those sections, seek assistance from a Japanese speaker. Interviews in the selection process are also in principle conducted in Japanese, but if that is problematic, English is acceptable.

## 2) JST contract research expenses

Q: Are there restrictions on how JST contract research expenses can be used?

A: Details regarding contract research expenses are available at the following website under Contract Research Agreement Administrative Procedures.

<http://www.jst.go.jp/global/itaku.html> (Japanese)

## 3) Implementation structure

Q: Can the implementation structure described in the research proposal documents be changed during

interviews or after selection?

A: The selection process is based on the research proposal documents, so the structure should be given careful consideration when writing the research proposal, in order to ensure that no need for unnecessary changes arises. Adjustments etc. may be made if authorized by the Research Supervisor (RS), and changes may be requested during the process of JICA signing the R/D with the counterpart institution before commencing the international joint research.

#### 4) Research contracts

Q: Can the research contract with the lead joint researcher's institution in Japan be structured as subcontracting (see note) via the principal investigator's institution?

Note: Subcontracting in the research contract refers to a situation where only the principal investigator's institution signs a contract with JST, and a research contract is signed by that affiliated institution and the joint researcher's affiliated institution.

A: Under the SATREPS program, a subcontracting structure is not used for research contracts. JST concludes separate research contracts with the research institutions that the principal investigator and lead joint researcher are affiliated with. \* JICA only has a contractual relationship with the principal investigator's institution, not with any other institutions involved in the joint research.

### (3) Q&A about JICA/ODA (mainly Q&A about implementation of research in the partner country)

#### 1) Countries eligible for international joint research

Q: Is it possible to conduct joint research with multiple research institutions in the partner country?

A: Yes, it is possible to conduct joint research with multiple research institutions in a single partner country. In such cases, the names of all institutions must be listed in the ODA request form, and the main research institution for joint research in the partner country must be specified.

#### 2) ODA application by the partner country

Q: In addition to the proposal documents submitted to JST, is it necessary for the government agency handling ODA in the partner country, at the instigation of the counterpart research institution in the partner country, to make a request for the implementation of an ODA technical cooperation project (submit a request for cooperation)?

A: It is essential for the partner country side to submit a request for ODA, in addition to the proposal documents for a research project submitted to JST. Only projects where both the research proposal and the ODA request have been submitted are screened. If either of these documents is not received by the specified deadline, the project will be automatically excluded from selection.

Q: Is it necessary for the details of the technical cooperation project in the partner country to have already been fixed in the request form at the point that the proposal documents are submitted to JST?

A: You need to coordinate the content of the request from the partner country before the request form is submitted. In particular, as noted on the proposal forms, there needs to be consensus between the Japan-side and the partner country side regarding the proposed research project title (English), research objectives, research outcome targets, research plans and implementation of plans, implementation structure, approximate amounts and details of machinery and equipment, personnel, etc. to be used, and research period, etc. After provisional selection, JICA will finalize detailed plans for the purpose of signing the R/D

with the partner country institution. Please understand that as a result of that process, you may be required to modify the research plans presented in the proposal. The research project title (English) has to be the same as the project name on the ODA technical cooperation project request form. Ensure that there is sufficient coordination with the counterpart institution on this point.

Q: Where can I obtain the ODA request form?

A: A template for the ODA request form is available on the following JICA website, but the actual ODA request form is fixed by the government agency handling ODA in each country. For details, the counterpart institution should contact the government agency that covers it, or the government agency handling ODA.

<http://www.jica.go.jp/activities/schemes/science/faq/answer.html#a1-3> (Japanese)

Q: Has JICA informed each developing country of the purposes and structure of the SATREPS program? Also, does the applicant in Japan need to be able to respond to the partner country's inquiries about procedures, etc.?

A: MOFA/JICA has informed the government agency handling ODA in each of the developing countries eligible for the program. However, due to individual circumstances within each country, that information may not have reached as far as the partner country researchers who are potential research counterparts. The applicant should be aware of that situation and ensure sufficient coordination in advance with the partner country researcher (and his or her affiliated institution).

3) Eligible counterpart institutions, partner country researchers; relationships

Q: Are companies and NGOs in other countries able to participate in a project?

A: The SATREPS program is implemented as technical cooperation projects on the basis of formal requests from the partner country and international commitments between the partner country and Japan. NGOs and simple private-sector companies without government ownership are not covered by the program. However, this does not prevent the participation of private-sector companies and NGOs in the research as partners collaborating within the partner country when the partner country side research institution is a government entity.

Q: Are international agencies able to participate in a project?

A: Regional international agencies in the developing country are not excluded from participating, but as explained in the Q&A regarding the ODA request form submission process, pre-conditions include submission to the Japanese embassy of an ODA request by the formal route via the partner country government agency handling ODA and the partner country government agency responsible for facilitating operation of the international agencies, providing them with special privileges and immunities, and pledging tax exemptions and other special rights and exemptions for the SATREPS program experts and machinery and equipment, etc. They also include securing the entity's own personnel and costs required to implement the joint research. Handling of intellectual assets also needs to be taken into account.

Q: If the principal investigator's institution in Japan has already signed agreements with the partner country government or research institution, is there any need for JICA to sign a new agreement of some form with the partner country side in order to implement the project?

A: Yes, it is necessary. The SATREPS program is a collaborative program linked with ODA, and projects are implemented as JICA technical cooperation projects based on international commitments between the two countries. Based on these international commitments, JICA must sign documents such as an R/D with the

partner country side.

4) ODA project expenses, etc.

Q: What level of authority is required for signing the Agreement and project contract between JICA and the principal investigator's institution?

A: For the main Agreement, which only needs to be signed once on the first occasion for each principal investigator's institution, we envisage the Agreement being signed at the institute's top level (president or chair of the board of a university), and by the president of JICA. For the annexes to the Agreement (signed for each project), we envisage them being signed by the head of research at the principal investigator's institution (dean, etc.) and by JICA's director of the department in charge of the project. For the project contract, we envisage it being signed by a director of the principal investigator's institution with authority for contracts, and by JICA's vice-president in charge of finance and accounting.

Q: Why are clinical trials and medical practice not eligible for joint research? (Please give more details.)

A: Refer to the following JICA Policy.

(a) Clinical trials/clinical studies/clinical research

Clinical trials with the aim of development, manufacture, or sale of pharmaceuticals or medical devices, or clinical studies/clinical research that is invasive, or infringes privacy are not acceptable as JICA projects. It is however possible for JICA projects to include training, instruction, or counseling of workers (medical staff, etc.) involved in such activities.

(b) Handling of medical practices\*

Medical practices are not acceptable as JICA projects (the reasons are that researchers are not sent abroad with the aim of conducting medical practices, are not licensed as clinicians in the host country, and it is not appropriate for JICA to take responsibility for medical practice).

\* What is considered medical practice differs according to each country's circumstances. Even if something is considered to be medical practice, JICA will give approval (with conditions concerning safety and responsibility) if consulted in advance for practices such as blood sample collection, fecalexamination, and measurement of body temperature or blood pressure that are not significantly risky.

Ask JICA if clarification is required.

(c) Safety measures and ethical considerations for research projects

Research projects must comply with ethical guidelines in Japan and in the partner country. They must be assessed by an ethics committee in the partner country, and the safety of all persons directly or indirectly involved in the project, together with safety for the environment, must be secured before the project commences.

## Appendix 1. Countries eligible for the SATREPS program

| No. | Region                           | Name of Country                            | No.                            | Region                      | Name of Country                              | No.                                   | Region                         | Name of Country                  |
|-----|----------------------------------|--|--------------------------------|-----------------------------|--|---------------------------------------|--------------------------------|----------------------------------|
| 1   |                                  | India                                      | 39                             |                             | Republic of Angola                           | 90                                    |                                | Argentine Republic               |
| 2   |                                  | Republic of Indonesia                      | 40                             |                             | People's Democratic Republic of Algeria      | 91                                    |                                | Antigua and Barbuda              |
| 3   |                                  | Kingdom of Cambodia                        | 41                             |                             | Republic of Uganda                           | 92                                    |                                | Republic of Ecuador              |
| 4   |                                  | Democratic Socialist Republic of Sri Lanka | 42                             |                             | Arab Republic of Egypt                       | 93                                    |                                | Republic of El Salvador          |
| 5   |                                  | Kingdom of Thailand                        | 43                             |                             | Federal Democratic Republic of Ethiopia      | 94                                    |                                | Republic of Guyana               |
| 6   |                                  | Nepal                                      | 44                             |                             | State of Eritrea                             | 95                                    |                                | Republic of Cuba                 |
| 7   | A<br>s<br>i<br>a                 | Islamic Republic of Pakistan               | 45                             |                             | Republic of Ghana                            | 96                                    | L<br>a<br>t<br>i<br>n<br>a     | Republic of Guatemala            |
| 8   |                                  | People's Republic of Bangladesh            | 46                             |                             | Republic of Cape Verde                       | 97                                    |                                | Grenada                          |
| 9   |                                  | The Democratic Republic of Timor-Leste     | 47                             |                             | Gabonese Republic                            | 98                                    |                                | Republic of Costa Rica           |
| 10  |                                  | Republic of the Philippines                | 48                             |                             | Republic of Cameroon                         | 99                                    |                                | Republic of Colombia             |
| 11  |                                  | Kingdom of Bhutan                          | 49                             |                             | Republic of The Gambia                       | 100                                   |                                | Jamaica                          |
| 12  |                                  | Socialist Republic of Viet Nam             | 50                             |                             | Republic of The Guinea                       | 101                                   |                                | Republic of Suriname             |
| 13  |                                  | Malaysia                                   | 51                             |                             | Republic of Guinea-Bissau                    | 102                                   |                                | Saint Vincent and the Grenadines |
| 14  |                                  | Union of Myanmar                           | 52                             |                             | Republic of Kenya                            | 103                                   |                                | Saint Lucia                      |
| 15  |                                  | Republic of Maldives                       | 53                             |                             | Republic of Cote d'Ivoire                    | 104                                   |                                | Commonwealth of Dominica         |
| 16  |                                  | Mongolia                                   | 54                             |                             | Union of Comoros                             | 105                                   |                                | Dominican Republic               |
| 17  | Lao People's Democratic Republic | 55   |                                | Republic of Congo           | 106  | Republic of Nicaragua                 |                                |                                  |
| 18  | M<br>i<br>d<br>d<br>l<br>e       | Islamic Republic of Afghanistan            | 56                             |                             | Democratic Republic of the Congo             | 107                                   | Republic of Haiti              |                                  |
| 19  |                                  | Republic of Iraq                           | 57                             |                             | Democratic Republic of Sao Tome and Principe | 108                                   | Republic of Panama             |                                  |
| 20  |                                  | Islamic Republic of Iran                   | 58                             |                             | Republic of Zambia                           | 109                                   | Republic of Paraguay           |                                  |
| 21  |                                  | Palestine Liberation Organization          | 59                             |                             | Republic of Sierra Leone                     | 110                                   | Federative Republic of Brazil  |                                  |
| 22  |                                  | Hashemite Kingdom of Jordan                | 60                             |                             | Republic of Djibouti                         | 111                                   | Bolivian Republic of Venezuela |                                  |
| 23  |                                  | Republic of Azerbaijan                     | 61                             | A<br>f<br>r<br>i<br>c<br>a  | Republic of Zimbabwe                         | 112                                   | Belize                         |                                  |
| 24  |                                  | Republic of Armenia                        | 62                             |                             | The Republic of the Sudan                    | 113                                   | Republic of Peru               |                                  |
| 25  |                                  | Republic of Albania                        | 63                             |                             | Kingdom of Swaziland                         | 114                                   | Republic of Bolivia            |                                  |
| 26  |                                  | Ukraine                                    | 64                             |                             | Republic of Seychelles                       | 115                                   | Republic of Honduras           |                                  |
| 27  |                                  | Republic of Uzbekistan                     | 65                             |                             | Republic of Equatorial Guinea                | 116                                   | United Mexican States          |                                  |
| 28  | E<br>u<br>r<br>o<br>p<br>e       | Republic of Kazakhstan                     | 66                             |                             | Republic of Senegal                          | 117                                   | Republic of Kiribati           |                                  |
| 29  |                                  | Kyrgyz Republic                            | 67                             |                             | United Republic of Tanzania                  | 118                                   | Cook Islands                   |                                  |
| 30  |                                  | Georgia                                    | 68                             |                             | Republic of Chad                             | 119                                   | Independent State of Samoa     |                                  |
| 31  |                                  | Republic of Kosovo                         | 69                             |                             | Republic of Tunisia                          | 120                                   | Solomon Islands                |                                  |
| 32  |                                  | Republic of Tajikistan                     | 70                             |                             | Republic of Togo                             | 121                                   | Tuvalu                         |                                  |
| 33  |                                  | Turkmenistan                               | 71                             | Federal Republic of Nigeria | 122  | Kingdom of Tonga                      |                                |                                  |
| 34  |                                  | Republic of Serbia                         | 72                             | Republic of Namibia         | 123  | Republic of Nauru                     |                                |                                  |
| 35  |                                  | Bosnia and Herzegovina                     | 73                             | Republic of Niger           | 124  | Niue                                  |                                |                                  |
| 36  |                                  | Former Yugoslav Republic of Macedonia      | 74                             | Burkina Faso                | 125  | Republic of Vanuatu                   |                                |                                  |
| 37  |                                  | Republic of Moldova                        | 75                             | Republic of Burundi         | 126  | Independent State of Papua New Guinea |                                |                                  |
| 38  | Montenegro                       | 76   | Republic of Benin              | 127                         | Republic of Palau                            |                                       |                                |                                  |
|     |                                  | 77   | Republic of Botswana           | 128                         | Republic of the Fiji Islands                 |                                       |                                |                                  |
|     |                                  | 78   | Republic of Madagascar         | 129                         | Republic of the Marshall Islands             |                                       |                                |                                  |
|     |                                  | 79   | Republic of Malawi             | 130                         | Federated States of Micronesia               |                                       |                                |                                  |
|     |                                  | 80   | Republic of Mali               |                             |  |                                       |                                |                                  |
|     |                                  | 81   | Republic of South Africa       |                             |  |                                       |                                |                                  |
|     |                                  | 82   | Republic of South Sudan        |                             |  |                                       |                                |                                  |
|     |                                  | 83   | Republic of Mauritius          |                             |  |                                       |                                |                                  |
|     |                                  | 84   | Islamic Republic of Mauritania |                             |  |                                       |                                |                                  |
|     |                                  | 85   | Republic of Mozambique         |                             |  |                                       |                                |                                  |
|     |                                  | 86   | Kingdom of Morocco             |                             |  |                                       |                                |                                  |
|     |                                  | 87   | Republic of Liberia            |                             |  |                                       |                                |                                  |
|     |                                  | 88   | Republic of Rwanda             |                             |  |                                       |                                |                                  |
|     |                                  | 89   | Kingdom of Lesotho             |                             |  |                                       |                                |                                  |

Note1: This table is subject to change depending on a country's situation.

Note2: The security situation and circumstances in parts of the partner country where research will be conducted may be examined as part of the selection process for proposals where they may result in restrictions on travel to the country and on the ability to implement the project.

Note3: Adequate supports from JICA may not be accessible if research will be conducted in a country where JICA does not have an office.

## Appendix 2. Instructions for research proposal forms

There is no overall restriction on the number of pages in the research proposal documents. However, a clearly legible font size should be selected (about 10.5 points on Windows) to ensure legibility when printed, and the content should be clear and simple, but cover all essential points.

Please add a running page number at the bottom of each page.

The comments, explanations, and examples in the forms are not needed when the forms are submitted. Please delete them before submission.

The research proposal forms, and Instructions on how to formulate the Target Outcomes Sheet in Form 2, are available from the following website.

<http://www.amed.go.jp/global/koubo.html> (Japanese)

## Form 1: Proposal

Research proposal of FY2018 international collaborative research program on “Science and Technology Research Partnership for Sustainable Development (SATREPS)”

- The information given in Form 1 will be published if the project is selected. The completed form should fit on no more than 2-3 sheets of A4 paper.
- Items (a)-(j) need to be directly entered into e-Rad.
- If the proposal includes the participation of multiple collaborating institutions in Japan and/or counterpart institutions, the names and roles of all the institutions involved must be included in the Implementation Structure Concept Diagram on the next page.
- If the proposal includes the participation of multiple collaborating institutions in Japan and/or counterpart institutions, the names and roles of all the institutions involved must be included in the ”implementation structure concept diagram (Form 4)”.
- There are two formats, Japanese one and English one. Both forms should be filled correctly and each Japanese items is needed to be directly entered into e-Rad.

- ✓ There is no overall restriction on the number of pages in the research proposal documents. However, a clearly legible font size should be selected (about 10.5 points on Windows) to ensure legibility when printed, and the content should be clear and simple, but cover all essential points.
- ✓ Please add a running page number (-1-) at the bottom of each page.
- ✓ The comments, explanations, and examples in the forms are not needed when the forms are submitted. Please delete them before submission.
- ✓ The research proposal forms are available from the following website.

<http://www.amed.go.jp/program/list/03/01/035.html>



**平成 30 年度「医療分野国際科学技術共同研究開発推進事業  
地球規模課題対応国際科学技術協カプログラム」 研究開発提案書**

**Japanese institution implementation structure**

List the researchers expected to participate in the Japan-side research team, giving name, researcher ID No., affiliation, position, effort, and a brief outline of research responsibility.

|                  |   |
|------------------|---|
| 研究開発課題名          | 提案課題名にサブタイトルは付けないでください。   |
| 研究開発代表者氏名（フリガナ）  |   |
| 所属機関 部署 役職       |   |
| 連絡先              | 住所：〒<br>E-mail：<br>TEL： FAX：  |
| 研究者番号            | 府省共通研究開発管理システム(e-Rad)に研究者情報を登録した際に付与される 8 桁の研究者番号を記載ください。   |
| 生年月日             | 西暦 年 月 日  |
| 学歴(大学卒業以降)       | (記載例)<br>昭和〇〇年 〇〇大学〇〇学部卒業<br>昭和〇〇年 〇〇大学大学院〇〇研究科修士課程〇〇専攻修了<br>(指導教官：〇〇教授)【記載必須】<br>昭和〇〇年 〇〇大学大学院〇〇研究科博士課程〇〇専攻修了<br>(指導教官：〇〇教授)【記載必須】<br>昭和〇〇年 博士(〇〇学)(〇〇大学)取得<br>指導教官名、所属研究室の室長名は必ず記載ください。 |
| 研究歴(主な職歴と研究開発内容) | (記載例)<br>昭和〇〇年～〇〇年 〇〇大学〇〇学部 助手<br>〇〇教授研究室で〇〇〇〇〇〇について研究<br>昭和〇〇年～〇〇年 〇〇研究所 研究員<br>〇〇博士研究室で〇〇〇〇に関する研究に従事<br>平成〇〇年～〇〇年 〇〇大学〇〇学部 教授<br>〇〇〇〇について研究   |

|                             |  |               |
|-----------------------------|--|---------------|
|                             | 指導教官名、所属研究室の室長名は必ず記載ください。  |               |
| 現職位における定年年齢（予定）             | 才  |               |
| 研究開発期間                      | 年間<br>相手国研究機関と調整した共同研究期間を記載ください。尚、この期間には、暫定期間【R/D 署名までの期間（半年～初年度末）】は含めません。             |               |
| 希望する研究開発費<br>(AMED 委託研究開発費) | 年度   | 研究開発費（円）      |
|                             | H30 年度   | X,XXX,XXX 円   |
|                             | H31 年度   | XX,XXX,XXX 円  |
|                             | H32 年度   | XX,XXX,XXX 円  |
|                             | H33 年度   | XX,XXX,XXX 円  |
|                             | H34 年度   | XX,XXX,XXX 円  |
|                             | H35 年度   | XX,XXX,XXX 円  |
|                             | 総 額  | XXX,XXX,XXX 円 |
| 国内参画機関名                     | 参画する研究者全ての所属機関名、専攻/研究室を記載ください。   |               |
| 相手国名                        | 国名を日本語で記載ください。（相手国が複数ある場合、実際に R/D 締結をすることになる全ての国を記載ください。）                              |               |
| 相手国研究機関名                    | 相手国研究機関名を日本語で記載ください。（日本語の対訳がない場合は、英語名で記載ください（英語限定）。相手国研究機関が複数の場合は、代表機関、協力機関の順に記載ください。） |               |
| 研究開発目的                      | 250 文字以内（改行、スペース含む）で入力ください。  |               |

|                          |  |                             |                           |                            |              |  |
|--------------------------|--|-----------------------------|---------------------------|----------------------------|--------------|--|
| 研究開発概要                   |  | 250 文字以内（改行、スペース含む）で入力ください。 |                           |                            |              |  |
| 実施体制<br>（参加者リスト）         | 氏名   | 所属<br>役職                    | 年齢<br>※2018年4月1日<br>現在の年齢 | 本研究提案に<br>おいて担当す<br>る研究の概要 | エフォート<br>（%） | SATREPSプロジェクト参加状況<br>（すでに参加経験がある場合は、<br>該当課題名を明記のこと） |
|                          |  |                             |                           |                            |              |  |
|                          | <p>本提案研究に参加する全ての研究参加者について、研究開発代表者から順に、研究開発分担者、研究開発協力者等として記載ください。</p> <p>参加者が多数の場合は、適宜、行を追加して記載ください。</p> <p>※日本側の研究参加者の要件は、（1）国内の研究機関に所属していること、及び（2）相手国機関のメンバーでないことです。</p> <p>※応募時に参加の可否が不確定な研究参加者については、「研究者A」等として記載することが可能です。その場合、その方の研究者番号、所属機関や現役職等は空欄のままですが、その他の内容（年齢、エフォート、担当する研究の概要）については、そのポストに想定される条件を勘案して記入ください。</p> |                             |                           |                            |              |  |
|                          |  |                             |                           |                            |              |  |
|                          |  |                             |                           |                            |              |  |
| 研究開発代表者が<br>所属する機関の事務担当者 | 住所：〒<br>機関名：<br>役職 氏名：<br>E-mail：<br>TEL： FAX：   |                             |                           |                            |              |  |
| キーワード                    | AMED 内の動向調査等に活用するため、本研究提案に関するキーワードを列挙ください。   |                             |                           |                            |              |  |

## Counterpart institution implementation structure

Main joint researcher of collaborating institution in partner country (provide this information for each of the collaborating institutions)

|                          |   |   |    |  |
|--------------------------|---|---|----|--|
| 氏名                       | ※アルファベットで必ず記載ください。  |   | 国籍 |  |
| 所属機関名                    | (日本語) ※日本語名がある場合のみ記載ください。   |   |    |  |
|                          | (英語) ※英語表記で必ず記載ください。  |   |    |  |
|                          | 国名  |   | 役職 |  |
| 職歴等                      | 最終学歴  | 〇〇年 〇〇大学〇〇学部卒業 西暦で記載ください。   |    |  |
|                          | 学位  | 〇〇年 PhD (〇〇学) 取得 (〇〇大学) 西暦で記載ください。  |    |  |
|                          | 主な職歴と研究内容等  | <p>(記述例) 西暦で記載ください。</p> <p>19〇〇年～〇〇年 〇〇大学〇〇学部 助手<br/>         〇〇〇〇について研究</p> <p>20〇〇年～〇〇年 〇〇大学〇〇学部 研究員<br/>         〇〇〇〇に関する研究に従事</p> |    |  |
| 【参考】<br>機関内のその他の研究参加者    | ・氏名、役職、役割を記載ください(複数可)。  |   |    |  |
| 【参考】<br>相手国研究機関からの協力要請内容 | ・相手国研究機関より提出されるODA協力の要請の内容について、可能な範囲で記載ください。(複数の国と共同研究を実施する場合は、それぞれの相手国の研究機関より提出されるODA協力の要請の内容について、可能な範囲で記載ください。) |   |    |  |

Collaborative joint researcher of collaborating institution in partner country (provide this information for each of the collaborating institutions)

|                       |                           |   |    |  |
|-----------------------|---------------------------|---|----|--|
| 氏名                    | ※アルファベットで必ず記載ください。        |   | 国籍 |  |
| 所属機関名                 | (日本語) ※日本語名がある場合のみ記載ください。 |   |    |  |
|                       | (英語) ※英語表記で必ず記載ください。      |   |    |  |
|                       | 国名                        |   | 役職 |  |
| 職歴等                   | 最終学歴                      | 〇〇年 〇〇大学〇〇学部卒業 西暦で記載ください。   |    |  |
|                       | 学位                        | 〇〇年 PhD (〇〇学) 取得 (〇〇大学) 西暦で記載ください。  |    |  |
|                       | 主な職歴と研究内容等                | <p>(記述例) 西暦で記載ください。</p> <p>19〇〇年～〇〇年 〇〇大学〇〇学部 助手<br/>〇〇〇〇について研究</p> <p>20〇〇年～〇〇年 〇〇大学〇〇学部 研究員<br/>〇〇〇〇に関する研究に従事</p> |    |  |
| 共同研究における役割            | ・共同研究の役割を具体的に記述ください。      |   |    |  |
| 【参考】<br>機関内のその他の研究参加者 | ・氏名、役職、役割を記載ください(複数可)。    |   |    |  |

1-2. English format

|   |  |
|---|--|
| (a) Title of proposed research project                                  | Do not include a subtitle in the proposed research project's title.<br>Liaise carefully and agree English title of research project with the counterpart institution. <b>Make sure to use the same title as the counterpart's ODA technical cooperation project application.</b> |
| (b) Research period   | ____ years<br>Give the period of joint research agreed with the counterpart institution. It does not include the time leading up to the signing of the R/D (about six months to the end of the first fiscal year).   |
| (c) Total research expenses<br>(Japan: AMED contract research expenses) | Give in thousand yen units (round to the nearest 1,000).<br>Total ____,000 yen (including indirect expenses)   |
| (ODA project expenses)  | Total ____,000 yen (no indirect expenses)  |
| (d) Principal investigator's name and title                             | Give the principal investigator's name and title.  |
| (e) Principal investigator's affiliation                                | Give full title of affiliated institution for principal investigator, including the name of institute, department/laboratory.  |
| (f) Collaborating institutions in Japan                                 | Give full titles of affiliated institutions for all researchers, including the name of institute, department/laboratory.   |
| (g) Counterpart country   | (If there is more than one partner country, list all countries with which an actual R/D will be signed.)   |
| (h) Counterpart institution(s)  | (If there are multiple counterpart institutions, list the principal institution first before the collaborating institutions.)  |
| (i) Project objective   | (Approx. 120 words)  |
| (j) Outline of project  | (Approx. 120 words)  |

## Japanese institution implementation structure

List the researchers expected to participate in the Japan-side research team, giving name, researcher ID No., affiliation, position, effort, and a brief outline of research responsibility.

| Name<br>(Researcher<br>ID No. *1) | Affiliated<br>institution                   | Current<br>position,<br>title,<br>etc. | Age<br>(Age as of<br>April 1,<br>2018) | Effort *2<br>(Proportion<br>of time<br>allocated) (%) | Research<br>responsibility<br>in project           | Experience of<br>working on<br>SATREPS project<br>(specify project) |
|-----------------------------------|---|--|--|---|--|---|
| _____<br>(XXXXXX)                 | XX University<br>XX Faculty<br>X Department | Professor                              |  | __%   | Overall<br>management of<br>the research,<br>_____ |   |
| _____<br>(XXXXXX)                 | YY University                               | Associate<br>Professor                 |  | __%   | _____  |   |
| _____<br>(XXXXXX)                 | ZZ Research<br>Center                       | Research<br>fellow                     |  | __%   | _____  |   |
| Researcher A<br>(XXXXXX) *3       | WW University<br>WW Faculty<br>W Department | Post-doc                               | *3                                     | __%   | _____  |   |

(Japan-side participants must be (1) affiliated with a Japanese research institute, and (2) not included in the list of members of the partner country's institution.)

\*1 For the Researcher ID No., give the ID No. registered with e-Rad. Each lead joint researcher intending to conclude a Contract Research Agreement with AMED must acquire a Researcher ID No. in advance of the Contract Research Agreement.

\*2 This is based on the Council for Science and Technology Policy's definition of 'effort', which is "the percentage of working hours required for conducting the relevant research when the researcher's total annual working hours are 100%". Note that "total working hours" does not refer only to the number of hours spent in research activities but to the substantive total working hours, including educational and medical activities.

\*3 If the appointment of a researcher has not been finalized at the application stage, "Researcher A" etc. can be used instead of the researcher's name. In such cases, the Researcher ID No., affiliated institution, and current position etc. can be left blank for that researcher, but other items (age, effort, research responsibility in project) should be completed as conditions envisaged for the post.

## Principal investigator of Japan-side principal research institution

Give the following details for the Japan-side principal investigator.

|   |  |
|---|--|
| Name  |  |
| Affiliated institution  |  |
| Department/Title  |  |
| Academic Background (University onwards)                          | <p>(Example)</p> <p>20XX: Graduated from ___ University, Faculty of ___</p> <p>20XX: Completed Masters course in ____, ___ University ___ Graduate School<br/>(Advisor: ___ Professor)</p> <p>20XX: Completed Doctoral course in ____, ___ University ___ Graduate School<br/>(Advisor: ___ Professor)</p> |
| Research background (Main professional appointments and research) | <p>(Example)</p> <p>19XX – 20XX: Research Associate, ___ University, Faculty of ___</p> <p>Researched _____ under Professor ___</p> <p>Since 20XX: Researcher at ___ Research Center</p> <p>Conducting research into ___ under Dr. ___</p>   |
| Age at which retirement from current position is scheduled        | _____ years of age   |



## Counterpart institution implementation structure

- Give the joint research partner country, counterpart institution, research location, partner country principal investigator's name and title, partner country principal investigator's profile, research activities and role in joint research, etc.
- Describe the collaborative relationship etc. with counterpart institutions, including particulars for which the counterpart institution is considering making an application for technical cooperation.
- If conducting joint research with multiple research institutions in one partner country, it is necessary to specify the research institution that will be the main joint research entity in the partner country. For that reason, the main research institution in the partner country should be listed as the principal institution, and the other research institutions in the partner country should be listed as collaborating institutions. Normally, only information concerning a single researcher should be given for each counterpart institution.
- If conducting joint research with multiple partner countries, the information for the principal institution (and collaborating institutions) should be given for each country.
- If organization charts etc. for the counterpart institutions are available, include them in the text.

### 1. Principal investigator of principal research institution in partner country (provide this information for each of the partner countries)

| Name  | (Give in alphabetic characters)                            |  | Nationality    |  |
|---|--|--|----------------|--|
| Affiliated institution  | Japanese name: (omit if Japanese name does not exist)      |  |                |  |
|   | English name: (English name is essential)                  |  |                |  |
|   | Country  |  | Position/title |  |
| Background  | Highest level of education attended                        | 20XX (year): Graduated from __ University Faculty of ____  |                |  |
|   | Highest degree earned                                      | 20XX (year): PhD (__), __ University)  |                |  |
|   | Main professional appointments and research, etc.          | Example:<br>19XX – 20XX: Research Associate, __ University, Faculty of __<br>Research into ____<br><br>20XX – 20XX: Researcher, __ University, Faculty of __<br>Pursued research into ____ |                |  |
| (For reference) Other participating researcher(s) at same institution | - For each researcher, give name, position/title, and role |  |                |  |

|   |   |
|---|---|
| (For reference)<br>Request for ODA technical cooperation submitted by counterpart institution | - Describe as far as possible the particulars of the request for ODA technical cooperation to be submitted by the counterpart institution. <u>When implementing joint research with a number of countries</u> , describe as far as possible the particulars of the requests for ODA technical cooperation to be submitted by the counterpart institution in each country. |
|---|---|

**2. Main joint researcher of collaborating institution in partner country (provide this information for each of the collaborating institutions)**

|  |   |  |                |
|--|---|--|----------------|
| Name   | (Give in alphabetic characters)                                 | Nationality  |                |
| Affiliated institution   | Japanese name: (omit if Japanese name does not exist)           |  |                |
|  | English name: (English name is essential)                       |  |                |
|  | Country   |  | Position/title |
| Background   | Highest level of education attended                             | 20XX (year): Graduated from __ University Faculty of ____  |                |
|  | Highest degree earned   | 20XX (year): PhD (__), __ University)  |                |
|  | Main professional appointments and research, etc.               | Example:<br>19XX – 20XX: Research Associate, __ University, Faculty of __<br>Research into ____<br><br>20XX – 20XX: Researcher, __ University, Faculty of __<br>Pursued research into ____ |                |
| Role in joint research   | - Describe the researcher's specific role in the joint research |  |                |
| (For reference)<br>Other participating researcher(s) at same institution | - For each researcher, give name, position/title, and role      |  |                |

## From 2. Research theme concept

### 1. Background to research

- Include figures or tables if necessary. Black-and-white copies are used for assessment, so make sure that any figures or tables are comprehensible without color.
- Form 2 must not exceed 6 pages of A4 paper. To ensure impartiality, forms exceeding 6 pages will be considered non-compliant, and excluded from assessment. Use of small print or small figures/tables to fit within the 6 page limit, or use of reduced-size (2-in-1) copies to fit two pages of information onto one page is not acceptable.
- Include a description from the perspectives of relevance, effectiveness, efficiency, impact, and sustainability as an ODA project.

#### (1) Background to research theme that contributes to resolving global issue(s)

Specify the global issue (unresolved science and technology issue, and the socioeconomic disadvantages and international trends attributable to it) addressed by this research initiative. Also specify the role of the research initiative in contributing to the resolution of the issue, including the following perspectives.

- Significance of contribution to resolving the global issue
- Science and technology/academic creativity and novelty

#### (2) Partner country needs

Specify how the research initiative can contribute to meeting the needs of the partner country, including a description of current status and issues associated with the partner country's socioeconomic and science and technology background. Give a description of the structure and capacity etc. of the counterpart institution, and a description of the need for assistance and effectiveness of assistance. If Ministry of Foreign Affairs (MOFA) has published a Country Assistance Policy or Rolling Plan\* for the partner country, describe how the research initiative is related to that policy or plan, taking into account consistency with the partner country's development strategy. If the project is also likely to make a contribution outside the partner country, describe that too.

\*For details see the MOFA website, including the following pages:

Country Assistance Policies:

<http://www.mofa.go.jp/mofaj/gaiko/oda/region/index.html> (Japanese)

<http://www.mofa.go.jp/policy/oda/assistance/index2.html> (English)

ODA policies (Rolling Plans):

[http://www.mofa.go.jp/mofaj/gaiko/oda/seisaku/kuni\\_enjyo.html](http://www.mofa.go.jp/mofaj/gaiko/oda/seisaku/kuni_enjyo.html) (Japanese)

<http://www.mofa.go.jp/policy/oda/policy.html> (English)

## **2. Research objectives**

Specify the objectives of the research initiative.



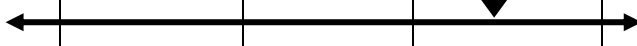


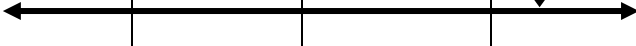

- Specify how application of outcomes of this research initiative is envisaged—including anticipated scientific and technical development, creation of new industries, and contributions to society attributable to the project within 5-10 years of the project termination.
- Describe contributions to achieving Japan’s major science and technology policies, such as policies set out in the 5th Science and Technology Basic Plan, etc.

\* When making a research proposal that involves collaboration between industry, academia, and government, specify on Form 10 how the businesses involved envisage the project leading to application of outcomes. Submit Form 10 together with the other forms.

**Form 3. Research plans and implementation of plans (Technical cooperation project activity plan)**

- Indicate the outline framework of a time schedule for achieving the research outcome targets, giving research items and milestones (timing and judgment criteria for assessing the level of achievement of the research partway through the research period).
- Include plans for application of outcomes and for capacity development (developing organizational and individual capacity at Japanese and counterpart institutions; building external links).
- Describe currently-expected issues, together with solutions proposed for such issues in order to attain the research objectives.

(1) Overall research activities and research plans (Use the form below)

| Research item/activity   | Provisional selection period | Year 1 | Year 2   | Year 3 | Year 4   | Year 5   |
|--|------------------------------|--------|--|--------|--|--|
| 1. Research item 1<br>(Outcome 1)<br>1-1 Research activity 1-1<br>(Activity 1-1)<br>1-2 Research activity 1-2<br>(Activity 1-2)  |                              |        | Realization of AAA<br>      |        | Achievement of BBB<br>   |  |
| 2. Research item 2<br>(Outcome 2)<br>2-1 Research activity 2-1<br>(Activity 2-1)<br>2-2 Research activity 2-2<br>(Activity 2-2)  |                              |        | Realization of CCC<br>   |        | Development of DDD<br>   |  |
| 3. Research item 3<br>(Outcome 3)<br>3-1 Research activity 3-1<br>(Activity 3-1)<br>3-2 Research activity 3-2<br>(Activity 3-2)<br>3-3 Research activity 3-3<br>(Activity 3-3) |                              |        | EEE scheme submission<br> |        | Establishment of FFF<br> | Achievement of GGG<br> |

(2) Collaboration and division of functions etc. with counterpart institution for each research item

| Research item/activity    | Details of research to be conducted jointly | Roles of Japan-side institutions (Leader's name) | Roles of partner country institutions (Leader's name) | Plan for travel to partner country by Japan-side researchers *1 | Plan for inviting researchers from partner country to Japan *2 | Machinery and equipment provided to partner country *3 |
|---------------------------|---|--|---|---|--|--|
| 1. Research item 1        |   | Research for AA (○○○)                            | Survey for BB (○○○)                                   |   |  |  |
| 1-1 Research activity 1-1 |   |  |   |   |  |  |
| 1-2 Research activity 1-2 |   |  |   |   |  |  |
| 2. Research item 2        |   |  |   |   |  |  |
| 2-1 Research activity 2-1 |   |  |   |   |  |  |
| 2-2 Research activity 2-2 |   |  |   |   |  |  |
| 3. Research item3         |   |  |   |   |  |  |
| 3-1 Research activity 3-1 |   |  |   |   |  |  |
| 3-2 Research activity 3-2 |   |  |   |   |  |  |
| 3-3 Research activity 3-3 |   |  |   |   |  |  |

\*1. Give the plan for visits required by Japan-side researchers, in terms of the number of days per visit and the number of visits.

- Give the plan for visits by the principal investigator for the purpose of overseeing the project. (Give information in this format: Year 1: \_\_ days x \_ visits, Year 2: \_\_ days x \_ visits, etc.)
- Give details of researchers who can follow the principal investigator and be stationed in the partner country full-time or close to full-time. (Give information in this format: Name/affiliation/position/age/specialty, stationed for \_\_\_ days per year. If there are multiple researchers in this category, give the same information for each researcher. If there are none, write "N/A.")

\*2. Give plans for inviting people from the partner country to Japan (length of visit, number of people, etc.) In particular, describe any plans for long-term visits as government-sponsored foreign students, JICA long-term trainees, or using similar schemes.

\*3. List the main items of machinery and equipment provided to the partner country, including their main specifications (differentiate between general purpose machinery and equipment and machinery and equipment requiring customization/special order), estimated price, country of purchase (differentiate between local purchases and purchases in Japan). Machinery and equipment maintenance (consumables, spare parts, inspection, adjustment, repair, etc.) and running costs (electricity/gas/water, raw materials, operator labor costs, etc.) should in principle be covered by the partner country.

(3) Activity plan for application of outcomes

(3-a) Conditions necessary for application of research outcomes

Specify the methodology for application of outcomes, proposed schedule up to and including application of outcomes, and also the means and targets for application, and issues to be overcome in applying the research outcomes.

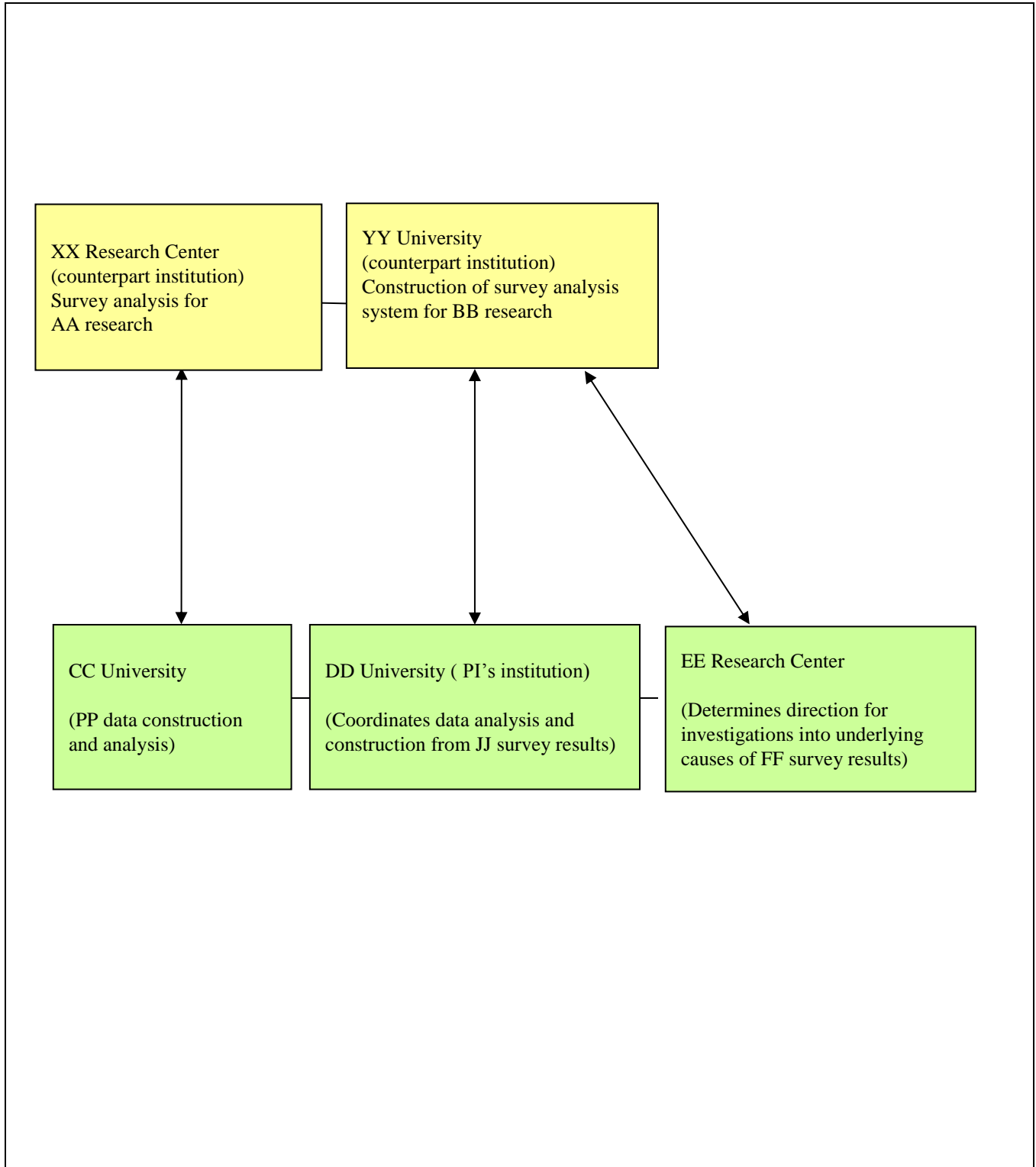
(3-b) Activities that can be conducted within the research period for meeting the conditions for application of outcomes set out above, functions required at the partner country institution, and activity plan for the activities

(4) Capacity development plan for the partner country

Describe policy and plan for capacity development at organizational, individual, and external link levels, including construction of links between the counterpart institution's research implementation structure and administrative entities and the private sector, and training and capacity development of researchers.

#### Form 4. Implementation structure concept diagram

- Provide a diagram of the implementation structure for the research theme.
- Make sure to clearly show the division of roles between the Japanese institution and the counterpart institution, together with the structure of links between institutions.





## **From 5. Research plan in each fiscal year**

Indicate the certain strategy and/or methods, research outcome targets, and achievement for each research item on the research partway during the following years within 3 pages.

(1) Research item 1

Leader (Affiliated institution, name)

Sub-leader (Affiliated institution, name)

Outline and achievement of the project: Approx. 200 words

Provisional selection period (2018):

Year 1 (2019):

Year 2 (2020):

Year 3 (2021):

Year 4 (2022):

Year 5 (2023):

(2) Research item 2

Leader (Affiliated institution, name)

Sub-leader (Affiliated institution, name)

Outline and achievement of the project: Approx. 200 words

Provisional selection period (2018):

Year 1 (2019):

Year 2 (2020):

Year 3 (2021):

Year 4 (2022):

Year 5 (2023):

## From 6. Research expense plan

- Submit the plan (budget) for contract research expenses from AMED, listing expenses by category.
- The start of the research period varies according to when the R/D is signed. Consequently, the specific FY is not required for this form.
- The uses for which AMED contract research expenses can be disbursed are explained.
- If separate research groups are to be formed in Japan, also provide the research expenses plan for each research group.
- When a project is selected, the actual budget available for research may not match the amount given in this research expenses plan. This is regarded as the plan at the application stage. After selection, the plan will be adjusted, including support for the counterpart institution, etc.

### 1. AMED contract research expenses plan for whole research group

|  | Provisional selection period <sup>*1</sup> | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Total (thousand yen) |
|--|--|--------|--------|--------|--------|--------|----------------------|
| Equipment                                      |  |        |        |        |        |        |                      |
| Materials/ Consumables                         |  |        |        |        |        |        |                      |
| Travel   |  |        |        |        |        |        |                      |
| Personnel and services                         |  |        |        |        |        |        |                      |
| Other  |  |        |        |        |        |        |                      |
| Subtotal: Direct expenses (thousand yen)       |  |        |        |        |        |        |                      |
| Indirect expenses <sup>*2</sup> (thousand yen) |  |        |        |        |        |        |                      |
| Total (thousand yen)                           |  |        |        |        |        |        |                      |

\*1. Expenses for the provisional selection period up to the point where the R/D and MOU are signed are limited to a maximum of 6.5 million yen (including indirect expenses). Expenses for each of the Years 1-5 should be about 35 million yen (including indirect expenses). Expenses for each fiscal year may be slightly adjusted according to the research plan, provided, however, that the total expenses, including expenses for the provisional selection period, must not exceed 175 million yen for a 5-year project, 140 million yen for a 4-year project, or 105million yen for a 3-year project (including indirect expenses).

\*2. Indirect expenses up to a maximum of 30% of the amount of direct expenses can be included in the contract research expenses.

When including indirect expenses, calculate as Indirect expenses = Direct expenses x 0.3.

Employment risks: When making employment decisions during the provisional selection period, be aware of the risk that the R/D may not be signed, and the project may not go ahead. Ensure that any employees appointed during that period are also aware of the risk.

Tax: Give expenses as amounts including Japanese consumption tax. The tax rate may be raised to 10% in October 2019.

## 2. AMED contract research expenses plan by group

- Principal investigator's group (代表機関)

Principal investigator name (Affiliation/position): \_\_\_\_\_ ( \_\_ University \_\_ Research Dept.)

|  | Provisional selection period | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Total (thousand yen) |
|--|------------------------------|--------|--------|--------|--------|--------|----------------------|
| Equipment                                |                              |        |        |        |        |        |                      |
| Materials/Consumables                    |                              |        |        |        |        |        |                      |
| Travel                                   |                              |        |        |        |        |        |                      |
| Personnel and services                   |                              |        |        |        |        |        |                      |
| Other                                    |                              |        |        |        |        |        |                      |
| Subtotal: Direct expenses (thousand yen) |                              |        |        |        |        |        |                      |
| Indirect expenses (thousand yen)         |                              |        |        |        |        |        |                      |
| Total (thousand yen)                     |                              |        |        |        |        |        |                      |

- Joint research group

Name of lead joint researcher (Affiliation/position): \_\_\_\_\_ ( \_\_ University \_\_ Research Dept.)

|  | Provisional selection period | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Total (thousand yen) |
|--|------------------------------|--------|--------|--------|--------|--------|----------------------|
| Equipment                                |                              |        |        |        |        |        |                      |
| Materials/Consumables                    |                              |        |        |        |        |        |                      |
| Travel                                   |                              |        |        |        |        |        |                      |
| Personnel and services                   |                              |        |        |        |        |        |                      |
| Other                                    |                              |        |        |        |        |        |                      |
| Subtotal: Direct expenses (thousand yen) |                              |        |        |        |        |        |                      |
| Indirect expenses (thousand yen)         |                              |        |        |        |        |        |                      |
| Total (thousand yen)                     |                              |        |        |        |        |        |                      |

\* During the provisional selection period, only the principal investigator's group is counted.

**3. (For reference) Counterpart institution's research expenses plan (including costs expected to be applied for. List each partner country separately)**

Costs covered by partner country side

|   |  | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Total<br>(Local currency and<br>Yen equivalent) |
|---|--|--------|--------|--------|--------|--------|---|
| Costs covered by<br>partner country side<br>(scheduled) | Equipment                                    |        |        |        |        |        |   |
|   | Materials/<br>Consumables                    |        |        |        |        |        |   |
|   | Travel                                       |        |        |        |        |        |   |
|   | Personnel<br>and services                    |        |        |        |        |        |   |
|   | Other  |        |        |        |        |        |   |
|   | Subtotal                                     |        |        |        |        |        |   |
|   | counterpart<br>institution's<br>total budget |        |        |        |        |        |   |

|  | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Total   |
|--|--------|--------|--------|--------|--------|---|
| Research expenses (scheduled) in<br>technical cooperation requested<br>by the partner country<br>(= ODA project expenses budget) |        |        |        |        |        | Local currency<br>Yen equivalent<br>_____,000 yen<br>(Maximum 300million yen<br>in 5 years) |

- When conducting joint research with multiple countries, add extra rows to the table for the additional information.
- Actual budget for ODA project expenses is fixed after the Detailed Design (D/D) study by JICA after the selection of the project. The figures to be given here are “For reference” only.
- ODA cannot cover all the costs for the developing country side. In order to encourage self-reliant and sustainable economic growth, the developing country is expected to bear a portion of the costs. Consequently, costs such as the partner country side's personnel costs, office rental in the partner country, consumables and the costs of operating and maintaining to be provided to machinery and equipment in the partner country, and the cost of travel by partner country researchers within the partner country are in principle borne by the partner country side. This point applies equally to the SATREPS program, so the whole of the amount set out above will not be provided by ODA. JICA's D/D study will include discussion of an appropriate level of costs to be borne by the partner country side, including costs for securing research locations in the partner country, and personnel costs for the partner country side researchers. Please understand that the budget for ODA project expenses will be finalized after the D/D study.

## **From 7. Basis for research and state of preparations**

### (1) Current basis for research

#### (1-a) Research and research outcomes to date

- Give an outline and results etc. for domestic and international research outcomes, and of research by the principal investigator (research proposer) in person (and if necessary, research participants), that will form the basis for the research initiative.

#### (1-b) List of academic papers and books (author, title, journal, volume/page/year of publication)

- Give details of recent books and papers published in academic journals etc. by researchers included in the implementation structure, focusing on important publications that are relevant to the proposal. Select up to 10 publications for the project as a whole, and list them in date order, with the most recent first.

#### (1-c) List of associated patents (application No./inventor/title/applicant/date of application)

- Give details of patents applied for recently by research participants, selecting important applications that are relevant to the proposal. Select up to 10 patents for the project as a whole.

### (2) State of preparation in conjunction with counterpart institution

- Describe the construction of infrastructure at the counterpart institution, the basis of research by the counterpart institution that was the reason for choice of institution, the state of coordination with partner country's government agencies, etc., and the state of preparation for international joint research. If an agreement has already been signed with the counterpart institution, give details of the agreement and current contact and interaction with the institution.

### (3) Ethical considerations

- State any requirement for inspection of compliance with ethical standards of the country where the research is implemented (partner country or Japan), and the status of any such inspection.

### (4) Status of examination into handling of bio-resources/intellectual property, etc.

- Give details of coordination with the counterpart institution regarding the ownership of rights to research outcomes, implementation of research outcomes, and incoming and outgoing material transfer, etc.

**Form 8. Grants received through other programs (Japanese institution only)**

- List any grants under national competitive funding schemes or other research grant schemes that the principal investigator and lead joint researchers are currently receiving, are currently applying for, or are planning to apply for. For each funding program, include details of the research project title, research period, amount of research expenses, role of researcher, and differences from/relation to the proposed research project.

**Principal investigator: Name** \_\_\_\_\_

| Funding program <sup>1)</sup>   | Research project title | (1)Research expenses <sup>3)</sup><br>(entire term)<br>(2) "<br>(FY2019)<br>(3) "<br>(FY2018)<br>(thousand yen) | Research period | Role <sup>2)</sup><br>(Principal/<br>Co-researcher) | Effort <sup>4)</sup><br>(Proportion<br>of time<br>allocated)% | Status  | Differences from/relation to proposed<br>research project |
|---|------------------------|---|-----------------|---|---|---|---|
| Grants-in-Aid<br>for Scientific<br>Research (S)<br>(Kakenhi Kiban<br>Kenkyu (S) )                     | _____                  | (1) 100,000<br>(thousand yen)<br>(2) 20,000<br>(thousand yen)<br>(3) 20,000<br>(thousand yen)                   | 2016-2022       | Principal   | 30%   | In progress<br>* List any projects<br>in progress or any<br>other projects<br>under application | _____   |
| SATREPS   | _____                  | (1) 100,000<br>(thousand yen)<br>(2) 25,000<br>(thousand yen)<br>(3) 20,000<br>(thousand yen)                   | 2013-2018       | Co-researcher                                       | 10%   | In progress   | _____   |
| Funds for<br>Integrated<br>Promotion of<br>Social System<br>Reform and<br>Research and<br>Development | _____                  | (1) 32,000<br>(thousand yen)<br>(2) 8,000<br>(thousand yen)<br>(3) 8,000<br>(thousand yen)                      | 2017-2020       | Co-researcher                                       | 5%  | Under application   | _____   |

- 1) Give details of grants etc. currently received, or already finalized, listing the grants in order of size of research expenses (entire term) with the largest first. Then give details of grants etc. already applied for or scheduled to be applied for (mark the project as “Applied for” etc. under Status.)
  - 2) Under Role, specify the researcher’s role (principal researcher or co-researcher etc.) in each project.
  - 3) Under Research expenses, give the amount received by the researcher in person (direct expenses).
  - 4) Under Effort, give a figure based on the Council for Science and Technology Policy’s definition of ‘effort’, which is “the percentage of working hours required for conducting the relevant research when the researcher’s total annual working hours are 100%”. Note that “total working hours” does not refer only to the number of hours spent in research activities but to the substantive total working hours, including educational and medical activities. Give the figure envisaged after the project is selected for the SATREPS program.
- \* If false information is provided here, the application may be rejected, or have the selection decision reversed or the project budget reduced.

**Main joint researcher: Name** \_\_\_\_\_

| Funding program <sup>1)</sup>   | Research project title | (1) Research expenses <sup>3)</sup> (entire term)<br>(2) " (FY2019)<br>(3) " (FY2018)<br>(thousand yen) | Research period | Role <sup>2)</sup> (Principal/Co-researcher) | Effort <sup>4)</sup> (Proportion of time allocated)% | Status   | Differences from/relation to proposed research project |
|---|------------------------|---|-----------------|--|--|--|--|
| SATREPS   | _____                  | (1) 35,000 (thousand yen)<br>(2) 10,000 (thousand yen)<br>(3) 10,000 (thousand yen)                     | 2013<br>-2018   | Co-researcher                                | 15%  | In progress<br>* List any projects in progress or any other projects under application | _____  |
| Grants-in-Aid for Scientific Research (S) (Kakenhi Kiban Kenkyu (S) )               | _____                  | (1) 70,000 (thousand yen)<br>(2) 25,000 (thousand yen)<br>(3) 20,000 (thousand yen)                     | 2016<br>-2022   | Principal                                    | 10%  | In progress  | _____<br>_____   |
| Funds for Integrated Promotion of Social System Reform and Research and Development | _____                  | (1) 32,000 (thousand yen)<br>(2) 8,000 (thousand yen)<br>(3) 8,000 (thousand yen)                       | 2017<br>-2020   | Co-researcher                                | 5%   | In progress  | _____  |



**Form 9. Written approval from institution director**

Date: \_\_\_\_\_

**Written Approval**

To:  
Japan Agency for Medical Research and Development  
Japan International Cooperation Agency

I hereby declare that if the underwritten research project proposed for the SATREPS (Science and Technology Research Partnership for Sustainable Development) program is selected, this institution will carry out the international joint research as set out below.

(Principal investigator's institution)

Director (name, title): \_\_\_\_\_

\_\_\_\_\_

Institution: \_\_\_\_\_

(Official Seal):

Research project

Research project title: \_\_\_\_\_

Principal investigator: \_\_\_\_\_

Support to be provided

- Support for the exchange of documents agreeing to the implementation of international joint research with the counterpart institution
- Commitment to sign and comply with the Agreement (Agreement Regarding the Implementation of Technical Cooperation under the Framework of SATREPS) and execute the Project Contract with JICA, and to administer expenses
- Compliance with the responsibilities of the principal investigator's institution in the case of a joint research framework being constructed
- Provision of systems for clarifying responsibility and safety management in relation to the international dispatch of students and graduate students as part of efforts to train young researchers
- Support for other procedures, etc., required in order to conduct international joint research
- Provision of a research structure led by the principal investigator for the duration of the research project (Also respond to the question etc. below)

|   |  |
|---|--|
| Is the principal investigator expected to reach retirement age (or similar) during the duration of the project? | If the answer to this question is <b>YES</b> , please describe how your institution will ensure the continuity of the research implementation structure. |
| ( YES / NO )  |  |

## Form 10. Plans by private-sector corporations, etc.

(To be completed by Japan-side businesses participating in the project)

Date: \_\_\_\_\_

### Corporate initiatives concerning application of outcomes

To:

Japan Agency for Medical Research and Development  
Japan International Cooperation Agency

I hereby declare that if the underwritten research project proposed for the SATREPS (Science and Technology Research Partnership for Sustainable Development) program is selected, \_\_\_\_\_ (company) will implement initiatives aiming at the application of research outcomes, following the principles set out below.

Company official of participating business (having authority concerning the content of this document):

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Company: \_\_\_\_\_

Position/title: \_\_\_\_\_

#### Research project

Research project title: \_\_\_\_\_

Principal investigator: \_\_\_\_\_

Principles for corporate initiatives concerning application of outcomes  
(Give specific details concerning initiatives for the application of research outcomes.)

- (1) Method for application of outcomes:
- (2) Roadmap and schedule for application of outcomes:
- (3) Effects for partner country and other countries (including Japan):
- (4) Utilization and fields of application envisaged for the technology:
- (5) Risks pertaining to commercialization/practical application:

## Form 11. Proposal coordination status

- In response to each of the following questions, circle either YES or NO (or alternatively, strike out the answer that does not apply).
- Note that selection of a project is not conditional on a YES response to all questions. Details of the proposal and the coordination status are considered together when making selection decisions.

### Status of coordination with partner country

|   |   |           |
|---|---|-----------|
| 1 | Regarding the project name and research plans (overall plans including implementation of research in either Japan or the partner country), have you jointly examined the content of the plans in accord with the intent of the SATREPS program and of the research area for which the project is proposed, and reached broad agreement with the partner country researchers?  | YES<br>NO |
| 2 | An ODA request needs to be submitted to the Japanese government by the partner country side via the government agency handling ODA. Have you confirmed that the partner country researchers will make those arrangements by the domestic deadline in the partner country?   | YES<br>NO |
| 3 | Have you confirmed the details of the research proposal and ODA request together with the partner country researchers in the light of understanding that (1) ODA support is provided through the framework of a technical cooperation project, (2) no financing is provided to the counterpart institution, and (3) some expenses are subject to the principles of the recipient country's responsibility to shoulder expenses? | YES<br>NO |
| 4 | Have you confirmed the partner country researchers understand that the SATREPS program is not simply a technology transfer project; it is a joint research project with the aim of acquiring new knowledge and technology?  | YES<br>NO |
| 5 | Are you considering the roadmap for future application of outcomes on the basis of policies and views of partner country government agencies and the private sector as well as the partner country research institution?  | YES<br>NO |
| 6 | Have you confirmed that the partner country researchers understand and have taken the necessary actions regarding the systematic response required from the counterpart institution under the SATREPS program?  | YES<br>NO |

### Status of coordination with joint researchers in Japan

|   |  |           |
|---|--|-----------|
| 7 | Have you confirmed that each joint researcher understands that unlike regular competitive funding schemes, capacity development of the partner country institution through joint research is included in the SATREPS program because the project is linked with ODA? | YES<br>NO |
| 8 | Form 2 of the research proposal documents is limited to a maximum of 6 A4 pages. To ensure impartiality, forms exceeding 6 pages will be considered non-compliant. Is your Form 2 within the 6-page limit?   | YES<br>NO |

### Status of coordination with affiliated institution

|   |   |           |
|---|---|-----------|
| 9 | The SATREPS program involves responsibilities not required for ordinary competitive funding schemes, such as requiring an agreement for the implementation of joint research to be signed with the partner country institution, an Agreement and project contract for the technical cooperation project to be signed with JICA, and the use of appropriate ODA cost accounting. Have you held discussions with the institution you are affiliated with, including discussion of this point, and obtained a Written Approval from Institution Director (Form 9)? | YES<br>NO |
|---|---|-----------|

### Status of coordination with principal investigator's other work

|    |   |           |
|----|---|-----------|
| 10 | Under the SATREPS program, the principal investigator is required to provide more management than ordinary competitive funding schemes, and to commit to the necessary effort. In particular, the principal investigator needs to spend time liaising between Japan and the partner country in the period leading up to the signing of the R/D. Based on that point, have you investigated whether you can arrange to devote the necessary effort when the project is selected? | YES<br>NO |
|----|---|-----------|

Status of coordination with overseas diplomatic missions

|    |   |           |
|----|---|-----------|
| 11 | In applying for the SATREPS program, have you exchanged information sufficiently with overseas diplomatic missions and JICA local offices as part of the process of examining the details of your proposal? | YES<br>NO |
|----|---|-----------|

Security measures

|    |   |           |
|----|---|-----------|
| 12 | Are you checking the security situation and travel information for the partner country and domestic locations where research will be conducted?<br>Explanation: Projects cannot be implemented in areas where it is judged difficult to ensure the security of people involved in the project. Access the MOFA website ( <a href="http://www.anzen.mofa.go.jp/">http://www.anzen.mofa.go.jp/</a> ) and other sources of information to check foreign travel and security information etc. | YES<br>NO |
|----|---|-----------|

Counterpart institution implementation structure, etc.

|    |   |           |
|----|---|-----------|
| 13 | Have you reached agreement with the partner country principal research institution concerning the research activities and how the research will actually progress? Does the institute have a sufficient understanding of the SATREPS system?<br>(Explanation) Lack of sufficient agreement in advance has a substantial influence on subsequent progress. In some cases, a difference of expectations between the parties can make it difficult to proceed with the research.   | YES<br>NO |
| 14 | Is the counterpart's principal investigator a principal researcher with the ability to unify the partner country implementation structure, including the various institutions involved in the project? Also, does the research institution have an adequate support structure?<br>(Explanation) Under SATREPS, which is a program for joint research between institutions in Japan and in developing countries, the partner country's principal investigator, in addition to personally having research abilities, must have the ability to unify the whole of the counterpart's implementation structure, and must also receive sufficient support from affiliated institutions. This is a key factor in the smooth implementation of the project.       | YES<br>NO |
| 15 | Is the research staff sufficient (in terms of both abilities and numbers) for conducting joint research?<br>(Explanation) To conduct joint research effectively, it is important that the counterpart institution allocates a sufficient number of capable research staff members. Having an inadequate staff may adversely affect the progress of the project, or may result in the research being over-reliant on the Japan side, making it difficult to promote capacity development at the counterpart institution.   | YES<br>NO |
| 16 | Has sufficient budget been acquired for the joint research? (Do the partner country principal research institution and other institutions involved understand that SATREPS does not provide funding from Japan?)<br>(Explanation) Under the SATREPS system, as an ODA project, the partner country is required to bear an appropriate amount of expenses to encourage self-reliant development. For this reason, the counterpart side must acquire a budget to cover its expenses. To ensure this, it is important to obtain the understanding of the overseeing agency involved in budgeting. If you do not already have experience of joint research with the partner country, particular attention must be paid to whether a budget has been acquired. | YES<br>NO |
| 17 | Has the infrastructure (facilities/machinery and equipment) needed for implementing joint research been put in place at the partner country principal research institution?<br>(Explanation) Provision of the required facilities and space for the joint research is in principle the responsibility of the partner country. Providing the counterpart institution with facilities and machinery and equipment is not one of the aims of the SATREPS project. If there are problems with the current infrastructure, it is necessary to check whether sufficient maintenance will be possible after the project finishes.  | YES<br>NO |
| 18 | Have you confirmed coordination with and allocation of functions between the counterpart institution's overseeing agency and the other government agencies involved?<br>(Explanation) The participation of the supervising agency and the other government agencies involved is important for ensuring the acquisition of a budget for the smooth implementation of the SATREPS project and in ensuring the application of research outcomes. Furthermore, it is necessary to ensure a clear definition of functions in advance. The supervising agency and other agencies are also involved in the SATREPS application procedure handled by the partner country, so, in addition   | YES<br>NO |

|  |  |  |
|--|--|--|
|  | to the details of the joint research proposal, it is important to explain and obtain sufficient understanding of the costs that need to be borne by the partner country. |  |
|--|--|--|

#### Provision of machinery and equipment

|    |  |                  |
|----|--|------------------|
| 19 | <p>Do you have an internal system providing and monitoring administrative duties and responsibilities sufficient to proceed international transfer of machinery and equipment, according to the policy of security export control?</p> <p>(Explanation) Japanese principal research institution is expected to legally perform consistent supply of machinery and equipment from procurement to transportation and installation. It is necessary to check the institution's system and its procedures for foreign exportation of machinery and equipment.</p>  | YES<br>NO        |
| 20 | <p>Are you taking account of points requiring special attention when the machinery and equipment to be supplied includes specialist machinery and equipment and plant constructed to order?</p> <p>(Explanation) It is envisioned that general procurement of machinery and equipment via JICA will be unable to handle specialist machinery and equipment and plant constructed to order. Consequently it is necessary to check in advance that the Japan-side principal investigator's institution has the ability to handle the procurement procedures and the necessary construction and maintenance.</p>  | YES<br>NO<br>N/A |
| 21 | <p>Does the plan for provision of machinery and equipment take account of the setup for handling and maintenance of the machinery and equipment after the project finishes?</p> <p>(Explanation) After the SATREPS project finishes, the machinery and equipment provided by Japan are to be used for further research activities, etc., with the partner country becoming responsible for the costs of maintaining the machinery and equipment provided by Japan. Consequently, the introduction of machinery and equipment that exceed the partner country's maintenance capabilities is considered inappropriate, even if the machinery and equipment are essential for the research. Also, machinery and equipment provided by ODA is provided on the assumption that the machinery and equipment will continue to be used after the project finishes for the lifetime of the machinery and equipment, so the system does not cover machinery and equipment that will not be used on an ongoing basis in the partner country, or will only be used for purposes such as gathering data for research.</p> | YES<br>NO        |

#### Development or improvement of facilities

|    |  |                  |
|----|--|------------------|
| 22 | <p>Are you taking account of points requiring special attention when the development or improvement of facilities is included?</p> <p>(Explanation) The development or improvement of facilities will require, for example, securing land for building the facilities, legal and contractual procedures pertaining to design and construction, safety management for handling hazardous materials, maintenance and management systems, and securing of funding. Please give adequate consideration to these points with the implementing agency of the counterpart country, and include in the plan only those that are essential for project implementation, can be completed within the project period, and can be maintained and managed without any problems following the termination of the project. The development or improvement of facilities that do not meet these requirements will not be permitted. In addition, if during project implementation it becomes clear that the development or improvement of facilities is unlikely to be completed within the project period, you will need to review your plan for the development or improvement of facilities.</p> | YES<br>NO<br>N/A |
|----|--|------------------|

#### Application of outcomes

|    |  |           |
|----|--|-----------|
| 23 | <p>Has a clear roadmap been produced as a practical plan for application of outcomes?</p> <p>(Explanation) One of the major characteristics of SATREPS is that the outcomes of joint research are not only used for research. The outcomes are applied to benefit society. Even from an ODA perspective, it is important to have a practical and realistic plan for application of outcomes, not just a hypothetical plan.</p> | YES<br>NO |
|----|--|-----------|

|    |   |           |
|----|---|-----------|
| 24 | <p>In order to prepare for application of outcomes, does the implementation structure include the participation of related institutions or entities such as private sector businesses?</p> <p>(Explanation) The SATREPS joint research period lasts a maximum of 5 years. In order to achieve the application of outcomes to a certain extent, it is important to have private sector businesses and other entities that will handle the application of outcomes section of the project actually participate from the idea stage, and prepare for implementation in a planned manner.</p> | YES<br>NO |
|----|---|-----------|

Other Japanese projects in the same field

|    |  |           |
|----|--|-----------|
| 25 | <p>Have you confirmed whether any other Japanese aid projects (JICA projects, etc.) have been implemented or are being implemented in the same field?</p> <p>(Explanation) If the partner country principal research institution for the current project has acted as the counterpart (C/P) for other aid projects in a related field in the past, then from the perspective of making effective use of ODA, consider research plans that build on that past experience as far as possible. If there are related ODA aid projects such as JICA technical cooperation projects currently in progress (or scheduled to be implemented soon), confirm that there is no duplication of content between such projects and the proposed SATREPS project. In particular, if the counterpart institution is the same institution, there is a risk of the new project impacting the implementation structure of the existing project. Take this into account, and if circumstances warrant, consider adjusting the timing or content of the proposal.</p> | YES<br>NO |
|----|--|-----------|

Projects backed by other donors in the same field

|    |   |           |
|----|---|-----------|
| 26 | <p>Have you confirmed whether any other aid projects have been implemented or are being implemented in the same field but backed by other donors?</p> <p>(Explanation) Confirm whether there is any duplication, and how the project is scheduled to proceed. In particular, if the counterpart institution is the same institution, make sure to question the donor's representatives and the counterpart institution sufficiently to confirm the likely extent of the resulting impact if the proposed joint research is implemented.</p> | YES<br>NO |
|----|---|-----------|

Contribution to SDGs

|    |   |  |
|----|---|--|
| 27 | <p>Which of the 17 United Nations Sustainable Development Goals (SDGs) does your proposal contribute to the most in your opinion? Please write the goal number in the right column (one number only).</p> <p>(Reference: <a href="http://www.un.org/sustainabledevelopment/sustainable-development-goals/">http://www.un.org/sustainabledevelopment/sustainable-development-goals/</a>)</p> |  |
|----|---|--|



## Japan Agency for Medical Research and Development (AMED)

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