FY2022

Science and Technology Research Partnership for Sustainable Development (SATREPS)

Application Guidelines

September 2021

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

Important Points to Note When Submitting a Research Proposal for FY2022

This solicitation for research proposals is for the purpose of soliciting and selecting projects that are to be implemented after the FY2022 budget has been approved. However, because the SATREPS program operates in cooperation with the official development assistance (ODA) project and time is required to coordinate with the partner institutions, solicitation is carried out before the budget is approved to enable research on selected projects to commence as early as possible. Please understand, therefore, that the research area content, contracted R&D funds, number of projects adopted, and other aspects of the program may change depending on the budget content and amount that is ultimately approved, and that applicants may be required to submit additional documents.

In addition, when formulating a research proposal, please devise a research plan that takes into account the effects of the COVID-19 pandemic (restrictions on travel to the partner country, etc.).

1. How to Apply

Research proposals for FY2022 are to be submitted via the Cross-ministerial Research and Development Management System (e-Rad). In order to use the e-Rad system, it is necessary in advance of application submissions for a researcher affiliated with a research institution to register his/her research institution on the e-Rad system, ask staff in charge of clerical affairs of the institution to register his/her information on the e-Rad system; likewise in advance of applications submissions it is necessary for a researcher not affiliated with a research institution to register his/her researcher information on the e-Rad system. Please refer to section “2.2.2. Cross-ministerial Research and Development Management System (e-Rad)” of these Application Guidelines for details, and to the e-Rad portal site (Cross-ministerial Research and Development Management System: https://www.e-rad.go.jp/en/) for information about how to register on e-Rad.

Deadline for submission of proposal documents: noon (Japan Standard Time) on Monday, November 8, 2021

2. Status as an ODA Technical Cooperation Project

The Science and Technology Research Partnership for Sustainable Development (SATREPS) is a program that operates in cooperation with ODA, and so projects conducted under this program are also required to fulfil the role of an ODA technical cooperation project. ODA-related expenses are to be disbursed based on the technical cooperation project framework rather than as contracted research expenses. Before submitting a research proposal to AMED, please be sure to carefully read section “1.1.7. Outline of Technical Cooperation through ODA” of these Application Guidelines and determine whether or not it is possible for your research institution to implement the project as the Principal Institution in accordance with the Japan International Cooperation Agency (JICA) Agreement Regarding the Implementation of Technical Cooperation under the Framework of SATREPS (the “Agreement”) and the Implementation Guide for Science and Technology Research Partnership for Sustainable Development (SATREPS) Projects. Furthermore, it is also necessary for the Principal Institution to thoroughly coordinate the joint research content with partner country researchers before having the partner institution submit a Request for Technical Cooperation Project (Request Form) through the ministry or agency responsible for ODA in their country to Japan’s MOFA headquarters in Tokyo via the Embassy of Japan in their

county. The deadline for MOFA headquarters in Tokyo to receive the Request Form is Friday, October 29, 2021 (Japan Standard Time), which is earlier than the deadline for submission of research proposals in Japan. In coordinating with partner institutions, please note that partner country governments usually set the deadline for submission of Request Forms for a date earlier than October 29, 2021. Also, if the Request Form is not submitted by the partner country's government, the research proposal from the Japanese research institution will be deemed to have not fulfilled the selection requirements and become ineligible for selection.

Contents

Chapter 1. SATREPS

These Application Guidelines specify the conditions and solicitation details regarding the R&D projects in the infectious diseases control field being solicited under the Science and Technology Research Partnership for Sustainable Development (SATREPS) of the International Collaborative Research Program, which is administered by the Japan Agency for Medical Research and Development (hereinafter referred to as "AMED").

1.1 Program Outline

1.1.1 Program Objectives

Based on the needs of developing countries, the SATREPS program, in collaboration with official development assistance (ODA), promotes international joint research targeting global issues[1] for which there are plans for the utilization of research outcomes.[2] 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 innovation. The international joint research under this program is also aimed at the creation of a continuous activities system that contributes to improving the independent R&D capabilities of developing countries and the resolution of 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 support for basic and applied research. It is also a program with the goals of promoting the utilization of research outcomes in science and technology to address the issues and needs of partner countries and contributing to science, technology and innovation in those countries, thereby facilitating the strengthening of diplomatic relations between Japan and the partner country and helping the national interests of Japan.

1.1.2 Background to the Program

As a means by which the promotion of science and technology and the training and development of human resources are mutually facilitated, the needs are recognized for joint research and capacity building of universities and research institutions based on the needs of developing countries. Japan has given these 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 (hereinafter referred to as "MEXT") and Ministry of Foreign Affairs (hereinafter referred to as "MOFA") started to implement the SATREPS program in FY2008 in close collaboration with science & technology and ODA, enabling the research institutions of

---

[1] Global issues: Issues that are difficult to resolve by a single country or region acting on its own and that require the international community as a whole to purse initiatives.

[2] Utilization of research outcomes: The returning to society of concrete research outcomes. The future commercialization and popularization in the market of the research outcomes and new knowledge or technologies obtained from research, or the endowment in society and the economy of the benefits of their incorporation in government services.

Japan and developing countries to take part in international joint research that can contribute to the resolution of global issues.

1.1.3 Policy Status of the Program

Carrying on from the 5th Science and Technology Basic Plan, in the 6th Science, Technology, and Innovation Basic Plan (March 2021, Cabinet decision) the following are recognized as major issues: global constraints on energy, resources, and food; environmental issues; domestic risks such as the declining birthrate and aging population, exhaustion of local economies and societies, and risk of natural disasters.

Accordingly, in concrete terms Japan needs to collaborate and cooperate with universities, public research institutions, and the business community, as well as other countries and international organizations, to promote R&D aimed at finding solutions to global issues. In addition, Japan needs to promote a wider application and adoption of research outcomes in and outside of Japan, and take the lead in achieving international consensus. Furthermore, the section on "Promotion of international joint research and international brain circulation" in the 6th Science, Technology, and Innovation Basic Plan states that the Japanese government will promote science and technology cooperation with emerging and developing countries regarding the Sustainable Development Goals (SDGs)[3] and contribute to the development of science and technology, human resource development, and the resolution of global issues, including medium- and long-term perspectives. The policy of the SATREPS program is also to contribute to the international community by proactively addressing SDGs.

In science and technology cooperation with emerging and developing countries, it is important to break away from the aid-driven forms of cooperation that have prevailed up until now and move instead towards strategically establishing frameworks for more equitable partnerships with these countries in order to facilitate the generation of socially inclusive and sustainable innovation ("inclusive innovation"[4]). It is also important to strengthen international human resource networks. Accordingly, in our science and technology cooperation with emerging and developing countries, Japan needs to develop systems for promoting inclusive innovation by pursuing collaborations with partner countries' governments, universities, public research institutions, funding agencies, and companies, as well as helping to foster young researchers and industry professionals in each country.

In addition, the 6th Science, Technology, and Innovation Basic Plan points out that in order to reinforce our foundation of science, technology and innovation, Japan needs to train and secure highly skilled personnel capable of generating new knowledge and values, as well as a diversified workforce that will accelerate the creation of innovation. At the same time, Japan needs to create environments that enable each individual to maximize their contribution in

---

[3] Sustainable Development Goals (SDGs): The outcome document "Transforming our world: the 2030 Agenda for Sustainable Development"— the key part of which is the Sustainable Development Goals (SDGs) as a new and more comprehensive, and universal action agenda for people, planet and prosperity—was adopted at the United Nations Sustainable Development Summit held in September 2015.

https://www.un.org/sustainabledevelopment/

[4] Inclusive innovation: Under the SATREPS program, attention is focused on the potential of developing countries in particular, and people in these countries are involved in the innovation process.

the most appropriate setting in accordance with their own capabilities and motivations. The SATREPS program is expected to develop Japanese human resources who can adapt to globalization through international joint research projects.

The crucial factors for advancing science, technology, and innovations effectively are enhancing efforts aimed at strengthening the functions of the various actors involved in science, technology, and innovation activities (such as universities, public research institutions, and companies) and expanding industry-academia-government partnerships.

The FY2022 solicitation for research proposals is seeking projects that incorporate these policies while meeting the aims of the SATREPS program.

1.1.4 The SATREPS Program Structure

With the cooperation of AMED and JICA, the SATREPS program promotes international joint research between Japan and developing countries targeting global issues, and 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 together with the recipient country research institution. (See Figure 1).

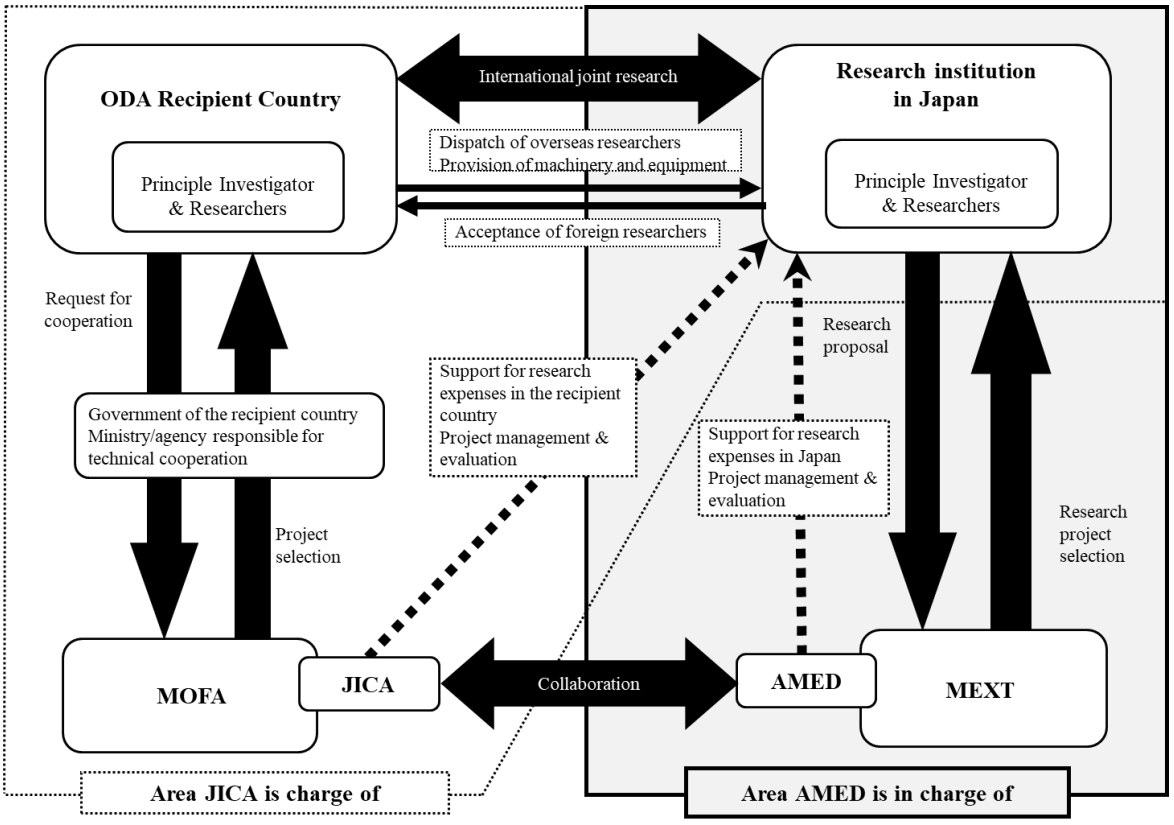


Figure 1. The SATREPS Program Structure

Specifically, AMED provides contracted R&D funds to support research expenses in Japan and outside of the recipient country, while JICA mainly bears the expenses necessary for the implementation of technical cooperation projects in the recipient country (including dispatch of researchers from Japan, acceptance by Japan of researchers from the recipient country, and provision of machinery and equipment). Management of R&D for international joint

research as a whole is conducted cooperatively between AMED, an agency supporting research in the medical field conducted by research institutions in Japan, and JICA, an agency implementing technical cooperation in developing countries. It is expected that the promotion of international joint research activities under this program will enable Japanese research institutions to conduct research more effectively using fields and targets in developing countries. Meanwhile, it is also hoped that research institutions in developing countries (universities and research institutions engaging in activities of a public nature, but excluding those related to military affairs) will be able to establish research bases and develop human resources through joint research activities, thereby making it possible to develop self-reliant, sustainable research systems.

1.1.5 The SATREPS Program Main Flow

(a) Solicitation of proposals and requests for technical cooperation

AMED solicits researchers at universities and research institutions in Japan to submit research proposals. Decisions on which research projects are to be selected are made by an Evaluation Panel comprising a Program Supervisor (PS), Program Officers (PO) and external experts.

In parallel with AMED's selection of proposals, MOFA accepts requests from developing countries for ODA technical cooperation projects conducting international joint research, and reviews these requests with JICA in Japan. Therefore, it is essential that the Principal Investigator (hereinafter referred to as "PI") in Japan thoroughly discusses the details of joint research with researchers in the recipient country before submitting the research proposal to AMED. It is also required that official requests for technical cooperation projects, clearly stating that they are for the SATREPS program, be submitted by the research institution in the recipient country and received by Japan's MOFA headquarters in Tokyo by the specified deadline, through the ministry or agency responsible for ODA in the recipient country and via the Embassy of Japan that handles affairs for the recipient country. As was the case last fiscal year, due to diplomatic considerations the number of requests from a single country is limited to a maximum of 12. If this number of requests is exceeded, the government of the recipient country will have to reduce the number of requests.

(b) Proposals adopted by AMED as research projects and by MOFA/JICA as technical cooperation projects

The selection process for research projects at AMED and the request review process for technical cooperation projects at MOFA/JICA are interlinked. In the case that a research proposal is deemed to be worthy of implementation as both a research project and as a technical cooperation project, the proposal will be provisionally selected as a research project. MOFA notifies the prospective recipient country of this decision. Figure 2 shows the processes taken by AMED and JICA under their respective frameworks.

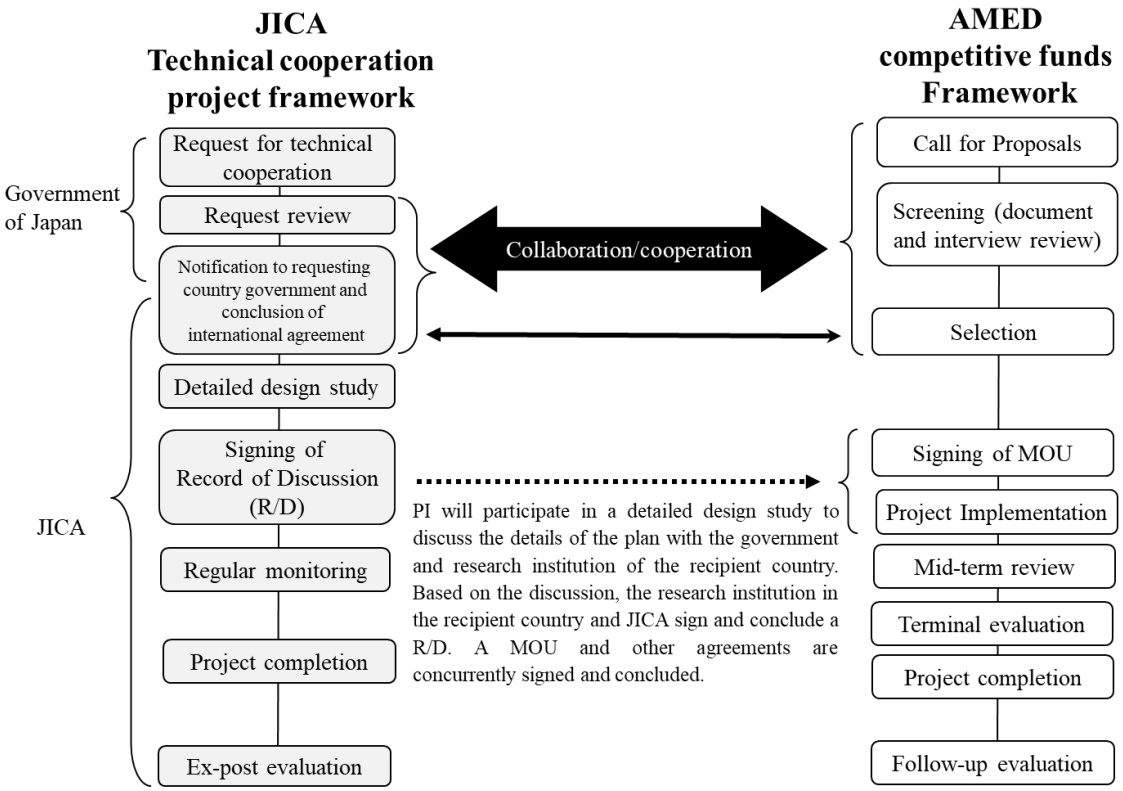


Figure 2. The SATREPS program flow from solicitation and selection through to implementation, evaluation and completion

(c) Preparations for implementing international joint research

To implement the international joint research, a Record of Discussions (hereinafter referred to as "R/D"), as an agreement for implementing the technical cooperation project, must be signed by the representative of a recipient country and JICA. In addition, a Memorandum of Understanding (hereinafter referred to as "MOU") regarding joint research, the details of which shall be consistent with the R/D and AMED's contracted R&D agreement, must be signed between the research institutions (the parties concerned). Since both processes are required to conduct joint research, the PI and other research participants are requested to complete the above procedures immediately after receiving notification of provisional selection.

After giving notification that a research project has been provisionally selected, AMED concludes a contracted R&D agreement with the PI's institution in Japan. This enables AMED to make contracted R&D 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. Only the expenses requisite for the preparation of joint research within Japan shall be provided before the R/D is signed.

JICA sends to the recipient country an investigation team composed of the PI in Japan and other members, in order to verify the background and details of the request and discuss the content of the joint research (this is called the "detailed design study"). During this study, the investigation team summarizes the details of the agreement in a Minutes of the Meeting (hereinafter referred to as "M/M") and the M/M is signed between JICA and the recipient

country. JICA then creates an R/D based on the M/M. Once the R/D is signed by the Chief Representative of the JICA overseas office and a representative in the recipient country, the technical cooperation project is launched.

However, if the R/D and MOU are not signed before the end of the fiscal year in which the project is provisionally selected (the end of FY2022) and the R/D and MOU are not likely to be signed in the near future, they shall be regarded as invalid. In such cases, the international joint research cannot be implemented even if a research project has been provisionally selected or a provisional contracted R&D agreement concluded. Please be aware in advance that pursuant to the provisional contracted R&D agreement, AMED's contracted R&D funds shall no longer available from the time of the agreement being deemed invalid.

(d) Implementation of the international joint research

When implementing an international joint research project under the SATREPS program, the PI and other research participants shall act in accordance with the contract with AMED (contracted R&D agreement) and the contracts with JICA (the Agreement Regarding the Implementation of Technical Cooperation under the Framework of SATREPS (hereinafter referred to as "the Agreement") and the project contract[5]). The PI shall be responsible for supervising the research project and its management as a whole. The PI does not necessarily stay in the recipient 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 on as near as possible a permanent basis in the role of an expert (designated under this program as an "overseas researcher" (Japanese researcher dispatched to foreign countries)).[6, 7.]

(e) Human resource development

- Possibility of human resource development through the Japanese Government (MEXT) Scholarship Program

---

[5] The Agreement Regarding the Implementation of Technical Cooperation under the Framework of SATREPS (the Agreement) is a comprehensive document stipulating the rights and obligations of JICA and the PI's institution (Principal Institution). In order to implement a SATREPS research project, JICA and the Principal Institution shall conclude the Agreement when the R/D for the institution's first adopted project is signed. In addition, JICA and the Principal Institution shall conclude a project contract to clarify the details of expenses that JICA bears and mutually verify the estimated amounts and accounting procedures (JICA will have a contractual relationship only with the Principal Institution, not with other joint research institutions.)

[6] An overseas researcher dispatched to the recipient country does not necessarily have to be the PI. Other members of the Japanese research team necessary for the joint research are also eligible for dispatch. However, undergraduate and graduate students are not eligible to be dispatched as "overseas researchers."

[7] In ordinary technical cooperation projects, JICA solicits applications from the public for the position of project coordinator, hires and stations them in the recipient country to provide support to experts in monitoring technical cooperation projects and other works, and to manage overseas project support expenses (local operating expenses) or to support procurement of machinery and equipment by the local JICA office. JICA similarly stations project coordinators in the recipient country for the SATREPS program. Project coordinators cannot simultaneously participate in research work. It should be noted that an alternative format is available in which JICA does not dispatch project coordinators and instead allocates indirect costs to a Principal Institution and entrusts them with comprehensive contract execution including local work.

The Japanese Government (MEXT) Scholarship Program (via university recommendation) secures the slots for those engaged in projects selected for the SATREPS program. The aim of the SATREPS slots is to facilitate the development of young researchers with the potential to be future key players in relevant research in their own countries by their conducting research or studying as an international student and taking a doctorate at a Japanese research institution. Solicitations for this Japanese government scholarship program are implemented by MEXT, and the scholarship is budgeted separately from the SATREPS program. 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 situation regarding budget appropriation.

- The Japanese Government (MEXT) Scholarship Program

https://www.mext.go.jp/a_menu/koutou/ryugaku/boshu/1330944.htm

- Acceptance of foreign researchers

In addition to the Japanese Government (MEXT) Scholarship Program, there is also an Acceptance of Trainees system (called “acceptance of foreign researchers” in the SATREPS program) for inviting researchers from recipient countries to Japan using the ODA budget. Under this system, researchers at research institutions carrying out international joint research in recipient countries are invited to Japan for the purpose of carrying out research. To be eligible to participate in this system, researchers must be expected to play a long-term key role at their research institutions in the recipient countries after returning from Japan and be regarded as indispensable for promoting joint research. Please note that as a general rule, acceptance of foreign researchers is premised on the condition that the foreign researcher’s research work in Japan concludes within the cooperation period stipulated in the R/D.

However, given the current situation regarding the spread of COVID-19 both in Japan and overseas, as of August 2021 entry of foreign nationals to Japan has been suspended except in “special circumstances.” If it is impossible for trainees to come to Japan, it will be necessary to take measures such as providing training remotely or postponing the trainees’ visit to Japan.

*URLs for the major science and technology policies related to the program are as follows:

Toward the Reinforcement of Science and Technology Diplomacy (May 19, 2008, Council for Science and Technology Policy)

https://www8.cao.go.jp/cstp/english/doc/s_and_t_diplomacy/20080519_tow_the_reinforcement_of.pdf

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

https://www8.cao.go.jp/cstp/sonota/kagigaiko/8kai/siryo1-1.pdf (in Japanese)

Recommendation for the Future: STI as a *Bridging Force* to Provide Solutions for Global Issues— Four Actions of Science and Technology Diplomacy to Implement the SDGs— (May 12, 2017, Advisory Board for the Promotion of Science and Technology Diplomacy)

https://www.mofa.go.jp/files/000255801.pdf

The 6th Science, Technology, and Innovation Basic Plan (March 26, 2021, Cabinet decision)

https://www8.cao.go.jp/cstp/english/sti_basic_plan.pdf

Integrated Innovation Strategy 2021 (June 18, 2021, Cabinet decision)

https://www8.cao.go.jp/cstp/tougosenryaku/togo2021_honbun.pdf (in Japanese)

Sustainable Development Goals (SDGs) (September 2015, United Nations Sustainable Development Summit 2015)

https://sdgs.un.org/goals

The SDGs Implementation Guiding Principles (December 22, 2016, SDGs Promotion Headquarters decision)

https://www.mofa.go.jp/files/000252819.pdf

The Healthcare Policy (March 27, 2020, Cabinet decision/April 9, 2021, partial revision)

https://www.kantei.go.jp/jp/singi/kenkouiryou/suisin/ketteisiryou/kakugi/r030406senryaku.pdf (in Japanese)

1.1.6 R&D Period and Expenses

(a) R&D period

The period of international joint research (cooperation period to conduct the technical cooperation project set forth in the R/D) is from three to five years (the period from the official launch of the joint research following the conclusion of the R/D and MOU, not including the provisional period).

As shown in Figure 3, within the limits of the budget for AMED contracted R&D funds determined at the time of selection, the R&D period of the Japanese side funded by AMED contracted R&D funds may extend up to the end of the last fiscal year of the international joint research set forth in the R/D (however, payment of expenses incurred by the ODA side is not possible after the cooperation period specified in the R/D ends.). Following selection of research projects, even before the signing of the R/D, MOU and other agreement documents, AMED contracted R&D funds are available to the Japanese side as research expenses limited to use for research preparations in order to launch the international joint research immediately after the signing of these documents.

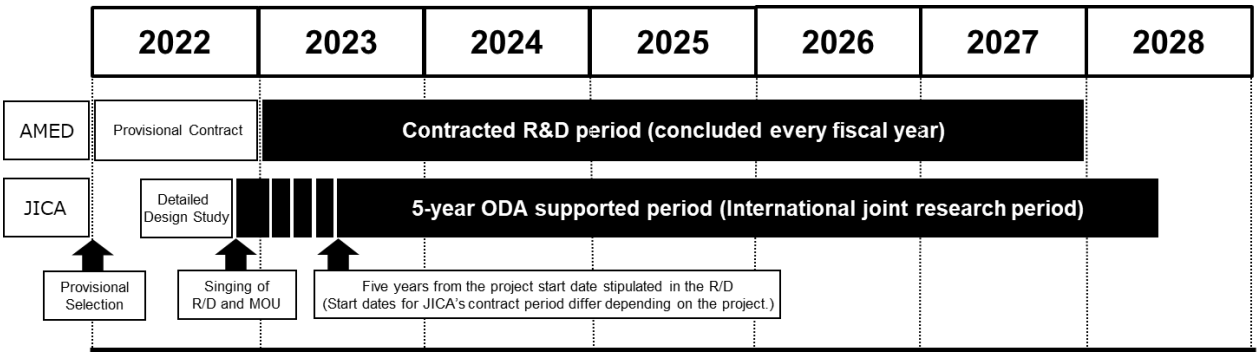


Figure 3. R&D period (in the case of 5-year contracted R&D period)

(b) Research funds (AMED contracted R&D funds and ODA project funds)

Research expenses incurred in Japan and outside of the recipient country are supported by AMED contracted R&D funds, and expenses necessary for technical cooperation project implementation (dispatch of the Japanese researchers, acceptance of the recipient country researchers, provision of machinery and equipment, etc.) are borne by JICA. As shown in Table 1, the total expense covered by AMED and JICA is around 90 million yen per year per project.

Funds provided by AMED and JICA Around. 90 million yen per year for each project (including indirect costs)	
AMED: Contracted R&D funds	**JICA: ODA technical cooperation funds**
Around 32 million yen per year (Final fiscal year: around 20 million yen per year) (For a five-year project, max. 154.5 million yen including expenses during the provisional period)	Around 60 million yen per year not including indirect costs (Max. 300 million yen over 5 years) Around 70 million yen per year including indirect costs (Max. 350 million yen over 5 years)

Table 1. AMED and JICA funds

During the provisional period, a ceiling of 6.5 million yen (including indirect costs) is set for expenses until the R/D and MOU are signed. The expenses for the contracted R&D period are around 32 million yen per year, including indirect costs (around 20 million yen for the final fiscal year), but the expenses for each fiscal year may be adjusted slightly depending on the research plan. However, please ensure that total expenses do not exceed 154.5 million yen for a five-year research plan, 122.5 million yen for a four-year research plan, and 90.5 million yen for a three-year research plan (including indirect costs and provisional period expenses). Furthermore, this solicitation for research proposals is premised on the FY2022 government budget being approved, and there is a possibility that the content may change. For this reason, please understand that the total amount is merely a guide for calculating your R&D funds plan. Changes or adjustments to the scale of R&D funds may be necessary depending on the situation regarding budget appropriation.

As a general rule, AMED allocates the total amount of research funds (contracted R&D funds) to the research institutions with which the PI and Co-Investigators are affiliated, and the research institutions in question execute the funds. Based on the contracted research agreement, AMED pays the research institutions contracted research funds, which comprise research funds (direct costs) and indirect costs (30% of direct costs as a general rule). In addition, rules and guidelines unique to this program have been set for certain items in accordance with the contracted research agreement, Administration Manual for Contracted R&D Agreement, and governmental ministries' and agencies' expenditure tables, etc. Furthermore, there may be differences in the handling of some items between universities, etc. (universities, public research institutions, public interest corporations, and other organizations that are recognized by AMED) and companies, etc. (mainly research institutions of private companies other than those of universities, etc.).

In accordance with the governmental ministries' and agencies' expenditure table used in common for the competitive research funds, items of expenditure have been set for this program. With regard to the handling of expenses, please refer to section "8.2.1 Scope of Contracted R&D Funds."

As a guide, the ceiling for annual ODA project expenses for one project is 60 million yen per year and 300 million yen for five years if there are no indirect costs; 70 million yen per year with a ceiling of 350 million yen for five years if there are indirect costs. Also, concrete budget amounts for ODA project expenses are decided within the scope of the ceiling amounts stated above at around the time the project activity content is decided in accordance with the research plan following the detailed design study conducted after provisional selection of the project.

JICA ODA project funds are technical cooperation funds, and the project contract has the nature of contracting Principal Institutions to carry out the technical cooperation duties that JICA ordinarily performs. Accordingly, the use and disbursement supervision of these funds may differ greatly from other research subsidies or grants. Please carefully read section "1.1.7 Outline of Technical Cooperation through ODA" regarding the type and scope of available expenses as well as project contract conditions.

(c) Division of expenses between AMED and JICA

As a general rule, research expenses are categorized into those covered by AMED under contracted research funds and those covered by JICA. Please also refer to Table 2.

A. Research expenses incurred in Japan and outside of the recipient country will be covered by AMED's contracted R&D funds.

B. Costs incurred in the recipient country (research activity costs, machinery and equipment procurement costs, etc.) and expenses for inviting researchers from the recipient country to Japan (round-trip and accommodation expenses, domestic travel expenses, partial acceptance costs) are, as a general rule, covered by JICA.

C. As a general rule, round-trip and accommodation expenses (for those who are dispatched for more than one year, round-trip expenses, transfer allowance, other allowances, etc.) are covered by JICA. Activities related to international joint research undertaken by researchers from Japan within the recipient country will be governed by the provisions on tax immunity and permission for activities prescribed in the R/D, etc. concluded for promoting joint research between JICA and the recipient country's research institutions.

When SATREPS project team members are dispatched to the recipient country, JICA does not cover any supplementary personnel costs, overhead costs, or in-country salaries (which are paid directly to the team member as a fixed monthly salary when he/she is affiliated with an institution but not paid) that are incurred by the researchers' affiliated institution in Japan. Similarly, this applies when the researchers' affiliation is a company or NGO, etc.

Recipient countries are required to make self-supporting efforts as the JICA funds are allocated for the purpose of assisting recipient countries' autonomous development through ODA technical cooperation projects. Accordingly, personnel costs in the recipient country, office rental costs in the recipient country, consumables used in the recipient country, costs for operating, maintaining, and managing supplied machinery and equipment, travel expenses in the recipient country for recipient country researchers, and meeting allowance are as a general rule to be paid by the recipient country in accordance with the items agreed to in the R/D.

Expenses	AMED	JICA
A: Research expenses incurred in Japan	●	
A: Research expenses incurred outside of the recipient country (Travel expenses to a third country, on-site expenses, etc.)	● *1	
B: Activity costs incurred in the recipient country	▲ *2	● *3
B: Travel expenses for inviting researchers from the recipient country to Japan	▲ *4	●
C: Travel expenses between Japan and the recipient country	▲ *5	●

Table 2. Categories of expenses covered by AMED and JICA

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

Note 2. Limited to travel and accommodation expenses, and other expenses incurred in the recipient country that cannot be covered by JICA but are recognized as being an extension of research being conducted in Japan and may be covered by AMED contracted R&D funds.

Note 3. Research expenses incurred in the recipient country include equipment, research supplies, and consumables required for the Japanese researchers to conduct international joint research in the recipient country.

Note 4. Limited to travel expenses for inviting external experts, etc., who are not part of the recipient country's research team.

Note 5. Limited to the travel expenses of students, external experts, etc., who cannot be dispatched to the recipient country as JICA experts.

When companies, etc., submit an application as the Principal Institution for a project, the categories of expenses covered may differ from the explanation provided above. Please check with AMED/JICA in advance for details.

1.1.7 Outline of Technical Cooperation through ODA

1.1.7.1 What is Official Development Assistance (ODA)?

Official Development Assistance (ODA) is a means of cooperation using public funds in the form of financial support and technical cooperation provided by donor governments or their implementing agencies to developing countries with the aim of contributing to the promotion of economic and social development as well as the improvement of people's welfare and stabilization of people's livelihoods in these countries. Japan began providing development aid after joining the Colombo Plan (a cooperation organization launched in January 1950 for the purpose of promoting economic and social development in South and Southeast Asian countries, and countries in the Pacific region) in 1954, and has been providing economic and technical cooperation to developing countries ever since.

The Japanese government has set forth the philosophy, priority policies, and implementation arrangements for implementing ODA in the Development Cooperation Charter (February 2015), which states 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," and that "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."

1.2.7.2 What is Technical Cooperation?

JICA aims to contribute to the promotion of international cooperation and sound economic and social 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 (technical cooperation projects, acceptance of trainees, expert dispatch, provision of machinery and equipment, etc.), bilateral government loans, grant aid, the promotion of cooperation activities by Japanese nationals (dispatch of JICA Japan Overseas Cooperation Volunteers, etc.) and international disaster relief.

Technical cooperation provides technical assistance in order to support developing countries in their comprehensive and self-motivated cultivation of the capacity to address development issues independently through institution building, institutional development and human resource fostering, according to the international agreements made with them.

A technical cooperation project, one type of technical cooperation, is a key project for technical cooperation to implement an optimal mix of measures including acceptance of trainees, expert dispatch and provision of machinery and equipment. In collaboration with stakeholder agencies in developing countries, JICA systematically and comprehensively manages and implements a project plan from planning to implementation and evaluation in order to achieve more robust outcomes.

The SATREPS program promotes joint research between research institutions in Japan and research institutions in recipient countries using the technical cooperation project framework. The SATREPS program is expected to implement international joint research projects, as part of ODA projects, that aim to utilize research outcomes for the benefit of society.

For more details of the implementation of the SATREPS project, please refer to the following:

JICA Implementation Guide for Science and Technology Research Partnership for Sustainable Development (SATREPS) Projects

https://www.jica.go.jp/activities/schemes/science/form/ku57pq00000nj5mf-att/general_01.pdf (in Japanese)

1.1.7.3 Requirements of an ODA Program

As explained in the previous section, technical cooperation projects aim to contribute to the economic and social development of developing regions and to promote the sound growth of the international community, and in implementing such projects, it is imperative that the project be managed and carried out systematically and comprehensively. Similarly, the SATREPS program emphasizes resolution of issues facing developing countries utilizing research outcomes as well as the implementation system on not only in Japan but also in the recipient country and its sustainability after the project has completed. Accordingly, please take especial care with the following points when formulating your research proposal.

- Is the research cooperation in line with the country assistance policy for respective countries, and does the recipient country have high priority/needs for the research theme to be addressed?
  - * For information about the Country Assistance Policy for Respective Countries, please refer to the MOFA website. (https://www.mofa.go.jp/policy/oda/assistance/country2.html)
- Is the project constructed so as to "conduct research and utilize its research outcomes in society," and does the project plan include measures to develop human resources and improve organizational capabilities in the recipient country?
  - * The content of the research cooperation must include not only research activities but also utilization of research outcomes in society (content, timeframe, system, method, and prospects of being realized).
- Is the research cooperation location safe and secure?
  - * For information regarding the safety of the research cooperation location, please refer to the MOFA website. (https://www.anzen.mofa.go.jp, in Japanese).
- Are the research institution/relevant government ministry or agency responsible for ODA or related organizations in the recipient country appropriate for carrying out the research activities and utilizing the research outcomes in society, and has the recipient country's understanding been obtained sufficiently?
  - * If the research institution in the recipient country is unable to sufficiently utilize or diffuse the research outcomes in society, a private sector company or public organization in the recipient country that is capable of providing

support for the utilization and diffusion of the research outcomes must also participate in the project.

- Are the content and approach of the research activities appropriate for achieving the initial goals at the end of the research cooperation period/outcomes that should be achieved three to five years after the research cooperation ends?
- Is the plan for utilizing the research outcomes in society clear and feasible?
  * While it is possible that not all research outcomes will be utilized in society during the research cooperation period, a concrete utilization of research outcomes plan (body to promote/diffuse research outcomes in society, implementation system, recipient country activities, blueprint for spreading research outcomes to other regions and markets) for utilizing the research outcomes to be implemented during the research period—such as how the expected research outcomes stated in the research plan are to be utilized in society—must be formulated.

1.1.7.4 Stance Regarding Medical Procedures Carried Out in Partner Countries by SATREPS Program Personnel

With regard to SATREPS projects in the field of infectious diseases, proposals for joint research including the performance of medical procedures by SATREPS program personnel[8] in the partner country have been eligible for selection for the SATREPS program on a trial basis since the FY2020 solicitation for research proposals. However, such research proposals must fulfill all of the requirements stipulated in items (a) – (c) below, and JICA will determine whether or not the performance of medical procedures are appropriate based in the consultation results shown in (b). In addition, as a general rule a researcher who is a national of a third country (not Japan or the relevant partner country) is not allowed to perform medical procedures as part of a SATREPS project. Furthermore, joint research involving clinical trials, etc.,[9] conducted in the partner country, as before, are not eligible for adoption under the SATREPS program.

(a) Definition of medical procedures under the SATREPS program

Medical procedures carried out under the SATREPS program are defined as procedures that can only be performed by a licensed medical professional[10] under the laws of Japan and the partner country. This definition includes not only invasive procedures but also diagnostic examinations, medical examinations/check-ups, rehabilitation, etc. However, as a general rule it does not include instruction/training, etc., given to local medical professionals, that are related to medical procedures performed outside a clinical setting.

(b) Consultation prior to application

PIs who are planning to submit a research proposal including medical procedures to be performed by SATREPS program personnel in the partner country as part of a joint research project as well as persons performing medical

---

[8] SATREPS program personnel refer to researchers, etc. who have been dispatched by the Principal Institution in Japan (including joint research institutions) to work on a SATREPS project (including those whose expenses are not being covered by JICA).

[9] Clinical trials, etc. include not only company-sponsored or investigator-initiated trials but also clinical research, etc. conducted by researchers using unapproved drugs and/or medical devices.

[10] In Japan, this applies to medical qualifications obtained by passing a national examination administered under the jurisdiction of the Ministry of Health, Labour and Welfare (MHLW). For details, please refer to the MHLW website.
https://www.mhlw.go.jp/kouseiroudoushou/shikaku_shiken/index.html (in Japanese)

procedures[11] must consult with JICA prior to submitting their application. PIs and persons performing medical procedures to whom this applies should contact JICA (gpgsd@jica.go.jp) to request consultation no later than one month prior to the deadline for submission of applications to AMED. During consultation, JICA staff will check whether or not the project fulfills the requirements for implementation stipulated in (c) as well as the necessity for medical procedures to be carried out by SATREPS program personnel; the partner country's healthcare situation and healthcare system; existence and details of the partner country's legal system, ethical standards, and medical lawsuits; suitability of the persons performing medical procedures; whether or not insurance related to medical procedures can be taken out. Please note that research proposals (for projects that include medical procedures to be performed by SATREPS program personnel) that are submitted without the project's PI/persons performing medical procedures undergoing consultation beforehand will be ineligible for selection for the SATREPS program.

(c) Requirements for implementation of joint research including medical procedures performed by Japanese nationals

When a Japanese national is to perform a medical procedure as part of joint research under the SATREPS program, all of the following requirements must be fulfilled.

(i) The SATREPS program personnel to perform the medical procedure is recognized as having the qualifications required to perform the medical procedure in the partner country or has written permission from the partner country (central or regional government) to perform the medical procedure. In addition, the SATREPS program personnel must comply with the laws, regulations, and ethical guidelines with which the governments of Japan and the partner country require compliance when medical research on human subjects is being conducted.

(ii) An international agreement has been concluded (please refer to Section "1.1.7.6 Flow Prior to Commencement of the Technical Cooperation Project"). In addition, exemption from liability for JICA and SATREPS program personnel is assured in practical terms through a written agreement with the competent authority in the partner country. The Principal Institution in Japan, which is the applicant, confers with the competent authority in the partner country (the Ministry of Health, etc. in the case of a public institution; the Ministry of Health or a private hospital in the case of a private institution) regarding exemptions from liability. Among the competent authority in the partner country, JICA, and the Principal Institution and joint research institution in Japan involved in the medical procedure (hereinafter referred to as the "Principal Institution, etc."), etc. a legally binding written agreement is then concluded where in the event that JICA, the Principal Institution, etc. or the personnel dispatched by the Principal Institution, etc., are held responsible for a medical accident, etc. except in the case of bad faith or gross negligence by JICA, the Principal Institution, etc., or personnel dispatched by the Principal Institution, etc., the competent authority in the partner country is held responsible in place of JICA, the Principal Institution, etc., or personnel dispatched by the Principal Institution, etc. (Medical procedures are not allowed to be performed prior to the conclusion of the written agreement.)

[11] Person performing medical procedures: A provider of medical procedures, such as a researcher, who has been dispatched by the research institution in Japan.

(iii) JICA and persons performing medical procedures conclude a contract (including agreements, etc.) stipulating that in the event that persons performing medical procedures face civil or criminal liability for medical malpractice, etc. due to bad faith or gross negligence, full responsibility is born by the persons performing medical procedures and no claims will be made on JICA.

(iv) Performance of medical procedures is premised on informed consent[12] being obtained from the patient and/or their family members.

1.1.7.5 System for Implementing Technical Cooperation Projects

Technical cooperation projects are joint projects implemented together with the recipient country. Ownership by the recipient country is important in terms of encouraging the recipient country's self-motivated development, and the recipient country PI has important duties and obligations on par with that of the Japanese PI (please refer to Figure 4). Furthermore, to ensure that implementation of the joint research proceeds smoothly, as a general rule a Joint Coordinating Committee (JCC) should be established. Membership of the JCC should comprise representatives of both Japan and recipient country (Japan: Embassy of Japan in the recipient country, Chief Representative of JICA overseas office, PI, researchers. project coordinators, etc.; recipient country: ministry/agency responsible for ODA, ministry/agency overseeing the research institution, related ministries/agencies, research institutions, etc.) and hold meetings regularly to facilitate discussion and resolution of common issues. Given that the SATREPS program aims to promote international joint research cooperation, it is appropriate that the JCC is operated jointly by Japan and the recipient country. The system for implementing technical cooperation projects is explained below.

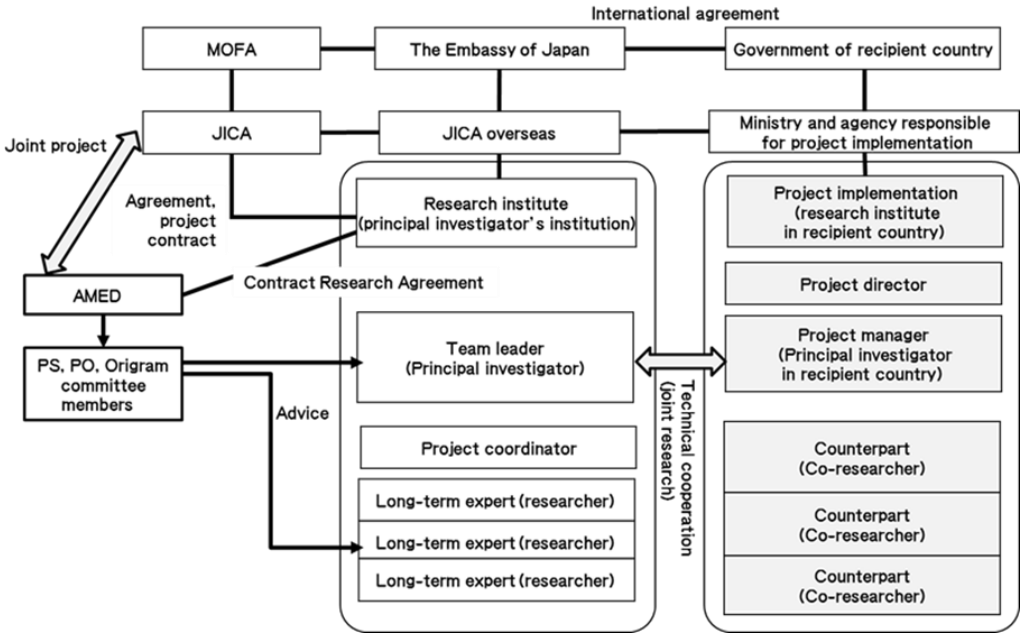


Figure 4. The framework for implementing a technical cooperation project

[12] Although the informed consent system differs from country to country and does not even exist in some countries, the patient or person undergoing examination must be given sufficient explanation regarding the content and risks of the medical procedure and their consent to the procedure must be obtained in writing.

1.1.7.6 Flow Prior to Commencement of the Technical Cooperation Project

(1) From submission of a request for cooperation to examination and selection of a project

JICA's technical cooperation is initiated following the receipt of requests from developing countries and implemented in accordance with a specific flow.

Japan's ODA involves a process called a "request survey," in which requests for new projects to be implemented in the next fiscal year onward are examined in the fiscal year before their implementation. In this process, a research institution in a recipient country prepares a request for technical cooperation, gains approval from the competent authority, submits the request to the Embassy of Japan in the recipient country via the ministry or agency responsible for ODA. The Embassy of Japan then forwards the request with other required documents to Japan's MOFA headquarters in Tokyo. The last part of this process is called a "request for cooperation."

When a request for cooperation has been received by MOFA, the Japanese government considers whether or not to select the project requested. If the project is deemed to be appropriate for implementation, notification of the project's selection is sent to the recipient country's government via the Embassy of Japan and an international agreement is subsequently signed between Japan and the recipient country.

The process for selecting projects for the SATREPS program only considers projects for which both a request for cooperation from the recipient country and a research proposal from the Principal Institution in Japan have been received (projects for which only one of these documents has been received are ineligible for consideration). Candidate projects are considered by an evaluation panel established by AMED, and notification that a project has been selected is sent from the Japanese government to the relevant recipient country government via the Embassy of Japan in the recipient country. As mentioned above, selection is provisional until the Record of Discussions (R/D) has been signed.

Furthermore, given that the SATREPS program is aimed at targeting global issues, research proposals may also be submitted for projects involving joint research with multiple recipient countries. However, in the case of research proposals for projects involving joint research with multiple recipient countries, if the requests for cooperation from all the recipient country governments are not received by Japan's MOFA headquarters in Tokyo by the submission deadline, the research proposal will be deemed to have not fulfilled the requirements for selection and become ineligible for selection. Moreover, in order for the research to commence, an R/D must be signed with all of the relevant countries.

All requests for cooperation regarding the SATREPS program for FY2022 must be received by Japan's MOFA headquarters in Tokyo **no later than Friday, October 29, 2021 (Japan Standard Time)**.

Please note that **recipient country governments usually set an application deadline before the above-mentioned deadline**, so please bear this in mind when negotiating requests with research institutions in recipient countries. As with the deadline for research proposals submitted via the e-Rad system, requests received after the deadline will not be considered for selection.

In addition, even if a request for technical cooperation has already been submitted prior to FY2021, the recipient country must submit a new request for technical cooperation for project applications being submitted for the FY2022 solicitation for research proposals. Please note that if the request for technical cooperation for a project is not received by Japan's MOFA headquarters in Tokyo by the submission deadline, the project will become ineligible for selection

even if the research proposal has been submitted.

(2) Implementation of a detailed design study

As stated above, JICA will conduct a detailed design study after notification of the project's selection has been sent by the Embassy of Japan to the recipient country government and an international agreement has been concluded. The detailed design study is to examine the current status and issues of the field for cooperation and the background to a request for cooperation. During the process, JICA discusses with the recipient country stakeholders the basic project plans, implementation structure and responsibilities of Japan and the recipient country; what was discussed is summarized in a Minutes of Meeting (M/M); the M/M is signed by the both parties. The PI who manages the Japan research team is required to participate in the detailed design study, in which the expected results obtained through cooperation are more clearly identified, and an ex-ante evaluation is concurrently performed to comprehensively examine the appropriateness of the project.

If the study discovers significant problems concerning the recipient country's implementation structure or its responsibilities, etc. and it is judged that these 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 of the Record of Discussions (R/D)

After conducting a detailed design study, JICA simultaneously carried out procedures for approving implementation of the project and prepares the Record of Discussions (R/D) (an agreement regarding the project's implementation, activity content, and necessary measures), which is then signed by JICA and the recipient country institutions implementing the project. At the time the R/D is signed, JICA also prepares a Project Design Matrix (PDM) showing the causal relationships (logical framework or log frame) among the project's inputs, activities, outcomes, and goals as a technical cooperation project, maintaining consistency with the project's research plan, and a Plan of Operation (PO), as well as defines the cooperation period for the project, and submits these to the recipient country. The PDM and PO are attachments to the R/D. Under the SATREPS program, selection of a provisionally selected project is made official upon the signing of the R/D.

*Please refer to Chapter 5 of the Project Management Handbook (JICA Ogata Research Institute) for information regarding the PDM and Chapter 6 for information regarding the PO.
https://www.jica.go.jp/jica-ri/IFIC_and_JBICI-Studies/jica-ri/publication/archives/jica/field/200712_aid.html (in Japanese)

Typical timeframes for (2) and (3) are as follows.

Item	Typical timeframe
Preparation of a detailed design study (meetings, conclusion of contracts with consultants responsible for evaluation analysis, procedures for dispatching survey team, response policy meetings, etc.)	Around 2.5 months
Detailed design study (local survey), signing of the M/M, debriefing meeting in Japan	Around 0.5-1 months

Ex-ante evaluation by JICA	Around 1.5-2 months
Signing of the R/D (between the Chief Representative of JICA overseas office and head of the competent authority or research institution in the recipient country)	Around 0.5-2 months

1.1.7.7 Flow after Commencement of the Technical Cooperation Project

(1) Documents concluded between JICA and the Principal Institution

After conclusion of the R/D, in addition to contracted research agreements the Principal Institution selected for the SATREPS program concludes **three documents** with JICA: **(1) an Agreement Regarding the Implementation of Technical Cooperation under the Framework of SATREPS (hereinafter referred to as "the Agreement"), (2) an appendix to be attached to the Agreement, and (3) a project contract.** The Principal Institution acts as representative to JICA for all the project-related research activities, including those to be carried out by other Japanese research institutions, and so no research institutions other than the Principal Institution conclude these documents.

The Agreement clearly sets out the details of the work, duties and obligations, etc., of JICA, the PI, and the PI's institution with relation to the selected projects, and accordingly each organization is requested to manage joint research conducted in the recipient country. Moreover, only one Agreement shall be concluded between JICA and the PI's institution. That is to say, if an Agreement has already been concluded between JICA and the Principal Institution and there is an ongoing SATREPS project conducted by the Principal Institution, there is no need to conclude a new Agreement. However, even if an Agreement was concluded in the past, a new Agreement needs to be concluded if the SATREPS project has already been completed and no projects are being implemented at that time.

The appendix must be concluded for each project.

The project contract needs to be concluded every contract period during a five-year project period. For example, if the contract is divided into five contract periods, contract must be concluded and expenses settled every contract period.

(2) The Agreement

The Agreement stipulates the duties and obligations, etc., of both the Principal Institution and JICA. It states that the Principal Institution is responsible for dispatching Japanese researchers to the recipient country (including the activities of other Japanese research institutions), inviting researchers from the recipient country to Japan, and procuring machinery and equipment, and is also obligated to consider the safety and security of persons involved in the project. The Agreement further states that the PI's institution shall check the accounting regulations and other related regulations of the Principal Institution and apply these to expenses administered by the PI's institution itself.

For the Agreement form, please refer to the following website:

https://www.jica.go.jp/activities/schemes/science/form/ku57pq00000nj5mf-att/arrangements_01.pdf (in Japanese)

(3) Appendix

The appendix defines the project title and the project cooperation period.

For the appendix form, please refer to the following website:

https://www.jica.go.jp/activities/schemes/science/form/ku57pq00000nj5mf-att/arrangements_02.pdf (in Japanese)

(4) Project contract

i) **Introduction**

The R/D becomes the grounds of the project implementation. After the conclusion of the R/D, a project contract is concluded between JICA and the Principal Institution, and the project is started. It is possible to extend the project contract until the end of the project period specified in the R/D. Based on the contents of the project contract and in order to achieve the project's objectives, experts are dispatched (overseas researcher dispatch), trainees accepted (researcher acceptance), and machinery/equipment supplied, and other necessary inputs provided.

In addition, JICA monitors the project regularly based on the R/D and its attached documents, namely the PDM and PO, to check the progress of the project in terms of technical cooperation, whether research outcomes are being obtained, the degree of improvement of the items concerned at the time of project selection, and the feasibility of utilizing research outcomes.

JICA's spending shall be based on the project contract and JICA cannot fund any expenses associated with a project under this program before the project contract is concluded.

ii) **Preparation of a project plan for drawing up a project contract**

Project expenses are around 60 million yen per year per project if indirect costs are not included, with a ceiling of 300 million yen for a 5-year project. If indirect costs are included, project expenses are around 70 million yen per year per project, with a ceiling of 350 million yen for a 5-year project. This 300 million yen (or 350 million yen) includes expenses that are administered directly by JICA (for detailed information, please refer to the Implementation Guide for Science and Technology Research Partnership for Sustainable Development (SATREPS) Projects mentioned above), and so bear in mind that the 300 million yen (or 350 million yen) project expenses are the total of the project contract amount managed by the PI's institution added to the expenses directly administered by JICA.

Accordingly, JICA and the PI's Institution hold discussions for preparing the project contract and formulate an overall plan and plans for each contract period, including budgets. Plans for each contract period may be reviewed at the mid-point of the project contract periods based on the said plans in accordance with the project's progress. The duration for each contract period needs not necessarily be set to within one fiscal year but rather may cover several fiscal years. Furthermore, please make adjustments to ensure that various activities (from the procurement to the delivery of machinery and equipment, from the dispatch of Japanese researchers to their return to Japan, from the arrival of foreign researchers in Japan to their departure) do not stretch over multiple contract periods.

iii) **Details of project contract**

The project contract stipulates the project content, cost burden, and accounting procedures, and is concluded between JICA and the Principal Institution for each period plan, as mentioned above. These plans include the overall activities of the Principal Institution and other Japanese research institutions involved in the project. Expenses may be incurred only after the project contract has been concluded.

Based on the Agreement and project contract, the Principal Institution shall incur expenses and settle them within the project contract period in accordance with the Institution's rules and regulations. Furthermore, approximate advance payments may also be made during the contract period in addition to final payments.

For the project contract forms, please refer to the following website:

https://www.jica.go.jp/activities/schemes/science/form/ku57pq00000nj5mf-att/contract_01.pdf (in Japanese)

iv) **Expenses stipulated by the project contract**

Under the project contract, in general only the following costs are incurred and disbursed: (1) costs for dispatching oversees researchers (Japanese researchers) to the recipient country, (2) costs necessary for conducting on-site research, (3) costs for accepting foreign researchers (recipient country researchers) in Japan (4) costs for supplying machinery/equipment needed for joint research, and (5) direct administrative costs in Japan. In addition, in the case that the Principal Institution is planning to procure expensive machinery/equipment or construct facilities near the end of the project, if the period of use of the machinery/equipment after delivery or that of facilities after completion is less than one year, these orders many be suspended even if they have been included in the R/D or research plan.

There are two project contract patterns: "Including indirect costs" and "Not including indirect costs." The main differences between the two contract types is whether or not costs incurred for project coordinators (please refer to section "1.1.7.7 (5) Project coordinator") is included in the project contract and/or "Administrative costs in Japan" are included in the project contract. Indirect costs must be 30% or less of the total direct costs explained in (1) – (4) above.

- Not including indirect costs: JICA secures project coordinators and pays the expenses for dispatching them directly.
  Administrative costs in Japan are included in the project contract.
- Including indirect costs: The Principal Institution secures project coordinators and includes the expenses for dispatching them in the project contract.
  Administrative costs in Japan are not included in the project contract (paid out of indirect costs)

An outline of expense items that can be included in the project contract is provided below.

Item	Details
(1) Costs for dispatching oversees researchers (Japanese researchers) to the recipient country	Air fare, daily allowance, accommodation costs, sundry expenses, etc. (For researchers who are dispatched for more than one year, travel costs for dispatch and return, transfer allowance, other allowances, etc.)
(2) Costs necessary for conducting on-site research	Costs necessary for conducting on-site research (costs for purchasing goods, hiring local consultants, travel/transportation costs for Japanese researchers, etc.)
(3) Costs for accepting foreign researchers (recipient country researchers) in Japan	Air fare, daily allowance, accommodation costs, training expenses, etc. Acceptance period is classified into two types: short-term (less than one year) and long-term (one year and over)
(4) Costs for supplying machinery/equipment needed for joint research	Costs for purchasing, transporting, installing, and adjusting machinery and equipment to be provided to the government of the recipient country. From the standpoint of security trade control, the PI's institution carries out the entire process, from purchase through to

	transportation and installation. After the machinery/equipment has arrived in the recipient country, it is immediately handed over to the government of the recipient country and used in joint research. Does not include machinery/equipment used in Japan.
(5) Administrative costs in Japan (in the case only of project contracts not including indirect costs)	Personnel costs for part-time administrative workers, costs for office supplies, etc. (excluding expenditure for research purposes)

For the estimation form to be attached to the project contract, please refer to the estimation forms on the following website.

https://www.jica.go.jp/activities/schemes/science/form/index.html (in Japanese)

In addition, please refer to the above-mentioned the Implementation Guide for Science and Technology Research Partnership for Sustainable Development (SATREPS) Projects on the JICA website for policies regarding detailed items of expenditure, estimates, approximate advance payments, final payments, and other administrative procedures.

v) **Policy regarding recipient countries' responsibility to shoulder expenses**

Because of the focus on recipient countries' self-help efforts and their sustainability after projects have been completed, ODA projects generally require the recipient country to shoulder certain expenditures. **Please note that,** in line with this policy, **Japanese-side (JICA) does not offer financial support for all expenses incurred** under the SATREPS program as part of international cooperation through ODA, **but rather requires recipient countries to shoulder some expenses in order to promote their self-help efforts. Regarding the expenses to be borne by recipient countries, as explained in the section "(3) Signing of the Record of Discussions (R/D)" of "1.1.7.6 Flow Prior to Commencement of the Technical Cooperation Project" above, these are decided through discussion between the Japanese-side and recipient country-side and stipulated in the Record of Discussion (R/D).** The following are examples of expenses that recipient countries are required to shoulder.

Personnel costs for researchers and other relevant persons at research institutions in the recipient country, and staff employed directly by the relevant research institutions.
Rent and utility costs for project offices, which are the activity bases in the recipient country where the Japanese and recipient country research institutions collaborate.
Transportation fees, travel expenses (daily allowance and accommodation costs), and daily meeting allowance for domestic business trips required for regular work or research by researchers or other relevant persons at research institutions in the recipient country.
Costs for equipment, office supplies, facilities, etc. used for research activities, conducted solely by recipient country research institutions (no involvement by Japanese researchers).

Note that JICA requests that recipient countries shoulder expenses for facilities and equipment needed for joint research and utilize existing facilities and equipment, thereby focusing support on truly essential areas.

vi) **Management of expenses**

With regard to the Principal Institution's expenses under the project contract, excluding necessary expenses paid directly by JICA in the recipient country, expenses shall be managed in accordance with the rules and regulations of the Principal Institution based on the Agreement and the project contract concluded between the Principal Institution and JICA.

For technical cooperation projects, no funding is provided directly to the recipient country, and no financial assistance is provided for activities undertaken solely by research institutions in the recipient country.

No project funding is allocated directly to research institutions in recipient countries. There have been numerous cases of misunderstandings with recipient countries over this point in particular, so please be sure to provide sufficient explanation to recipient country institutions in advance.

(5) Project coordinator

JICA solicits applications from the public for the position of project coordinator, hires and stations them in the recipient country at the earliest possible date after the R/D is signed. Project coordinators' responsibilities include: support of on-site project monitoring; JICA expense management (including budget implementation); arrangements with the recipient country government, and administrative procedures regarding the dispatch of overseas researchers (Japanese researchers) to the recipient country and acceptance of the foreign researchers (recipient country researchers) in Japan; communication with the JICA Overseas Office regarding the procurement of machinery and equipment in the recipient country. The project coordinator is a member of the Japanese project team working together with Principal Institution researchers and co-researchers, although the project coordinator won't be involved in research activities. JICA requires the project coordinator to share information with the PI and other team members to ensure that the project is conducted smoothly and properly. JICA will dispatch a project coordinator only if a project contract does not stipulate the provision of indirect costs. If a project contract stipulates the provision of indirect costs, the Principal Institution employs a project coordinator using the funds stipulated in the project contract.

(6) Typical timeframe from conclusion of R/D to commencement of the project

Timeframe is as shown below.

Item	Typical timeframe
Implementation approval procedures following signing of the Record of Discussions (R/D); conclusion of Agreement, appendix, and project contract between JICA and the Principal Institution	Around 2 months
Procedures for selection/dispatch, etc., of project coordinators	Around 6 months

(7) Monitoring of projects

For technical cooperation projects, progress of the project is checked through regular monitoring carried out in accordance with the R/D and the PDM and PO (documents attached to the R/D).

Monitoring is performed over the duration of a technical cooperation project as part of the overall management of the project. Accordingly, the Japanese and recipient country research institutions, etc., carry out monitoring

jointly and create monitoring sheets.

For the project monitoring sheets, please refer to the Regular Monitoring section on the following website:

https://www.jica.go.jp/activities/schemes/science/form/index.html

For more information regarding JICA project monitoring, please refer to the Implementation Guide for Science and Technology Research Partnership for Sustainable Development (SATREPS) Projects (in Japanese) on the JICA website.

1.1.7.8 Countermeasures to Misconduct, etc.

In the event it is discovered that a Principal Institution or the research institutions contracted by the Principal Institution committed an act of misconduct when executing a project contract with JICA, were involved with anti-social forces or organized crime groups, or were in breach of the Guidelines on Ethical Conduct for JICA's Implementing Partners that JICA establishes, JICA shall impose penalty charges on the Principal Institution, cancel the project contract with the institution and take other necessary measures according to the Agreement Regarding the Implementation of Technical Cooperation under the Framework of SATREPS (revised on May 24, 2016, JICA decision) or the project contract. In addition, if the researchers who participated in a project committed an act of misconduct (including, but not limited to, fabrication, falsification, or plagiarism of data) and JICA becomes aware of such a fact, JICA shall take the necessary measures in line with the Guidelines for Responding to Misconduct in Research (August 26, 2014, MEXT decision).

1.1.7.9 Inquiries regarding ODA

(1) JICA Headquarters

The contact office for SATREPS at JICA Headquarters is the Office for Science, Technology and Innovation, and Digital Transformation in the Governance and Peacebuilding Department. Any inquiries regarding ODA project expenses or outline of technical cooperation through ODA should also be directed to this office. In addition, JICA actively accepts requests for individual consultation to enable applicants to deepen their understanding of ODA projects. Please note that requests for consultation are not accepted after the application period has begun. Please also refer to the following website. For inquiries regarding other matters related to the content of the Application Guidelines, please contact AMED.

Office for STI and DX, Governance and Peacebuilding Department, JICA

E-mail: gpgsd@jica.go.jp

https://www.jica.go.jp/activities/schemes/science/faq/index.html (in Japanese)

(2) JICA: domestic and overseas offices

A list of JICA domestic offices

https://www.jica.go.jp/english/about/organization/domestic/index.html

A list of JICA overseas offices

https://www.jica.go.jp/english/about/organization/overseas/index.html

(3) Websites on ODA and technical cooperation

MOFA ODA website

https://www.mofa.go.jp/policy/oda/

ODA policy and information by country and region

(The website offers information to check whether or not proposed research objectives are in line with Japan's ODA policy for the recipient country and related region.)

https://www.mofa.go.jp/policy/oda/region_index.html

JICA Technical Cooperation Projects

(The website outlines ODA technical cooperation projects.)

https://www.jica.go.jp/project/english/index.html

JICA Science and Technology Cooperation (The website is about science and technology cooperation including SATREPS)

https://www.jica.go.jp/english/our_work/science/index.html

JICA Library search

(When you search by project name, reports of the previous SATREPS projects (PDF format) can be viewed.)

https://libopac.jica.go.jp/top/index.do?method=change&langMode=ENG

Terminology of ODA

Ministry or agency responsible for ODA:

The partner/requesting country's ministry or agency acting as a contact point regarding assistance from other countries. The ministry or agency in question differs from country to 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 (ministry or agency responsible for ODA) of a country wishing to obtain technical cooperation to the Government of Japan. The Ministry of Foreign Affairs of Japan and JICA receive requests for technical cooperation 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 Japan's MOFA headquarters in Tokyo via the Embassy of Japan in the requesting country.

International agreement:

An agreement that stipulates the rights and obligations under international law and is concluded by actors authorized to conclude an international agreement including countries or international organizations.

Technical cooperation project:

Activities that aim 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 the set objectives.

Expert dispatch:

Dispatch of personnel from Japan to the recipient country to transfer technology, provide policy advice to counterparts (government officials and technicians to whom technical cooperation is offered) or to manage a project. In this program, Japanese researchers who conduct research in the recipient country within the framework of JICA expert dispatch are referred to as "overseas researchers," those who are dispatched for a period exceeding one year (from departure date to return date) are referred to as "long-term overseas researchers" and those who are dispatched for a period less than one year as "short-term overseas researchers." Procedures concerning the dispatch of short-term overseas researchers are undertaken by the PI's institution (associated expenses are included in the expenses stipulated in a project contract concluded between JICA and PI's institution). However, procedures for dispatching long-term overseas researchers are undertaken directly by JICA (associated expenses are not included in the expenses stipulated in the said project contract).

Acceptance of trainees:

Human resources development support implemented by accepting counterparts as trainees in Japan from recipient countries, and transferring expertise and technology in respective fields. In the SATREPS program, co-researchers invited from recipient countries are referred to as "foreign researchers," who are accepted as JICA trainees.

Ex-ante evaluation:

Comprehensive evaluations conducted prior to the implementation of cooperation, examining the appropriateness of technical cooperation by checking their priorities and necessities and identifying the content of

cooperation and expected outcomes. Evaluation indicators set in ex-ante evaluations are used as criteria to measure the progress and effects of cooperation at each phase.

Local costs:

Costs to be borne by the recipient country in implementing and managing the project. Local cost includes: personnel expenses, land acquisition cost, costs associated with collecting and transporting the machinery and equipment provided, recurrent costs (cost incurred repeatedly including costs of operation and maintenance of facilities built or machinery and equipment provided, and personnel costs).

Capacity development:

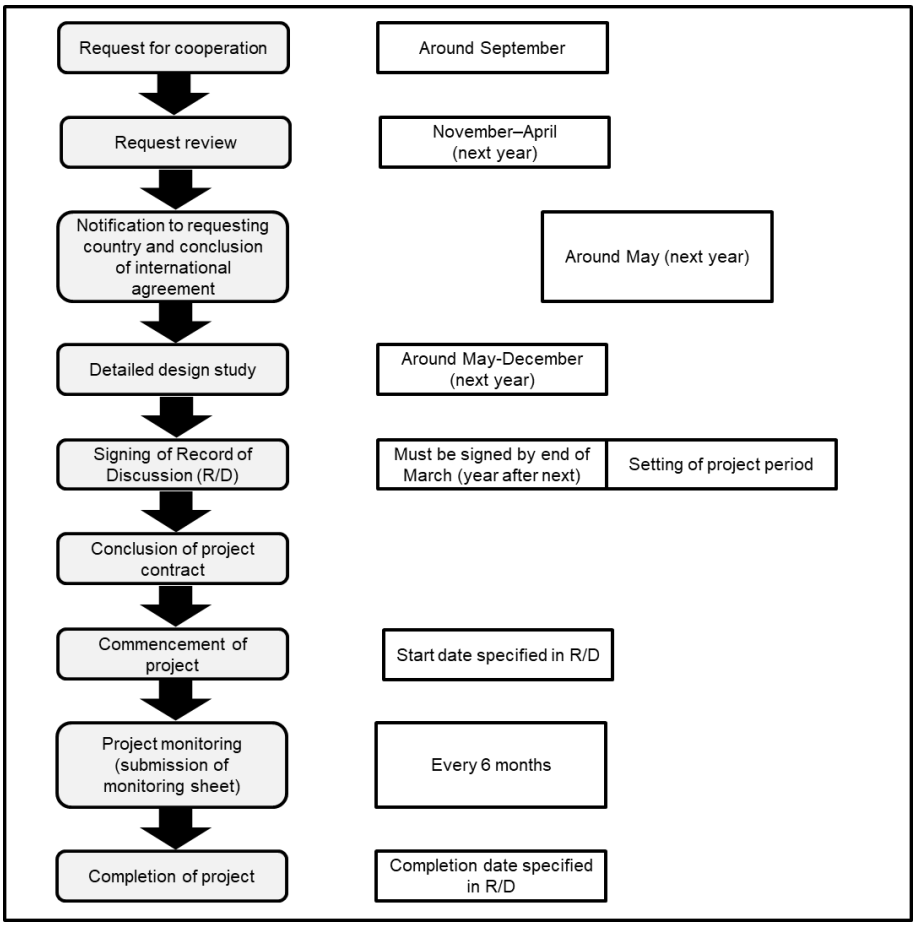
The process whereby developing countries strengthen their capabilities (capacity) to address their development issues. In contrast to "capacity building," whereby capabilities are strengthened from outside, "capacity development" addresses a developing country's capacity comprehensively on multiple levels—individuals, organizations, systems, and society—in a process that encourages the developing country to take the initiative in improving their country's capacity. JICA cooperation takes the form of providing lateral support for developing countries' capacity development in the role of facilitator.

https://libopac.jica.go.jp/top/index.do?method=change&langMode=ENG

At the above-mentioned JICA library search webpage, it is possible to search and view materials related to capacity development. Entering "capacity" in a search window enables the "Capacity Assessment Handbook" (URL below, in Japanese) and other materials to be viewed.

https://libopac.jica.go.jp/images/report/P0000245021.html (in Japanese)

Overall flow of technical cooperation projects



1.1.8 Duties and Obligations of PIs, etc., Selected for the SATREPS Program

From the moment that the research proposal has been provisionally selected for the SATREPS program, PI, etc. (PI and Co-Investigators) shall have the following duties and obligations. For other duties and obligations of the PI, please refer to Chapter 11.

a. PIs bear responsibility for the international joint research overall through the program implementation period. Based on their own research concept, the PI must assemble the optimal research team for conducting the relevant research project. Accordingly, PI must be a researcher with the ability to carry out the relevant research project themselves while at the same time demonstrating leadership. Under the SATREPS program, it is possible for PIs to assemble a research team in Japan comprising researchers affiliated with other research institutions in Japan (including companies, etc.,) as well as researchers specializing in other academic fields, such as humanities or social sciences, and then carry out the relevant research project based on joint research with research institutions in the recipient country.

b. As the person with overall responsibility for a JICA technical cooperation project, the PI must coordinate and supervise the planning and implementation of inputs by Japan (dispatch of overseas researchers (experts),

acceptance of foreign researchers (inviting recipient country researchers to Japan), provision of machinery/equipment) with their counterparts, etc. As such, he/she is required to submit regular activities reports to AMED/JICA, respond to evaluation surveys conducted by AMED/JICA, appropriately execute and oversee the project contract content, and manage implementation of the project overall. Furthermore, as a general rule, it is not possible for the research project to be unilaterally suspended part-way through the research implementation period due to the personal circumstances of the PI.

c. PIs must participate in meetings with AMED/JICA held in Japan following provisional selection of the relevant project (around three to five meetings) as well as the detailed design study, etc., conducted in the recipient country.

d. In the case that the PI is assembling a research team in Japan, the PI shall bear responsibility for the entire research team including matters related to formulating and implementing research and input plans. In such cases, the PI needs to be especially careful with regard to ensuring adequate communication with the recipient country and securing a place for Japanese and recipient country's young researchers to play an active role in the project when formulating and implementing plans for dispatching co-researchers and providing machinery/equipment. The PI shall also attend meetings of the Joint Coordinating Committee (JCC) held in the recipient country to report on the progress of the research and discuss implementation and management of the project.

e. The PI shall submit the requisite reports, etc., to AMED/JICA and respond to evaluations conducted by AMED/JICA (mid-term review, terminal evaluation) as well as related on-site surveys and progress reports involving recipient country stakeholders of the project. A follow-up evaluation is to be conducted after a specified period following the completion of the project, and the PI is to provide their cooperation in this (for details, please refer to Section 9.4). In addition, the PI must submit reports concerning the progress status of joint research that may be requested by AMED/JICA at any time.

f. The PI shall be responsible for coordinating, communicating, and sharing information with related organizations within research institutions such as the headquarters of universities and companies.

g. As the research project is funded by the Japanese government, contracted research funds must be executed and managed appropriately. Please be proactive in publishing research outcomes both in Japan and overseas with due consideration to the acquisition of intellectual property rights.

h. When publishing research outcomes obtained in the course of implementing the research project in academic papers or presenting them at academic conferences etc., please be sure to mention that the research outcomes are the fruits of the SATREPS program.

i. Given that the project comprises international joint research, please be proactive in obtaining intellectual property rights to the extent that recipient country research institutions are not disadvantaged. As a general rule, applications

for intellectual property rights shall be submitted by the affiliated institution in accordance with the contracted research agreement.

j. PIs shall provide cooperation in participating and presenting research outcomes in workshops and symposiums held by AMED/JICA both in Japan and overseas.

k. PIs may be required to hold workshops or symposiums aimed at promoting collaboration with Asia, Africa, and other regions.

1.2 Program Structure

1.2.1 Program Implementation System

In accordance with the Japanese government's Plan for Promotion of Medical Research and Development,* AMED promotes R&D centering on the six integrated projects of drug discovery and development; medical devices and healthcare; regenerative medicine and cell and gene therapies; genomic medicine; basic medical research; and translational and clinical research centers. To ensure efficient utilization of competitive research funds and generation of excellent research accomplishments, a Program Director (hereinafter referred to as "PD") is assigned to each integrated project, and a Program Supervisor (hereinafter referred to as "PS") and Program Officer(s) (hereinafter referred to as "PO") to each program. In addition, with regard to programs related to the areas of disease (cancers, lifestyle-related diseases, mental and neurological disorders, geriatrics and dementia, rare and intractable diseases, growth and infectious diseases etc.) conducted in a cross-cutting manner under the integrated projects, in order to flexibly manage each area Disease Area Coordinators (hereinafter referred to as "DC") are assigned to each area.

The PS and PO have complete knowledge and understanding of the progress status of this program overall and provide the necessary guidance and advice to ensure that this program runs smoothly. Furthermore, research institutions and researchers are obligated to cooperate with the PS and PO. Based on the guidance and advice provided by the PS and PO, R&D plans may be revised or cancelled (including early conclusion of projects due to achievement of R&D plans) as deemed necessary.

*https://www.kantei.go.jp/jp/singi/kenkouiryou/senryaku/index.html (in Japanese)

1.2.2 Roles, etc. 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 institution with which the R&D Principal Investigator (PI) is affiliated and that is their main place of research;[1] which has concluded a direct contracted R&D agreement with AMED;[2] and which is the research institution, etc., in Japan referred to in Chapter 2.

(B) "Subsidiary Institution" refers to a research institution, etc. other than the Principal Institution with which a Co-Investigator is affiliated and that is their main place of research[1] and which has concluded a subcontracted R&D agreement with the Principal Institution.

(C) “PI” refers to a researcher (one person) who is affiliated with the Principal Institution and who takes 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 during the implementation period.

(D) “Co-Investigator” refers to a researcher who is affiliated the Principal Institution or a Subsidiary Institution and who shares implementation of R&D items with the PI and takes responsibility for carry out the relevant R&D items.

(E) “Representative Investigator” refers to either the PI or the Co-Investigator affiliated with the Principal Institution or a Subsidiary Institution who is the representative researcher (one person) for the relevant research institution. (E.g.: the PI is the R&D Representative for the Principal Institution.)

[1] If the affiliate institution and the main place of research differ, please contact us.

[2] For details regarding contracted R&D agreements with institutions under this program, please refer to Chapter 8.

Chapter 2. Application Requirements

2.1 Eligible Applicants

Eligible Applicants for this program shall be researchers affiliated with a research institution in Japan that fulfills the conditions shown in (1)–(5) below and that is their main place of research,[1] and who 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 ("R&D Principal Investigator" (PI)).

Applicants must be researchers who are either affiliated with a research institution in Japan: or researchers who are not affiliated with a specific research institution in Japan at the time of application submission or affiliated with an overseas research institution at the time of application submission but will become affiliated with a research institution in Japan and be able to establish a system for carrying out the research project by either the contract conclusion date or June 1, 2022, whichever comes first. Applicants must also have the ability to fulfill the duties and obligations of the PI of an international joint research project and carry out the relevant international joint research from beginning to end. If the researcher is unable to become affiliated with a research institution in Japan and establish a system for carrying out the research project by either the contract conclusion date or June 1, 2022, as a general rule selection of the project for the SATREPS program will be cancelled. Furthermore, in order to confirm the research institution'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.).

(1) Eligible Applicants shall be affiliated with a research institution or other organization shown in (A)–(H) below.

(A) National facility or other organization[2] (limited to institutions/facilities where the PI is employed in an educational position, research position, medical care position[3], welfare service position[3], or designated position[3], or as a fixed-term contract researcher).

(B) Public test and research institution run by local government[4]

(C) University as prescribed under the School Education Act (Act No. 26 of 1947) or university affiliated research institution, 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 agency as prescribed under Article 2 of the Act on General Rules for Incorporated Administrative Agencies (Act No. 103 of 1999; partially amended on June 13, 2014) or local incorporated administrative agency as prescribed under Article 2 of the Local Independent Administrative Agency Act (Act No. 118 of 2003) whose main activity purpose is research.

(G) Non-profit, charitable technology research associations[5]

(H) Other institution deemed appropriate by the President of AMED.

[1] If the affiliate institution and the main place of research differ, please contact us.

[2] Refers to a test and research institution affiliated with the Cabinet office; a test and research institution, 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 under Article 3 Paragraph 2 of the National Government Organization Act.

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

[4] Test and research institution, etc., affiliated with a local government.

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

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

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

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

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

2.2 Important Items Regarding Application

2.2.1 Contracted R&D Agreements

In implementing selected R&D projects, as a general rule a contracted R&D agreement shall be concluded between the research institution carrying out the R&D project and AMED. For details, please refer to Chapter 8.

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

The Cross-ministerial Research and Development Management System (hereinafter referred to as "e-Rad"*) is a system that makes available online the series of processes relating to management of solicitation-based research funding programs at individual ministries and agencies (receipt of application => selection => management of selected projects => application to register research achievements and accounting reports). 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 5.

* "e-Rad" is the acronym for the Cross-ministerial Research and Development Management System, composed of the first letters of Research and Development, preceded by the "e" of electronic.

2.2.3 Security Trade Control (Countermeasures to Technology Leakage Overseas)

At research institutions, 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

institutions 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 (Act 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, guidelines, and directives, etc., issued by the Japanese government, beginning with the Foreign Exchange Act. In the case that R&D is carried out in infringement of relevant laws or guidelines, in addition to the imposition of punishments and penalties according to legislation, the allocation of R&D funds may be suspended and the decision to allocate R&D funds may be cancelled.

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

Not only the export of goods but also the provision of information is subject to regulations under the Foreign Exchange Act. When providing List Control technology to a foreign national (non-resident of Japan) or outside 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, DVD, USB flash drive, or other storage medium but also the provision of operational knowledge through technological guidance or skills training and technological support at seminars, etc. There are cases in which large amounts of technological exchange that could be subject to regulation under the Foreign Exchange Act may be included in joint research activities or when international students are involved.

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

- Ministry of Economy, Trade and Industry: Security Trade Control (general)
  https://www.meti.go.jp/policy/anpo/
- Ministry of Economy, Trade and Industry: Handbook for Security Trade Control
  https://www.meti.go.jp/policy/anpo/seminer/shiryo/handbook.pdf
- Center for Information on Security Trade Control
  https://www.cistec.or.jp/
- Guidance for Management of Sensible Nuclear Technology (SNT) in Relation to Security Trade Control (for universities/research institutions)

https://www.meti.go.jp/policy/anpo/law_document/tutatu/t07sonota/t07sonota_jishukanri03.pdf

2.2.4 Enthusiastic Participation and Action of Young Researchers

In line with the common intent of programs funded by public research funding AMED broadly promotes the nurturing and fostering of researchers who will shoulder the future of Japan and who through which R&D accomplishments will be put to use for the good of society. Subsequently, it is desirable that enthusiastic efforts are made to assign young researchers in AMED programs.

Some of the programs, in order to encourage the sort of young researchers who perform the role of taking charge of some of the research of professors under whose tutelage they are to become PIs and autonomously pursue research, also provide a special provision requiring that the PI is a young researcher (a quota for fostering young researchers). It is thus hoped that young researchers will eagerly apply to take part in the program. Note that Chapter 3 should be referred to regarding the definition of PI of a R&D project within in the quota for fostering young researchers.

(1) Research activities conducted at their own initiative by young researchers engaged

In line with the Implementation Guidelines Concerning Research Activities Conducted at Their Own Initiative by Young Researchers Employed for Project Implementation Using Competitive Research Funds (agreed on February 12, 2020 at the Liaison Meeting of Relevant Ministries on Competitive Research Fund), and with regard to the certain degree (set at a ceiling of 20%) of effort made by young researchers who are engaged in this program and whose personnel costs are paid by this program, in the event that the PI etc. judge that the young researcher's own initiative does not obstruct the R&D in question but at the same time contributes to it, the consent of their institution of affiliation is obtained it is possible to allot that effort to activities that contribute to research activities conducted at their own initiative or improvements in research and management capabilities. For more details please refer to the Administration Manuals and Forms* in the Program Administrative Procedures (Forms and other documents) section of the AMED website.

* https://www.amed.go.jp/keiri/index.html (in Japanese)

2.2.5 Data Sharing

With regard to the treatment of data arising from the results of R&D in the medical field, the importance of data sharing between researchers is recognized as the data is also useful to researchers sharing the same awareness of problems. At the same time, in the case of data arising from R&D implemented through public funding, because of its highly public nature and considerable public benefit moves are afoot to attempt to expand the possibility of their secondary use through registration with repositories and timely release. Moreover, in order to aim for the practical application of R&D there is a need to share detailed and accurate clinical information and genome information among not only academic research bodies such as universities and research institutions but also the industrial sector, including private corporations that will make industrial use of such data, to cooperate and develop new diagnostic and treatment methods.

At AMED, whenever contracted R&D agreements are concluded the submission of a data management plan is made obligatory; the AMED Guidelines Concerning Utilization of Research Data* that compile the definition of R&D data, policy regarding the treatment etc. of R&D data, and specific management guidelines have also been formulated,

and are available on the AMED website. For the details regarding submission of data management plans, please refer to Chapter 7.

Furthermore, the contracted R&D agreements applied in common to all contracted R&D that uses AMED's public funding in principle forbid the disclosure or provision to third parties of any type of R&D data generated, acquired or collected. However, in cases in which it is permitted according to guidelines already published by AMED, or when the prior consent of AMED has been obtained, it is possible to disclose or provide data to third parties.

In addition, R&D data is categorized into the four types of "unrestricted openly shared data," "restricted openly shared data," "restricted closed shared data," and "unshared data," while data other than data that it would be inappropriate to divulge to third parties is designated as either unrestricted release data or restricted release data, and is required to be published. Furthermore, even if certain data falls under the categories of either unrestricted release data or restricted release data it is permitted to share it only with specific third parties for the duration of the period when it is treated as restricted sharing data prior to release. For further details please refer to the AMED Guidelines Concerning Utilization of Research Data*

* https://www.amed.go.jp/koubo/datamanagement.html (in Japanese)

Chapter 3. 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 1; for application/selection implementation methods, please refer to Chapter 4.

3.1 Scale of R&D funds, R&D Period, Planned Number of Awarded Projects, etc.

No.	Field/R&D Projects Being Solicited	Scale of R&D Funds	Period in which R&D is Scheduled to be Implemented	Planned Number of New Awarded Projects
1	Infectious disease field "Research on measures to address infectious diseases control attuned to the needs of developing countries"	Around 90 million yen per year for each project AMED contracted R&D funds: around 32 million yen per year (Including indirect costs) (Final fiscal year: around 20 million yen per year) (Provisional period: max. 6.5 million yen) JICA technical cooperation funds: around 60 million yen per year (Not including indirect costs)/ around 70 million yen per year (Including indirect costs)	3 to 5 years starting from 2023 (Provisional period is secured in FY2022 for preparation)	Around 3 projects

Note 1. "Scale of R&D Funds" is an approximate estimate guide.

Note 2. 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.

Note 3. Although applicants may submit applications for multiple R&D projects being solicited, in order to show that there is no unreasonable duplication or excessive concentration of research funds (for details refer to Chapter 5), 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. Furthermore, in the event that applications are adopted please swiftly report so to the division in charge of this program.

Note 4. An applicant can submit only one research proposal as PI for this program across all the SATREPS research areas (including Environment and Energy, Bioresources, Disaster Prevention and Mitigation research fields handled by the Japan Science and Technology Agency (JST)).

3.2 Outline of R&D Projects for Which Applications Are Being Solicited

3.2.1 Research Content

HIV/AIDS, Ebola hemorrhagic fever, malaria, dengue fever, tuberculosis, highly-pathogenic avian influenza, rabies, infections caused by carbapenem- and colistin-resistant bacteria, and COVID-19 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. Several examples are given below of potential R&D projects that target solutions for global issues in the field of infectious diseases control.

- ◆ R&D on Zoonoses such as highly-pathogenic avian influenza and rabies
- ◆ R&D on epidemiology, diagnostics, prevention and therapeutics regarding HIV/AIDS, Ebola hemorrhagic fever, malaria and other protozoan or parasitic infections, dengue fever, tuberculosis, infections caused by carbapenem- and colistin-resistant bacteria, and COVID-19 and other emerging and re-emerging infectious diseases

*The following research proposals are not eligible: those only involving technology transfer or knowledge provision from Japan but not involved in joint research; those only conducting surveys that will not contribute to the advancement of science and technology.

*As a general rule, this program mainly covers research ranging from basic research to nonclinical research. If you wish to conduct research involving medical procedures, please consult with JICA before submitting your application.

*This program does not cover clinical trials. With regard to joint research including medical procedures performed by Japanese nationals in partner countries, please refer to "1.1.7.4 Stance Regarding Medical Procedures Carried Out in Partner Countries by SATREPS Program Personnel" of "1.1.7 Outline of Technical Cooperation through ODA."

3.2.2 Target Countries (Partner Countries Carrying Out Joint Research)

Please refer to Appendix 1. for the countries targeted by this program.

3.2.3 Points to Note

- From the viewpoint of diplomatic and science and technology policies, the appropriate regional balance of recipient countries with which joint research is conducted (avoiding excessive concentration of adopted projects in one country or region) and the balance of the research project theme (avoiding excessive concentration on certain research fields) shall be considered.
- Due to the circumstances in an activity area of recipient countries concerning security, the state of affairs, and the spread of COVID-19, there may be a possibility that travel bans to recipient countries will be imposed or research activities limited in the countries. These factors may be considered during the selection process.
- In order to check the security condition of countries and regions, please check for a "travel advice and warning" at the "Safety Information by Country and Region" page of the MOFA Overseas Travel Safety Information website (https://www.anzen.mofa.go.jp/, in Japanese). A "travel advice and warning" is issued with regard to countries and regions where special caution is required when traveling and staying. It indicates the level of safety measures according to the situation of relevant countries and regions, based on the comprehensive judgement of the security or other socio-political situations made from a mid-to long-term perspective. At the top of the "travel advice and warning" page the appropriate safety measures for a relevant country or region are posted according to the following four levels (see the table below).

・ Four levels of appropriate safety measures

Level 1: Exercise caution	Japanese nationals traveling to and residing in the country or area are advised to stay alert regarding the security situation.
Level 2: Avoid Non-essential travel	Japanese nationals are advised to avoid non-essential travel, stay alert regarding the security situation and take appropriate safety measures should they decide to travel.
Level 3: Avoid all travel	All Japanese nationals are urged to avoid all travel regardless of purpose. Japanese residents might be advised to consider the possibility of evacuation or to prepare for evacuation.
Level 4: Evacuate and Avoid all travel	All Japanese nationals are urged to evacuate immediately from the country or the area, and urged to avoid all travel regardless of purposes.

- For the ODA projects, consultation with JICA and MOFA is required when traveling to Level 3 or higher areas. Although judgement shall be made on a case-by-case basis, as a general rule, in the Level 3 areas, activities are allowed only if the project's urgency and priority are higher and appropriate safety measures are certain to be implemented. In the Level 4 areas, no activities are allowed. Appendix 1. is a list of target countries in view of the current circumstances as of August 2021. When submitting proposals, please check the latest information on the above-mentioned MOFA Overseas Travel Safety Information website.
- MOFA issues "travel advice and warnings on infectious diseases" separately from the "travel advice and warnings" mentioned above. The "travel advice and warnings on infectious diseases" are overseas safety information issued regarding the countries and regions where special caution is required when traveling and staying due to significant risks such as Pandemic Influenza and other highly infectious diseases. For more information, please refer to the MOFA's Travel Advice and Warning on Infectious Diseases (https://www.anzen.mofa.go.jp/masters/kansen_risk.html, in Japanese) page on the MOFA Overseas Travel Safety Information website. In addition, restrictions upon travel from Japan to and entry into other countries and regions are highly changeable. For the latest situation, please refer to "Restriction measures for entry of Japanese nationals or persons from Japan to other countries and regions and restriction of movement after entry" (https://www.anzen.mofa.go.jp/covid19/pdfhistory_world.html, in Japanese) page on the MOFA's Overseas Travel Safety Information website.
- In addition, if an international agreement regarding the SATREPS project is not likely to be concluded, this factor may be considered in the selection process.
- Proposals for joint research to be conducted with countries that have never or only rarely been selected as partner countries of the SATREPS project are particularly welcome.
- If the person responsible for the research outcomes after the research period has ended is involved in the R&D from the early stages, plans for utilization of the research outcomes become more robust. Furthermore, in order to effectively promote science, technology and innovation, the expansion of industry-academia-government collaboration is imperative. From these perspectives, research proposals that involve collaboration with the companies, etc. that will be

responsible for R&D and utilization of the research outcomes (industry-academia-government collaboration[13]) are welcomed. When submitting a research proposal involving industry-academia-government collaboration, please provide details of the collaboration concept in concrete terms for the Principal Institution in Section "(4) Plan for Capacity Development in the Partner County and Path to Social Implementation" on R&D Proposal Form 1 and for the participating company in Annex 7 (if the Principal Institution is a private company, please also complete and submit Annex 7). The company submitting Annex 7 may be required to submit a report after the research period has ended on its initiatives aimed at utilization of research outcomes.

- AMED may conduct reviews of companies' finances and so on where necessary.
- AMED welcomes project proposals targeting Africa and least developed countries (LCDs).[14] In these countries personnel training, implementation of on-site investigation and its analysis, and development and application of the appropriate technology and technology for prompt problem-solving are important. Accordingly, AMED hopes for proposed initiatives involving this perspective.
- In the LDCs, there are many cases where medium-and-long term support is needed to secure the sustainability of research activities, such as action plans to be implemented under technical cooperation by JICA etc. or by PI following the completion of the SATREPS project. Proposals targeting the LDCs, therefore, are expected to incorporate medium-and-long term support at the time of submission.
- Use of information and communication technology (ICT) as a tool for R&D and utilization of research outcomes is encouraged.
- In view of the importance of fostering young researchers, project proposals are encouraged in which either the PI is aged 45 or younger or more than half of the Japanese team members (those listed on the research organization (a list of participants)) are aged 35 or younger.
- As part of the effort to ensure diversity, proposals from women researchers are encouraged. In addition, the participation of women researchers in the research team is expected.
- Based on the policies and needs of the recipient country, organizational initiatives including those that involve the participation of administrative bodies in the recipient country are expected. Please refer to "1.1.7.3 Requirements of an

---

[13] For the SATREPS program, the institutions that participate in a project as the "industry" are companies that have corporate status in Japan.

[14] The OECD's DAC list identifies the 46 countries shown below as the least developed countries (LCSs). For the target countries of the SATREPS program, please refer to Appendix 1.

- Africa (33): Angola, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Djibouti, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Somalia, South Sudan, Sudan, Togo, Tanzania, Uganda, Zambia
- Asia (7): Bangladesh, Bhutan, Cambodia, Lao People's Democratic Republic, Myanmar, Nepal, Timor-Leste
- Oceania (3): Kiribati, Solomon Islands, Tuvalu
- Middle East (2): Afghanistan, Yemen
- Latin America (1): Haiti

ODA Program."

- It is anticipated that during the project implementation period the recipient country research institution will build collaborative relationships with the private sector and related government agencies and continue the R&D even after the research period has ended, thereby strengthening capabilities and systems aimed at utilizing research outcomes; or, in order to give the research outcomes back to society, collaborate with the activities of private companies, such as Base of Pyramid (BOP) businesses and the overseas expansion of small and medium-sized Japanese companies, as well as grass root development activities by NGOs and volunteer organizations, etc.
- As a research strategy that makes the best use of the characteristics of each region, it is expected to utilize the excellent research bases (research institutions, universities, etc.) in the region that have been established by Japanese ODA in the past.
- Research proposals that are similar to projects selected for the SATREPS program between FY2008 and FY2021 will additionally be screened from the perspectives of "Can the proposed research content be deemed to be markedly different or novel based on the objectives, subjects, approach, and implementation area, etc. of the research?" and "Can pursuing research based on the outcomes of existing similar projects be expected to produce even greater outcomes that contribute to the resolution of global issues?" In particular, with regard to research proposals that simply expand the research subjects or implementation area of previous projects, careful consideration will be given to the scale of the new contribution that the proposed research would make to problem-solving.
- It is also important that the institution to which the research participant belongs has the necessary foundation for international exchange activities to carry out the joint research and is willing to provide sufficient support and cooperation.
- Proposals based on a sufficient record of exchanges with the partner country are expected.

Chapter 4. Schedule, Review Method, etc.

4.1 Period of Acceptance of Proposal Documents/Selection Schedule

The period of acceptance of proposal documents and selection schedule is, as at the time that the call for applications opens, planned as follows.

Period of acceptance of proposal documents/ selection schedule (Please be sure to bear in mind Notes 1. to 11.)	
Period of acceptance of proposal documents	**Tuesday, September 7, 2021 ~ Noon on Monday, November 8, 2021 (Observe strictly)**
Document review	The middle of November, 2021 ~ the middle of February, 2022 (tentative)
Interview review (hearing review)	Tuesday, March 15, 2022 (tentative)
Notification of selection/rejection	The middle of May, 2022 (tentative)
Date of commencement (contracting, etc.) of R&D Project	Friday, July 1, 2022 (tentative)

Note 1. For all proposals documents, the documents received after the deadline will not be accepted.

Note 2. If not completed correctly, proposal documents may not be accepted.

Note 3. After the period of acceptance of proposal documents has ended, AMED may contact the PI by e-mail or telephone, etc., to confirm administrative details. Please respond to such requests for confirmation promptly using the methods designated by AMED (if AMED does not receive a response, the proposal in question may be ineligible for review.)

Note 4. Receipt of the request for technical cooperation from the recipient country's government by Japan's MOFA headquarters in Tokyo by Friday, October 29, 2021 (Japan Standard Time) is required to be eligible for a screening review. For detailed information, please refer to "1.1.7.6 Flow Prior to Commencement of the Technical Cooperation Project." As was the case last fiscal year, a maximum of 12 requests may be submitted by one country due to diplomatic considerations, and if requests exceed this upper limit, the government of the recipient country is to reduce the number of requests.

Note 5. Interview reviews (hearing reviews) may sometimes be conducted over the Internet etc.

Note 6. In the case that an interview review (hearing review) 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 an interview review (hearing review) or interview reviews (hearing reviews) 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 interview reviews (hearing reviews), this will be posted on the Application Information page on the AMED website listed in Chapter 5, so please refer to this page for details. Note that we cannot answer questions regarding the eligibility of individual projects for interview reviews (hearing reviews).

Note 7. The PI may be sent via e-mail a list of matters of inquiry that have arisen through the document review process. Please respond promptly to these matters of Inquiry by the deadline designated by AMED at the time of inquiry via the method designated by AMED.

Note 8. As a general rule, the interview review (hearing review) shall be attended by the PI. The date and time of the interview review (hearing review) cannot be changed.

Note 9. Following the interview review (hearing review), administrative matters may be confirmed with the PI as necessary. Please respond swiftly to the relevant checks via the method specified by AMED.

Note 10. The method of interview reviews (hearing reviews) may be altered or cancelled due to unforeseen circumstance such as social disorder caused by outbreaks of infectious diseases, natural disasters or other reasons. In addition, in the event that interview reviews (hearing reviews) are cancelled the period for the document review may be extended.

Note 11. 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.

Note 12. The tentative date of the commencement (contracting, etc.) of R&D project has been set in consideration of the time period required for formulating an optimal R&D plan at the time of submitting the proposal with a view to the timing of the commencement of R&D, and to enabling researchers to make the preparations they can between the time of the decision to adopt the project and the time the contracted R&D agreement is concluded so that R&D can commence as swiftly as possible after conclusion of the agreement, and does not guarantee conclusion of a contracted R&D agreement, as is the case with regard to the handling of all other items stipulated in these Application Guidelines. In order to conclude the contracted R&D agreement on the tentative date, the cooperation and efforts of research institutions, 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. AMED will also endeavor to coordinate with the PS/PO, etc. of a project as swiftly as possible to ensure that the contracted R&D agreement can be concluded as early as possible.

4.2 Method for Reviewing Proposal Documents

4.2.1 Review Method

In accordance with AMED's "Regulations Regarding the Evaluation of R&D Projects," in selecting R&D projects under this program, ex-ante evaluations (reviews) shall be conducted by Project Evaluation Panel members 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. The Project Evaluation Panel will evaluate the stipulated evaluation items, based upon which AMED decides the projects to be awarded.

In addition, in order for AMED to contribute to the internationalization of the R&D environment as well as further enhance the quality of project evaluations, it has been decided to include researchers affiliated with an overseas research institution (AMED reviewer) in the ex-ante evaluation process. Accordingly, with regard to the relevant project, at the time of proposal submission, please submit [(Example document name) "Presence/Absence of Items Subject to Export Regulations under the Foreign Exchange and Foreign Trade Act)]. For details regarding security trade control, please refer to Chapter 2.

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

(B) The Project Evaluation Panel shall evaluate project proposals by conducting a document review of the content of the submitted proposal documents and conducting interview reviews (hearing reviews) as necessary and deliberating on the project content. Please not that, 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. Furthermore, in the case that the project is adopted, the objectives, etc., revised at this stage shall be used as evaluation indicators when a Mid-term Review and an Ex-Post Evaluation are carried out. Please refer to Chapter 9 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) Project Evaluation Panel members are obligated to maintain confidentiality regarding any secret information learned during the course of performing their evaluation duties, including after these duties have concluded, in order to prohibit leakage or misappropriation of this information.

(F) The names of the R&D projects adopted for the program and the names of the PIs will be published at a later date on the AMED website. Furthermore, as a general rule, the names of all Project Evaluation Panel members shall be published by AMED once each year. (For details about publication on the AMED website, please refer also to Chapter 6.)

(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's By-Law Regarding the Treatment of Conflict of Interest Management for Members of the Research & Development (R&D) Project Review Panel. 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.

i) The evaluatee is a family member/relative of the Project Evaluation Panel member.

ii) The evaluatee is affiliated with the same department at a university, the National Research and Development Agency, or a national research institute or other research institution or business enterprise as the Project Evaluation Panel member.

iii) The evaluatee has worked closely with the Project Evaluation Panel member on a joint research project within the past three years including the fiscal year in which the Project Evaluation Panel evaluation is conducted.

iv) 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.

v) 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.

vi) The Project Evaluation Panel member is in a direct competitive relationship with the evaluatee.

vii) 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 and staff members, PD, PS, PO, or Project Evaluation Panel members regarding evaluations or project selection.

(I) From the perspective of verifying the appropriateness of R&D management, AMED may require submission of the materials regarding management of R&D for drugs,[1] regenerative medicine, etc.[2] and medical devices.[3] In addition, inquiries may be made regarding the content of these materials as necessary. Please refer to the following web pages for more details.

[1] https://www.amed.go.jp/koubo/iyakuhin_check.html (in Japanese)

[2] https://www.amed.go.jp/koubo/saisei_check.html (in Japanese)

[3] https://www.amed.go.jp/koubo/medical_device_check.html (in Japanese)

(J) In the course of this program there may be cases in which, from among research expenses received in the past by applicants, reviews are conducted of the submitted proposal documents based on the Mid-term Reviews and Ex-Post Evaluations of R&D projects put to use to create the current project proposal the current proposed project.

4.2.2 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.

(a) Compatibility with the program's purpose

- Is the project compatible with the program's purpose and objectives, etc.?
- Does the project contribute to the solution of global issues and the advancement of science and technology?
- Is the project based on the higher need for implementing R&D to solve problems and developing capacity of researchers in the recipient country?
- Will the joint research outcome be given back to the relevant recipient country and wider society?

(b) Scientific/technological significance and advantage

- Is the current technological level and previous performance sufficient?
- Does the project proposal have originality and novelty?
- 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?
- Will the research project facilitate the development of new technologies to solve global issues and the improvement of the level of science and technology?
- Is the recipient country expected to contribute to the development of science and technology that would not be achieved by research activities only in Japan, and the validation of the resulted technologies?
- Is the project expected to improve the efficacy and presence of Japan's science and technology in the recipient country and the wider world?

(c) Appropriateness of the plan

- Are the overall content and objectives of the plan clear?
- Are 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?

  *In accordance with the coming into force of the Ethical Guidelines for Life Science and Medical/Health Research Involving Human Subjects on June 30, 2021, the hitherto Ethical Guidelines for Medical and Health Research Involving Human Subjects and the Ethical Guidelines for Human Genome/Gene Analysis Research were abolished, so please follow the new guidelines from now on.

  https://www.mext.go.jp/b_menu/houdou/mext_00525.html (in Japanese)
- Does the project have a concrete joint research plan with the recipient country researchers?
- Has an appropriate research plan (including a financial plan) been prepared, in which the promotion of the joint research with the recipient country research institution takes into account cost-effectiveness? In addition, is it possible for the plan to be executed within the project period?
- Are the breakdown of costs and spending plan appropriate?
- Regarding the travel plan, is the duration of stay of the PI and co-researchers in the recipient country sufficient to conduct research?

(d) 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?
- Is the PI able to exercise leadership to coordinate matters regarding research implementation with other research institutions and research institutions in the recipient country?
- Is the PI enthusiastic about promoting international joint research as team leader of a JICA technical cooperation project with the recipient country researchers, willing to understand the social needs of the recipient country, and capable of exercising leadership based on mutual trust?

- Are the representatives of the Japanese and recipient country researchers clearly identified? Is there an organizational setup available to implement research in both Japan and recipient country?
- Can the Japanese researchers stay and conduct research in the recipient country with the necessary frequency and duration during the research period? Can the recipient country research institution secure an implementation system without spending excessive effort on other projects?

(e) Costs

- Are the breakdown of costs and spending plan appropriate?

(f) Plan and feasibility for utilization of research outcomes

- Are there clear and concrete roadmaps for research outcomes to be given back to society (a roadmap for activities by the recipient country and roadmap to spread the research outcomes to other regions and markets)?
- Is participation in the project by private companies and recipient country's public institutions—which are potential actors in the utilization and diffusion of research outcomes—being considered?

(g) Needs of the recipient country and conformity to ODA policy

- Does the recipient country have clear needs regarding an issue that should be addressed on a global scale?
- Is the project in line with Japan's ODA policy towards the recipient country?
- Is the project appropriate and feasible as an ODA project aimed at utilizing research outcomes?

(h) Prospects for sustainable development

- Is it possible for the recipient country to maintain the provided machinery and equipment and continue relevant research following the completion of Japanese cooperation?
- Is possible to foster the Japanese young researchers and researchers in the recipient country?

4.3 Enhancement of AMED Project Evaluations

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

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

Chapter 5. Preparation and Submission Method of Proposals, etc.

5.1 Preparation of Proposal Document

5.1.1 Proposal Documents Necessary for Application

No.	Mandatory or optional	Necessary proposal documents	Remarks
1	Mandatory	Form 1	Research Proposal
2	Mandatory	Attached 1	Summary of Proposal
3	Mandatory	Attached 2	Main Schedule of Proposal
4	Mandatory	Attached 3	Implementation Structure Concept Diagram
5	Mandatory	Attached 4	About Collaboration and/or Sharing with Partner Country Research Institutes for Each Research Item
6	Mandatory	Attached 5	Achievement Goal Sheet
7	Mandatory	Attached 6	Written Approval from Institution Director
8	Mandatory	Attached 7	Plans by Private-Sector Corporations, etc.
9	Mandatory	Attached 8	Proposal Coordination Status
10	Mandatory	Attached 9	Check Sheet for Security Trade Management
11	Mandatory	Form 2	Proposer Information, Research Concept
12	Optional	Annex 1	International Reviewer Assignment Request

5.1.2 Methods for Obtaining Proposal Forms

Please download the forms for proposal documents that AMED has prepared from the “Calls for Applications” page on the AMED website.

https://www.amed.go.jp/koubo/ (in Japanese)

5.1.3 Proposal Document Forms and Notes for Preparation

(1) Preparation of Proposal Documents

Please be careful with regard to the following items when inputting information into the proposal document forms.

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

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

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

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

(D) Please number the pages of proposal documents with numbers placed centrally at the bottom of each page.

(E) 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.

(F) The "title of proposed research project (in English)" must include the word "project" (e.g.: "Climate Change Project…," "The Project for Climate Change…"). As a general rule, please do not include "in Country X" in the project title. Please be sure to coordinate sufficiently with the partner country research institution and use the same project title as that of the ODA technical cooperation project submitted by the partner country.

(G) Under the SATREPS program, as a general rule Japanese researchers proactively travel to partner countries to promote international joint research, but please also explain your plans and methods for pursuing international joint research in the event that travel to the partner country is made difficult by the spread of COVID-19 (alternative proposals such as communication and training using remote systems) ("2. Research plan and research methods" of Form 1).

(H) In order for AMED to contribute to the internationalization of the R&D environment as well as further enhance the quality of project evaluations, it has been decided to include researchers affiliated with an overseas research institution (AMED reviewer) in the ex-ante evaluation process. Accordingly, Form 2 (in English) and Annex 9 "Security Trade Control Check Sheet" must be submitted at the same time as the project proposal.

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

In preparing R&D proposals, be sure to comply with relevant laws and ministerial ordinances/ethical guidelines prescribed by government ministries and agencies. For details, please refer to Chapter 11.

(3) Approval of R&D Project Proposals by Affiliated Research Institutions

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

(4) Revision of Proposal Content

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

(5) Ineligible Project Proposals

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

(A) Proposals that aim simply to purchase ready-made facilities and equipment.

(B) 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.

5.2 Required Proposal Documents Apart from R&D Proposals

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

With regard to research institutions conducting animal experiments using animal species specified under the Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Academic Research Institutions (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) No. 71 of 2006) and Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Implementing Agencies under the Ministry of Health, Labour and Welfare (Notification by Director, Health Science Division, Minister's Secretariat, Ministry of Health, Labour and Welfare on June 1, 2006; partially revised on February 20, 2015), based on these fundamental guidelines, research institutions may be required to submit a copy of the results of their most recently implemented self-monitoring/self-evaluation related to the research institution's conformance with these fundamental guidelines.

(2) Materials etc. regarding management of R&D

In order to implement the "Items for Checking Related to Research Management (Drugs)," which was notified as "Items for Checking Related to Research Management for Drug Development" on December 27, 2017, on the AMED website, applicants who apply for drug development are required to submit an "Items for Checking Sheet." Please download the "Items for Checking Sheet" on the AMED website, complete it, and submit it along with the proposal documents to the division in charge of this program by the deadline. With regard to specific tasks to be performed in preparing the "Items for Checking Sheet," please refer to "Items for Checking Related to Research Management (Drugs)," "Explanatory Materials for Applicants," and "Instructions for Completing the 'Items for Checking Sheet' for Applicants," which are available from the same website. In addition, inquiries may be made regarding the content of "Items for Checking Sheet" as necessary.

https://www.amed.go.jp/koubo/iyakuhin_check.html (in Japanese)

5.3 Engagement of Young Researchers

5.3.1 Definition of Young Researchers and Requisite Documents etc.

The purpose of this program is to promote human resources training, and support the engagement of young researchers serving that purpose. Please note that "young researchers" whose engagement is supported under this program are defined as being those meeting all of the requirements below.

- The person has a doctoral degree or who is deemed to have equivalent research capability as of April 1, 2021. However, in the case of a physician (holder of a Japanese medical license), a minimum of two years must have

passed since the person graduated from medical school, regardless of whether or not they hold a doctoral degree.

- Those males who are under 40 years old as of April 1, 2021 (i.e. who were born on or after April 2, 1981); females who are under 43 years old as of April 1, 2021 (i.e. who were born on or after April 2, 1978); or those who acquired their doctorate less than 10 years ago. However, those who have taken pre- or post-natal leave or child-rearing leave may add the said amount of days to the respective ages of 40 and 43 according to gender.

5.4 How to submit Proposal Documents

Please submit proposal documents via e-Rad by the deadline. It should be noted that web access increases shortly before the deadline and errors sometimes occur, so allow yourself plenty of time for submission. Applications will not be accepted if the proposal documents are not submitted by the deadline. 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 Operation Manuals for Researchers. Please note that submitted proposal documents cannot be replaced after the application deadline.

Note 1: The e-Rad system is available for use between 00:00 and 24:00 on weekdays and public holidays. Please note that the operation of the e-Rad site is sometimes suspended during operating hours due to maintenance or inspections. In the event that e-Rad is to be temporarily shut down, notice will be posted in advance on the e-Rad portal site.

Note 2: The data file for proposal documents can only be submitted in PDF format. (e-Rad has a feature for converting Word and Ichitaro (Japanese document) files to PDF format. It is not necessary to use this feature for PDF conversion, but if you do use them, be sure to refer to user' manual (Quick Guide for Researchers). 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.)

Note 3: The maximum size of single files that can be uploaded is 15MB.

5.4.1 Checking Acceptance Status on the e-Rad

Verifying the acceptance of proposal documents can be done by viewing the "Manage submitted proposals" screen on the e-Rad. Proposal documents whose application status has not changed to "Processing (Funding Agency) /Application in progress" or "Accepted" by the deadline will become invalid. In the event that although a researcher has submitted the proposal documents prior to the deadline and acknowledgment has been given by the clerical affairs supervisor their status has not changed to "Processing (Funding Agency) /Application in progress" or "Accepted," please contact the division in charge of this program. Note that in the event that there is a fault in the e-Rad system during the application period, there may be Notices from Funding Agencies or Notices from System Administrator displayed on the screen after logging in to e-Rad, or related information displayed on the top page of the AMED website, so please check these details.

Application status	Application type (status) display
i) Application submitted	The application type (status) will change to "**Processing (Research institution) /Application in progress**," which indicates that the acknowledgement by the research institution is still unfinished. (Application to the program is not complete at the point that the PI submits the application to their affiliated research institution via e-Rad. Be sure to undergo procedures to obtain approval of the submission of the R&D project from your affiliated research institution) In the event of difficulties in the procedures for the acknowledgement by the research institution please consult with the division in charge of this program.
ii) Procedures for acknowledgement by the research institution completed	The application type (status) will change to "**Processing (Funding Agency) /Application in progress.**"
iii) Accepted by the funding agency (AMED)	The application type (status) will change to "**Accepted**."

5.4.2 Points to Note in Using the e-Rad

(1) Prior registration of research institution

In the case that researchers are applying for the program through a research institution, the "Principal Institution" and "Subsidiary Institution" must be registered with e-Rad prior to the time of application as a general rule. For information regarding how to register research institutions, please refer to the e-Rad portal site.

Please appoint one person within the research institution to serve as a clerical affairs supervisor for e-Rad matters, and download the research institution registration application form from the e-Rad portal site and then fill out and submit it by postal mail. Registration 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 your affiliated institution with e-Rad, there is no need for you to register it again for R&D programs or projects under the jurisdiction of other ministries or agencies. (If you have already registered it with e-Rad for R&D programs or projects under the jurisdiction of other ministries or agencies, there is no need for you to register it again.) In the case that you are not affiliated with a specific research institution at the time of application or are affiliated with a research institution outside of Japan, please separately contact the division in charge of this program as early as possible before submitting your application.

(2) Prior registration of researcher information

The PI, an applicant, and the Co-Investigators participating in the research must register their researcher information and obtain a login ID and password.

The research institution should register information for researchers who are affiliated with it.

Please note that researcher information registered previously for the Grants-in-Aid for Scientific Research (KAKENHI) or other grant programs is already registered in the e-Rad system. Please check your researcher number and input additional information regarding your affiliated research institution. Information for

researchers who are not affiliated with a research institution shall be registered by e-Rad system operation managers at the Ministry of Education, Culture, Sports, Science and Technology (MEXT). Please refer to the e-Rad portal site for the necessary procedures.

5.4.3 Contact for inquiries regarding e-Rad operation

For inquiries regarding how to operate the e-Rad, please contact the e-Rad portal site's Help Desk. (Please refer to Chapter 14.) Please be sure to check the portal site and see the "Frequently Asked Questions" page before contacting the Help Desk. Please note that the Help Desk cannot answer any inquires whatsoever regarding the content of the Application Guidelines, application review status, or acceptance/rejection of applications.

5.5 Elimination of Unreasonable Duplication or Excessive Concentration of Research Funds

5.5.1 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 agencies (including hereinafter national research and development agencies) for the same R&D project (name or content of the research receiving competitive research funds) being conducted by the same researchers, and if 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."). Although there are no restrictions on submitting applications for other competitive research funding programs at the stage of applying for this program, please notify the AMED division 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.

(A) Applications are submitted simultaneously for multiple competitive research funding programs, that are essentially the same (including if the projects overlap to a considerable degree; the same shall apply hereinafter) and multiple R&D projects are adopted on an overlapping basis.

(B) Applications are repeatedly submitted of R&D projects that are essentially the same as an R&D project that has already been adopted and been allocated competitive research funds.

(C) There is duplication regarding the use of research funds amongst multiple R&D projects.

(D) Other equivalent cases

5.5.2 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 R&D period, and any of the following apply, the decision to adopt the R&D project under this program may be cancelled.

Accordingly, in the case that a proposal document for an R&D project is submitted to and adopted by another competitive research funding program after 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 division 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.

(A) Excessive research funds are allocated in comparison to the researcher's abilities or research methods

(B) 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* (100%) that is needed for implementing the relevant research).

(C) Unnecessarily expensive research equipment is purchased.

(D) Other equivalent cases

* Based on the Council for Science, Technology and Innovation's definition of "effort": the percentage of researchers' time exclusively spent for the R&D activities concerned against the researcher's annual working hours (100%). Researchers' total working hours refer to not only the time spent in research activities but also total substantive working hours, including educational/clinical activities and administrative duties.

5.5.3 Provision of Information Related to Application Content in Order to Eliminate Unreasonable Duplication/Excessive Concentration

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

5.5.4 Status of Application and/or Acceptance Under Other Competitive Research Funding Programs, Including Other Government Ministry/Agency Programs

Applicants may be required to provide information in proposal documents regarding the status of application and/or acceptance under other competitive research funding programs, including other government ministry/agency programs (name of program, name of R&D project, project implementation period, budget amount, effort, etc.) In the event that the application documents contain anything other than the truth, 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.

Chapter 6. Handling of Information

6.1 Handling of Information Contained in Proposal Documents

6.1.1 Purpose of Use of Information

In addition to reviewing R&D project proposals as part of the selection process, information included in proposal documents regardless of whether they are accepted or not, shall be used in analysis of research trends or macro analysis that contributes to the operation of the AMED program management, such as the creation of new programs; in the procedures regarding contracted R&D funds; for research support purposes as described in Chapter 13.

It should be noted that in order to prevent the rights and interests of the researchers submitting research proposals or the research institutions to which they are affiliated from being unfairly infringed, the information in question acquired shall be used solely for the work detailed above, and those using it shall be limited to AMED executive officers and staff members involved in the above-mentioned administrative work.

In addition, with regard to the information included in proposal documents regardless of whether they are accepted or not, AMED shall manage it in line with its Provisions for Management of Corporate Documents, and in accordance with both the Act on Access to Information Held by Incorporated Administrative Agencies etc. and the Act on the Protection of Personal Information Held by Incorporated Administrative Agency, etc., the confidentiality of secret information included in proposal documents shall be strictly maintained to ensure that the rights and interests of the researchers submitting research proposals or the research institutions to which they are affiliated are in no way unfairly infringed. For details, please refer to the Ministry of Internal Affairs and Communications website.*

* "Introduction to the information disclosure system in the information disclosure system" section of the website (Ministry of Internal Affairs and Communications)
https://www.soumu.go.jp/main_sosiki/gyoukan/kanri/jyohokokai/shoukai.html (in Japanese)
"Introduction of legal systems in the protection of personal information by government organizations/independent administrative agencies, etc." section of the website (Ministry of Internal Affairs and Communications)
https://www.soumu.go.jp/main_sosiki/gyoukan/kanri/horei_kihon.html (in Japanese)

6.1.2 Necessary Disclosure/Provision of Information

(A) Information related to each adopted project (program title, R&D project title, PI's affiliated institution/position/name, e-Rad project/researcher/research institution number, budget amount, R&D period, research outline/abstract or Contracted R&D Result Report (public information))[1] may be sorted, classified, and made public on AMED's website, the AMED R&D projects database (AMEDfind), and public databases operated by funding agencies, etc., providing cooperation under an agreement, etc., with AMED (World RePORT,[2] etc.)

(B) With regard to all projects for which applications have been submitted, information requiring micro analysis will be analyzed by AMED and the analysis results provided to related government ministries and agencies as well as funding agencies, etc., and made public, and may also be posted on funding information databases, etc.[3]

(C) The information registered on e-Rad will be utilized for the appropriate evaluation of R&D conducted with government funding, and the planning and formulation of efficient and effective comprehensive strategies, and policy on allocation of funds. Accordingly, the Council for Science, Technology and Innovation (CSTI) and related government ministries and agencies call for thoroughness in registering accomplishment information about academic papers and patents etc., and account records on e-Rad, in order to connect the output/outcome information with the input by solicitation-type research funding programs. For this reason, even after the relevant project has been selected, researchers are requested to input into e-Rad the R&D accomplishment information for each fiscal year (academic papers, patents, etc.) as well as accounting report information and information on actual disbursement of indirect costs related to competitive funding. Information required for micro-analysis including research R&D accomplishment information and accounting report information will be provided to the Cabinet Office.

(D) 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 programs.

[1] Information shall be treated as "information expected to be made public" as per the stipulations of Article 5, Item (i) (a) of the Act on Access to Information Held by Independent Administrative Agencies (Act No. 140 of 2001). Furthermore, the same shall apply to items designated for public disclosure in the R&D Proposal and the above-mentioned items shown on the Contracted Items Sheet that is to be completed if the relevant R&D project is adopted.

[2] What is "World RePORT"?

"World RePORT" is a database for international collaborative research supported by research funding agencies in major countries. Its purpose is the visualization of international research collaboration carried out by various countries, which was previously difficult to verify. Managed and operated by the United States' National Institutes of Health (NIH), the database currently records information for twelve research funding agencies around the world, including the NIH, the UK's Medical Research Council (MRC), the Bill & Melinda Gates Foundation (BMGF), European Commission (EC), Canadian Institutes of Health Research (CIHR), and the Wellcome Trust.

https://worldreport.nih.gov/app/#!/about

[3] "Databases, etc." includes World RePORT, ERP and other databases.

Chapter 7. Points to Note between Selection and Conclusion of Agreement

7.1 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.

(A) Documents required by AMED to be submitted are not submitted by the submission deadline.

(B) A researcher/researchers involved in the relevant R&D project have had their application to/eligibility for participation in AMED R&D programs restricted for a certain period of time.

(C) An investigation has been opened into allegations of misconduct.

(D) Conditions that were set for adoption of the R&D project ultimately have not been fulfilled.

(E) It is discovered that the R&D project does not fulfill the conditions for application, etc.

7.2 Representation and Warranty for Researchers Undergoing Investigation/Researchers Discovered to Have Undertaken Misconduct

Please note that in concluding contracted R&D agreements, AMED requires Principal Institutions 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 under this program), 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 institution to have carried out misconduct in accordance with Japanese Government guidelines for responding to misconduct[1] or AMED Regulations for Responding to Misconduct in Research Activities, but excluding, however, persons regarding whom restrictions have not been placed regarding application to/eligibility for participation in competitive research funding programs implemented by the national government or independent administrative agencies based on the findings of the research institution, or whose period of restriction on application to/eligibility for participation in competitive research funding programs implemented by the national government or independent administrative agencies has ended).[2]

(B) In the case that persons who are the subject of an investigation (hereinafter referred to as the "Investigation") being conducted by the research institution in accordance with Japanese Government guidelines for responding to misconduct or AMED Regulations for Responding to Misconduct in Research Activities are affiliated with the research institution in question and either the PI or Co-Investigator (if there is a subcontracted institution, including the Co-Investigator or equivalent person affiliated with the subcontracted institution) for the R&D Plan, AMED has been notified of the relevant target person by the day before the contracted R&D agreement will be concluded and AMED's consent has been obtained with regard to handling of the relevant target person(s).

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

[1] The "Japanese Government guidelines for responding to misconduct" referred to in this section is a blanket term for all of the various policies and guidelines concerning response to misconduct formulated by the Japanese Government.

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

7.3 Preparations for Concluding Agreement

Following the adoption of an R&D project, the research institution implementing the R&D project shall be required to prepare the following (A) to (C) in order to enable procedures for concluding the contracted R&D agreement to proceed quickly and smoothly. Documents required for the agreement (plan forms etc.) shall be provided separately after projects have been adopted.

One Overall R&D Plan is to be prepared for each R&D project based on the R&D proposal at the time of adoption of the project. Centered on the proposed R&D concept for the entire project implementation period, please include the basic plan, R&D content, R&D system, and budget plan (This plan shall be used as a base material for considering budget allocation each fiscal year, conducting a Mid-term Review and an Ex-Post Evaluation, and managing project progress.). One R&D Plan is to be prepared for each agreement when contracted R&D agreements for each fiscal year are concluded (Please note that some parts of the R&D Plan may be required to be submitted in English.).

(A) Prepare an Overall R&D Plan, R&D Plan and other documents required for the agreement

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

(C) Organize accounting regulations, contracted research regulations, and rules for employee inventions, etc.

7.4 Submission of Data Management Plans

With regard to awarded projects, the PI is requested to submit* a data management plan (DMP) to AMED when they conclude a contracted R&D agreement after adoption. Successful applicants will be separately informed regarding the requisite documents (forms) after adoption.

* The data etc. arising from R&D programs using public funds are the shared assets of the general public, and one of AMED's roles is to ascertain the location of data that is currently unknown, collect it, secure its quality, assess its significance, store and use it in an appropriate and fair manner.

* By ascertaining the types of R&D data, where they are stored, the person in charge of managing the data, the data usage and sharing plan policy, and the location of the human resources related to the data through DMPs, AMED seeks to strengthen its

management and catalytic functions, and to the greatest extent possible be of use in encouraging collaboration between different R&D projects, and avoiding duplicated R&D.

* The DMP is a document recording what sort of data arises from what R&D project and who is storing it.
* It is requested that DMPs include the program year, program name and R&D project name, a general term for the data and data sets deriving from the project, an explanation of the R&D data, the affiliation and name of the data scientist and repository and any other requisite details.
* Please complete the DMP in strict accordance with the AMED Guidelines Concerning Utilization of Research Data and the Guide for Completing Data Management Plans. (The AMED Guidelines Concerning Utilization of Research Data explain the obligation of submitting DMPs, and functions and role etc. of the plans, so please refer to them.)
* With regard to the DMP content that can be made public or information that the content is statistically processed these may be made public along with other project information.
* AMED Guidelines Concerning Utilization of Research Data and obligation of submission of data management plans
https://www.amed.go.jp/koubo/datamanagement.html (in Japanese)

Chapter 8. Conclusion of Contracted R&D Agreements

8.1 Conclusion of Contracted R&D Agreements

8.1.1 Agreement Conditions

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

In concluding contracted R&D agreements, in the case that the conditions decided at the time the R&D project was adopted have not been fulfilled based on the opinions of the Project Evaluation Panel, PS, PO, etc., and agreement is not reached regarding both the content of the agreement (including expenditure estimates) and method, an agreement may 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 plan may be revised or suspended (including early conclusion of projects due to achievement of R&D plans).

The PS, 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.

It should be noted that, 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 test and research institutions run by local government), 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 this 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 government inspection and auditing by AMED in response to requests from AMED.

8.1.2 Administrative Procedures Regarding Conclusion of Agreements

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

*https://www.amed.go.jp/keiri/index.html (in Japanese)

8.1.3 Ensuring the R&D Period through the End of the Fiscal Year

To enable R&D to be conducted through the end of the fiscal year, the Contracted R&D Accomplishments Report should be submitted to AMED no later than the 61st day as calculated from the last day the Contracted R&D period.

Each research institution should work to put in place the necessary mechanism in-house to ensure a R&D period up through the end of the fiscal year is secured.

8.1.4 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. For details, please refer to Chapter 12.

8.2 Scope and Payment of Contracted R&D Funds

8.2.1 Scope of Contracted R&D Funds

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

Currently, improvements regarding the systems for competitive research funds are being promoted, with the 6th Science, Technology, and Innovation Basic Plan, the Integrated Innovation Strategy 2020 and the Comprehensive Package for Research Competitiveness Enhancement and Young Researcher Support. Based on this, under this program the direct costs can cover personnel costs for PIs and Co-Investigators as well as expenses for entrusting other persons with PIs' work other than research and development ordinarily performed by PIs at their affiliated institutions (buyout expenses).

	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 (including personnel costs for PIs and Co-Investigators[2]) Service costs: expenditure for services such as lecture requests, guidance/advice, test subjects, interpretation/translation, and unskilled labor.

	Other	Costs for implementing the relevant contracted R&D other than the above. Examples: R&D results publication costs (academic paper contribution costs, academic paper offprint costs, website production costs, etc.), conference costs, equipment leasing costs, Equipment repair costs, printing costs, subcontract costs, licensing fee, expenses for entrusting other persons with PIs' work other than research and development ordinarily performed by PIs at their affiliated institutions (buyout expenses), [2] amount equivalent to consumption tax related to untaxed transactions, etc.
Indirect costs [3, 4]	Expenditure used by research institutions as necessary costs for managing the research institutions during implementation of the relevant R&D, paid at a fixed percentage of direct costs (with a 30% rule of thumb) as an allowance.	

[1] https://www.amed.go.jp/keiri/index.html (in Japanese)

[2] With regard to the requisite conditions and details of procedures in the event of disbursing personnel costs and buyout expenses for PIs and Co-Investigators, please refer to the Administration Manuals and Forms[1] in the Program Administrative Procedures (Forms and other documents) section of the AMED website.

[3] Indirect costs are allocated when AMED concludes a contracted R&D agreement with a national university corporation, inter-university research institute corporation, independent administrative agencies, 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. The fixed percentage will not exceed 30%. With regard to Subsidiary Institutions (excluding researchers affiliated with national facilities or other institutions) also, indirect costs are allocated in accordance with direct costs.

[4] In cases in which the indirect subsidies payment method is used with regard to researchers affiliated to a national facility or other institution (excluding the National Institute for Educational Policy Research) they become ineligible for allocation of indirect costs.

8.2.2 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."[1]

Note 1: Contracted R&D agreements for researcher-initiated trials or clinical studies under AMED shall employ "Contract management method using value per procedure (VPP) charts in clinical 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 institution has created a system for registering cases for clinical trials/clinical studies in accordance with newly prescribed internal consignment regulations (Regulations for Handling Contracted R&D in Researcher-initiated Trials and Clinical Studies (tentative title), the head of the research institution can request case registration from other medical institutions in a kind of outsourcing method. For details, please refer to the AMED website below.[2] Facilities where there is a sufficient administrative support system for clinical trials/clinical studies may continue using their current management method for the foreseeable future.

Note 2: In order to mitigate the expenses involved in the use of computers and aim for effective cost management to accelerate research, AMED provides all R&D projects with a joint service for using the Tohoku University Tohoku Medical Megabank Organization's supercomputer at a special rate. Those planning to use this service should calculate the costs by referring to the Tohoku University Tohoku Medical Megabank Organization Supercomputer Usage Fee Rules.[3]

[1] https://www.amed.go.jp/keiri/index.html (in Japanese)

[2] https://www.amed.go.jp/program/kenkyu_unyo.html (in Japanese)

[3] https://sc.megabank.tohoku.ac.jp/wp-content/uploads/2019/04/uses_fee_20190401.pdf (in Japanese)

8.2.3 Encouragement of Shared Use of Research Equipment

From the perspective of the efficient use of contracted R&D funds and the effective use of research equipment, joint use of research equipment and combining research funds for multiple projects based on certain requirements are permitted. Details should be confirmed with the AMED "Administration Manual for Contracted R&D Agreement."*

* https://www.amed.go.jp/keiri/index.html (in Japanese)

8.2.4 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.

8.2.5 Diversion of Costs between Items

When the diverted amount for each cost item (main item) does not exceed fifty percent (50%) of direct costs (or five million yen (JPY 5,000,000), if the amount equal to fifty percent (50%) of direct costs is less than five million yen (JPY 5,000,000)) for that fiscal year, the amount may be diverted without approval from AMED on the assumption that the diversion is appropriate and consistent with the R&D plan. For details, please refer to the AMED "Administration Manual for Contracted R&D Agreement."*

* https://www.amed.go.jp/keiri/index.html (in Japanese)

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

You should prepare documentary evidence of appropriate expenditure, from the standpoint of ensuring transparency of use as noted in the "Common guidelines relating to the expenditure of indirect costs for competitive fund" (revised on July 18, 2019 at the Liaison Meeting of Relevant Ministries on Competitive Research Fund) and retain it for a period of five years following the year of the completion of the R&D project. A Report on Indirect Cost Expenditures must be prepared for the expenditure of indirect costs for each fiscal year and submitted by June 30 of the following year. For details, please refer to the AMED "Administration Manual for Contracted R&D Agreement."*

* https://www.amed.go.jp/keiri/index.html (in Japanese)

8.2.7 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 in implementing preliminary surveys or deciding 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."*

*https://www.amed.go.jp/keiri/index.html (in Japanese)

8.3 Handling of Acquired Goods

8.3.1 Ownership of Acquired Goods

Ownership of goods, etc. acquired by Universities and Research Institutions,[1] through direct costs (hereinafter referred to as "Acquired Goods") shall revert[2] to the university, etc.

Ownership of acquired goods by Companies, etc.,[3] 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 useful 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. Companies, etc. shall, throughout the contracted R&D period, manage the relevant acquired goods properly with the due diligence of a prudent manager.

[1] "Universities and Research Institutions" include:

a. Incorporated educational institutions such as national university corporations, public university corporations, and private universities
b. Public research institutions such as national research institutions, public test and research institutions run by local government, and independent administrative agencies
c. Organizations with a public nature, such as public-service corporations, that are recognized by AMED

[2] The submission of contracted research regulations etc. will be necessary in the event that goods acquired using contracting expenses are made the property of a university.

[3] "Companies, etc." is a general term for research institutions other than "Universities and Research Institutions."

8.3.2 Handling of Acquired Goods after Completion of R&D Period

For the purpose of continued application of the relevant R&D, as a general rule Companies etc., may continue to borrow free-of-charge tangible property and whose ownership has reverted to AMED for the duration of its useful life* and the tangible property may be transferred to the Companies etc., for a fee upon the evaluation of AMED after its useful 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 duration of useful life shall be the number of years stipulated in Appended Table 6 "Useful Life Table of Depreciable Assets for R&D of the Ministerial Order on Useful Life of Depreciable Assets" (Ministry of Finance Order No. 15 of 1965). (Four years for tools, appliances and equipment.)

8.3.3 Disposal of Radioactive Waste

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

Chapter 9. Progress Management of Awarded R&D Projects

9.1 Progress Management of Projects

In all awarded projects, the PS, PO, etc. shall manage progress of their projects. In doing so, important research data (including experiments) on which the R&D project proposal is based may be verified from the perspective of progress management, even if the relevant research was conducted prior to conclusion of the contracted R&D agreement.

A Contracted R&D Result Report, serving as an appendix to the Contracted R&D Accomplishments Report, is required to be submitted each fiscal year for all awarded R&D projects according to the contracted R&D agreement.

It should be noted that 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). Please also note that, upon referral to the R&D plan and depending on the progress status, review of the project plan or cancelation (early conclusion) of the project may be carried out.

In addition, R&D projects moving into the practical application stage (R&D projects that are within the target scope of the regulatory science strategy consultation or other PMDA consultation services), are, as a condition of adoption, required to implement each clinical trial according to the research plan agreed in advance at the regulatory science strategy consultation or other consultation services (face-to-face advice) provided by the Pharmaceuticals and Medical Devices Agency (PMDA). Furthermore, based on appropriate information management, the research institution shall consent to AMED attending various kinds of consultation interviews under the “regulatory science strategy consultation” program etc. during the R&D period and share face-to-face advice records and related information with AMED.

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

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

9.2 Mid-term Review, Ex-Post Evaluations etc.

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

Review shall be conducted by the Project Evaluation Panel. Furthermore, in the case that it is deemed necessary, projects under this program shall undergo a Mid-term Review, regardless of the timing.

Based on evaluation results, AMED may cancel (conclude early) a project in accordance with the overall decision of the PS, PO, etc.

In addition, all awarded projects are to undergo Ex-Post Evaluations at an appropriate time following the conclusion of the project. Moreover, a follow-up evaluation may be carried out after a certain period of time after conclusion of the project if deemed necessary.

*"Five years" refers to five fiscal years.

9.3 Presentations at Accomplishments Report Meeting

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

9.4 Follow-up Evaluation

A follow-up evaluation is to be conducted after a specified period following the completion of the project with regard to the status of utilization of research outcomes from the perspectives stated below.

- Have activities aimed at achieving the overall goal of the relevant project been continued or expanded since the project ended? (Includes not only research activities but also related initiatives.)
- Are the research outcomes also having an effect on/contributing to the development and expansion of science and technology aimed at resolving global issues?
- How are the research outcomes being spread in the partner country?
- Have there been any ripple effects on Japan? What do the research outcomes mean for Japan?
- What outcomes/ripple effects has implementation of the international joint research had? (Human resources development in Japan and the partner country, improvement of the partner country's capacity to carry out independent R&D, increase in joint research, research contracted by the partner country, etc.)

Chapter 10. Handling of R&D Accomplishments

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

10.1 Inclusion of Systematically Assigned Numbers in the Acknowledgement Section of Papers

When publicizing the R&D accomplishments made under this program, please be sure to state that the accomplishments are due to AMED support and include the grant number for acknowledgements in the acknowledgements section. For more details please check the AMED "Administration Manual for Contracted R&D Agreements."*

* https://www.amed.go.jp/keiri/index.html (in Japanese)

10.2 Submission and Publication of R&D Accomplishments Reports

Research institutions shall submit a Contracted R&D Result Report that summarizes the research accomplishments of the R&D project, serving as an appendix to the Contracted R&D Accomplishments Report. Please note that the deadline for submission of the report 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 Result Report is not submitted by the deadline, it shall be deemed that the contracted R&D agreement has not been fulfilled, so please be sure to strictly comply with the submission deadline. It should be noted that some parts of the Contracted R&D Result Report may be required to be submitted in English.

A part of the items in the Contracted R&D Result Reports and outline of accomplishments will be treated as publicly open information. As it will be published at appropriate times on the AMED website please be careful to indicate parts that are not to be made public in the section "Non-Disclosure Items" in the report form with regard to information prior to patent applications, unpublished information about the details of patents being applied for, knowhow and other confidential sales information and any other undisclosed information.

Moreover, with regard to final Result Reports produced at the end of R&D projects that have lasted for several years, the content under the section of "Items for Disclosure" in the report compiled by the PI upon Ex-Post Evaluation will be published at appropriate times on the AMED website.

10.3 Attribution of R&D Accomplishments

With regard to patent rights, copyrights and other intellectual property (IP) relating to R&D accomplishments, these can revert to the research institutions under the condition that the requirements provided for in Article 17 of the Industrial Technology Enhancement Act (Act No.44 of 2000, the Bayh-Dole Act. The Japanese version of the Bayh-Dole Act) are satisfied. The purpose of the Bayh-Dole Act is to invigorate R&D activities through the reversion of IP rights to research institutions so that the results of these R&D activities can be used efficiently in business activities. Under this program, it is expected that research institutions themselves will make the maximum effort to achieve

practical application of their research accomplishments, and for this reason the Bayh–Dole Act has been applied. For details regarding conditions, please refer to contracted items prescribed under the contracted R&D agreement at the time the agreement is concluded. Furthermore, please consult with AMED in advance in the event that R&D accomplishments or intellectual property rights relating to R&D accomplishments are succeeded from a domestic subsidiary to an overseas parent company.

10.4 Measures towards the Practical Application of R&D Accomplishments

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

AMED's Division of Intellectual Property, Department of Intellectual Property and Technology Transfer, provides consistent support for maximizing and achieving the practical application of R&D accomplishments that have reverted to the research institutions, so do not hesitate to contact the Medical IP Desk (For details, please refer to Chapter 13).

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

10.5 IP Educational Materials for Medical Researchers

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

* https://www.amed.go.jp/chitekizaisan/chizai_kyouzai.html (in Japanese)

10.6 Securing Open Access to R&D Accomplishments

Having secured the necessary IP rights, research institutions are requested to cooperate in ensuring open access to research accomplishments (including data etc. acquired) as far as possible.

10.7 Handling of Data

With regard to the data created, obtained or collected, or data (R&D data) produced through the processing etc. of data as a result of a contracted R&D agreement in which AMED is the assignor, please treat it in pursuance with the contracted R&D agreements of FY2020 onwards and the AMED Guidelines Concerning Utilization of Research Data.*

* https://www.amed.go.jp/koubo/datamanagement.html (in Japanese)

Chapter 11. Obligations of Research Institutions and Researchers in Implementing this Program

11.1 Compliance with Laws and Ordinances

In implementing this program, research institutions 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 institutions shall be required to take measures to prevent misconduct,[1] fraudulent use,[2] and fraudulent receipt[3] (hereinafter referred to collectively as "Misconduct, etc.").

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

a. Fabrication: creation of data or research accomplishments that do not exist.

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

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

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

[3] "Fraudulent receipt" refers to a researcher 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.

11.2 Management Responsibility for Executing Contracted R&D Funds

The contracted R&D funds shall be executed by the research institution in accordance with the contracted R&D agreement. For this reason, research institutions shall abide by the principles stipulated under "Competitive research funding should be managed at the responsibility of the research institution," and research funds shall be managed under the responsibility of research institutions. Moreover, researchers participating in this program should be fully aware of the fact that AMED contracted R&D funds are provided by precious tax paid by the general public, and are obligated to execute funds fairly, appropriately, and efficiently.

11.3 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. Accordingly, research institutions shall implement research ethics education for researchers and report to AMED on the status of participation. 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.

11.3.1 Persons Required to Undergo Ethics Training/Program(s) to be Undertaken/Educational Materials

Research institutions, etc., should ensure that researchers who are deemed to be substantially participating in research activities that are being conducted using research funding provided by AMED undergo training using one of following programs/materials.

• A Casebook for Responsible Research Conduct (AMED) (in Japanese)
• Compilation of Near Incidents regarding Research Integrity (AMED) (in Japanese)
• APRIN e-Learning Program (eAPRIN) (in Japanese)
• "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") (in Japanese)
• Programs implemented by research institutions whose content is deemed to be equivalent to the that of the above programs (in Japanese)

Furthermore, the Clinical Trials Act stipulates that the "Kenkyusekinin Ishi" (Principal Investigator) and "Buntankenkyu Ishi" (Co-Investigator) must undergo sufficient education and training regarding research-related ethics and the knowledge and skills of the research methods required for implementation of the research in order to carry out the relevant clinical research appropriately in accordance with their required responsibilities. Researchers required to undergo training must undertake one of the following training programs.

i) Training conducted by a Clinical Research Core Hospital for persons working in the clinical research field.
ii) Training that is recognized by the research institution as being equivalent to the above (including training conducted by facilities other than a Clinical Research Core Hospital)

Note 1: Simply participating in academic meetings does not qualify as education/training.

Note 2: Certain quality-assured e-learning programs such as APRIN e-learning program (eAPRIN), Clinical Research e-Training Center (Center for Clinical Trials, Japan Medical Association), Introduction to Clinical Research (ICRweb) may also be acceptable for ii), but it is essential that the "Kenkyusekinin Ishi" (Principal Investigator) undergoes thorough training and understands the training content.

* With regard to training conducted by a Clinical Research Core Hospital, please check the section "Regarding Clinical Research Core Hospitals" on the website below.

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/chiken.html (in Japanese)

11.3.2 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.)

11.3.3 Role of Research Institutions and Reporting Research Ethics Training Status

Research institutions shall ensure that persons required to undergo research ethics training as listed above who are affiliated with their institution (included a subcontracted institution) undergo the R&D ethics education using one of the programs/materials listed above; 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 (Division of Research Integrity and Legal Affairs, Department of Research Integrity and Project Management). (Seal need not be affixed.).

Information regarding where and how to submit reports is to be posted on the "The Responsible Conduct of Research (RCR) Education Program" page under "Research Integrity" on the AMED website (refer to URL shown above) around March 2021.

• Subject of report	Persons required to undergo research ethics training in programs commencing in/after FY2021
• Deadline for submission	May 31, 2022
• Documents to be submitted	Report on the Status of Participation in R&D Ethics Education Programs (Please download the form from the AMED website)
• URL	https://www.amed.go.jp/kenkyu_kousei/kyoiku_program.html (in Japanese)

11.4 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 and Article 21 of the Ordinance for Enforcement of the Clinical Trials Act, the situation regarding conflict of interest for researchers involved in R&D projects shall be managed appropriately and reported.

In the case of research institutions 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 institution to improve the situation or suspend provision of R&D funds, as well as require the research institution to return all or part of the R&D funds already paid.

11.4.1 Conflict of Interest Management in Accordance with AMED's Regulations Regarding Conflict of Interest (COI) Management in Research Activities

(3) Target Persons

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

(4) Requests for COI Reviews

(c) 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.

11.4.2 Conflict of Interest Management in Accordance with Article 21 of the Ordinance for Enforcement of the Clinical Trials Act

Please carry out conflict of interest management in accordance with relevant laws and ordinances.

11.4.3 Submission of Reports on the State of COI Management

Each research institution, etc. should prepare a Report on the State of COI Management, and submit it to AMED within 61 days after the end of each fiscal year or the conclusion of the contracted R&D project. The Reports on the State of COI Management are to be posted on the AMED website.*

Information including the forms of the Report on the State of COI Management, where and how to submit reports is to be posted on the "Conflict of Interest (COI) Management in R&D" page under "Research Integrity" on the AMED website* around March 2021.

* For details regarding conflict of interest management, please refer to the AMED website below.

- Regulations for Managing COI in Research Activities
- Regulations Q&A/ Reports on the State of COI Management

https://www.amed.go.jp/kenkyu_kousei/riekisohan_kanri.html (in Japanese)

11.5 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 guidelines that must be complied with, in addition to the imposition of punishments and penalties according to legislation, 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 institutions must take appropriate measures with regard to the handling of the guarantee of human rights and interests.

Within 61 days after the end of each fiscal year or the conclusion of the contracted R&D project, research institutions shall report to AMED regarding the status of ethical reviews by research institutions concerning related laws/ordinances and policies as an item related to the Contracted R&D Result Report, which is an appendix to the Contracted R&D Accomplishments Report.

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 amendment of laws/ordinances, etc.

- Act on Regulation of Human Cloning Techniques (Act No. 146 of 2000)
- Act on the Prevention of Infectious Diseases and Medical Care for Patients Suffering from Infectious Diseases (Act No. 106 of 2006)
- Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Act No. 97 of 2003)
- Act on Securing Safety of Regenerative Medicine (Act No. 85 of 2013)
- Clinical Trials Act (Act No. 16 of 2017)
- Ordinance for Enforcement of the Clinical Trials Act (Ordinance of the Ministry of Health, Labour and Welfare (MHLW) No. 17 of 2018)
- 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)
- Guidelines on the Handling of Specified Embryos (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) No. 31 of 2019)
- 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. 4 of 2019)
- Guidelines for the Distributing institute of Human Embryonic Stem Cells (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) No. 69 of 2019)
- Guidelines on the Utilization of Human Embryonic Stem Cells (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) No. 68 of 2019)
- 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 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; partially revised on February 28, 2017)
- On the Approach of Research and Development Using Human Tissues Obtained from Surgery (Report of the Health Science Council, the Ministry of Health and Welfare, 1998)

○ Ethical Guidelines for Medical and Health Research Involving Human Subjects (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT), and Ministry of Health, Labour and Welfare (MHLW) No. 1 of 2017; partially revised on February 28, 2017)

The above guidelines were abolished on June 30, 2021, and the Ethical Guidelines for Life Science and Medical/Health Research Involving Human Subjects (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 2021) have come into force.

https://www.mext.go.jp/b_menu/houdou/mext_00525.html (in Japanese)

○ 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; partially revised on February 28, 2017)

The above guidelines were abolished on June 30, 2021, and the Ethical Guidelines for Life Science and Medical/Health Research Involving Human Subjects (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 2021) have come into force.

https://www.mext.go.jp/b_menu/houdou/mext_00525.html (in Japanese)

○ Ethical Guidelines for Life Science and Medical/Health Research Involving Human Subjects (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 2021)

*The above guidelines have come into force on June 30, 2021.

○ Policies on Clinical Research Involving Gene Therapy (Public Notice of the Ministry of Health, Labour and Welfare (MHLW) No. 344 of 2015; partially revised on February 28, 2019)

○ 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)

○ Guidelines on Opportunities for Acquisition of Genetic Resources and on Fair and Equitable Distribution of the Profits Generated through their Use (Public Notice of the Ministry of Finance (MOF), the Ministry of Education, Culture, Sports, Science and Technology (MEXT), the Ministry of Health, Labour and Welfare (MHLW), the Ministry of Agriculture, Forestry and Fisheries (MAFF), the Ministry of Economy, Trade and Industry (METI), and the Ministry of Environment (MOE) No. 1 of 2017)

*Please refer to the following websites for details regarding bioethics and ensuring safety.

- MEXT's Life Sciences Forum "Initiative on Bioethics and Biosafety"

  https://www.lifescience.mext.go.jp/bioethics/index.html (in Japanese)

- Regarding Guidelines on Research (Ministry of Health, Labour and Welfare (MHLW))

  https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/hokabunya/kenkyujigyou/i-kenkyu/index.html (in Japanese)

11.6 Obligation to Take Action with Regard to System Maintenance, etc.

11.6.1 Obligation to Take Action with Regard to System Maintenance

All research institutions must strictly comply with the items required to be implemented by research institutions in accordance with the Guidelines for Responding to Misconduct in Research* (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 1, 2021).

*Please refer to the following websites for details of each guideline.

- Guidelines for Responding to Misconduct in Research

  https://www.mext.go.jp/a_menu/jinzai/fusei/__icsFiles/afieldfile/2015/07/13/1359618_01.pdf

- Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards)

  https://www.mext.go.jp/a_menu/kansa/houkoku/1343904_21.htm (in Japanese)

11.6.2 Confirmation of System Maintenance

In concluding the agreement for this program, each research institution will be asked to submit to the following checklist to MEXT regarding the implementation status of system maintenance based on the various guidelines.

According to the format of the various websites all research institutions are requested to submit a checklist to MEXT via e-Rad by the deadline stipulated by AMED.

(A) Self-evaluation (Including System Maintenance) Checklist	
• Basis	Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards)
• Submission method	https://www.mext.go.jp/a_menu/kansa/houkoku/1324571.htm (in Japanese)
• Submit to	Office of Research Funding Administration, Policy Division, Research Promotion Bureau, MEXT
(B) Checklist of research misconduct	
• Basis	Guidelines for Responding to Misconduct in Research
• Submission method	https://www.mext.go.jp/a_menu/jinzai/fusei/1420301_00001.htm (in Japanese)
• Submit to	Office for Research Integrity Promotion, Human Resources Policy Division, Science and Technology Policy Bureau, MEXT

11.6.3 Necessity of Submitting a Checklist

With regards to the checklists (A) and (B) cited above in 11.6.2, in the case that applicants 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 MEXT program or concluding a contracted R&D agreement in the same fiscal year.

However, both of these checklists are required to be submitted on an annual basis, so research institutions that are continuing implementation in the following year and beyond must also submit the checklists to MEXT once each fiscal year.

Furthermore, with regard to the checklist (A) above, institutions that are not allocated by the competitive research funding of MEXT or independent administrative agencies under MEXT are not required to submit the checklist. With regard to checklist (B), submission is not required by institutions other than those that are allocated a budget by MEXT or the independent administrative agencies under MEXT and conduct research activities.

*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 institutions 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 web page on How to Register (for research institutions) on the e-Rad portal site detailed below.

https://www.e-rad.go.jp/organ/index.html (in Japanese)

11.6.4 Cooperation with Surveys

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

11.6.5 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 system improvement that a research institution's system improvement is inadequate shall be issued management conditions by MEXT stating the items requiring improvement and the deadline for implementing these improvements. In addition, in cases in which the management conditions are not deemed to have been fulfilled by the research institution it may become subject to measures such as reducing the indirect costs with regard to all competitive research funding allocated by MEXT and independent administrative agencies under the jurisdiction of MEXT.

Chapter 12. Countermeasures to Misconduct, Fraudulent Use, and Fraudulent Receipt

12.1 Reporting of and Cooperation in Investigations of Misconduct, Fraudulent Use, and Fraudulent Receipt

In the case that a complaint (including criticism from external organizations such as the media or the Board of Audit) related to misconduct, fraudulent use, or fraudulent receipt (hereinafter collectively referred to as "misconduct") by a research institution in relation to this program, the research institution 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, etc. in Research Activities with regards to Programs relating to Cabinet Budgets for Japan Agency for Medical Research and Development (formulated on March 1, 2017 by Office for Japan Agency for Medical Research and Development, Cabinet Office); Guidelines for Responding to the Misuse of Research Funds with regards to Programs relating to Cabinet Budgets for Japan Agency for Medical Research and Development (formulated on March 1, 2017 by Office for Japan Agency for Medical Research and Development, Cabinet Office); and AMED Regulations for Responding to Misconduct in Research Activities.

In the event that it is deemed necessary for the research institution 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 accused and/or the research institution to suspend use of research funds under this program as a temporary measure during the investigation if necessary.

Furthermore, the research institution 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. For details regarding items that should be incorporated into the final report, please refer to Guidelines for Responding to Misconduct, etc. in Research Activities with regards to Programs relating to Cabinet Budgets for Japan Agency for Medical Research and Development (formulated on March 1, 2017 by Office for Japan Agency for Medical Research and Development, Cabinet Office); Guidelines for Responding to the Misuse of Research Funds with regards to Programs relating to Cabinet Budgets for Japan Agency for Medical Research and Development (formulated on March 1, 2017 by Office for Japan Agency for Medical Research and Development, Cabinet Office); and AMED Regulations for Responding to Misconduct in Research Activities.

In the case that it is confirmed that misconduct has occurred even partially and even before the investigation has been completed, the research institution 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 institution 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 institution extends the deadline for submission of the final report, AMED may take measures against the research institution such as reducing indirect costs by a certain percentage or suspending execution of contracted R&D funds.

12.2 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 institution and researcher(s) in accordance with Guidelines for Responding to Misconduct, etc. in Research Activities with regards to Programs relating to Cabinet Budgets for Japan Agency for Medical Research and Development (formulated on March 1, 2017 by Office for Japan Agency for Medical Research and Development, Cabinet Office); Guidelines for Responding to the Misuse of Research Funds with regards to Programs relating to Cabinet Budgets for Japan Agency for Medical Research and Development (formulated on March 1, 2017 by Office for Japan Agency for Medical Research and Development, Cabinet Office); and AMED Regulations for Responding to Misconduct in Research Activities.

12.2.1 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 institution and demand the return of all or part of the contracted R&D funds from the research institution. In the event that contracted R&D funds are returned, the relevant research institution will be required to pay interest calculated in accordance with the number of days from the date of the receipt of contracted R&D funds until the date of return. The interest will be determined by AMED within the scope of 10.95% per annum for the contracted R&D funds (if a portion of the amount has been returned already, the already returned amount will be subtracted from the balance for the remaining time). Furthermore, AMED may not provide contracted R&D funds to the relevant research institution for the next fiscal year or thereafter.

12.2.2 Restrictions on Applications to and Eligibility for 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 eligibility for participation in AMED programs restricted in accordance with the degree of misconduct as shown in the table below. 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 eligibility for participation in AMED programs, the related government ministries and agencies will be informed of an outline of the misconduct in question (name of the researcher responsible for misconduct, program name, research institution, research project, budget amount, fiscal year of research, details of the misconduct and details of measures taken against them etc.). In this way competitive research funding programs provided by related government ministries/agencies may similarly be restricted in some cases.

• In the case of misconduct

The period of restriction deemed appropriate in consideration of the misconduct and its nature, on or after the day that the misconduct is recognized, and between one year and ten years from the fiscal year in which the day on which the misconduct is recognized or the next fiscal year.

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

• In the case of fraudulent use/fraudulent receipt

The period of restriction deemed appropriate in consideration of the content etc. of the fraudulent use/fraudulent receipt, on or after the day that AMED decides upon the measures, and between one year and ten years from the fiscal year in which the day on which AMED decides upon the measures or the next fiscal year.

<table>
<tr><th>Researchers involved in fraudulent use or receipt whose applications will be restricted</th><th colspan="2">Severity of fraudulent use</th><th>Period of application restriction</th></tr>
<tr><td rowspan="4">1. Researcher who perpetrated fraudulent use and conspiring researchers</td><td colspan="2">(1) Personal diversion of funds for private benefit</td><td>10 years</td></tr>
<tr><td rowspan="3">(2) Other than (1)</td><td>i) The researcher’s actions are deemed to have a large social impact and be highly malicious.</td><td>5 years</td></tr>
<tr><td>ii) Those other than i) and iii)</td><td>2—4 years</td></tr>
<tr><td>iii) The researcher’s actions are deemed to have a small social impact and be slightly malicious.</td><td>1 year</td></tr>
<tr><td>2. Researchers who received competitive funds through falsehoods or other dishonest means and conspiring researchers</td><td colspan="2"></td><td>5 years</td></tr>
<tr><td>3. Researchers not directly involved in fraudulent use but who use the research funds in a manner infringing duty of diligence</td><td colspan="2"></td><td>Maximum of two years and minimum of one year depending on the severity of infringement of diligence by the researcher with duty of diligence</td></tr>
</table>

Note 1: In the following cases, the offender shall be given a reprimand without imposing restrictions on eligibility for participation.

- In 1, the researcher’s actions are deemed to have a small social impact and be slightly malicious, and the funding amount used fraudulently is small.
- In 3, the researcher’s actions are deemed to have a small social impact and be slightly malicious.

Note 2: With regard to 3 above, periods will be decided upon with due consideration of the severity of infringement of diligence by the researcher with duty of diligence.

12.2.3 Restrictions on Researchers Whose Application to and Eligibility for Participation in Other Competitive Research Funding Programs Has Been Restricted

With regard to researchers who have been found to have carried out misconduct under competitive research funding programs (including programs for which new applications are solicited in FY2021 or later, and programs completed in or before FY2020) other than this program, which are under the jurisdiction of the national government or an independent administrative agency and are government-financed either wholly or in part, and whose application to and eligibility for participation in these programs has been restricted, application to and eligibility for 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 this program becomes known after the conclusion of the contracted R&D agreement, the relevant agreement may be cancelled.

12.2.4 Cases in Which it is Suspected that Misconduct Has Occurred Under Another Competitive Research 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 competitive research funding program, the research institution 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 institution to which the relevant researcher is affiliated fails to make the above report, the contracted R&D agreement may be cancelled.

12.2.5 Disclosure of Misconduct

In the case that the measures and/or restrictions prescribed in 12.2.1 and 12.2.2 above are implemented under this program, an outline of the misconduct in question (program name, research institution, fiscal year of research, details of the misconduct and details of measures taken against them) shall as a general rule be publicly disclosed in accordance with Guidelines for Responding to Misconduct, etc. in Research Activities with regards to Programs relating to Cabinet Budgets for Japan Agency for Medical Research and Development (formulated on March 1, 2017 by Office for Japan Agency for Medical Research and Development, Cabinet Office); Guidelines for Responding to the Misuse of Research Funds with regards to Programs relating to Cabinet Budgets for Japan Agency for Medical Research and Development (formulated on March 1, 2017 by Office for Japan Agency for Medical Research and Development, Cabinet Office); and AMED Regulations for Responding to Misconduct in Research Activities. In addition, the misconduct may be similarly disclosed by the related government ministries/agencies.

Furthermore, as both MEXT guidelines state that when misconduct is identified the research institution must swiftly publicize the results of its findings all institutions are asked to take the appropriate steps. MEXT currently makes public an outline of matters of misconduct, so please refer to these at the following web pages.*

* https://www.mext.go.jp/a_menu/jinzai/fusei/1360483.htm (in Japanese)

https://www.mext.go.jp/a_menu/kansa/houkoku/1364929.htm (in Japanese)

12.3 Registration with AMED Rio Network

To promote research integrity activities in an efficient manner, it is essential for AMED and the research institution or research institutions among themselves to exchange information and work together. Accordingly, to promote efficient research integrity activities nationwide, the RIO Network was established in FY 2017 to provide a venue where the Research Integrity Officers (RIO) of research institutions which are allocated research funds from AMED can easily exchange information. Detailed information on the RIO Network is provided on the following website*:

The officers in charge of R&D ethics education and the officers in charge of promoting compliance (collectively referred to as “Research Integrity Officers” or RIO) who are participating in AMED programs should become members of the RIO Network.

There is a space on the Breakdown of Expenses, etc. and Contracted Items Sheet, which is submitted when the contract is concluded, for entering information about the officers in charge of R&D ethics education and the officers in charge of promoting compliance, so be sure to fill in this information. AMED will register Research Integrity Officers with the RIO Network. When registering personnel other than the above who are engaged in research integrity related tasks with the RIO Network, please do so in accordance with the instructions on the AMED RIO Network website.

*https://www.amed.go.jp/kenkyu_kousei/rionetwork.html (in Japanese)

Chapter 13. Other

While these items do not impact evaluations under each program unless noted as a special condition, AMED requires grant program participants to proactively endeavor to adhere to comply with each of these items due to their importance. Research institutions and researchers are asked to gain a thorough understanding of the purposes of these items and comply with these in carrying out their R&D.

Moreover, to ensure that the results of these efforts contribute to the improved implementation of AMED programs in the future, not only may they be used in analysis of research trends, but also the analysis results may be publicized in a form that does not identify the R&D project (E.g.: published by program rather than individual project). Accordingly, it may be requested that details of these efforts be included in Contracted R&D Result Reports.

13.1 Promotion of Dialogue and Cooperation with Society

According to "Promotion of Dialogue on Science and Technology with the Public (a Basic Approach Policy)" (June 19, 2010, decision of the Minister of State for Science and Technology Policy and expert members of the Council for Science and Technology Policy), if a proposal is selected in this call for proposals and receives an allocation of public research funds (competitive funds or project research funds) in an amount of 30 million yen per year or more for one project, it is considered essential to have an attitude in which excellent achievements in science and technology are constantly produced, and achievements in science and technology are returned to the public in order to further develop science and technology in Japan, and science and technology are advanced jointly with the understanding and support of the public through "Dialogue on Science and Technology with the Public." In addition, the 5th Science and Technology Basic Plan (Cabinet decision of January 22, 2016) calls for deepening the conventional relationship, in which science and technology and society are opposed, into a relationship of dialogue and cooperation by various stakeholders, i.e., researchers, citizens, the media, industry, and policymakers, in other words, a relationship that promotes "co-creation." From these viewpoints, efforts to explain the content and results of research activities to society and the public in easily understood terms, and efforts to promote dialogue and cooperation among various stakeholders are demanded. Based on this, we ask that program participants make active efforts in connection with these activities, including holding public lectures and symposiums on research achievements, continuously posting information on research achievements on the internet, and holding roundtable meetings with various stakeholders.

Reference: Regarding the Promotion of Dialog with Citizens on Science and Technology (basic initiative guidelines)
https://www8.cao.go.jp/cstp/stsonota/taiwa/taiwa_honbun.pdf (in Japanese)

Reference: Fifth Science and Technology Basic Plan
https://www8.cao.go.jp/cstp/kihonkeikaku/5honbun.pdf (in Japanese)

13.2 Promotion of the Patient and Public Involvement (PPI) in Medical Research/Clinical Studies

AMED's mission is to approach each patient individually, staying close and providing support for LIFE (being alive, living each day, living life) while ensuring the practical application of research results in the medical field as quickly as possible and delivering these results to patients and their families. In view of this mission, AMED is

promoting initiatives that promote Patient and Public Involvement (PPI)* in medical research and clinical studies. These efforts are expected to generate research results that are even more beneficial to patients, etc., as well as lead to smoother implementation of research and improved protection of clinical trial subjects. For these reasons, AMED requests that program participants proactively incorporate PPI into medical research and clinical studies.

* AMED's definition of "Patient and Public Involvement (PPI) in Medical Research/Clinical Studies"

As part of the medical research/clinical study process, researchers are endeavoring to incorporate the knowledge and opinions of patients and members of the general public. Here, "Patient and Public" includes patients, patients' families, former patients (survivors), and future patients.

Reference: AMED's "Patient/Public Involvement (PPI) in Medical Research/Clinical Studies"

https://www.amed.go.jp/ppi/index.html (in Japanese)

13.3 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.[1] For details such as contact information, please refer to the AMED Administration Manual for Contracted R&D Agreement in Japan Agency for Medical Research and Development.[2]

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

[1] https://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/kenkoukiken.doc (in Japanese)

[2] https://www.amed.go.jp/keiri/index.html (in Japanese)

13.4 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.

13.5 Measures Related to the IP Strategic Program

The Intellectual Property 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. As the Intellectual Property Strategic Program 2014 (Intellectual Property Strategy Headquarters on July 4, 2014),[1] sets forth the strategic utilization of certification in order to further invigorate international standardization activities, AMED is also to promote R&D with a view to international standardization/certification.

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

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

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

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

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

13.6 IP consultation support through AMED IP Consultants and AMED IP Liaisons

In order to encourage the practical application of R&D accomplishments obtained from AMED projects implemented, AMED provides a free-of-charge IP consultation service run by AMED IP Consultants and AMED IP Liaisons covering IP strategy and out-licensing strategies. Furthermore, as one facet of this IP consultation service, when requested we also provide a free service to formulate precise IP strategies for R&D accomplishments through investigating the available literature, etc.

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

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

[1] AMED IP Liaisons: https://www.amed.go.jp/chitekizaisan/chizai_riezon.html (in Japanese)

[2] Medical IP Desk https://www.amed.go.jp/chitekizaisan/medical_ip_desk.html (in Japanese)

13.7 Seeds/Needs Matching Support System

In April 2018, AMED launched the "AMED ぷらっと®/AMEDplat " private information network system, the purpose of which is to match at the earliest possible stage the R&D seeds information of universities and other academia with corporate needs information, providing support aimed at achieving early practical application and

commercialization of R&D results in the medical field. This enables research seeds to be showcased to staff in charge of in-licensing at multiple companies, facilitating university-company collaboration at an early stage. In order to achieve this it is requested that you proactively register research seeds in the medical field in the AMED ぷらっと® /AMEDplat system. Note that you should refer to the AMED ぷらっと® /AMEDplat website* regarding details about the launch of use of the AMED ぷらっと® /AMEDplat.

*AMED ぷらっと® /AMEDplat website:

https://www.amed.go.jp/chitekizaisan/amed_plat.html (in Japanese)

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

In order to link the results of outstanding basic research by universities to the practical application of drugs, AMED's Department of Innovative Drug Discovery and Development (hereinafter referred to as the "iD3") 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 out-licensing to a company.

The iD3 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 out-licensing to drug companies; provides technological support for applied research (exploratory study, optimization study, etc.) and nonclinical studies (conforming to GLP (Good Laboratory Practice)); provides introduction and contracted support of CROs (Contract Research Organizations) and CMOs (Contract Manufacturing Organizations), etc.; and facilitates out-licensing process to drug companies.

In this way, the iD3 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 out-licensing to drug companies. For this reason, R&D projects that are related to drug development may receive active support from the iD3 in coordination with the division in charge of this program.

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 6.). Furthermore, the iD3 provides the above-mentioned support based on requests by researchers on the premise of maintaining confidentiality and protecting IP rights that have reverted to the researcher.

In the same way, with regards to the applied R&D projects related to drug development that is or was supported by the iD3, AMED provides the information on the support content to the division in charge of this program.

Please refer to Chapter 14 for references related to support provided by the AMED Drug Discovery Support Network and the iD3.

13.9 Support for Research Seeds and R&D through Translational and Clinical Research Core Centers

AMED is building a system to consistently link the results of basic research conducted by academia etc. with practical application at Translational and Clinical Research Core Centers (Translational Research Support Centers and Clinical Research Core Hospitals).

In order to support the development of drugs and medical devices, the Translational and Clinical Research Core Centers secure human resources specialized in pharmaceutical affairs, biostatistics, project management, intellectual property, as well as provide biomarker evaluation equipment, cell processing facilities, and management centers securely handling clinical study data, supporting processes from the basic research stage through clinical studies, clinical trials, and practical application of research seeds generated by Translational and Clinical Research Core Centers and other research institutions. Furthermore, the Translational and Clinical Research Core Centers run programs to foster the young human resources taking on R&D into drugs and medical devices and medical entrepreneurs, and host seminars and symposia for those aiming to achieve practical application in medical fields.

The various services, consultations and shared facilities provided by the Translational and Clinical Research Core Centers are not restricted to within its centers and hospitals, but can also be used by a wide range of researchers ranging from those of external research institutions to corporate researchers including those of ventures. (There are charges for part of the support business and services according to the regulations of each organization.) For programs in which disbursement of Academic Research Organization (ARO) support expenses as research expenses is approved, those wishing the support of Translational and Clinical Research Core Centers when planning and implementing research aimed at the practical application of medical seeds are requested to refer to the contact points provided in the List of Translational and Clinical Research Core Centers provided below.

*List of Translational and Clinical Research Core Centers

https://www.amed.go.jp/program/list/16/01/001_ichiran.html (in Japanese)

13.10 Registration of Researcher Information on researchmap

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

Note that there is a link from researcher names on the AMED funding for innovation database (AMEDfind) website to researchmap.

* https://researchmap.jp/?lang=en

13.11 Deposit of Developed Resources in Domestic Resource Centers

It is strongly recommended that after using bioresources developed under this program and publishing the research accomplishments obtained via academic papers, etc., the persons implementing this program are to deposit[2] the relevant bioresources in domestic resource centers,[1] and make them broadly available for researchers' use.

[1] Domestic public centers conducting deposit, storage and provision such as The National Bioresource Project (NBRP), RIKEN BioResource Research Center, National Institutes of Biomedical Innovation, Health and Nutrition, universities and so on.

[2] "Deposit": Procedure for permitting the use (storage/provision) of resources at domestic resource centers etc. listed in 1 above without transferring various rights related to the relevant resources. By prescribing conditions for provision within the deposit consent form, it is possible to add conditions regarding restrictions on use of resources and citation in academic papers, etc., for users receiving the relevant resources.

13.12 Cooperation with Databases

(1) Publicizing of Data from the National Bioscience Database Center

The National Bioscience Database Center (NBDC) (https://biosciencedbc.jp/en/) was established in April 2011 in the Japan Science and Technology Agency in order to promote the integrated use of the life science database that has been created through the efforts of many research institutions. "The State of Progress and Future Direction of the Life Science Database Integration Project" that was published on January 17, 2013, states that an expansion of the programs eligible to receive data and databases will be implemented with the Center playing a central role.

Based on this, you are asked to cooperate with the provision of data to the Center with regard to the following types of data and databases resulting from this program.

No.	Type of data	Publication platform	Publication platform URL
1	Outline of the database created for publication	Integbio Database Catalog	https://integbio.jp/dbcatalog/?lang=en
2	Copies of data concerning results published in academic papers, or other means, or copies of the database created for publication.	Life Science Database Archive	https://dbarchive.biosciencedbc.jp/index-e.html
3	Data or databases concerning humans from 2above	NBDC Human Database	https://humandbs.biosciencedbc.jp/en/

(2) Registering with the Patient Registry Database Search System

By using a disease registry system (patient registry) in clinical development the Clinical Innovation Network (CIN) aims to vitalize clinical development of drugs and medical devices in Japan, and is a project led by the Ministry of Health, Labour and Welfare in which the environmental preparations are made by an industry-government-academia alliance. Through the promotion of the use of a disease registry system (patient registry) the National Center for Global Health and Medicine creates an information search system regarding the patient registries in existence in Japan as a part of support for efficient clinical development of drugs and medical devices, and makes this available to the general public (https://cinc.ncgm.go.jp/) (in Japanese). Those working on R&D

projects related to patient registries and cohort studies (not including clinical trials and intervention studies) who have yet to register with the system are requested to do so.

(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.

13.13 Improvement of Incentives for Doctoral Students

Under the 6th Science, Technology, and Innovation Basic Plan (Cabinet decision of March 26, 2021), aiming to increase three-fold the number of doctoral students receiving the amount equivalent to living expenses (equivalent to about 30% of all doctoral students receiving the amount equivalent to living expenses) was cited as a numerical target in order to attract excellent students and working adults from Japan and overseas, and enhance the financial support of graduate students and in particular doctoral students. In addition, the Basic Plan states that in order to promote the payment of salaries to doctoral students at an appropriate level for research assistants (RA) from competitive research funds and joint research funds, the government will formulate rules for the payment of RA expenses relating to employment and remuneration for RAs at each business and university, and implement them sequentially from FY2021, and urges the expansion of the employment of doctoral students as RA at universities and research and development agencies, and the improved treatment of doctoral students.

In addition, the Guidelines on Employment and Fostering of Postdoctoral Students (formulated on December 3, 2020, by MEXT's Council for Science and Technology's Committee on Human Resources) state as follows with regard to doctoral students:

While being students, doctoral students also have the facet of being researchers, and improving the environment for research activities and employment status is an important responsibility of universities as the fosters of researchers. (…) It is particularly vital that the contributions of doctoral students are appropriately evaluated by setting wages appropriate to the nature and content of work and the payment of salaries corresponding to the amount of time they have spent on work. (…) It is essential that universities budget as direct costs the requisite expenses in the event that they employ RAs when applying for competitive research funds, and that they conduct reviews and so on of their internal regulations in order to enable the payment to RAs of an acceptable level of wages.

In the light of that fact, in this program the doctoral students requisite for the execution of the research should be enthusiastically employed as RAs. At the same time, unit costs fitting to the nature and content of their work should be set, and it is requested that doctoral students be paid a salary in accordance with the time they spend working under appropriate work management. It is also requested that when applying for this program applications are made with a funding plan paying due consideration to the salary levels of the above-mentioned doctoral students.

Points to Note

- Under the 6th Science, Technology, and Innovation Basic Plan the amount equivalent to living expenses of doctoral students is set as a minimum of 1.8 million yen per year. Furthermore, in order that excellent doctoral students can

apply themselves to their research without feeling any financial concerns, the Basic Plan states the wide-sweeping expansion of those receiving around 2.4 million yen per year, equivalent to the stipend paid through the JSPS Research Fellowship for Young Researchers (Doctoral Course Students (DC)) program.

- With regard to the employment of doctoral students in order to execute research projects, the Guidelines on Employment and Fostering of Postdoctoral Students state that "Considering the average salary of assistant professors without tenure who are employed in competitive research funds etc., it is thought that the payment of an hourly wage of around 2,000 yen to 2,500 yen would be a standard amount."

  * Considering the average salary of assistant professors without tenure who are employed in competitive research funds etc., it is thought that the payment of an hourly wage of around 2,000 yen to 2,500 yen would be a standard amount. (The August 2020 bulletin edition of the Survey on The Employment Status of Instructional Staff Members at Research Universities calculates the hourly wage of doctoral students by dividing the median value of the monthly salaries of assistant professors without tenure (between 400,000 and 450,000 yen) by a 19- to 20-day shift (excluding holidays etc.) of seven and three-quarter hours to eight hours, and subtracting 20% in consideration of the recipients' status as doctoral students.)

- Research institutions are requested to decide by themselves the specific amounts and period the doctoral students will be paid. The salary level indicated above does not restrict salary payments of either a higher or lower amounts.
- When employing a doctoral student as an RA pay consideration to ensuring they do not work excessive hours and allow the doctoral students to maintain a balance with their own research and studies.

13.14 Securing of an Autonomous and Stable Research Environment for Young Researchers

Since both "Improving and Reforming Research Capability 2019" (formulated on April 23, 2019 by MEXT) and "Development of Science and Technology Innovation Policy Towards the Creation of Knowledge-intensive Value: Towards a Nation that Leads the World in Achieving Society 5.0 (final summary)" (formulated on March 26, 2020, by MEXT's Council for Science and Technology's Comprehensive Policy Special Committee) points out that with regard to fixed-term positions such as specially appointed faculty members and postdoctoral fellows short-term appointments may hinder their career development, and securing tenures of five years or more is important.

In addition, with regard to national university corporations and inter-university research institute corporations, the "Guidelines on Personnel Salary Management Reform at National University Corporations etc.: Towards the Creation of Personnel Salary Management that are Attractive and Contribute to Improving Education and Research Capabilities" (formulated on February 25, 2019 by MEXT) state that "In order to achieve the twin perspectives of fostering young researchers and stable employment, even in the cases of fixed tenures, by using expenses with a high degree of freedom such as indirect costs and donations, it is to be hoped that certain terms of employment of between five to ten year are secured, and systems that maintain flexibility while incorporating researcher-fostering perspectives are designed and promoted."

In the light of all of the above, in the event that young researchers such as specially appointed faculty members and postdoctoral fellows are employed in this program please strive to secure tenures of the length of the R&D period, having checked with the persons in charge of personnel and accounts in the relevant department, and also make an

effort to, as far as possible, secure tenures of five years or more through the utilization of other external funding such as indirect expenses, basic expenses and donations.

13.15 Support for Diverse Career Paths for Young Researchers

According to the Basic Policy on Support for Diverse Career Paths for Young Postdoctoral Fellows to Be Employed through MEXT Public Research Funds (formulated on December 20, 2011 by MEXT's Council for Science and Technology's Personnel Committee), "The public research institutions and their representatives should eagerly involve themselves in the support of young postdoctoral researchers in order to secure for these young people a variety of career paths inside and outside of Japan." Furthermore, the 6th Science, Technology, and Innovation Basic Plan (Cabinet decision of March 26, 2021) also cites targets for the "expansion of career paths for doctoral researchers to the industrial sector" and "promotion of human resource mobility." In addition, the Guidelines on Employment and Fostering of Postdoctoral Students (formulated on December 3, 2020, by MEXT's Council for Science and Technology's Committee on Human Resources) state: "It is essential that doctoral human resources with sophisticated professionalism and excellent research capabilities are active in a variety of places including venture businesses and global corporations, and that they create innovation. Initiatives towards the diversification of career paths after the completion of post-doctoral terms are imperative." In response to this statement, those involved in the projects adopted by this program are requested to pursue positive initiatives to secure a variety of potential career paths for young researchers such as specially appointed professors and postdoctoral fellows employed using the competitive research funds, funding from other research projects, solicitation-based education and research funds aimed at universities, or other public research funds. In addition, please consider the use of indirect costs for the funding of these initiatives.

13.16 Accreditation of Partnership on Research Assistance Service (A-PRAS)

The "Development of Science and Technology Innovation Policy Towards the Creation of Knowledge-intensive Value: Towards a Nation that Leads the World in Achieving Society 5.0 (final summary)" (formulated on March 26, 2020, by MEXT's Council for Science and Technology's Comprehensive Policy Special Committee) states that "There is a need for the creation of new public private partnership (PPP) mechanisms based on the emergence of start-ups conducting their business with a strong determination and passion for returning to society the results of research assistance and research results from projects implemented as public projects by the government."

In the midst of these circumstances, MEXT established the Accreditation of Partnership on Research Assistance Service (A-PRAS) in FY2019. It aims through the accreditation by the Minister of Education, Culture, Sports, Science and Technology of services - among the research assistance services conducted by private sector businesses - that satisfy certain conditions, to improve researchers' research environments, promote science and technology in Japan, accelerate the creation of innovation, and support the development of a variety of initiatives regarding research assistance services. As of the end of FY2020 nine services had been accredited.

Details of the accredited services can be viewed at the MEXT webpage* shown below. It is very much hoped that this service will be widely used.

*https://www.mext.go.jp/a_menu/kagaku/kihon/1422215_00001.htm (in Japanese)

Chapter 14. Contact

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

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

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

[3] https://www.amed.go.jp/en/news/proposals.html

Content of inquiry	Contact address
R&D projects being solicited; review; how to fill in proposal documents	Division of International Strategy, Department of International Strategy, AMED Tel: +81-3-6870-2210 E-mail: amed-satreps"AT"amed.go.jp
Misconduct/fraudulent use/fraudulent receipt	Division of Research Integrity and Legal Affairs, Department of Research Integrity and Project Management, AMED E-mail: kouseisoudan"AT"amed.go.jp
Management of conflict of interest/research ethics education programs	Division of Research Integrity and Legal Affairs, Department of Research Integrity and Project Management, AMED E-mail: kenkyuukousei"AT"amed.go.jp
RIO Network	Division of Research Integrity and Legal Affairs, Department of Research Integrity and Project Management, AMED E-mail: rionetwork"AT"amed.go.jp
Medical IP Desk (Contact point for medical IP consultation)	Division of Intellectual Property, Department of Intellectual Property and Technology Transfer, AMED E-mail: medicalip"AT"amed.go.jp
Support provided by the AMED Drug Discovery Support Network/Department of Innovative Drug Discovery and Development	East Japan Office, Department of Innovative Drug Discovery and Development, AMED 8F Muromachi Chibagin Mitsui Bldg, 1-5-5 Nihonbashi-Muromachi, Chuo-ku, Tokyo 103-0022, Japan Tel: +81-3-3516-6181 E-mail: id3navi"AT"amed.go.jp
How to use the e-Rad system	e-Rad Portal Site Help Desk Before telephoning, please check the "Frequently Asked Questions (FAQ)" page. =>After checking the FAQ page, log in to e-Rad (https://www.e-rad.go.jp/contact.html) so that you can check the operation manual, then dial: Tel: 0570-066-877 (NAVI-DIAL) or +81-3-6631-0622 (direct line) if the NAVI-DIAL service is unavailable. Operating hours: 9:00–18:00 (weekdays) *Excludes Saturdays, Sundays, public holidays, or Year-end/New Year holidays (December 29 – January 3)
Bioscience Database	Japan Science and Technology Agency (JST) National Bioscience Database Center (NBDC) Tel: 03-5214-8491 E-mail: nbdc-kikaku"AT"jst.go.jp

Appended Table

Summary of Submission Timing and Content of All Types of Information Material Required at AMED (Drugs)

	New drugs, etc.			New indications		Clinical study under ethical guidelines Clinical research under the Clinical Research Act
	Nonclinical study	Investigator-initiated clinical trial		Investigator-initiated clinical trial		
		Phase I (Safety)	From Phase II on	Phase I (Safety)	From Phase II on	
Schedule	When making R&D proposal, submit a schedule indicating the process steps and milestones up to approval.	Same as on the left	Same as on the left	Same as on the left	Same as on the left	When making R&D proposal, submit a schedule indicating the process steps and milestones up to attaining objectives.
Clinical Trial Implementation Plan	When making R&D proposal, submit a protocol concept statement or clearly state submission timing in Milestones.	When making R&D proposal, submit a Clinical Trial Implementation Plan or a a Clinical Trial Implementation Plan Outline, and submit a Clinical Trial Implementation Plan before implementing the trial.	Same as on the left	When making R&D proposal, submit a Clinical Trial Implementation Plan or a a Clinical Trial Implementation Plan Outline, and submit a Clinical Trial Implementation Plan before implementing the trial.	Same as on the left	When making R&D proposal, submit a Clinical Study Implementation Plan or an Implementation Plan Outline, and submit a Clinical Study Implementation Plan before implementing the study.
Regulatory Science Strategy Consultation (Face-to-face advice)	Consultation geared to research phase and content (face-to-face advice) is to be sought as a rule in the first or second year after adoption. It is not essential at the time of application, but it is desirable to have had a consultation. If you have a record of already implemented consultation (in the case of an advance interview, a summary prepared by the academia side is acceptable), then submit it.	Consultation geared to research phase and content (face-to-face advice) is to be sought as a rule after adoption and before clinical trial initiation. It is not essential at the time of application, but it is desirable to have had a consultation. If you have a record of already implemented consultation (in the case of an advance interview, a summary prepared by the academia side is acceptable), then submit it.	Same as on the left	Same as on the left	Same as on the left	-
Main substance of consultation	● Nonclinical study sufficiency ● Quality and standards, specifications of trial drug, etc.	Clinical trial design	● Clinical data package ● Clinical trial design	● Clinical trial design	● Clinical data package ● Clinical trial design	—
Record of involvement of biostatistician recorded in the R&D Proposal	-	Necessary to make note of whether or not there is involvement. If there is involvement, make note of it in a comment regarding clinical trial design. If there is no involvement, make note of the reason there is not.	Same as on the left	Same as on the left	Same as on the left	Same as on the left
Necessity for biostatistician involvement	Not necessarily needed.	Should have involvement in some cases.	Should have involvement.	Should have involvement in some cases.	Should have involvement.	Should have involvement in some cases.
Intellectual property	Make note of status and strategy regarding intellectual property, etc.					Not needed
Items regarding status of intellectual property, etc., recorded in the R&D Proposal	Status of own technology, status of relevant technology belonging to others, policy on corporate out-licensing (practical application) of research results					
Collaboration with corporations	Make note regarding status of collaboration.					
Status of trial drug procurement	Make note regarding status of trial drug (including comparison drugs) procurement.	Same as on the left	Same as on the left	Same as on the left	Same as on the left	—

Summary of Submission Timing and Content of All Types of Information Material Required at AMED (Medical Devices)

	Unapproved medical device (including expanded purpose of use)				Approved medical device (use within scope of approval)
	Nonclinical study	Investigator-initiated clinical trial		Clinical study under ethical guidelines Specified clinical research	Clinical study under ethical guidelines Specified clinical research
		Exploratory clinical trial	Clinical trial (pivotal test)		
Research objectives	● Acquisition of production and marketing approval (including expanded purpose of use)				● Build up new evidence (Establish standard treatment, establish procedure, etc.)
Schedule	When making R&D proposal, submit a schedule indicating the process steps and milestones up to acquisition of approval. (Also make concise note of listing for reimbursement under insurance and establishment as standard treatment.)	Same as on the left	Same as on the left	When making R&D proposal, clearly state how test is positioned and submit a schedule indicating exit strategy (future clinical trial implementation scheduling, corporate collaboration, production and marketing approval, listing for insurance).	When making R&D proposal, submit a schedule indicating how the evidence obtained is to be used together with steps and milestones leading to that use.
Implementation Plan	When making R&D proposal, submit a protocol concept statement or clearly state submission timing in Milestones.	When making R&D proposal, submit a Clinical Trial Implementation Plan or a Clinical Trial Implementation Plan Outline, and submit a Clinical Trial Implementation Plan before implementing the trial.	Same as on the left	When making R&D proposal, submit a Clinical Study Implementation Plan or a Clinical Study Implementation Plan Outline, and submit a Clinical Study Implementation Plan before implementing the study. When making R&D proposal, also submit information materials relating to nonclinical study.	When making R&D proposal, submit a Clinical Study Implementation Plan or a Clinical Study Implementation Plan Outline, and submit a Clinical Study Implementation Plan before implementing the study.
Consultation with regulatory authorities, etc.	Seek PMDA consultation geared to research phase and content in a timely manner. If you have a record of already implemented consultation at the time of application (in the case of an advance interview, a summary prepared by the academia side is acceptable), then submit it.	Same as on the left	Same as on the left	In addition to the left, when consultation with regulatory authorities is underway regarding the following, make a note of the status of consultations. ● Device procurement ● Utilization of advanced medical care system When consultations are underway with committees, etc., within the facility, make a note of the status of those consultations.	When consultation with regulatory authorities is underway regarding the following, make a note of the status of consultations. ● Utilization of advanced medical care system
Main substance of consultation	● Whether clinical trial is needed or not needed ● Nonclinical study sufficiency	● Clinical trial design	● Clinical trial design ● Clinical data package		
Record of involvement of biostatistician recorded in the R&D Proposal	–	Make note as to whether or not there is involvement. If there is involvement, make note of it in a comment regarding clinical trial design. If there is no involvement, make note of the reason there is not.	Same as on the left	Same as on the left	Same as on the left
Necessity for involvement of biostatistician	Not necessarily needed.	Should have involvement in some cases.	Should have involvement.	Should have involvement in some cases.	Should have involvement in some cases.
Intellectual property	Make note of status and strategy regarding intellectual property, etc.				Make note of status of intellectual property, etc., as necessary.
Items relating to status of intellectual property, etc. recorded in the R&D Proposal	Status of own technology, status of relevant technology belonging to others, policy on corporate out-licensing (practical application) of research results				-
Collaboration with corporations	Make note regarding status of collaboration where applicable	Make note regarding the following in the event that collaboration has taken place: ● Whether or not there is a joint research agreement or memorandum ● System for managing safety information ● Response and responsibility in event of malfunction			If there is collaboration, make note of its status.
Status of procurement or provision of trial device	Make note regarding procurement status of trial medical device (including comparison devices).				-

Appendix 1. Countries eligible for the SATREPS program

No.	Region	Name of Country
1	Asia	India
2		Republic of Indonesia
3		Kingdom of Cambodia *
4		Democratic Socialist Republic of Sri Lanka
5		Kingdom of Thailand
6		Federal Democratic Republic of Nepal *
7		Islamic Republic of Pakistan
8		People's Republic of Bangladesh *
9		The Democratic Republic of Timor-Leste *
10		Republic of the Philippines
11		Kingdom of Bhutan *
12		Socialist Republic of Viet Nam
13		Malaysia
14		Republic of Maldives
15		Mongolia
16		Lao People's Democratic Republic *
17	Middle East	Republic of Turkey
18		Palestine Liberation Organization
19		Hashemite Kingdom of Jordan
20	Europe	Republic of Azerbaijan
21		Republic of Albania
22		Republic of Armenia
23		Ukraine
24		Republic of Uzbekistan
25		Republic of Kazakhstan
26		Kyrgyz Republic
27		Republic of Kosovo
28		Georgia
29		Republic of Serbia
30		Republic of Tajikistan
31		Turkmenistan
32		Bosnia and Herzegovina
33		Republic of North Macedonia
34		Republic of Moldova
35		Montenegro

No.	Region	Name of Country
36	Africa	People's Democratic Republic of Algeria
37		Republic of Angola *
38		Republic of Uganda *
39		Arab Republic of Egypt
40		Kingdom of Eswatini
41		Federal Democratic Republic of Ethiopia *
42		State of Eritrea *
43		Republic of Ghana
44		Republic of Cape Verde
45		Gabonese Republic
46		Republic of Cameroon
47		Republic of The Gambia *
48		Republic of The Guinea *
49		Republic of Guinea-Bissau *
50		Republic of Kenya
51		Republic of Cote d'Ivoire
52		Union of Comoros *
53		Republic of Congo
54		Democratic Republic of the Congo *
55		Democratic Republic of Sao Tome and Principe *
56		Republic of Zambia *
57		Republic of Sierra Leone *
58		Republic of Djibouti *
59		Republic of Zimbabwe
60		Republic of Sudan *
61		Republic of Seychelles
62		Republic of Equatorial Guinea
63		Republic of Senegal *
64		United Republic of Tanzania
65		Republic of Tunisia
66		Republic of Togo *
67		Federal Republic of Nigeria
68		Republic of Namibia
69		Burkina Faso *
70		Republic of Burundi *
71		Republic of Benin *
72		Republic of Botswana
73		Republic of Madagascar *
74		Republic of Malawi *
75		Republic of South Africa
76		Republic of Mozambique *
77		Republic of Mauritius
78		Islamic Republic of Mauritania *
79		Kingdom of Morocco
80		Republic of Liberia *
81		Republic of Rwanda *
82		Kingdom of Lesotho *

No.	Region	Name of Country
83	Latin America	Argentine Republic
84		Antigua and Barbuda
85		Oriental Republic of Uruguay
86		Republic of Ecuador
87		Republic of El Salvador
88		Republic of Guyana
89		Republic of Cuba
90		Republic of Guatemala
91		Grenada
92		Republic of Costa Rica
93		Republic of Colombia
94		Jamaica
95		Republic of Suriname
96		Federation of Saint Christopher and Nevis
97		Saint Vincent and the Grenadines
98		Saint Lucia
99		Republic of Chile
100		Commonwealth of Dominica
101		Dominican Republic
102		Republic of Trinidad and Tobago
103		Republic of Nicaragua
104		Republic of Haiti *
105		Republic of Panama
106		Commonwealth of The Bahamas
107		Republic of Paraguay
108		Barbados
109		Federative Republic of Brazil
110		Belize
111		Republic of Peru
112		Republic of Bolivia
113		Republic of Honduras
114		United Mexican States
115	Pacific	Republic of Kiribati *
116		Cook Islands
117		Independent State of Samoa
118		Solomon Islands *
119		Tuvalu *
120		Kingdom of Tonga
121		Republic of Nauru
122		Niue
123		Republic of Vanuatu *
124		Independent State of Papua New Guinea
125		Republic of Palau
126		Republic of the Fiji Islands
127		Republic of the Marshall Islands
128		Federated States of Micronesia

* Late departure developing country (LDC: Least Developed Country)

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.

Note4: Secondary to last year, the number of the requests from one country is assumed up to 12 cases from diplomatic consideration. When the upper limit surpassed, the recipient country government will perform narrowing.

Division of International Strategy, Department of International Strategy

Japan Agency for Medical Research and Development (AMED)

23F Yomiuri Shimbun Bldg., 1-7-1 Otemachi, Chiyoda-ku, Tokyo, JAPAN. 100-0004

Tel: +81-3-6870-2210; Fax: +81-3-6870-2240

September 2021