FY 2021

International Collaborative Research Program for Tackling the NTDs (Neglected Tropical Diseases) Challenges in African Countries

Application Guidelines

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

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Chapter 1. Introduction

These Application Guidelines specify the conditions and solicitation details regarding the R&D (hereinafter referred to as “R&D”) projects being solicited under International Collaborative Research Program for Tackling the NTDs (Neglected Tropical Diseases) Challenges in African Countries, which is administered by the Japan Agency for Medical Research and Development (hereinafter referred to as “AMED”).

1.1 Program Outline

1.1.1 Background

Neglected Tropical Diseases (NTDs) are a group of diseases that mainly affect people in low- and middle-income countries in tropical and subtropical regions, and are thought to threaten the health of more than one billion people worldwide. NTDs urgently need to be addressed internationally, as they create a vicious cycle by spreading most readily among people who live in conditions with inadequate hygiene due to poverty, whilst causing morbidity that interferes with the ability of those people to extract themselves from poverty. In particular, people in African countries are known to be particularly exposed to the risk of various NTDs, and the burden of NTDs is a major obstacle to the health improvement, education, and employment which are key to their development.

This program was launched in fiscal year 2015 with the aim of contributing to combating NTDs, which are a major impediment to the development of African countries, and strengthening human resource development in both African countries and Japan by leveraging Japan's science and technology. Fighting against NTDs in African countries will not only support their development, but will also contribute to the fight against tropical diseases that may occur or enter Japan in today's increasingly globalized society. In addition, eliminating NTDs is a health improvement target of the United Nations Sustainable Development Goals (SDGs), and would also contribute to the achievement of other SDGs, such as ending poverty and hunger, promoting economic growth and education, and correcting inequality.

1.1.2 Program Aims

In this program, with a view to overcoming NTDs, researchers from Japan and African countries will conduct cooperative research in the fields of medicine and public health that will contribute to the development of new preventive, diagnostic, and therapeutic methods, as well as the establishment and strengthening of public health management systems such as surveillance, and policy and operational recommendations for the control of NTDs. This program aims to support close joint activities in areas affected by NTDs and the creation of networks for international joint research that can be sustained in the long term. In addition, the program aims to develop the capabilities of young researchers in Japan and Africa who will lead future research on NTDs, and to maintain and expand a joint research system that will contribute to innovation in Africa.

1.1.3 Specific Objectives

[Objectives during the implementation period]

- To obtain research outcomes that will contribute to the establishment and implementation of measures for the control of NTDs in partner countries.
- To promote the development of human resources necessary in the control of NTDs in Japan and partner countries, and to build a strong system for collaboration.

- To improve the research capabilities of Japanese and partner country researchers participating in the research on NTDs.
- To clarify the requirements for the establishment and implementation of measures to control NTDs in partner countries based on research outcomes.

[Expected development after the implementation period]

- Establishment and implementation of measures to control NTDs in partner countries based on the research outcomes.
- Continuation and development of collaboration and cooperation for control of NTDs in partner countries.
- Development of research for control of NTDs by young researchers in Japan and partner countries.
- The spread of NTDs control methods established and implemented based on research outcomes to other African countries, contributing to stimulation of cooperation with international organizations.

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, etc. 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. in Japan 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)).

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

In this program, it is required that young researchers participate in R&D activities with the aim of fostering young researchers and strengthening their research capacities. For the definition of young researchers in this call, please refer to Chapter 5.

(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; amended on December 18, 2020), 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) Utilization of the Japanese Government (Monbukagakusho: MEXT) Scholarship

The Japanese Government (MEXT) Scholarship is accepting applications from international students (research students) to conduct research at Japanese universities with the aim of fostering human resources who will contribute to global development by building connections between Japan and their home countries. Applications to this program which include plans to train international students as young researchers should consider also applying for the MEXT Scholarship. For more details, please refer to the MEXT website*.

* The Japanese Government (MEXT) Scholarships; Ministry of Education, Culture, Sports, Science and Technology
https://www.mext.go.jp/a_menu/koutou/ryugaku/06032818.htm

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. Call Specifications

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.

Field/R&D Projects Being Solicited	Scale of R&D funds (excluding indirect costs)	Period in which R&D is Scheduled to be Implemented	Planned Number of New Awarded Projects
Neglected Tropical Diseases (NTDs)	Around 30 million JPY per year for each project	Max. of 5 years FY 2021 – FY 2025	0 – 1 project

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.

3.2 Scope of this Call for Proposals

3.2.1 Overview of the research area

In order to contribute to overcoming NTDs in Africa, it is necessary to conduct R&D that meets the needs of the partner country/region affected, and that takes into account the local social infrastructure, hygiene context, and economic conditions, whilst leveraging Japan's scientific and technological capabilities. In addition, it is necessary to conduct joint activities with an awareness of capacity building and improvement so that the partner country/region can proactively continue to implement measures against NTDs after the completion of the R&D. Moreover, in order to maintain and expand the close collaboration between organizations in Japan and partner countries, it is important to foster the development of young researchers from both Japan and partner countries who will lead countermeasures against NTDs in the future.

This year's call for proposals will focus on "Neglected Tropical Diseases" as defined by the World Health Organization (WHO), in consideration of the roadmap* published by WHO, the disease burden in African countries, and the research being implemented within and outside this program. While aiming to achieve outcomes that will lead to countermeasures against the target diseases in African partner countries, R&D proposals are expected to take into account both the international trends indicated in the aforementioned WHO roadmap and the current situation in the partner countries.

* For details of the roadmap published by WHO, please refer to the following URL:

"Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021-2030 "

https://apps.who.int/iris/handle/10665/338565

3.2.2 Target Diseases

Proposals should address a research subject from among the disease groups specified below. Multiple disease groups can be targeted.

[Target disease groups for this call]

Buruli ulcer; Echinococcosis; Human African trypanosomiasis; Leishmaniasis; Leprosy; Mycetoma, chromoblastomycosis and other deep mycoses; Onchocerciasis; Schistosomiasis; Taeniasis and cysticercosis

3.2.3 Research solicited

This call focuses on the development of scientific understanding and diagnostic methods, which are areas identified in the WHO roadmap as priorities for scientific and technological progress. Specifically, proposals are encouraged for research to develop diagnostic methods that are useful for local control of NTDs, whilst advancing scientific understanding of disease burden and pathogenesis in African partner countries. With a view to developing technologies that will enable the establishment of public health management systems or policy recommendations, proposals to demonstrate proof of concept in practical application are also encouraged. However, proposed activities for the development of infection control methods, system construction, and policy recommendations must be considered feasible in light of the social infrastructure, hygiene context, and economic conditions of the partner country. In addition, since NTDs are an international challenge, proposed research methods and protocols, and standardization of results, must be in accordance with international standards.

On the premise that research results will contribute to the development of countermeasures against NTDs, proposals for basic research are acceptable. Interdisciplinary research that incorporates approaches from academic fields such as medicine, public health, epidemiology, infectious diseases, and microbiology, and methodologies from other fields such as ICT (information and communication technology) is also encouraged.

In addition, it is recommended that young researchers from Japan and the partner country should conduct research activities together for a certain period of time in Japan or in the partner country, in order to develop and improve their research capabilities and to foster lasting networks.

3.2.4 Composition of Research Teams

A Principal Institution and, if necessary, Subsidiary Institutions should be designated in proposals from among the participating institutions in Japan, according to the definition given in Chapter 1. Any institution in Japan cooperating in the international collaborative research, but not receiving R&D funding, should be designated as a "Cooperating Institution".

Institutions in countries other than Japan conducting the international joint research with Japanese institutions should be designated as “Non-Japanese Participating Institutions”. One of the Non-Japanese Participating Institutions in African countries should be designated as the “Non-Japanese Principal Institution” responsible for coordinating the Non-Japanese Participating Institutions. Regarding the allocation of R&D funding to the Non-Japanese Participating Institutions, please refer to the special notes below.

Research teams submitting proposals to this program must meet the following criteria i. to vi.

i. Research teams must include at least one Non-Japanese Participating Institution from each African partner country in which the joint research will be conducted.
ii. The Non-Japanese Principal Institution must be a local institution based in the African partner countries where the joint research will be conducted.
iii. At the time of proposal submission, the research participants from the Principal Institution and/or the Subsidiary Institutions must have previously conducted joint research with the research participants from the Non-Japanese Participating Institutions in the African countries where the joint research will be conducted.
iv. Research teams must include young researchers from Japan and the African partner countries who are expected to continue engagement in NTDs research after the end of the research period. For the definition of "young researchers" in this call, please refer to Chapter 5.
v. Research teams must include skilled researchers from Japan and the African partner countries who are motivated to foster the development of young researchers, and the collaboration must be designed in such a way that enables the provision of support and advice to the participating young researchers in the execution of their research.
vi. Research teams should be committed to continuation of their research on NTDs, including the diseases targeted in this program, through continuous collaboration and cooperation with each participating institution even after the end of the research period.

In addition, this program strongly encourages the active participation of many young researchers, the appointment of young researchers in key roles, and the implementation of R&D in such a way that further enhances their development. It is hoped that experienced researchers will pass on their know-how relating to international collaborative research to enhance the capabilities of young researchers, and that this will facilitate the involvement of young researchers in networks with relevant institutions and other researchers in partner countries.

In anticipation of practical implementation of research outcomes after the R&D period, private companies are welcome to participate in proposals as Principal Institutions, Subsidiary Institutions, and/or Cooperating Institutions. An understanding of local needs and the status of network development from the R&D stage can be expected to lead to efficient implementation of research outcomes in society. Research institutes in third countries that have superior technologies unavailable in Japan and African countries are also welcome to participate in proposals, if such participation is expected to have a synergistic effect for the international joint research.

3.2.5 Special Notes

(1) Research planning

The PI who submits the application should draft the research proposal jointly with the representative of the Non-Japanese Principal Institution, having reached agreement among all parties involved as to the proposal content. Research plans should also take into consideration the restrictions on entry into Japan or partner countries due to the COVID-19 pandemic.

In this program, it is expected that research outcomes will be implemented in society to control the spread of infectious diseases. Therefore, even from the research planning stage, it is important to consider the need to establish systems of cooperation and to stimulate collaboration with government agencies and related national and international organizations in partner African countries.

(2) Allocation of R&D funding to Non-Japanese Participating Institutions

In this program, R&D funding cannot be allocated directly to Non-Japanese Participating Institutions. Non-Japanese Participating Institutions are therefore expected to cover the costs of their participation in the joint research, and/or to contribute to the R&D in-kind, by providing human resources, access to field sites, samples, facilities, or any other research resources. Agreement among all parties involved regarding the content of the research proposal, including on this issue, should be reached before submission.

(3) Research team agreement

For proposals selected for funding, research teams must conclude a formal agreement (Memorandum of Cooperation (MOC), Collaborative Research Agreement (CRA), etc.) between the relevant organizations in Japan and the partner African country/countries as soon as possible. In order to avoid conflicts of understanding among the research team members, the agreement should cover all matters necessary for the successful completion of the proposed research, including the roles, burdens, and responsibilities of each team member and institution involved, and the handling of research outcomes and any intellectual property. Before the agreement is concluded, the research can proceed for a period of time based on the assumption that the agreement will be concluded.

(4) During and after the period of R&D

During the research period, researchers at the Principal Institution, the Subsidiary Institutions, and the Non-Japanese Participating Institutions must work together to ensure effective coordination among all related institutions.

For the continuation of R&D and the future establishment of countermeasures against NTDs based on research outcomes, it is particularly important that projects gain the understanding and support of local communities in the partner African countries. Therefore, it is expected that research teams will make appropriate efforts, including information sharing with local organizations, raising awareness of the research outcomes, and conducting educational activities for the dissemination of results.

Projects selected for funding in this program may be asked to host a workshop or a joint collaboration meeting for the purpose of exchanging information among funded projects relating to disease control in Africa, during or after the period of R&D. In addition, in order to link the research results to implementation in society, researchers may be asked to present their results to other projects and programs within AMED.

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	June 8, 2021 – July 20, 2021, noon JST (Observe strictly)
Document review	Late July 2021 – Mid August 2021 (tentative)
Interview review (hearing review)	August 27, 2021 (tentative)
Notification of selection/rejection	Mid September 2021 (tentative)
Date of commencement (contracting, etc.) of R&D Project	Mid October 2021 (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. Interview reviews (hearing reviews) may sometimes be conducted over the Internet etc.

Note 5. 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 6. 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 7. 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 8. 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 9. 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 10. 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 11. 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 "安全保障貿易管理に係るチェックシート" (in Japanese). 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 the PI or other project participants, 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 order to select proposals for funding in this project, proposal documents will be reviewed based on the following criteria. The ability of the participating institutions to carry out the R&D, and the necessity of their involvement, will also be considered. Please note that duplication of effort with previously-funded proposals, in terms of countries and diseases targeted, may also be taken into consideration.

(A) Compatibility with the program's purpose

- Is the project compatible with the program's purpose and objectives, etc.?

(B) Scientific/technological significance and advantage

- Does the project proposal have originality and novelty?
- Does the project respond to social needs?
- Is the project compatible with national policies regarding R&D in the field of medicine?
- Does the project contribute to the advancement of the field of medicine?
- Does the project contribute to the generation of new technologies?

(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?

  * With the enforcement of the new "Ethical Guidelines for Life Sciences, Medical and Health Research Involving Human Subjects" on June 30, 2021, the existing "Ethical Guidelines for Medical and Health Research Involving Human Subjects" and "Ethical Guidelines for Human Genome/Gene Analysis Research" will be repealed. Please follow the new Guidelines after the enforcement.

(D) Implementation system

- Has an R&D system centered on the PI been organized appropriately?
- Is the current technological level and previous performance sufficient?
- Has a sufficient collaboration network been constructed?
- Are the efforts of the PI or other project participants appropriate?
- Is there unreasonable duplication/excessive concentration?

(E) Costs

- Are the breakdown of costs and spending plan appropriate?

(F) Specific considerations for this program

- Is the research collaboration expected to provide sufficient training and support to young researchers who will participate in the research?
- Are the research outcomes expected to lead to the establishment of new measures for the control of NTDs and policy recommendations?
- Is the frequency of visits by the PI and other participants to the research site(s) appropriate?
- Is the project mainly focused on the implementation of joint activities in the partner country?
- What are the prospects for the continuation of collaboration among the research team?
- Does the project have a strategy that will benefit not only the partner African country/countries but also Japan, such as the international deployment of Japan's technological expertise or the overseas implementation of research that would be difficult to achieve in Japan?

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 Documents

5.1.1 Proposal Documents Necessary for Application

No.	Mandatory or optional	Necessary proposal documents	Remarks
1	Mandatory	(Form 1) Research and Development Proposal	All information except the summary should be in English, and only the summary should be written in both Japanese and English.
2	Mandatory	（様式２）安全保障貿易管理に係るチェックシート	Please input information in Japanese.

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/en/news/program/2001B_00027.html

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 Research and Development Proposal is to be prepared in English, but the summary 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.

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

In the case that the applicant has already undergone ex-ante interviews with PMDA under their “regulatory science consultation” program or other consultation services, a summary of the interview must be submitted with the R&D proposal (free format; summary may be provided by the academic institution), and if the applicant has already undergone face-to-face advice, a record of the face-to-face advice or separate sheet (consultation content) such be submitted with the R&D proposal.

Note: 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).. Although is it not compulsory for the applicant to have undergone face-to-face advice at the time of application, it is desirable that face-to face consultation is undertaken and the consultation results are reflected in the R&D plan.

(2) 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.

(3) 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 submit proposals regarding 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

This program strongly encourages the active engagement of young researchers for the purpose of developing their research capabilities. The definition of "young researchers" in this program is as follows.

5.3.1 Young Researchers in Japan

A research team member who belongs to an institution in Japan is considered a "young researcher" if they meet the following conditions:

- On April 1, 2021, they are a male below the age of 40 years old (born on or after April 2, 1981) or a female below the age of 43 years old (born on or after April 2, 1978), or less than 10 years have passed since they obtained their Ph.D. degree. For those who have taken leave relating to childbirth or childcare, the number of days of that leave may be added to the above limits on age.

5.3.2 Young Researchers in African Partner Countries

As a general rule, if a research team member who belongs to an institution in the African partner country satisfies the conditions described in 5.3.1 above, they can be considered a "young researcher". However, researchers with the potential to fulfil leadership roles in future control and research on NTDs, if given the appropriate support and opportunity, may be considered as "young researchers" in this program as long as they do not deviate largely from the conditions described above.

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, etc. 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 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, etc. 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, etc.

(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 accomplishmemt 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, etc.

[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 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 Integrated Innovation Strategy 2019 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 R&D ordinarily performed by PIs at their affiliated institutions (buyout expenses). Please consult with the office in charge of this program when considering buyout expenses in a project under this program.

	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 R&D 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.

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

(1) Target Persons

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.

(2) Requests for COI Reviews

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

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)

* These Guidelines will be repealed, and the new "Ethical Guidelines for Life Sciences, Medical and 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) will enter into force on June 30, 2021.

○ 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)

* These Guidelines will be repealed, and the new "Ethical Guidelines for Life Sciences, Medical and 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) will enter into force on June 30, 2021.

○ Ethical Guidelines for Life Sciences, Medical and 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)

* These Guidelines will enter 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; amended on February 1, 2021) and the Guidelines for

Management and Audit of Public Research Funds at Research Institutions (implementation standards)" (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014).

*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 applying 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 date the contracted R&D agreement is concluded.

(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/1374697.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 funding of MEXT or independent administrative agencies under MEXT are not required to submit the checklist, likewise, with

regard to the checklist (B) above institutions that do not conduct research activities and institutions that conduct research activities but are not allocated a budget by the independent administrative agencies under MEXT are not required to submit the checklist.

*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 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 in Research (decided by the Minister of Education, Culture, Sports, Science and Technology on August 26, 2014); Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards) (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014; amened on February 1, 2021); 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 in Research (decided by the Minister of Education, Culture, Sports, Science and Technology on August 26, 2014); Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards) (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014; amened on February 1, 2021); 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 in Research (decided by the Minister of Education, Culture, Sports, Science and Technology on August 26, 2014); Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards) (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014; amened on February 1, 2021); 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 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.

Category of misconduct according to involvement		Degree of misconduct	Period deemed appropriate
Person Involved in the Misconduct	1. Especially malicious individual who intentionally engages in misconduct from the outset of the research		10 years

<table>
<tr><td rowspan="4"></td><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 Funding Programs etc. Has Been Restricted

With regard to researchers who have been found to have carried out misconduct under competitive funding programs etc. (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 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 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 in Research (decided by the Minister of Education, Culture, Sports, Science and Technology on August 26, 2014); Guidelines for Management and Audit of Public Research Funds at Research Institutions (implementation standards) (decided by the Minister of Education, Culture, Sports, Science and Technology on February 15, 2007; revised on February 18, 2014; amened on February 1, 2021); 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 Citizens and 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

The Fifth Science and Technology Basic Plan of the Japanese government, in an attempt to lure outstanding students and experienced professionals form within and outside Japan, states as one of their numerical targets to implement financial aid for doctoral students attending the latter part of the course (hereinafter referred to as “doctoral students”): “We will strive to enable 20 percent of doctoral students to receive an amount equivalent to their living expenses.” Accordingly, there is a need to expand the employment and improve the treatment of doctoral students as research assistants (RAs) in universities and research and development agencies. Moreover, the Comprehensive Package to

Strengthen Research Capacity and Support Young Researchers (formulated on January 23, 2020, by the Council for Science, Technology and Innovation) sets the objective of "enabling in the future doctoral students who so wish to be paid amounts commensurate with their living costs," and as a specific measure cites "promoting the securement of an appropriate salary level for RAs and so on paid from competitive research funds and joint research funds."

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

- Salary level (approx. 1.8 million to 2.4 million per year) equivalent to living expenses*

  With reference to the fact that the annual sum of 1.8 million yen is envisaged as being commensurate with living expenses in the Fifth Science and Technology Basic Plan, and the amount of the grants-in-aid for the JSPS Research Fellows (DC) that allows outstanding doctoral students to dedicated themselves to their research without financial anxiety, the rule of thumb for the scope of the sum required for living expenses is between 1.8 million and 2.4 million yen.
- 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." 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 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.

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	Office of International Collaboration, Division of International Strategy, Department of International Strategy AMED Tel: +81-3-6870-2210 E-mail: africa-ntds"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).				-

Office of International Collaboration, Division of International Strategy, Department of International Strategy

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