

## Innovative Research and Development Promotion Fund Subsidy Guidelines

### (General Rules)

Article 1 The Act on Regulation of Execution of Budget Pertaining to Subsidies, etc. (Act No. 179 of 1955; hereinafter referred to as “Regulation Act”) and the Order for Enforcement of the Regulation Act (Cabinet Order No. 255 of 1955; hereinafter referred to as “Order for Enforcement”) and, in addition to the provisions of the other laws and regulations, the Subsidy Guidelines (including its subsequent revisions) shall apply to the grant of subsidy of promotion service conducted by the Japan Agency for Medical Research and Development (hereinafter referred to as “AMED”) with Innovative Research and Development Promotion Fund Subsidy (hereinafter referred to as “Subsidy”) (In this case, the term “Head of the Respective Ministry or Agency” shall be deemed to be replaced with “AMED”; “Subsidy, etc.” and “Subsidized Project, etc.” shall be deemed to be replaced with “Subsidy” and “Subsidized Project”; “Subsidized Business Operator, etc.” shall be deemed to be replaced with “Business Operator Implementing Subsidized Project”; and “Indirect Subsidized Business Operator, etc.” shall be deemed to be replaced with “Contractor, etc.” in the Regulation Act and the Order for Enforcement of the Regulation Act.).

### (Purposes of Grant)

Article 2 The purpose of this Subsidy is to lead excellent research outcomes and seeds to practical application, through AMED’s grant of the Subsidy pertaining to the costs of research and development at universities, Research and Development Agencies (meaning Research and Development Agencies as specified in Article 2, Paragraph 8 of the Act on Improving the Capacity, and the Efficient Promotion of Research and Development through Promotion of Research and Development System Reform (Act No. 63 of 2008)) and other research organizations, as Specified-Calls-For-Proposals-Type Research and Development Operations stipulated in Article 27-2, Paragraph 1 of the Act on Vitalizing the Creation of Science, Technology, and Innovation (Act No. 63 of 2008) utilizing the Fund created under the same paragraph, with the goal determined by Headquarters for Healthcare Policy, etc. for AMED.

### (Definitions)

Article 3 The term “Subsidized Project” as used in the Subsidy Guidelines means “Strengthening Program for Pharmaceutical Startup Ecosystem” as a program to raise the standard of the pharmaceutical startup ecosystem by supporting innovative drug development for practical application by pharmaceutical startups receiving supports from venture capital registered by AMED.

- 2 The term “Business Operator” as used in the Subsidy Guidelines mean universities, colleges of technology, inter-university research institutes, incorporated administrative agencies (except AMED), national and local governments’ research and development institutes, enterprises, public interest incorporated associations, public interest incorporated foundations, general incorporated associations, general incorporated foundations, special provisions civil code incorporations, high schools, secondary schools and other research organizations.
- 3 The term “Researchers, etc.” as used in the Subsidy Guidelines individually or collectively means researchers, engineers, research assistants and other persons engaged in activities pertaining to Subsidized Project or activities incidental thereto who are engaged in research and development and the development of the environment, etc. in Subsidized Project, by belonging to a Business Operator or commissioned by a Business Operator.
- 4 The term “Competitive Research Funds, etc.” as used in the Subsidy Guidelines means (i) research funds classified as Competitive Research Funds as “those pertaining to research (including those organized as competitive funds), out of expenses competitively acquired through calls for proposals from ministries and agencies, etc. at universities, National Research and Development Agencies, etc.”; and (ii) other than the above-mentioned (i), expenses under the jurisdiction of a national administrative organ and funds allocation organ (including AMED), and the whole or part of the original source of which is the public funds (including but not limited to operating expense subsidy).

- 5 The term “Misconduct, etc.” as used in the Subsidy Guidelines collectively means Misconduct, Fraudulent Use and Fraudulent Receipt listed in the following Paragraph 6 through Paragraph 8.
- 6 The term “Misconduct” as used in the Subsidy Guidelines means Fabrication, Falsification and Plagiarism of data or survey results, etc. included in published research accomplishments such as submitted papers, etc. by Researchers, etc., either willfully or through gross negligence of the fundamental duty of diligence that researchers bear in carrying out their research and development 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, etc. without the approval of the relevant researcher or appropriate acknowledgement.
- 7 The term “Fraudulent Use” as used in the Subsidy Guidelines means use of Competitive Research 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 Competitive Research Funds (including, but not limited to, purposes or uses other than those stated in the R&D plan or other documents, or use of Competitive Research Funds that infringes laws, ordinances, regulations, notifications, guidelines, etc., agreements with AMED, etc. and the Application Requirements of AMED).
- 8 The term “Fraudulent Receipt” as used in the Subsidy Guidelines means Researchers, etc. receiving Competitive Research Funds, etc. through falsehoods or other unfair means.
- 9 The term “Government Guidelines for Responding to Misconduct” as used in the Subsidy Guidelines collectively means guidelines for responding to Misconduct, etc. formulated by National Office, Ministries and Agencies of Japan.
- 10 The term “AMED Regulations for Responding to Misconduct, etc. as used in the Subsidy Guidelines collectively means “Regulations for Responding to Misconduct, etc. in Research Activities” (including its subsequent revisions) and other regulations for responding to Misconduct, etc. set forth by AMED.
- 11 The term “Administration Manual” as used in the Subsidy Guidelines means Administration Manual for Subsidized Projects (including its subsequent revisions) set forth by AMED for the purpose of administration in Subsidized Projects.
- 12 The term “Laws and Regulations” as used in the Subsidy Guidelines collectively means laws, cabinet orders, rules, orders, ordinances, notifications, guidelines and all other regulations.
- 13 The term “AMED Regulations Regarding Conflict of Interest (COI) Management” as used in the Subsidy Guidelines collectively means “Regulations Regarding Conflict of Interest (COI) Management in Research Activities” (including its subsequent revisions) and other regulations for COI management set forth by AMED.
- 14 The term “Subsidized Project Accomplishments Report” as used in the Subsidy Guidelines means a report to be submitted to AMED to report the actual use of Subsidy in the Subsidized Project when a Business Operator Implementing Subsidized Project completes a Subsidized Project (including the case when the whole of the Grant Decision is rescinded and the case when a Subsidized Project is discontinued or abolished; the same shall apply hereinafter).
- 15 The term “Subsidized Project Year-End Report” as used in the Subsidy Guidelines means a report to be submitted to AMED by a Business Operator Implementing Subsidized Project to report the actual use of Subsidy in the Subsidized Project if the Subsidized Project is not completed at the end of the government’s fiscal year.
- 16 The term “Subsidized Project Results Report” as used in the Subsidy Guidelines means a report to be submitted to AMED to report the contents of the results of the Subsidized Project when a Business Operator Implementing Subsidized Project completes a Subsidized Project and when a Subsidized Project is not completed at the end of the government’s fiscal year.

- 17 The term “Subsidized Project Plan” as used in the Subsidy Guidelines means a plan pertaining to the implementation of a Subsidized Project by the Business Operator Implementing Subsidized Project stated in the Subsidized Project Plan Sheet.
- 18 The term “Subsidized Project Plan Sheet” as used in the Subsidy Guidelines means the Subsidized Project Plan Sheet (including those changed with AMED’s approval) with respect to the Subsidized Project period of a Subsidized Project.
- 19 The term “Subsidized Project Development Accomplishments” as used in the Subsidy Guidelines means the accomplishments obtained through a Subsidized Project.
- 20 The term “Expenses Covered by Subsidy” as used in the Subsidy Guidelines means the costs required by a Business Operator Implementing Subsidized Project to implement a Subsidized Project.
- 21 The term “Subsidy Objective” as used in the Subsidy Guidelines means the purpose stated in the Subsidy Grant Application as the purpose of a Subsidized Project.
- 22 The term “Intellectual Property Rights” as used in the Subsidy Guidelines collectively means those listed in the following items.
  - A Patent rights (hereinafter referred to as “Patent Rights”) set forth in the Patent Act (Act No. 121 of 1959), the right to obtain a patent set forth in the Patent Act, utility model rights (hereinafter referred to as “Utility Model Rights”) set forth in the Utility Model Act (Act No. 123 of 1959), the right to obtain a utility model registration set forth in the Utility Model Act, design rights (hereinafter referred to as “Design Rights”) set forth in the Design Act (Act No. 125 of 1959), the right to register the design set forth in the Design Act, the layout design license set forth in the Act on the Circuit Layout of a Semiconductor Integrated Circuits (Act No. 43 of 1985), the right to register the establishment of a layout design license set forth in the Act on the Circuit Layout of a Semiconductor Integrated Circuits, the breeder's right set forth in the Plant Variety Protection and Seed Act (Act No. 83 of 1998), the right to obtain the variety registration set forth in the Plant Variety Protection and Seed Act and the rights equivalent to the above-mentioned rights in foreign countries
  - B Copyrights set forth in the Copyright Act (Act No. 48 of 1970) (including all rights set forth from Article 21 through Article 28 of the Copyright Act) and the rights equivalent to the above-mentioned rights in foreign countries
  - C Rights to use technical information which may be hidden and of the financial value

(Subsidy Rate)

Article 4 The subsidy rate of the Subsidy (hereinafter referred to as “Subsidy Rate”) shall be 2/3.

(Grant Application Procedures, etc.)

Article 5 A Business Operator who intends to receive the grant of Subsidy shall make an application in accordance with the Application Guidelines set forth separately, and if selected by AMED as a Business Operator, submit Subsidy Grant Application in Form 1 to AMED by attaching the documents set forth by AMED by the deadline designated by AMED.

(Notification of Grant Decision)

Article 6 AMED shall, when receiving the submission of an Application under the provisions of the preceding article, review the contents of such Application, and if it deems Subsidy is to be paid, shall make Grant Decision of the Subsidy (hereinafter referred to as “Grant Decision”), and send the Subsidy Grant Decision Notification in Form 2 to the Business Operator.

- 2 The standard period to be normally required until Grant Decision is made after the arrival of the Application referred to in the preceding article shall be 30 days.
- 3 AMED may determine the calculation method pertaining to the grant amount by program separately as necessary.
- 4 AMED may, upon Grant Decision, if it is necessary to make a decision on the grant amount and other Grant Decision, request a Business Operator to submit additional materials.
- 5 AMED may impose conditions deemed necessary by AMED on the Grant Decision.

(Withdrawal of Application)

Article 7 If a Business Operator who has made an application for the grant of Subsidy under Article 5 and has received the notification of the Grant Decision of Subsidy intends to withdraw the application for the grant of Subsidy because of objection to the contents of the Grant Decision or the conditions imposed thereon, such Business Operator shall submit Subsidy Grant Application Withdrawal Request in Form 3 stating such effect to AMED, by attaching the reference documents, within 15 days from the day on which the notification of the Grant Decision is received.

(Compliance with Duty of Care of Prudent Manager, Laws and Regulations, Guidelines, etc.)

Article 8 A Business Operator Implementing Subsidized Project shall implement a Subsidized Project with the duty of care of a prudent manager appropriately and in good faith in compliance with the Subsidy Guidelines, Subsidized Project Plan Sheet, Application Guidelines, Administration Manual and the provisions of the documents presented by AMED such as a notifications with regard to the Subsidized Project, in light of the purpose of the Subsidized Project.

- 2 When implementing a Subsidized Project, a Business Operator Implementing Subsidized Project shall, sufficiently recognize that the financial resources of the Subsidized Project are public funds, comply with the Government Guidelines for Responding to Misconduct as well as AMED Regulations for Responding to Misconduct in Research Activities and AMED Regulations Regarding Conflict of Interest (COI) Management as well as the relevant Laws and Regulations, and make efforts to implement the Subsidized Project in an efficient manner.
- 3 A Business Operator Implementing Subsidized Project shall, on its own responsibility, take necessary measures under the Government Guidelines for Responding to Misconduct and AMED Regulations for Responding to Misconduct in Research Activities. Furthermore, AMED may give instructions to or take measures against a Business Operator Implementing Subsidized Project in accordance with the Government Guidelines for Responding to Misconduct and AMED Regulations for Responding to Misconduct in Research Activities, and the Business Operator Implementing Subsidized Project shall follow AMED's instruction and restrictions, etc.
- 4 A Business Operator Implementing Subsidized Project shall, on its own responsibility, take necessary measures under AMED Regulations Regarding Conflict of Interest (COI) Management. Furthermore, AMED may give instructions to or take measures against a Business Operator Implementing Subsidized Project in accordance with AMED Regulations Regarding Conflict of Interest (COI) Management, and the Business Operator Implementing Subsidized Project shall follow AMED's instruction and measures, etc.
- 5 A Business Operator Implementing Subsidized Project shall cause Researchers, etc. to complete a course of research ethics education in accordance with the Government Guidelines for Responding to Misconduct, etc. and the contents separately notifies by AMED.

(Business Operator's Report on Conflict of Interest (COI) Management Status, etc.)

Article 9 A Business Operator Implementing Subsidized Project shall report to AMED the Conflict of Interest (COI) Management Status, etc. of the Subsidized Project in the Business Operator Implementing Subsidized Project with "Conflict of Interest (COI) Management Status Report" in the form separately set forth by AMED by the deadline set forth by AMED.

- 2 A Business Operator Implementing Subsidized Project shall report to AMED the status of compliance by Researchers, etc. with the government's ethics guideline, etc. pertaining to the Subsidized Project with "Subsidized Project Accomplishments Report" in the form separately set forth by AMED by the deadline set forth by AMED.
- 3 A Business Operator Implementing Subsidized Project shall, with regard to education on research ethics, etc. the course of which such Business Operator Implementing Subsidized Project has caused Researchers, etc. to complete in accordance with the Paragraph 5, report the status to AMED with "Report on the Status of Participation in RCR (Responsible Conduct of Research) Education Programs" in the form separately set forth by AMED by the deadline set forth by AMED.

(Business Operator's Representation and Warranty)

Article 10 A Business Operator Implementing Subsidized Project represents and warrants that "Principal Investigator" as a person responsible for research and development or a person granted with a title equivalent thereto and "Co-Investigator" as a person who shares the research items with the Principal Investigator or a person granted with a title equivalent thereto (hereinafter together referred to as "Principal Investigator and Co-Investigator") in the Subsidized Project Plan Sheet are not persons registered by any research organizations, etc. as having committed Misconduct, etc. under the Government Guidelines for Responding to Misconduct or AMED Regulations for Responding to Misconduct in Research Activities (excluding persons on whom no restriction is imposed by the government or Incorporated Administrative Agencies, etc. in an application for or participation in Competitive Research Funds, etc. under the determination by research organizations, etc. and person for whom the period of the restriction in an application for or participation in Competitive Research Funds, etc. imposed by the government or Incorporated Administrative Agencies, etc. has ended).

- 2 A Business Operator Implementing Subsidized Project represents and warrants that if a person subject to an investigation under the Government Guidelines for Responding to Misconduct or AMED Regulations for Responding to Misconduct in Research Activities (hereinafter referred to as "Investigation") is included in Principal Investigator and Co-Investigator (including the program Co-Investigator belonging to the Contractor, etc., if any, or a person granted with a title equivalent thereto) belonging to the Business Operator Implementing Subsidized Project, the Business Operator Implementing Subsidized Project has already notified AMED with regard to such subject person by the time of a grant application and have obtained AMED's approval for treatment of such subject person.
- 3 A Business Operator Implementing Subsidized Project represents and warrants that matters research organizations are requested to implement as system development of the research organizations set forth in the Government Guidelines for Responding to Misconduct are complied with and implemented.

(Contracts, etc.)

Article 11 If a Business Operator Implementing Subsidized Project intends to conclude a contract for sale, service contract, or other contract to carry out the Subsidized Project, it shall offer an open tendering. Provided, however, that if it is difficult or inappropriate to offer an open tendering for the purpose of operation of the Subsidized Project, the Business Operator Implementing Subsidized Project may offer a selective tendering or a single tendering.

(Subcontracting, etc.)

Article 11-2 A Business Operator Implementing Subsidized Project shall not subcontract to or jointly implement with a third party the Subsidized Project. Provided, however, that the Business Operator Implementing Subsidized Project may, only if AMED judges that it is especially necessary in light of implementation of Subsidized Project and approves it in advance, subcontract to or jointly implement with a third party (hereinafter "Third Party" shall be collectively referred to as "Contractor, etc.") a part of Subsidized Project.

- 2 A Business Operator Implementing Subsidized Project shall cause the Contractor, etc. to assume the obligations of the same contents and the same degree the Business Operator Implementing Subsidized Project assumes to AMED under the Subsidy Guidelines and assume full responsibility to AMED for acts of the Contractor, etc. upon subcontracting or jointly implementing.
- 3 If a Business Operator Implementing Subsidized Project subcontracts to or jointly implements with a Contractor, etc. a part of Subsidized Project, the Business Operator Implementing Subsidized Project shall execute contracts with the Contractor, etc. for matters necessary for the Business Operator Implementing Subsidized Project to comply with the Subsidy Guidelines and matters AMED instructs, and cause the Contractor, etc. to comply with them.
- 4 If a Subsidized Project is terminated due to rescission of Grant Decision or any other reason, the contracts with the Contractor, etc. shall be automatically terminated. Furthermore, a Business Operator Implementing Subsidized Project shall, if instructed by AMED to temporarily suspend or discontinue the use of the Subsidy or temporarily suspend or discontinue the Subsidized Project, take the same measures

toward the Contractor, etc.

(Approval, etc. for Subsidized Project Plan)

Article 12 If a Business Operator Implementing Subsidized Project falls under any of the following items, such Business Operator Implementing Subsidized Project shall submit Application for Change to Subsidized Project Plan in Form 4 to AMED in advance and obtain its approval:

- (1) If intending to change the amount allocated to the Expenses Covered by Subsidy except for any minor change;
  - (2) If intending to change the contents of the Subsidized Project except for:
    - (A) Those which do not alter the Subsidy Objective and that are considered to contribute to more efficient achievement of the Subsidy Objective through free ingenuity of the Business Operator;
    - (B) those that will be made to the details of the business plan that are unrelated to the Subsidy Objective or business efficiency.
- 2 In granting the approval referred to in the preceding items, AMED may change the contents of the Grant Decision or impose conditions.

(Discontinuance or Abolishment of Subsidized Project)

Article 13 If a Business Operator Implementing Subsidized Project judges that it falls under any of the following items, such Business Operator Implementing Subsidized Project shall promptly submit Application for Discontinuance (Abolition) or Temporary Suspension of Subsidized Project in Form 5 to AMED, and seek AMED's approval. A Business Operator Implementing Subsidized Project may, if having obtained AMED's approval, discontinue or abolish the whole or a part of the Subsidized Project (hereinafter the "discontinuance" of a Subsidized Project as used in this Handling Guideline means to temporarily discontinue a Subsidized Project, and the "abolition" of a Subsidized Project as used in this Handling Guideline means to terminate a Subsidized Project.):

- (1) If the Principal Investigator or Co-Investigator becomes unable to sufficiently perform the role in the Subsidized Project due to transfer, long-term treatment, death, other mental or physical disorder, etc. of the Principal Investigator or Co-Investigator;
  - (2) if a Business Operator Implementing Subsidized Project reasonably judges that it is difficult to produce a result of the Subsidized Project or if any significant issue has arisen in terms of the performance of the Subsidized Project;
  - (3) if there is a natural disaster or any other unavoidable reason that makes it difficult to continue the Subsidized Project;
  - (4) if there is any cause similar to any of the preceding items and it is not appropriate to continue the Subsidized Project.
- 2 If the cause pertaining to the whole or a part of discontinuance of a Subsidized Project is solved and the implementation of the Subsidized Project may be resumed, the Business Operator Implementing Subsidized Project shall promptly submit a Subsidized Project Research Reinstatement Notification in Form 5-2 to AMED.

(Suspension of Use of Subsidy)

Article 13-2 A Business Operator shall, if it falls under any of the following items, immediately suspend the use of the Subsidy granted up to such a point:

- (1) If the whole or a part of the Subsidized Project implemented by the Business Operator is discontinued or abolished;
- (2) if the whole or a part of Grant Decision has been rescinded.

(Notification of Program Delay)

Article 14 If a Business Operator Implementing Subsidized Project expects not to be able to complete the Subsidized Project within the scheduled period, or if the performance of the Subsidized Project becomes difficult, promptly submit Subsidized Project Delay Report in Form 6 to AMED and receive its instructions.

(Status Report)

Article 15 A Business Operator Implementing Subsidized Project shall, if requested by AMED with regard to the status of the performance and the revenue and expenditure of the Subsidized Project, promptly submit the Subsidized Project Performance Status Report in Form 7 to AMED.

- 2 AMED may, if deemed necessary, investigate into the status of the performance and the revenue and expenditure of the Subsidized Project.

(Accomplishments Report)

Article 16 A Business Operator Implementing Subsidized Project shall, when completing the Subsidized Project, submit Subsidized Project Accomplishments Report in Form 8 to AMED by the last day of May after the end of the government's fiscal year or by the date designated by AMED within 61 days after the completion of the Subsidized Project.

- 2 A Business Operator Implementing Subsidized Project shall, if the Subsidized Project is not completed at the end of the government's fiscal year, submit to AMED the Subsidized Project Year-End Report in Form 9 upon the end of the government's fiscal year by the last day of May of the end of government's fiscal year for Subsidies.

(Inspection and Reporting)

Article 17 AMED shall, when receiving Subsidized Project Accomplishments Report under the provision of Article 16, Paragraph 1, promptly inspect the contents of such Subsidized Project Accomplishments Report.

- 2 AMED may, in addition to the inspection referred to in the preceding paragraph, carry out the inspection listed in the following items:
  - (1) Inspection with regard to the status of expenditure of expenses required for the implementation of the Subsidized Project which is conducted after the end of the government's fiscal year;
  - (2) Inspection with regard to the status of expenditure of expenses required for the implementation of the Subsidized Project which is conducted in principle after six months have passed from the beginning of the government's fiscal year;
  - (3) other inspection deemed necessary by AMED.
- 3 AMED may carry out the inspection referred to in the preceding two paragraphs with regard to the matters listed in the following items. In this case, AMED may, as necessary, request a Business Operator to submit reports and materials to be referred to.
  - (1) Consistency between the contents of the Subsidized Project stated in the Subsidized Project Accomplishments Report and Subsidized Project Year-End Report, and the expended expenses
  - (2) Consistency between the contents of the Subsidized Project Plan Sheet, and the Subsidized Project Accomplishments Report and Subsidized Project Year-End Report
  - (3) Books and records listed in Article 30
  - (4) Other matters AMED deems necessary with regard to the Subsidized Project
- 4 If AMED deems it necessary to confirm the facts, a Business Operator shall request a business partner to submit reports and materials to be referred to.
- 5 AMED may conduct the inspection set forth in Paragraph 1 and Paragraph 2 at the factories, research facilities and other places of business (including the places of business of contractors of the Business Operator; the same shall apply hereinafter) of the Business Operator.
- 6 AMED shall, when intending to implement the inspection set forth in Paragraph 1 and Paragraph 2, notify the Business Operator of the place, date and staff of the inspection, and other matters necessary to implement the inspection.
- 7 The Business Operator shall, when receiving the notification set forth in the preceding paragraph, prepare the documents designated by AMED in advance and dispatch a person who is able to explain the contents of the Subsidized Project and the contents of accounting to the place of inspection designated by AMED at the Business Operator's expense.
- 8 AMED may, if it deems it necessary, have the staff of Relevant Ministries and Agencies attend, and the

Business Operator shall accept such attendance.

- 9 The period during which AMED may carry out the inspection set forth in Article 17, Paragraph 2, item 3 shall be for five (5) years starting from the day following the date of ending of the government's fiscal year including the day on which the Subsidized Project period ends.

(Confidentiality)

Article 17-2 Neither a Business Operator Implementing Subsidized Project nor AMED may, without the prior written consent of the other party, disclose or divulge to any third party (i) information disclosed by the other party or the other party's information learned upon the implementation of a Subsidized Project which is clearly identified as being confidential in writing by the other party out of information which has been or has come to be independently held other than research and development in the Subsidized Project, and (ii) information agreed in writing with the other party to be kept in confidence out of information generated during the implementation of the Subsidized Project ("Confidential Information"). Furthermore, when disclosing Confidential Information to a third party with the prior written consent of the other party, the party who makes the disclosure shall cause the third party to assume confidentiality obligations of the same contents and same degree as those it assumes under the Subsidy Guidelines.

- 2 The Business Operator Implementing Subsidized Project and AMED shall use the other party's Confidential Information for the Subsidized Project, and shall not use it for any other purposes.
- 3 The Business Operator Implementing Subsidized Project and AMED shall appropriately manage materials in relation to Confidential Information and media, etc., in which Confidential Information is stored.
- 4 Notwithstanding the provisions of the preceding three paragraphs, if it falls under any of the following items, the provisions of Paragraph 1 through Paragraph 3 shall not apply:
  - (1) Information that can be proved to have already been in the possession of the receiving party at the time of disclosure or learning;
  - (2) Information that has already been in the public domain at the time of disclosure or learning;
  - (3) Information that has become part of the public domain after disclosure or learning for reasons not attributable to the receiving party;
  - (4) Information that can be proved to have been obtained from a duly authorized third party without assuming confidentiality obligation;
  - (5) Information that can be proved to have been independently developed or obtained without reference to information disclosed by the other party;
  - (6) Information that is stated in a document submitted by the other party, which was presupposed to be published.
- 5 Business Operator Implementing Subsidized Project and AMED may disclose Confidential Information to the extent necessary and reasonable if disclosure is obligated under Laws and Regulations, or if disclosure is required by Relevant Ministries and Agencies or a court and other public organizations.
- 6 A Business Operator Implementing Subsidized Project and AMED shall cause the Researchers, etc. and other officers and employees who belong to the party as well as the party's Contractors, etc. for the performance, evaluation, etc. of the Subsidized Project to assume confidentiality obligations of the same contents and same degree as those under this Article even for the period after their employments or contracts terminate.

(Reporting, etc. of Results)

Article 18 A Business Operator Implementing Subsidized Project shall, when completing the Subsidized Project, submit Subsidized Project Results Report in Attachment to Form 8 with regard to Subsidized Project Development Accomplishments to AMED by the last day of May after the end of the government's fiscal year or by the date designated by AMED within 61 days after the completion of the Subsidized Project.

- 2 A Business Operator Implementing Subsidized Project shall, if a Subsidized Project is not completed at the end of the government's fiscal year, submit to AMED the Subsidized Project Results Report in Form 9 attached hereto by the last day of May of the following year after the end of the government's fiscal



year.

- 3 If AMED conducts a survey with regard to Subsidized Project Development Accomplishments such as a follow-up survey, technology transfer survey, and survey on inventions, etc. and Intellectual Property Rights, a Business Operator Implementing Subsidized Project shall cooperate in such a survey, etc. by AMED.
- 4 A Business Operator Implementing Subsidized Project shall, to prevent unauthorized divulgence to any third party, take necessary measures with regard to the Subsidized Project Development Accomplishments to be kept secret, such as executing confidentiality agreements with employees, etc. including agreements after retirement.
- 5 A Business Operator Implementing Subsidized Project shall, in the event of unauthorized divulgence of Subsidized Project Development Accomplishments to any third party, report to AMED without delay and make an appropriate response such as taking legal measures against the persons involved in the unauthorized divulgence.

(Publication of Accomplishments)

Article 18-2 A Business Operator Implementing Subsidized Project and AMED shall, to the extent not violating Article 17-2, publish the Subsidized Project Development Accomplishments to the public.

- 2 A Business Operator Implementing Subsidized Project and AMED shall, if the other party publishes the Subsidized Project Development Accomplishments to the public, cooperate mutually to the extent reasonable to ensure that such publication is made smoothly.
- 3 Notwithstanding the provision of Paragraph 1, if the publication of Subsidized Project Development Accomplishments to the public by the Business Operator Implementing Subsidized Project or AMED may interfere with the obtainment of Intellectual Property Rights by the Business Operator Implementing Subsidized Project or other respective businesses, the Business Operator Implementing Subsidized Project and AMED shall discuss and decide on the response after discussion.
- 4 A Business Operator Implementing Subsidized Project shall, when publishing Subsidized Project Development Accomplishments to the public, clearly state that such Accomplishments have been obtained as a result of the Subsidized Project of AMED.

(Determination, etc. of the Amount of the Subsidy)

Article 19 AMED shall, when receiving the report set forth in Article 16, Paragraph 1, conduct the review of the report and other documents and conduct on-site inspections as necessary, and if it deems that the implementation results of the Subsidized Project pertaining to such report conforms to the contents of the Grant Decision (if the change to the Subsidized Project Plan is approved under Article 12, such approved contents; the same shall apply hereinafter in this article) and the conditions imposed thereon, it shall determine the amount of the Subsidy to be granted to the Business Operator Implementing Subsidized Project based on the total amount of the Expenses Covered by Subsidy (not exceeding the amount obtained by multiplying the total amount of Expenses Covered by Subsidy by the Subsidy Rate) and notify the Business Operator in Notification of Subsidy Determination of Form 12.

- 2 When AMED determines the amount of the Subsidy to be granted to the Business Operator Implementing Subsidized Project, if the Subsidy the amount of which exceeds the said amount has already been granted, AMED shall order the Business Operator Implementing Subsidized Project to refund the exceeding amount by Notification of Subsidy Determination of Form 13.
- 3 The refund of the Subsidy set forth in the preceding paragraph shall be made within twenty (20) days from the day on which the order is issued, and if the refund is not made within the due date, AMED shall collect penal interest for the unpaid amount calculated at the annual interest rate of ten point ninety-five percent (10.95%), depending on the number of days from the due date to the date of payment.

(Refund of Subsidy upon Determination of Tax Deductions for Taxable Purchases Pertaining to Consumption Tax and Local Consumption Tax)

Article 20 A Business Operator Implementing Subsidized Project shall, when tax deductions for taxable purchases pertaining to consumption taxes and local consumption taxes pertaining to Subsidy are determined through the reporting of consumption taxes and local consumption taxes after the end of

government's fiscal year and after completion of Subsidized Project (including the case in which the whole of Grant Decision is rescinded and the case in which Subsidized Project is discontinued or abolished; the same shall apply hereinafter), promptly report such tax deductions for taxable purchases to AMED by Report on Determination of Tax Deductions for Taxable Purchases Pertaining to Consumption Tax and Local Consumption Tax Pertaining to Subsidy of Form 14.

- 2 AMED shall, when receiving the report set forth in the preceding paragraph, order the refund of the whole or a part of deducted amount due to tax deductions for taxable purchases pertaining to such consumption taxes and local consumption taxes.
- 3 The provision of Paragraph 3 of the preceding article shall apply mutatis mutandis to the provision on the refund referred to in the preceding paragraph.

(Rescission, etc. of Grant Decision)

Article 21 AMED may, in any of the following cases, rescind or change the whole or part of the Grant Decision.

- (1) If the Business Operator Implementing Subsidized Project has committed wrongful or unjust acts in relation to the Grant Decision;
  - (2) If the Business Operator Implementing Subsidized Project has breached the Regulation Act or the Order for Enforcement or any other Laws and Regulations applicable to Business Operator Implementing Subsidized Project in the Subsidized Project;
  - (3) If the Business Operator Implementing Subsidized Project is discovered to not conform to the application requirements stipulated in the Application Guidelines, or falls under adoption rescission requirements, or if the Business Operator Implementing Subsidized Project has committed any material breach of Application Guidelines;
  - (4) If the Business Operator Implementing Subsidized Project has committed any material breach of the Subsidy Guidelines or there is any failure of representations and warranties of the Business Operator Implementing Subsidized Project;
  - (5) If the Business Operator Implementing Subsidized Project does not satisfy the conditions imposed by AMED on the Grant Decision under Article 6, Paragraph 5 or Article 12, Paragraph 2;
  - (6) If the Business Operator or AMED determine that the Researchers, etc. of the Business Operator Implementing Subsidized Project have committed Misconduct, etc. in Subsidized Project;
  - (7) If the Business Operator or AMED determine that the Researchers, etc. of the Business Operator Implementing Subsidized Project have committed Misconduct, etc. in research and development by Competitive Research Funds, etc.;
  - (8) If a Business Operator Implementing Subsidized Project has used Subsidy for any other purpose, or otherwise it has breached the contents of the decision of the grant of Subsidy or the conditions imposed thereon or other Laws and Regulations or AMED's disposition based thereon in relation to Subsidized Project, etc.;
  - (9) If a petition for commencement of bankruptcy procedures, commencement of civil rehabilitation procedures, commencement of corporate reorganization procedures, or special liquidation is filed against a Business Operator Implementing Subsidized Project, or if the fact that will be the cause therefor arises;
  - (10) If a Business Operator Implementing Subsidized Project is subjected to suspension of transactions with banks or goes into insolvency, or if there occurs a risk thereof;
  - (11) If a Business Operator Implementing Subsidized Project is subjected to attachment or disposition of delinquency in payment of taxes and public dues, etc., or if there occurs a risk thereof;
  - (12) If any event falling under items 1 through item 8 of this paragraph occurs at the Contractor, etc. if subcontracting to a third party or joint implementation with a third party is implemented under Article 11-2.
- 2 If AMED has rescinded the decision of the grant of Subsidy as falling under any event of the items of the preceding paragraph, it may, if Subsidy has been granted in relation to the part pertaining to the rescission of Subsidized Project, order the refund of the whole or a part of the Subsidy by setting a due date, and the Business Operator shall make refund of Subsidy by following AMED's order.
  - 3 AMED shall, if ordering the refund of the preceding paragraph, order the payment of interest calculated at the annual interest rate of ten point ninety-five percent (10.95%) of the amount of such Subsidy (the amount obtained by deducting the amount already paid with regard to the subsequent period if a part

thereof has been paid), depending on the number of days from the date of receipt of Subsidy to the date of payment, and the Business Operator shall pay the interest by following AMED's order.

- 4 The provisions of Article 19, Paragraph 3 shall apply mutatis mutandis to the provision on the refund of Subsidy under Paragraph 2.
- 5 The provisions of Paragraphs 1 through the preceding paragraph shall apply even after determination of the amount of Subsidy to be granted with regard to Subsidized Project.

(Treatment of Researchers, etc. Pertaining to Misconduct, etc.)

Article 22 A Business Operator Implementing Subsidized Project shall, in implementing Subsidized Project, agree the following items in advance and cause Researchers, etc. to understand them in advance.

- (1) AMED may, in accordance with AMED Regulations for Responding to Misconduct in Research Activities, impose a restriction in an application, participation, etc. under the same regulations on Researchers, etc. who have committed Misconduct, etc. in a Subsidized Project.
- (2) AMED may, under the Government Guidelines for Responding to Misconduct and AMED Regulations for Responding to Misconduct in Research Activities, impose a restriction in an application, participation, etc. on Researchers, etc. on whom restriction in application and participation is imposed based on the determination of Misconduct, etc. in relation to Competitive Research Funds, etc.

(Measures, etc. in Relation to Misconduct, etc.)

Article 23 AMED may, if it deems that Misconduct, etc. is suspected to have been committed in the Subsidized Project (including the cases in which Misconduct, etc. is suspected to have been committed in the Subsidized Project with regard to researchers and other persons of Contractor, etc. engaged in the Subsidized Project, if there are any Contractor, etc.), request the Business Operator Implementing Subsidized Project to investigate in accordance with AMED Regulations for Responding to Misconduct in Research Activities and AMED's instructions, and the Business Operator Implementing Subsidized Project shall report the results of the investigation to AMED in writing. Furthermore, AMED may investigate by itself as necessary, and the Business Operator Implementing Subsidized Project shall cooperate in AMED's investigation. The Business Operator Implementing Subsidized Project shall, if a preliminary investigation under Government Guidelines for Responding to Misconduct is commenced in the Subsidized Project, promptly report such a matter to AMED and make a necessary response after discussion with AMED.

- 2 The Business Operator Implementing Subsidized Project shall, if investigation with regard to Misconduct, etc. of Researchers, etc. (including researchers and other persons of Contractor, etc. engaged in the Subsidized Project, if there are any Contractor, etc.) in research and development (including those completed) by Competitive Research Funds, etc. other than the Subsidized Project is commenced by its own investigation, or if it has confirmed the commencement or finding of the investigation into Misconduct, etc. by an institution other than the Business Operator Implementing Subsidized Project, promptly report such a matter to AMED.
- 3 AMED may, if it deems that Misconduct, etc. is suspected to have been committed in the Subsidized Project (including the cases in which Misconduct, etc. is suspected to have been committed in the Subsidized Project with regard to researchers and other persons of Contractor, etc. engaged in the Subsidized Project, if there are any Contractor, etc.), or it receives any report from the Business Operator Implementing Subsidized Project with the effect that investigation into Misconduct, etc. has been commenced with regard to the Researchers, etc. in research and development by the Competitive Research Funds, etc. other than the Subsidized Project, instruct a temporary suspension of the use of the Subsidy during the period deemed necessary by AMED, and the Business Operator Implementing Subsidized Project shall follow such an instruction. In this case, even if no Misconduct, etc. is found as a result of the investigation into such Misconduct, etc., AMED shall assume no liability for damages incurred by the temporary suspension of use of the Subsidy.
- 4 AMED may, if it is found that Misconduct, etc. has been committed or such a finding has been confirmed as a result of the investigation or report set forth in Paragraph 1 through Paragraph 3, take necessary measures in accordance with the Government Guidelines for Responding to Misconduct and AMED

Regulations for Responding to Misconduct in Research Activities as well as the relevant Laws and Regulations in addition to the measures set forth in the Subsidy Guidelines, and the Business Operator Implementing Subsidized Project shall follow such measures.

- 5 In addition to the provisions set forth in the paragraphs, the Business Operator Implementing Subsidized Project shall comply with the obligations of a Business Operator Implementing Subsidized Project as set forth in the Government Guidelines for Responding to Misconduct and AMED Regulations for Responding to Misconduct in Research Activities, and AMED shall exercise the rights to a Business Operator Implementing Subsidized Project set forth in regulations.

(Responsibilities and Accident Reporting Obligations of Business Operator Implementing Subsidized Project)

Article 24 A Business Operator Implementing Subsidized Project shall implement the Subsidized Project on the responsibility of Business Operator Implementing Subsidized Project, and even if any damage is incurred to the life, body or property of the Business Operator Implementing Subsidized Project, Researchers, etc. or any third party in the course of performance of the Subsidized Project or otherwise any dispute, etc. has arisen, the Business Operator Implementing Subsidized Project shall solve such damage or dispute, etc. at its expense and on its responsibility and indemnify AMED from damages, etc., except for the cases due to AMED's intention or gross negligence.

- 2 A Business Operator Implementing Subsidized Project shall, in the case referred to in the preceding paragraph, promptly report the specific contents thereof to AMED in writing.

(Management, etc. of Assets)

Article 25 A Business Operator Implementing Subsidized Project shall manage the assets which are acquired by Subsidized Project or the utility of which is increased by Subsidized Project (hereinafter referred to as "Acquired Assets, etc.") with due care of a prudent manager even after completion of Subsidized Project, and make efforts for efficient utilization thereof in accordance with the objective of Subsidy grant.

- 2 A Business Operator Implementing Subsidized Project shall prepare and manage an Acquired Asset Ledger for the Acquired Assets, etc. in Form 15.
- 3 A Business Operator Implementing Subsidized Project shall, if there are any acquired assets in the relevant fiscal year, attach a Detailed Specification for the Management of the Acquired Assets, etc. in Form 16 to Subsidized Project Accomplishments Report set forth in Article 16, Paragraph 1 and Subsidized Project Year-End Report set forth in Article 16, Paragraph 2.
- 4 AMED may, if the disposal of Acquired Assets, etc. generates or is expected to generate income, cause the whole or a part of the income to be paid to AMED.

(Restrictions on Disposal of Assets)

Article 26 A Business Operator Implementing Subsidized Project shall not, without AMED's approval, use against the objective of the grant of the Subsidy, assign, exchange, lease or provide as collateral the following Acquired Assets, etc. (hereinafter referred to as "Assets Whose Disposal Is Restricted"):

- (1) Realty;
  - (2) ships, aircrafts, buoyage, floating bridges, and floating dock;
  - (3) appurtenances of those listed in the preceding two items;
  - (4) machinery and important appliances whose acquisition value or increased value of the utility is 500,000 yen or more per unit;
  - (5) in addition to the preceding items, machinery, appliances, furniture and other properties which are deemed especially necessary to achieve the objective of grant of Subsidy and whose acquisition value or increased value of the utility is 500,000 yen or more per unit.
- 2 Notwithstanding the provisions of the preceding paragraph, the following items shall not fall under Assets Whose Disposal Is Restricted:
    - (1) When AMED decides the grant of Subsidy to a Business Operator Implementing Subsidized Project, if it is deemed that such Business Operator Implementing Subsidized Project makes a considerable profit

by the completion of the Subsidized Project and the condition with the effect that the amount equivalent to the whole of such granted Subsidy is payable to AMED provided that it is not against the objective of grant is imposed, if the Business Operator Implementing Subsidized Project has paid the amount equivalent to the whole amount of Subsidy to AMED based on such a condition;

- (2) if the period set forth separately by AMED by taking into consideration the objective of the grant of Subsidy and the useful life of such Assets Whose Disposal Is Restricted (the number of years set forth in Appended Table 6. Table for the Number of Years of Useful Life of Depreciable Assets for Development and Research of the Ministerial Ordinance concerning the Useful Life, etc. of Depreciable Assets (Finance Ministry Ordinance No.15 of 1965) has passed.
- 3 A Business Operator Implementing Subsidized Project shall, if it intends to use against Subsidy Objective, assign, exchange, loan, demolish or provide as collaterals Assets Whose Disposal Is Restricted, during the period set forth under item 2 of the preceding paragraph, submit Application for Approval of Assets Disposal pertaining to Subsidized Project to AMED in Form 17 in advance and obtain its approval.
- 4 The provision of Paragraph 4 of the preceding article shall apply mutatis mutandis to the case in which the approval set out in the preceding paragraph is given.
- 5 Otherwise, AMED shall determine the treatment of Assets Whose Disposal Is Restricted each time as necessary.

(Elimination of Antisocial Forces)

Article 27 A Business Operator Implementing Subsidized Project represents and warrants that it does not fall under any of the following items, and AMED may, if a Business Operator Implementing Subsidized Project falls or is found to have fallen under any of the items, rescind Grant Decision without any prior notification to the Business Operator Implementing Subsidized Project:

- (1) That the Business Operator Implementing Subsidized Project is or was an organized crime group, a member of an organized crime group, a company or a person involved with an organized crime group, a corporate racketeer, or any other antisocial force (hereinafter referred to as “Antisocial Forces”);
- (2) that the Business Operator Implementing Subsidized Project’s officers or persons who substantively control the management are or were Antisocial Forces;
- (3) that the Business Operator Implementing Subsidized Project’s parent company, subsidiaries (both as defined in the Companies Act; the same shall apply hereinafter), or third parties such as Contractors, etc., the Business Operator Implementing Subsidized Project employs for the performance of the Subsidized Project fall under either of the preceding two items.
- 2 AMED may rescind Grant Decision without any prior notification to the Business Operator Implementing Subsidized Project if:
  - (1) The Business Operator Implementing Subsidized Project (including its officers or persons who substantively control the management; the same shall apply to item 2 through item 4 below) uses threatening words and behavior or violence against AMED, or conducts acts that defame or discredit AMED;
  - (2) the Business Operator Implementing Subsidized Project interferes with AMED’s businesses by using fraudulent means or force;
  - (3) the Business Operator Implementing Subsidized Project causes a third party to conduct any acts in the preceding two items;
  - (4) the Business Operator Implementing Subsidized Project conducts acts that encourage activities of Antisocial Forces such as providing them with funds, etc.; or
  - (5) the Business Operator Implementing Subsidized Project’s parent company, subsidiaries, or third parties such as Contractors, etc., the Business Operator Implementing Subsidized Project employs for performing the Subsidized Project (including their officers or persons who substantively control the management) conduct acts that fall under any of the preceding four items.
- 3 AMED may, if it rescinds the whole or part of Grant Decision under the preceding two paragraphs, demand from the Business Operator Implementing Subsidized Project payment of 10% of the amount equivalent to the amount of Subsidy amount as a penalty in addition to the compensation for the damage actually incurred, and the Business Operator Implementing Subsidized Project shall pay such amount by

the due date set forth by AMED.

- 4 The provision of Article 21, Paragraph 2 through Paragraph 4 shall apply mutatis mutandis to the case in which by AMED rescinds the Grant Decision under Paragraph 1 or 2 of this Article.

(Handling of Personal Information)

Article 28 A Business Operator Implementing Subsidized Project shall, if entrusted by AMED with personal information (as defined in Article 2, Paragraph 1 of the Act on the Protection of Personal Information (Act No. 57 of 2003); the same shall apply hereinafter) with regard to Subsidized Project, handle such personal information (hereinafter referred to as “Entrusted Personal Information”) with due care of a prudent manager.

- 2 A Business Operator Implementing Subsidized Project shall not conduct any act listed in the following items, except with AMED’s prior written approval:
  - (1) Entrust or provide any third party (including Contractor, etc.) with Entrusted Personal Information or notify such third party of the contents thereof;
  - (2) use, reproduce or alter Entrusted Personal Information beyond the scope of the objective of Subsidized Project.
- 3 A Business Operator Implementing Subsidized Project shall take measures to prevent the divulgence, loss or damage of Entrusted Personal Information and other measures necessary for appropriate management of personal information.
- 4 AMED may, if deemed necessary, investigate into the management status, etc. of Entrusted Personal Information at the Business Operator Implementing Subsidized Project’s office and other places where the program is implemented by the Business Operator Implementing Subsidized Project, etc. and give necessary instructions to the Business Operator Implementing Subsidized Project.
- 5 A Business Operator Implementing Subsidized Project shall return Entrusted Personal Information to AMED promptly after completion of the Subsidized Project. Provided, however, that if AMED otherwise instructs, the Business Operator Implementing Subsidized Project shall follow its instructions.
- 6 A Business Operator Implementing Subsidized Project shall, if divulgence, loss or damage of Entrusted Personal Information occurs, promptly report such a matter to AMED and follow its instructions.

(Payment of Subsidy)

Article 29 The payment of Subsidy shall be in principle made after the amount of Subsidy to be granted is determined under the provisions of Article 19. Provided, however, that AMED may, if deemed necessary, pay the whole or a part of the Subsidy based on estimation.

- 2 A Business Operator Implementing Subsidized Project shall, if it intends to receive payment of Subsidy under the preceding paragraph, submit a written request for payment based on estimation (or after settlement) in Form 18 to AMED.

(Accounting etc. of Subsidy)

Article 30 A Business Operator Implementing Subsidized Project shall prepare a balance book and evidence documents in relation to Subsidized Project, and record the income and expenditure of Subsidized Project and account for the use of Subsidy by making distinction from other accounting.

- 2 A Business Operator Implementing Subsidized Project shall, with regard to the preparation of documents evidencing the contents of the expenditure and the preparation as well as the retention of the balance book set forth in the preceding paragraph with regard to the expenditure set forth in the preceding paragraph, retain them for five (5) years after the fiscal year including the date on which the amount of Subsidy is determined (date of such decision if Subsidized Project is discontinued or abolished).

(Revenue Status Report)

Article 31 A Business Operator Implementing Subsidized Project shall, with regard to the revenue for the past one year pertaining to such Subsidized Project, submit Subsidy Revenue Status Report using Form 19 to AMED for five (5) years from the year following the government’s fiscal year in which the Subsidized Project is completed, within 20 days after finalization of the financial statements of the

government's each fiscal year.

(Payment of Proceeds from Subsidy)

Article 32 If AMED deems, based on the report referred to in the preceding article, that the Business Operator who implemented Subsidized Project has made a profit due to commercialization of results of implementation of the Subsidized Project (including assignment of Intellectual Property Rights or establishment of license or provide others with the results of implementation of the Subsidized Project), AMED may order the Business Operator Implementing Subsidized Project the payment of the amount equivalent to the whole or part of the Subsidy granted to the Business Operator in the fiscal years following the government's fiscal year in which Subsidized Project is completed.

- 2 The total amounts the payment of which may be ordered under the provision of the preceding paragraph shall not exceed the total amount of the determined amounts of Subsidy.

(Abolition and Downsizing of Program)

Article 32-2 A Business Operator agrees in advance that AMED may unavoidably have to abolish or downsize the Subsidized Project in any of the following cases. AMED shall not be liable for any damage incurred by the Business Operator due to abolition or downsizing of the Subsidized Project.

- (1) If the government has determined suspension or cut of the budget or abolishment or downsizing or the like of AMED's businesses in the business evaluation at the end of the period of AMED's Medium to Long-term Objectives set forth under the provisions of Article 35-4 of the Act on General Rules for Incorporated Administrative Agencies (Act No. 103 of 1999);
- (2) If, for events other than those of the preceding items, the government's budget measures for AMED's programs are temporarily suspended or cut or AMED's businesses are abolished or downsized.

(Other)

Article 33 In addition to the provisions of the Application Guidelines and the Subsidy Guidelines, any matters necessary in connection with the handling of the Subsidy shall be set separately each time.

(Survival)

Article 34 Article 8, Article 9, the provisions on the obligations of the response after termination of the Subsidized Project in the Government Guidelines for Responding to Misconduct as well as AMED Regulations for Responding to Misconduct in Research Activities and Regulations Regarding Conflict of Interest (COI) Management, the provisions of Article 11-2, Paragraph 2, Article 15 through Article 21, Article 23 through Article 26, Article 27, Paragraph 3 and Paragraph 4, Article 28 through Article 32, and Article 33 through Article 35 shall remain in force even after the end of such implementation year of the Subsidized Project and after termination of the Subsidized Project in accordance with the period if the period is specified and as long as necessary for the compliance with provisions if no period is specified.

(Jurisdiction)

Article 35 The Tokyo District Court shall have the exclusive jurisdiction of the first instance over any dispute in connection with the Subsidy Guidelines and Subsidized Project.

Supplementary Provisions (August 4, 2022; 04IKENKAI No. 2731)

These Guidelines shall enter into force on August 4, 2022.

Supplementary Provisions (March 24, 2023; 04IKENKAI No. 6400)

These Guidelines shall enter into force on March 24, 2023.

Supplementary Provisions (May 10, 2023; 05IKENKAI No. 1287)

These Guidelines shall enter into force on May 10, 2023.