

Act on the Japan Agency for Medical Research and Development, National Research and Development Agency

(Act No. 49 of May 30, 2014)

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Chapter I General Provisions

(Purpose)

Article 1 The purpose of this Act is to provide for matters concerning the name, purpose, scope of operations, etc. of the Japan Agency for Medical Research and Development.

(Name)

Article 2 The name of the incorporated administrative agency prescribed in Article 2, paragraph (1) of the Act on General Rules for Incorporated Administrative Agencies (Act No. 103 of 1999; referred to as the "Act on General Rules" below) that is to be established pursuant to the provisions of this Act and the Act on General Rules is the Japan Agency for Medical Research and Development.

(Purpose of the Agency)

Article 3 The purpose of the Japan Agency for Medical Research and Development, (referred to as the "Agency" below) is to comprehensively and effectively promote research and development in the medical care sector, from basic research and development, to research and development for implementation and its smooth utilization, and to improve and create the environment for smooth and effective research and development in the medical care sector, by carrying out operations such as medical care research and development utilizing the capabilities of universities, research and development corporations (meaning the research and development corporations prescribed in Article 2, paragraph (9) of the Act on Activation of Scientific

Technology and Innovation Creation (Act No. 63 of 2008)), and other research institutions (simply referred to as "research institutions" in this Article), and by providing aid for medical care research and development at research institutions and the creation of that environment, based on the promotion plan for research and development in the medical care sector (meaning the promotion plan for research and development in the medical care sector prescribed in Article 18, paragraph (1) of the Healthcare Policy Promotion Act (Act No. 48 of 2014)).

(National Research and Development Agency)

Article 3-2 The Agency is a National Research and Development Agency as prescribed in Article 2, paragraph (3) of the Act on General Rules.

(Offices)

Article 4 The Agency is to have its principal office in Tokyo.

(Stated Capital)

Article 5 (1) The stated capital of the Agency is to be the total amount of the contributions that are considered to have been made by the government pursuant to the provisions of Article 2, paragraph (2) and Article 3, paragraph (2) of the supplementary provisions.

(2) If the government finds it to be necessary, it may make additional contributions to the Agency within the scope of the amount specified in the budget.

(3) If the government has made a contribution pursuant to the provisions of the preceding paragraph, then the Agency is to increase its stated capital by the amount of that contribution.

(Restrictions on Name Usage)

Article 6 No person other than the Agency may use the name, "日本医療研究開発機構" (with pronunciation of "nihon-iryō-kenkyū-kaihatsu-kikō" and with a literal meaning of "Japan Agency for Medical Research and Development Agency").

Chapter II Officers and Employees

(Officers)

Article 7 (1) The Agency has, as officers, the president at its head, and two auditors.

(2) The Agency may have, as an officer, one director.

(Involvement of the Headquarters for the Healthcare Policy in the
Appointment of Officers)

Article 8 Before appointing the president pursuant to the provisions of Article 20, paragraph (1) of the Act on General Rules or before appointing an auditor pursuant to the provisions of paragraph (2) of that Article, the competent minister must hear the opinion of the Headquarters for the Healthcare Policy.

(Duties and Authority of the Director)

Article 9 (1) The director, under the direction of the president, is to assist the president in administering the operations of the Agency.

(2) The officer specified by the relevant individual Act, as referred to in Article 19, paragraph (2) of the Act on General Rules, is the director; provided, however, that if there is no director, then an auditor is the director.

(3) In the case referred to in the proviso to the preceding paragraph, an auditor who represents or performs the duties of the president, pursuant to the provisions of Article 19, paragraph (2) of the Act on General Rules, may not perform the duties of an auditor at the same time.

(The Director's Term of Office)

Article 10 The director's term of office is a period specified by the president for that director (limited to a period, the last day of which is on or before the last day of the term of office of the president under Article 21-2, paragraph (1) of the Act on General Rules).

(Special Provisions for Disqualification of Officers)

Article 11 Notwithstanding the provisions of Article 22 of the Act on General Rules, public employees in the field of education or research specified by Cabinet Order (excluding those falling under any of the items of the following Article) may become part-time directors or auditors.

Article 12 Beyond what is provided for in Article 22 of the Act on General Rules, a person who falls under any of the following items may not become an officer:

- (i) a person engaging in the manufacture or sale of goods, or undertaking contract work who has a close business relationship with the Agency, or if that person is a corporation, then its officer (including a person who has the same or greater authority or influence than that officer, irrespective of their title);
- (ii) an officer of a business association listed in the preceding item (including a person who has the same or greater authority or influence than that officer, irrespective of their title).

Article 13 (1) To apply the provisions of Article 23, paragraph (1) of the Act on General Rules concerning the dismissal of the president of the Agency, the term "the preceding Article" in that paragraph is deemed to be replaced with "the preceding Article and Article 12 of the Act on the Japan Agency for Medical Research and Development, National Research and Development Agency (Act No. 49 of 2014)".

(2) To apply the provisions of Article 23, paragraph (1) of the Act on General Rules concerning the dismissal of directors and auditors of the Agency, the term "the preceding Article" in that paragraph is deemed to be replaced with "the preceding Article and Articles 11 and 12 of the Act on the Japan Agency for Medical Research and Development, National Research and Development Agency (Act No. 49 of 2014)".

(Duty of Confidentiality)

Article 14 It is prohibited for the officer or employee of the Agency or a person that has held one of these positions to divulge or misappropriate any secret learned in the course of their duties.

(Status of Officers and Employees)

Article 15 To apply the Penal Code (Act No. 45 of 1907) and other penal provisions, officers and employees of the Agency are deemed to be personnel engaged in public service pursuant to laws and regulations.

Chapter III Operations

(Scope of Operations)

Article 16 The Agency conducts the following operations to achieve the purpose stated in Article 3:

- (i) carrying out research and development in the medical care sector and improving its environment;
- (ii) disseminating the results of the operations stated in the preceding item and promoting utilization of these results;
- (iii) providing subsidies for research and development in the medical care sector and the improvement of its environment;
- (iv) performing operations incidental to the operations stated in the preceding three items.

(Acquisition and Holding of Shares)

Article 16-2 The Agency may acquire and hold shares or share options pursuant to the provisions of Article 34-5, paragraphs (1) and (2) of the Act on Stimulating the Development of Science, Technology, and Innovation.

(Disposition of Reserve Funds)

- Article 17 (1) If the Agency has settled accounts pursuant to the provisions of Article 44, paragraph (1) or paragraph (2) of the Act on General Rules for the final business year of the period for the mid-to-long term objectives prescribed in Article 35-4, paragraph (2), item (i) of the Act on General Rules (referred to as the "period for the mid-to-long term objectives" in this paragraph), and reserve funds remain under Article 44, paragraph (1) of the Act, then the portion of the amount equivalent to the amount of reserve funds that has been approved by the competent minister may be appropriated for the operations prescribed in Article 16 during the period for the mid-to-long term objectives following the period for the next mid-to-long term objectives, in accordance with the mid-to-long term plan for which the approval stated in Article 35-5, paragraph (1) of the Act on General Rules has been obtained (when the approval for revision under the provisions of the second sentence in that paragraph has been obtained, in accordance with the revised plan).
- (2) If the competent minister intend to grant approval pursuant to the provisions of the preceding paragraph, then they must confer with the Minister of Finance.
- (3) If any surplus remains after deducting the amount approved pursuant to the provisions of paragraph (1) from the amount equivalent to the amount of the reserve funds prescribed in that paragraph, then the Agency must pay the remainder to the national treasury.
- (4) Beyond what is provided for in the preceding three paragraphs, the procedures for making payments and other necessary matters concerning the disposition of reserve funds are specified by Cabinet Order.

(Establishment of Funds)

- Article 17-2 (1) If the competent minister specifies, in the mid-to-long term objectives prescribed in Article 35-4, paragraph (1) of the Act on General Rules, matters concerning operations stated in the items of Article 16 that are to be conducted as specified, open call, research and development operations prescribed in Article 27-2, paragraph (1) of the Act on Stimulating the Development of Science, Technology, and Innovation, then the Agency is to set up a fund prescribed in that paragraph (referred to as the "fund" in this Article and the following Article) and appropriate subsidies received pursuant to the provisions of the following paragraph, for the fund.
- (2) The government may subsidize capital to be allocated to the Agency's funds, within the scope of its budget.
- (3) If the Agency has established a fund pursuant to the provisions of paragraph (1), then it must establish a special account for accounting the operations related to that fund.

(Mutatis Mutandis Application of the Act on Regulation of Execution of Budget on Subsidies)

Article 17-3 The provisions of the Act on Regulation of Execution of Budget on Subsidies (Act No. 179 of 1955) (including penal provisions) apply mutatis mutandis to subsidies granted by the Agency in the course of operations for the fund. In this case, the term "each ministry" in that Act (excluding Article 2, paragraph (7)) is deemed to be replaced with "Japan Agency for Medical Research and Development"; the term "the heads of each ministry" in that Act is deemed to be replaced with "the president of Japan Agency for Medical Research and Development"; the term "the State" in Article 2, paragraph (1) and paragraph (4), item (i), Article 7, paragraph (2), Article 19, paragraph (1) and paragraph (2), Article 24, and Article 33 of that Act is deemed to be replaced with "Japan Agency for Medical Research and Development"; and the term "the State fiscal year" in Article 14 of that Act is deemed to be replaced with "Japan Agency for Medical Research and Development business year".

Chapter IV Miscellaneous Provisions

(Competent Minister)

- Article 18 (1) The competent ministers concerned with the Agency under this Act (excluding Article 8 (including as applied mutatis mutandis pursuant to Article 4 of the supplementary provisions)) and the Act on General Rules (excluding Article 14 and Article 20, and Article 23, paragraph (1) as applied following the deemed replacement of terms pursuant to the provisions of Article 13, paragraph (1) or paragraph (2) of this Act) are the Prime Minister; the Minister of Education, Culture, Sports, Science, and Technology; the Minister of Health, Labour, and Welfare; and the Minister of Economy, Trade, and Industry.
- (2) The competent minister concerned with the Agency, referred to in Article 8, (including as applied mutatis mutandis pursuant to Article 4 of the supplementary provisions), Articles 14 and 20 of the Act on General Rules, and Article 23, paragraph (1) of the Act on General Rules as applied following the deemed replacement of terms pursuant to the provisions of Article 13, paragraph (1) or paragraph (2) of this Act, is the Prime Minister.
- (3) The order of the competent ministry in the Act on General Rules concerned with the Agency is to be an order issued by the competent minister.

(The Japan Agency for Medical Research and Development Council)

Article 19 (1) The Japan Agency for Medical Research and Development Council (referred to as the "Council" in the following paragraph and paragraph (3)) is

established in the Cabinet Office.

(2) The Council takes charge of the following affairs:

- (i) studying and deliberating on matters concerning the affairs and business of research and development conducted by the Agency in response to consultations with the competent ministers;
- (ii) stating its opinions to the competent minister regarding the matters stated in the preceding item.

(3) Beyond what is provided for in the preceding paragraph, necessary matters concerning the organization and operation of the council are specified by Cabinet Order.

(Participation of the Headquarters for the Healthcare Policy Concerning the Mid-to-Long Term Objectives)

Article 20 (1) If the competent minister intends to set or revise the mid-to-long term objectives pursuant to the provisions of Article 35-4, paragraph (1) of the Act on General Rules, then the minister must hear the opinions of the Headquarters for the Healthcare Policy in advance.

(2) In conducting a review under Article 35-7, paragraph (1) of the Act on General Rules, the competent minister must hear the opinions of the Headquarters for the Healthcare Policy in advance.

(Exclusion from Application of the National Public Officers' Housing Act)

Article 21 The provisions of the National Public Officers' Housing Act (Act No. 117 of 1949) do not apply to the officers and employees of the Agency.

Chapter V Penal Provisions

Article 22 A person who has violated the provisions of Article 14 is punished by imprisonment for not more than one year or a fine of not more than one million yen.

Article 23 In the case of falling under any of the following items, an officer of the Agency who has committed the violation is punished by a civil fine of not more than 200,000 yen:

- (i) conducting operations other than those prescribed in Article 16;
- (ii) failing to obtain the approval of the competent minister when the approval is required pursuant to the provisions of Article 17, paragraph (1).

Article 24 A person who has violated the provisions of Article 6 is punished by a civil fine of not more than 100,000 yen.

Supplementary Provisions [Extract]

(Effective Date)

Article 1 This Act comes into effect as of the date of promulgation.

(Succession to Rights and Obligations of the State)

Article 2 (1) The rights and obligations that the State actually holds in relation to the operations stated in the items of Article 16 at the time of the establishment of the Agency, and that are specified by Cabinet Order, are succeeded to by the Agency at the time of the establishment of the Agency.

(2) If the Agency has succeeded to the rights and obligations held by the State pursuant to the provisions of the preceding paragraph, then an amount equivalent to the total value of the machinery and equipment, and other property specified by Cabinet Order regarding the rights succeeded to is deemed to have been contributed to the Agency by the government at the time of succession.

(3) The value of the property stated in the preceding paragraph that are deemed to have been contributed by the government pursuant to the provisions in that paragraph evaluated by the evaluation committee members based on the market value as of the date of establishment of the Agency.

(4) The members of the evaluation committee stated in the preceding paragraph and other necessary matters concerning the evaluation are specified by Cabinet Order.

(Succession to the Rights and Obligations of the National Institutes of Biomedical Innovation, Health, and Nutrition)

Article 3 (1) At the time of establishment of the Agency, regarding the business listed in Article 15, item (i), (b) and item (iii) of Act on the National Institute of Biomedical Innovation, Independent Administrative Agency (Act No. 135 of 2004) prior to the amendment pursuant to the provisions of Article 8 of the supplementary provisions, among the rights and obligations held by the National Institutes of Biomedical Innovation, Health, and Nutrition (referred to as the "National Institute of Biomedical Innovation, Health and Nutrition" in the following paragraph and paragraph (4)), those specified by Cabinet Order are succeeded to the Agency at the time of its establishment.

(2) If the Agency has succeeded to the rights and obligations of the National Institutes of Biomedical Innovation, Health, and Nutrition pursuant to the provisions of the preceding paragraph, then the amount obtained by subtracting the amount of liabilities from the value of the assets succeeded to is deemed to have been contributed by the government to the Agency at the time of succession.

- (3) The provisions of paragraphs (3) and (4) of the preceding Article apply mutatis mutandis to the value of the assets referred to in the preceding paragraph.
- (4) If the Agency succeeds to the rights and obligations of the National Institutes of Biomedical Innovation, Health, and Nutrition pursuant to the provisions of paragraph (1), then the National Institutes of Biomedical Innovation, Health, and Nutrition is to reduce its stated capital by the amount specified by the Minister of Health, Labour, and Welfare as the amount corresponding to the amount considered to have been contributed to the Agency pursuant to the provisions of paragraph (2).

(Involvement of the Headquarters for the Healthcare Policy in the Nomination of Persons to Serve as Officers)

Article 4 The provisions of Article 8 apply mutatis mutandis to the nomination of a person to serve as the president and persons to serve as auditors of the Agency pursuant to the provisions of Article 14, paragraph (1) of the Act on General Rules.

(Transitional Measure Concerning the Restriction on Name Usage)

Article 5 The provisions of Article 6 do not apply to a person who is actually using the name "日本医療研究開発機構" (with pronunciation of "nihon-iryō-kenkyū-kaihatsu-kikō" and with a literal meaning of "Japan Agency for Medical Research and Development Agency") at the time of the enforcement of this Act for six months after the enforcement of this Act.

(Transitional Measure Concerning Penal Provisions)

Article 6 To apply penal provisions to acts committed before the enforcement of the provisions prescribed in the proviso to Article 1 of the supplementary provisions, the provisions then in force remain applicable.

(Delegation to Cabinet Order)

Article 7 Beyond what is provided for in Article 2 through the preceding Article of the supplementary provisions, the transitional measure necessary for the establishment of the Agency and other transitional measures necessary for the enforcement of this Act are specified by Cabinet Order.