

Act on Japan Institute for Health Security (Partially unenforced)

(Act No. 46 of June 7, 2023)

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Chapter I General Provisions

(Purpose)

Article 1 The purpose of Japan Institute for Health Security is, under the supervision and in close coordination with the Minister of Health, Labour and Welfare, to conduct research, studies, analysis, and technological development in connection with infectious diseases and other diseases for which the collection of information on overseas cases and international research and study are particularly required to ensure appropriate medical treatment (referred to below as "infectious and other diseases"), and with international cooperation on prevention and medical treatment; to engage in the provision of advanced and specialized medical treatment, the development of human resources, etc. closely relevant to the above operations; and to carry out examinations, etc. of the pathogens, etc. of infectious and other diseases and tests, etc. for medicine, etc.; thereby seeking to prevent the emergence and expansion of emergency situations in Japan in which the spread of an infectious disease or any other serious harm to public health occurs, or is likely to occur, and to contribute to the improvement and promotion of public health in and outside Japan.

(Legal Personality)

Article 2 Japan Institute for Health Security (referred to below as the

"Institute") is a corporation.

(Office)

Article 3 The Institute establishes its principal office in Tokyo.

(Stated Capital)

Article 4 (1) The stated capital of the Institute is the total amount of the contributions that are deemed to have been made by the government pursuant to the provisions of Article 12, paragraphs (2), and Article 17, paragraph (1) of the Supplementary Provisions.

(2) If the government finds it necessary, the government may make additional capital contributions to the Institute within the amount specified in the budget.

(3) When capital contributions are made by the government under the provisions of the preceding paragraph, the Institute is to increase its stated capital by the amount of the capital contributions.

(Restriction on Use of the Name)

Article 5 A person who is not the Institute may not use the name “国立健康危機管理研究機構” (pronounced “kokuritsu kenkou kiki kanri kenkyu kikou”; meaning “national health risk management research agency”).

(Application Mutatis Mutandis of the Act on General Incorporated Associations and General Incorporated Foundations)

Article 6 The provisions of Articles 4 and 78 of the Act on General Incorporated Associations and General Incorporated Foundations (Act No. 48 of 2006) apply mutatis mutandis to the Institute.

Chapter II Officers, Council, and Employees

(Officers)

Article 7 The Institute has, as its officers, a president, a vice president, up to nine directors, and two inspectors; provided, however, that not less than four directors must be part-time base outside directors (meaning those directors who fall under all of the requirements stated in the following items; the same applies in this Chapter below):

(i) a person who is not the Institute's president, vice president, director (excluding outside directors), or employee (referred to as the "Institute's officer or employee" in this Article below) or is not an executive director (meaning any of the directors of a stock company stated in the items of Article 363, paragraph (1) of the Companies Act (Act No. 86 of 2005) or other directors who executed the operations of that stock company), executive

officer, manager, or other worker of a subsidiary corporation of the Institute (meaning a subsidiary corporation as specified by Order of the Ministry of Health, Labour and Welfare as a corporation whose management is controlled by the Institute; the same applies below) (referred to "executive director, etc. of the Institute's subsidiary corporation" in this Article below), and also who has not served as the Institute's officer or employee, or an executive director, etc. of the Institute's subsidiary corporations within ten years before assuming the office concerned;

- (ii) in the case of a person who served as an inspector or financial auditor (if the financial auditor is a corporation, the member of that corporation who is supposed to perform its duties; the same applies in this item below) of the Institute or as a director, accounting advisor (if the accounting advisor is a corporation, the member of that corporation who is supposed to perform its duties; the same applies in this item below), or corporate auditor of a subsidiary corporation of the Institute at any time within ten years before assuming the office concerned (excluding a person who was an executive director, etc. of the Institute's subsidiary corporation), the person who had not served as the Institute's officer or employee or as an executive director, etc. of the Institute's subsidiary corporation within ten years before assuming the above office of inspector, financial auditor, director, accounting advisor, or corporate auditor;
- (iii) a person who is not the spouse or a relative within the second degree of kinship of the Institute's president, vice president, director, or other important employee of the Institute.

(Establishment of a Council and Its Duties)

Article 8 (1) The Institute has a council in place under it.

- (2) The council consists of the president, the vice president, and all directors.
- (3) The council is responsible for performing the following duties:
 - (i) deliberation and determination of the matters for which the authorization (excluding the authorization referred to in Article 11, paragraph (2) and in Article 15, paragraph (4)) or approval of the Minister of Health, Labour and Welfare must be obtained pursuant to the provisions of this Act (including the provisions of the Act on General Rules for Incorporated Administrative Agencies (Act No. 103 of 1999), as applied mutatis mutandis pursuant to Article 43, following the deemed replacement of terms; the same applies in Article 10, paragraph (6)), and other important matters deemed particularly necessary by the council; and
 - (ii) supervision of the execution of duties by directors.
- (4) The president, the vice president, and directors (excluding outside directors) must report on the status of execution of their duties to the council not less

than once every three months.

(Meetings of the Council)

Article 9 (1) The president calls the meetings of the council.

- (2) The president serves as chairperson of the council and presides over its operations.
- (3) The council may not hold meetings or make any resolutions unless a majority of the president, vice president, and directors are present.
- (4) A decision of the council is made by a majority vote of the president, vice president, and directors who are present or, in the case of a tied vote, by the chairperson.

(Duties and Authority of Officers)

Article 10 (1) The president represents the Institute and presides over its operations.

- (2) The vice president represents the Institute and, as determined by the president, assists the president in administering the operations of the Institute, acts on behalf of the president in the event the president is unable to attend to their duties, and performs those duties in the event the position of president is vacant.
- (3) A director (excluding outside directors), as determined by the president assists the president and the vice president in administering the operations of the Institute, acts on behalf of the president or vice president in the event the president or vice president is unable to attend to their duties, and performs those duties in the event the position of president or vice president is vacant.
- (4) An inspector audits the operations of the Institute. In this case, the inspector must prepare an audit report pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (5) An inspector may, at any time, request reports on affairs and business from officers (excluding another inspector) and employees, or investigate the status of the operations and assets of the Institute.
- (6) If the Institute intends to submit documents related to authorization, approval, certification, and notification under the provisions of this Act and any reports and other documents specified by Order of the Ministry of Health, Labour and Welfare to the Minister of Health, Labour and Welfare, an inspector must review those documents and reports.
- (7) If it is necessary for the performance of duties, an inspector may request reports on business from a subsidiary corporation of the Institute, or investigate the status of its operations and assets.
- (8) If reasonable grounds for refusal exist, the subsidiary corporation referred to in the preceding paragraph may refuse to submit the report, or to submit itself

to the investigation, referred to in that paragraph.

- (9) An inspector may attend a meeting of the council and express its opinions, if the inspector finds it necessary.
- (10) An inspector may request the president to call a meeting of the council, if the inspector finds it necessary.
- (11) An inspector may submit its opinions to the president or the Minister of Health, Labour and Welfare, if the inspector finds it necessary on the basis of an audit result,.
- (12) Beyond what is provided for from paragraph (4) through the preceding paragraph, the matters necessary for audits are specified by Order of the Ministry of Health, Labour and Welfare.

(Appointment of Officers)

- Article 11 (1) The president and inspectors are appointed by the Minister of Health, Labour and Welfare.
- (2) The vice president and directors are appointed by the president with the authorization of the Minister of Health, Labour and Welfare received.
 - (3) When appointing the vice president and directors pursuant to the provisions of the preceding paragraph, the president must make public the appointment without delay.

(Term of Office of Officers)

- Article 12 (1) The term of office of the president begins on the date of appointment and ends on the last day of the period for the medium-term objectives, including the date of appointment, provided for in Article 27, paragraph (1) (referred to as the "period for the medium-term objectives" in this paragraph and Article 2, paragraph (4) of the Supplementary Provisions below); provided, however, that if the Minister of Health, Labour and Welfare finds it to be particularly necessary in order to appoint a person who is considered to be more suitable, the term of office of the first president appointed on or after the first day of the period for the medium-term objectives may be a period that begins on the date of appointment and ends on the day on which three years have passed since the first day of the period for the medium-term objectives.
- (2) Notwithstanding the provisions of the preceding paragraph, the term of office of the president appointed to fill a vacancy is the remaining term of the predecessor.
 - (3) The term of office of an inspector corresponds to the term of office of the president (including the term of office of the president appointed to fill a vacancy; the same applies in this paragraph below), beginning on the date of appointment and ending on the date of approval, under the provisions of

- Article 33, paragraph (1), of the financial statements referred to in those for the business year in which the last day of the corresponding term of office of the president is included; provided, however, that the term of office of an inspector appointed to fill a vacancy is the remaining term of the predecessor.
- (4) The term of office of the vice president and directors is two years; provided, however, that the term of office of the vice president or directors appointed to fill a vacancy is the remaining term of the predecessor.
- (5) An officer may be reappointed.

(Disqualification of Officers)

Article 13 The national government or local government employee (excluding a part-time base employee) is ineligible to be an officer; provided, however, that a public employee in the field of education or research specified by Cabinet Order (excluding any person falling under either of the items of the following Article) may become a director or inspector.

Article 14 Beyond what is provided for in the main clause of the preceding Article, a person who falls under either of the following items is ineligible to become an officer:

- (i) a person whose business is to manufacture or sell goods, undertake contract construction work, or provide services, and who has close interests in transactions with the Institute, or, if this person is a corporation, an officer of it (including those with the equal or superior authority or controlling power irrespective of the officer's title)
- (ii) an officer of any association of businesses stated in the preceding item (including those with the equal or superior authority or controlling power irrespective of the officer's title)

(Dismissal of Officers)

Article 15 (1) The Minister of Health, Labour and Welfare or the president must dismiss an officer appointed thereby if the officer has become ineligible to serve as an officer pursuant to the provisions of the main clause of Article 13 or the provisions of the preceding Article.

- (2) The Minister of Health, Labour and Welfare or the president may dismiss an officer appointed by them if the officer falls under either of the following items or is otherwise found to be unfit to serve as an officer:
- (i) if the officer is found to be unable to perform their duties due to a mental or physical disorder;
 - (ii) if the officer violates an obligation in the course of their duties.
- (3) Beyond what is provided for in the preceding paragraph, the Minister of Health, Labour and Welfare or the president may dismiss an officer appointed

by them, if the operational performance of the Institute has deteriorated due to the improper execution of duties by the officer (excluding inspectors), and if they find it inappropriate to have the officer continue to perform those duties.

- (4) If the president is to dismiss an officer appointed thereby pursuant to the provisions of the preceding two paragraphs, the president must obtain the authorization of the Minister of Health, Labour and Welfare.
- (5) If the Minister of Health, Labour and Welfare finds that the vice president or a director falls under the grounds provided for in paragraph (2) or (3), the minister may order the president to dismiss the officer.
- (6) Upon dismissing an officer appointed thereby pursuant to the provisions of paragraph (2) or (3), the president must make public the dismissal without delay.

(Officers' Liability of Damages)

- Article 16 (1) If an officer or financial auditor of the Institute fails to perform their duties, the officer or financial auditor bears liability to compensate the Institute for damage arising from the failure.
- (2) The liability referred to in the preceding paragraph may not be exempted from without the approval of the Minister of Health, Labour and Welfare

(Status of Officers and Employees)

Article 17 An officer and employee of the Institute are deemed to be employees engaged in public services pursuant to laws and regulations, regarding the application of the Penal Code (Act No. 45 of 1907) and other penal provisions.

(Remuneration of Officers)

- Article 18 (1) The remuneration and retirement allowances (referred to as the "remuneration, etc." in this Article below) of an officer of the Institute must take into consideration the performance of the officer.
- (2) The Institute must establish standards for payment of the remuneration, etc. of its officer, notify the Minister of Health, Labour and Welfare of those standards, and make public them. The same applies when the Institute revises those standards.
 - (3) The standards for payment of remuneration, etc. referred to in the preceding paragraph must be established by taking into consideration the salaries and retirement allowances (referred to as "salaries, etc." below) of national government employees; the remuneration, etc. of officers of private enterprises; the operational performance of the Institute; the necessity to secure human resources with internationally outstanding abilities as officers to engage in the operations that are particularly required to be executed by utilizing the world's top-level expertise and experience; and other circumstances.

(Salaries of Employees)

Article 19 (1) The salary of an employee of the Institute must take the work performance of the employee into consideration.

(2) The Institute must establish standards for payment of the salaries, etc. of its employee, notify the Minister of Health, Labour and Welfare of those standards, and make public them. The same applies when the Institute revises those standards.

(3) The standards for payment of salaries, etc. referred to in the preceding paragraph must be established by taking into consideration the salaries, etc. of national government employees to whom the Act on Remuneration of Officials in the Regular Service (Act No. 95 of 1950) applies; the salaries, etc. of employees of private enterprises; the operational performance of the Institute; the nature of the duties of employees and their employment patterns; the necessity to secure human resources with internationally outstanding abilities as employees who are to solely engage in research, studies, analysis, and technological development (referred to as the "research and development" below) and whose operations are particularly required to be executed by utilizing the world's top-level expertise and experience; and other circumstances.

Chapter III Services

(Mission Statement of Services)

Article 20 (1) The main purport of the services of an officer and employee of the Institute must be to promptly and accurately respond to infectious and other diseases, profoundly recognize the situations that patients, etc. are in, respect their human rights, and execute the duties faithfully and fairly with a strong sense of responsibility so as to facilitate advanced and specialized medical treatment for those infectious and other diseases, as well as international cooperation, etc. in connection with medical treatment, as a result earning the trust and confidence of the people.

(2) Pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, each officer and employee of the Institute must submit to the appointer a document in which the officer or employee pledges to execute duties in light of the mission statement of services referred to in the preceding paragraph.

(3) Concerning the operations provided for in Article 23, paragraph (1), an officer and employee of the Institute must observe this Act or the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998; referred to "Act on Infectious Diseases" below),

orders based on these Acts or dispositions made by the Minister of Health, Labour and Welfare based on those Acts, or the operational method statement and other rules established by the Institute, and must execute their respective duties faithfully for the Institute.

(Obligation of Confidentiality of Officers and Employees)

Article 21 An officer and employee of the Institute must not reveal or misappropriate any confidential information learned in the course of their duties. The same applies even after they have left their jobs.

(Disciplinary Rules)

Article 22 (1) On commencing operations, the Institute must prepare disciplinary rules and obtain the authorization of the Minister of Health, Labour and Welfare. The same applies when the Institute intends to revise those rules.

(2) The disciplinary rules referred to in the preceding paragraph must provide that a sanction such as dismissal, suspension from work, reduction in pay, or admonition or any other discipline is imposed on an officer or employee of the Institute if this officer or employee violates this Act, the Act on Infectious Diseases, any order based on these Acts or any disposition made by the Minister of Health, Labour and Welfare based on those Acts or the operational method statement or other rules established by the Institute, or engages in any act unbecoming of an officer and employee of the Institute.

Chapter IV Operations

Section 1 Scope of Operations

(Scope of Operations)

Article 23 (1) The Institute performs the following operations in order to achieve the purpose referred to in Article 1:

- (i) to engage in research and development in connection with the prevention and medical treatment of infectious and other diseases;
- (ii) to provide medical treatment closely relevant to the operation stated in the preceding item;
- (iii) to engage in research and development in connection with international cooperation on prevention and medical treatment;
- (iv) to promote the development of human resources and the improvement of their quality in connection with international cooperation on the prevention and medical treatment of infectious and other diseases;
- (v) to investigate the pathogens and causes of infectious and other diseases, and to collect, organize, analyze, and provide scientific information on

- prevention and medical treatment;
- (vi) to collect, examine, and store the pathogens and toxins of infectious and other diseases, and to develop and disseminate the technologies necessary for those activities, as well as reagents, samples, and machinery and appliances;
 - (vii) to provide the employees of prefectural and municipal public health institutes, etc. provided for in Article 26, paragraph (2) of the Community Health Act (Act No. 101 of 1947) with training, technological support, and other necessary support in connection with the operations stated in the preceding two items;
 - (viii) to conduct the biological inspection, tests, and trial manufacturing of biological preparations, antibacterial substances and preparations, disinfectants, insecticides, and rodenticides in connection with the prevention and medical treatment of infectious and other diseases, and to manufacture the standard items necessary for biological inspections and tests of the above pharmaceuticals which are provided for in Article 2, paragraph (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960), and quasi-pharmaceutical products (excluding those intended exclusively for use on animals) in paragraph (2) of that Article;
 - (ix) to manufacture biological preparations which are rarely used or which manufacturing is technologically difficult;
 - (x) to conduct bacteriological and biological tests and inspections in relation to food sanitation;
 - (xi) to disseminate the results of the operations stated in each of the preceding items, and to make suggestions on political measures;
 - (xii) to establish and operate facilities for teaching and researching theories and technologies related to nursing care and for providing training, with the aim for the cultivation and training of employees of the Institute and those of highly specialized national medical research centers provided for in Article 3-2 of the Act on National Research and Development Agencies that Conduct Research related to Advanced and Specialized Medical Care (Act No. 93 of 2008; referred to below as "Act on National Research and Development Agencies for Advanced and Specialized Medical Care");
 - (xiii) to make contributions and provide personnel and technical assistance to a person engaged in the business that promote the utilization of the results of research and development by the Institute and that are provided for by Cabinet Order;
 - (xiv) to process the affairs provided for in Article 65-4 of the Act on Infectious Diseases and affairs related to the authority provided for in Article 65-5 of the Act on Infectious Diseases; and
 - (xv) to perform operations incidental to operations stated in each of the

preceding items.

- (2) Pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, the Institute is to report the implementation status of the operations stated in the items of the preceding paragraph to the Prime Minister and the Minister of Health, Labour and Welfare.
- (3) The Institute may, to the extent necessary for the execution of the affairs stated in the items of paragraph (1) (excluding item (xiv)), internally use the information that it has come to retain by processing the affairs referred to in item (xiv) of that paragraph, for purposes other than those that have been identified for the retention.
- (4) When intending to perform the operation of making contributions among the operations stated in paragraph (1), item (xiii), the Institute must obtain the authorization of the Minister of Health, Labour and Welfare.

(Acquisition and Holding of Shares or Share Options)

Article 24 (1) In providing a person who utilizes, or intends to utilize the results of the Institute's research and development for business activities (referred to as the "result-utilizing enterprise" in this paragraph below) with necessary support for the promotion of dissemination and utilization of such results, the Institute may provide the support for free upon finding it particularly necessary to do so with the financial resources and other circumstances of the result-utilizing enterprise taken into consideration, or may acquire shares or share options issued by the result-utilizing enterprise in the case for which the Institute sets the value of the support lower than its market value or takes other measures.

- (2) The Institute may hold shares or share options acquired pursuant to the provisions of the preceding paragraph (including shares issued or transferred through the exercise of those share options).

(Use of the Institute's Facilities and Equipment)

Article 25 In addition to the operations provided for in Article 23, paragraph (1), the Institute may, to an extent that does not hinder the execution of those operations, allow doctors, dentists, or other healthcare personnel who do not work for the Institute to use part of the Institute's buildings or its equipment, instruments, and tools for medical care, research, or technological development.

(Operational Method Statement)

Article 26 (1) On commencing operations, the Institute must prepare an operational method statement and obtain the authorization of the Minister of Health, Labour and Welfare. The same applies when the Institute intends to revise the method.

- (2) The operational method statement referred to in the preceding paragraph must contain matters concerning the development of a system for ensuring that the execution of duties by its officer (excluding its inspector) complies with this Act, the Act on Infectious Diseases, and other laws and regulations and any other system for ensuring the proper operations of the Institute, and other matters provided for by Order of the Ministry of Health, Labour and Welfare.
- (3) Upon obtaining the authorization referred to in paragraph (1), the Institute must make public the operational method statement without delay.

Section 2 Medium-term Objectives

(Medium-term Objectives)

- Article 27 (1) The Minister of Health, Labour and Welfare must set objectives concerning the operational management of the Institute to be achieved during a period of six years (referred to below as the "medium-term objectives"), give instructions to the Institute about them, and make public them. The same applies when the Institute revises them.
- (2) The medium-term objectives are to specifically provide for the following matters:
 - (i) matters concerning the development of a system to prepare for the outbreak and spread of infectious diseases that are likely to seriously affect the lives and health of the people;
 - (ii) matters concerning the maximization of the results of research and development and the improvement of the quality of any other operations;
 - (iii) matters concerning the improvement of operational efficiency;
 - (iv) matters concerning the improvement of the financial conditions; and
 - (v) other important matters concerning the operational management.
 - (3) When intending to set or revise medium-term objectives, the Minister of Health, Labour and Welfare must, in advance, hear the opinions of the Headquarters for the Healthcare Policy and those of the Committee on the System of Evaluating Incorporated Administrative Agencies provided for in Article 12 of the Act on General Rules for Incorporated Administrative Agencies (referred to below as the "Committee on the System of Evaluating Incorporated Administrative Agencies").
 - (4) When intending to hear opinions concerning medium-term objectives pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare must, in advance, hear the opinions of an organ with a council system, that is established under the Ministry of Health, Labour and Welfare pursuant to the provisions of Article 8 of the National Government Organization Act (Act No. 120 of 1948), and that is provided for by Cabinet Order (referred to below as the "research and development council"), regarding

matters concerning the affairs and business of the Institute's research and development (excluding those specified by Cabinet Order as minor affairs or business; the same applies in Article 30, paragraph (6), and Article 32, paragraph (2)).

- (5) The Minister of Health, Labour and Welfare may appoint a foreign national (meaning a person without Japanese nationality; the same applies in the following paragraph) who has valuable insight in research and development in a field such as public health or other field as a member of the research and development council.
- (6) In the case referred to in the preceding paragraph, a member of the research and development council who is a foreign national may not preside over the business of the research and development council or represent it, and the number of those members must not exceed one-fifth of the total number of members of the research and development council.
- (7) When the Headquarters for Healthcare Policy or the Committee on the System of Evaluating Incorporated Administrative Agencies states its opinions to the Minister of Health, Labour and Welfare pursuant to the provisions of paragraph (3), it must make public the details of those opinions.

(Medium-term Plan)

Article 28 (1) Upon receiving the instructions referred to in paragraph (1) of the preceding Article, the Institute must, based on the medium-term objectives, prepare a plan for achieving the medium-term objectives (referred to below as the "medium-term plan") pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and obtain the authorization of the Minister of Health, Labour and Welfare. The same applies when the Institute intends to revise that plan.

- (2) The medium-term plan is to provide the following matters:
 - (i) measures concerning the development of a system to prepare for the outbreak and spread of infectious diseases that are likely to seriously affect the lives and health of the people;
 - (ii) the measures to be taken for achieving goals concerning the maximization of the results of research and development and the improvement of the quality of any other operations;
 - (iii) the measures to be taken for achieving goals concerning the improvement of operational efficiency;
 - (iv) the budget (including an estimate of personnel expenses), an income and expenditure plan, and a funding plan;
 - (v) limits on the amount of short-term borrowings;
 - (vi) if the Institute has any unnecessary assets or any assets that are expected to be unnecessary assets, a plan for disposal of those assets;

- (vii) if the Institute intends to transfer or provide as collateral any important assets other than those provided for in the preceding item, a plan for the transfer or provision;
 - (viii) use of surplus; and
 - (ix) other matters concerning the operational management provided for by Order of the Ministry of Health, Labour and Welfare.
- (3) If the Minister of Health, Labour and Welfare finds that the medium-term plan authorized thereby as referred to in paragraph (1) has become inappropriate for properly and securely implementing the matters stated in the items of paragraph (2) of the preceding Article, the minister may order the medium-term plan to be revised.
- (4) Upon obtaining the authorization referred to in paragraph (1), the Institute must make public the medium-term plan without delay.

(Annual Plan)

Article 29 Before the start of each business year, the Institute must establish a plan for the operational management for the business year (referred to as "annual plan" in Article 31) on the basis of the medium-term plan authorized under paragraph (1) of the preceding Article, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and must notify the Minister of Health, Labour and Welfare of the plan and make public it. The same applies when the Institute revises the plan.

(Evaluation on Operational Performance in Each Business Year)

- Article 30 (1) The Institute must undergo an evaluation conducted by the Minister of Health, Labour and Welfare after the end of each business year concerning the matters provided for in each of the following items according to the applicable business year among the years stated in these items:
- (i) a business year other than the business years stated in the following item and item (iii): the operational performance during the relevant business year;
 - (ii) the business year preceding the last business year within the period for the medium-term objectives: the operational performance during the relevant business year and the operational performance during the period for the medium-term objectives that are expected to be achieved at the time of the end of the period for the medium-term objectives; or
 - (iii) the last business year within the period for the medium-term objectives: the operational performance during the relevant business year and the operational performance during the period for the medium-term objectives.
- (2) In addition to the evaluation under the provisions of the preceding paragraph, if the term of office of the first president appointed on or after the first day of the period for the medium-term objectives is determined pursuant to the

- provisions of the proviso to Article 12, paragraph (1), or if the term of office of the president who is deemed to have been appointed at the time of incorporation of the Institute pursuant to the provisions of Article 2, paragraph (3) of the Supplementary Provisions is determined pursuant to the provisions of paragraph (4) of that Article, the Institute must undergo an evaluation conducted by the Minister of Health, Labour and Welfare, after the end of the business year in which the last day of the term of office of the relevant president (referred to as the "first president" in this paragraph below) (including the term of office of the president appointed to fill a vacancy) is included, regarding the operational performance during the period from the business year that includes the date of appointment of the first president until the end of the business year in which the above-mentioned last day is included.
- (3) When intending to undergo the evaluation referred to in paragraph (1), the Institute must, within three months from the end of each business year, submit to the Minister of Health, Labour and Welfare and make public a report which clearly indicates the matters provided for in item (i), (ii), or (iii) of that paragraph and the results of its self-evaluation on these matters, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (4) When intending to undergo the evaluation referred to in paragraph (2), the Institute must, within three months from the end of the business year in which the last day provided for in that paragraph is included, submit to the Minister of Health, Labour and Welfare and make public a report which clearly indicates the operational performance provided for in that paragraph and the results of its self-evaluation on the operational performance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (5) The evaluation referred to in paragraph (1) or (2) must be conducted by comprehensively evaluating the matters provided for in paragraph (1), item (i), (ii), or (iii) or the operational performance provided for in paragraph (2). In this case, the evaluation on the operational performance during the relevant business year provided for in the items of paragraph (1) must be conducted by investigating and analyzing the status of implementation of the medium-term plan during the business year, and by taking into consideration the results of the investigation and analysis.
- (6) When intending to conduct the evaluation referred to in paragraph (1) or (2), the Minister of Health, Labour and Welfare must, in advance, hear the opinions of the research and development council regarding matters concerning the affairs and business of the Institute's research and development.
- (7) After conducting the evaluation referred to in paragraph (1) or (2), the Minister of Health, Labour and Welfare must, without delay, notify the Institute of the results of the evaluation and make public these results. In this case, if the Minister of Health, Labour and Welfare has evaluated the

operational performance during the period for the medium-term objectives that are expected to be achieved at the end of that period as provided in paragraph (1), item (ii), the minister must also notify the Headquarters for Healthcare Policy and the Committee on the System of Evaluating Incorporated Administrative Agencies of the results of the evaluation without delay.

(8) If the Headquarters for Healthcare Policy or the Committee on the System of Evaluating Incorporated Administrative Agencies finds it necessary, the headquarters or committee must state its opinions to the Minister of Health, Labour and Welfare on the evaluation results notified pursuant to the provisions of the preceding paragraph and make public the details of those opinions.

(9) If the Minister of Health, Labour and Welfare finds it necessary on the basis of the evaluation results referred to in paragraph (1) or (2), the minister may order the Institute to improve the operational management or take other necessary measures.

(Treatment of Evaluation Results)

Article 31 The Institute must ensure that the results of the evaluation referred to in paragraph (1) or (2) of the preceding Article are appropriately reflected in the medium-term plan, the annual plan, and the improvement of the operational management, and must make public how the evaluation results have been reflected in these items in each business year.

(Review at the End of the Period for the Medium-Term Objectives)

Article 32 (1) When the Minister of Health, Labour and Welfare conducts an evaluation on the operational performance during the period for the medium-term objectives that are expected to be achieved at the time of the end of that period as provided for in Article 30, paragraph (1), item (ii), the minister is to review, by the end of the period for the medium-term objectives, the necessity of having the individual affairs or business within the Institute's operations continued, the manner in which the Institute is managed as an organization, and other overall aspects of its operations and organization, and take the necessary measures based on the results of this review.

(2) When conducting a review under the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare must hear the opinions of the research and development council regarding matters concerning the affairs and business of the Institute's research and development.

(3) The Minister of Health, Labour and Welfare must notify the Headquarters for Healthcare Policy and the Committee on the System of Evaluating Incorporated Administrative Agencies of the results of the review referred to in paragraph (1) and the details of the measures to be taken pursuant to the

- provisions of that paragraph, and make public those results and details.
- (4) If the Headquarters for Healthcare Policy or the Committee on the System of Evaluating Incorporated Administrative Agencies finds it necessary, the headquarters or committee must state its opinions to the Minister of Health, Labour and Welfare on the matters notified pursuant to the provisions of the preceding paragraph and make public the details of those opinions.
 - (5) In the case referred to in the preceding paragraph, the Committee on the System of Evaluating Incorporated Administrative Agencies may make recommendations to the Minister of Health, Labour and Welfare regarding the reform or discontinuation of any major affairs and business of the Institute.
 - (6) If the Committee on the System of Evaluating Incorporated Administrative Agencies makes recommendations as referred to in the preceding paragraph, it must report the details of the recommendations to the Prime Minister, and make public those details.
 - (7) If the Committee on the System of Evaluating Incorporated Administrative Agencies makes recommendations as referred to in paragraph (5), it may request a report from the Minister of Health, Labour and Welfare regarding the measures that the minister has taken and intends to take on the basis of the recommendations.

Chapter V Finance and Accounting

(Financial Statements)

- Article 33 (1) For each business year, the Institute must prepare a balance sheet, a profit and loss statement, documents concerning the appropriation of profits or the disposition of losses, other documents provided for by Order of the Ministry of Health, Labour and Welfare, and any detailed statements annexed to those documents (referred to as the "financial statements" in this Article and Article 50, paragraph (1), item (viii) below), submit them to the Minister of Health, Labour and Welfare within three months from the end of the relevant business year, and obtain the approval of the minister.
- (2) When submitting the financial statements to the Minister of Health, Labour and Welfare pursuant to the provisions of the preceding paragraph, the Institute must attach to it a business report prepared for the relevant business year pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, a statement of accounts prepared in accordance with budget categories, and also an audit report and a financial audit report concerning the financial statements and the statement of accounts.
 - (3) When obtaining the approval of the Minister of Health, Labour and Welfare under the provisions of paragraph (1), the Institute must give public notice of the financial statements in the Official Gazette without delay, keep the

financial statements as well as the business report, statement of accounts, audit report, and financial audit report referred to in the preceding paragraph in the principal office of the Institute, and make them available for public inspection for the period provided for by Order of the Ministry of Health, Labour and Welfare.

(4) The Institute may give public notice of the detailed statements annexed to the documents referred to in paragraph (1) and other documents provided for by Order of the Ministry of Health, Labour and Welfare by either of the methods stated below, in lieu of giving public notice under the provisions of the preceding paragraph:

(i) method of publication in a daily newspaper that publishes matters on current affairs; or

(ii) electronic public notice (meaning a method of public notice using an electronic data processing system or other information and communication technology, which is provided for by Order of the Ministry of Health, Labour and Welfare and which implements what Order of the Ministry of Health, Labour and Welfare provides for as the measure to put the information that should be given through public notice into a form that enable a large number of unspecified people to access the relevant information; the same applies in the following paragraph).

(5) If the Institute gives public notice by means of electronic public notice pursuant to the provisions of the preceding paragraph, the Institute must continually maintain the public notice for the period provided for by Order of the Ministry of Health, Labour and Welfare under paragraph (3).

(Management of Profits and Losses)

Article 34 (1) For each business year, when profits accrue in the calculation of profits and losses, the Institute must offset any losses carried forward from the preceding business year and, if there is still any remaining amount, record the remaining amount as a reserve fund; provided, however, that this does not apply if the remaining amount is allocated for the use referred to in paragraph (3) pursuant to the provisions of that paragraph.

(2) For each business year, when losses arise in the calculation of profits and losses, the Institute must record the losses after reducing the amount of the reserve fund under the provisions of the preceding paragraph and, if there is still any shortfall, dispose of the amount of the shortfall as a loss carried forward.

(3) If there is any remaining amount under paragraph (1), the Institute may allocate all or part of the remaining amount for the use of surplus referred to in Article 28, paragraph (2), item (viii) under a medium-term plan authorized under paragraph (1) of that Article (or a revised plan if the Institute has

obtained authorization for revision under the provisions of the second sentence of that paragraph; the same applies below) upon obtaining the approval of the Minister of Health, Labour and Welfare.

(Disposition of Reserve Funds)

- Article 35 (1) After the Institute settles accounts under the provisions of paragraph (1) or (2) of the preceding Article for the final business year of the period for the medium-term objectives, if there remains any reserve funds under the provisions of paragraph (1) of that Article, the Institute may allocate the portion, out of an amount equivalent to the reserve funds, that has been approved by the Minister of Health, Labour and Welfare to the financial resources for the operations provided for in Article 23, paragraph (1) and Article 25, and to be conducted by the Institute during the next medium-term objective period after the above-mentioned period for the medium-term objectives, pursuant to the medium-term plan associated with the next medium-term objective period.
- (2) If any surplus remains after deducting the amount approved under the provisions of the preceding paragraph from the amount equivalent to the reserve funds provided for in that paragraph, the Institute must pay the remaining surplus to the national treasury.
- (3) Beyond what is provided for in the preceding two paragraphs, the procedure for making payments and other necessary matters concerning the disposition of reserve funds are provided for by Cabinet Order.

(Borrowings)

- Article 36 (1) The Institute may make short-term borrowings within the limits on the amount of short-term borrowings stated in the relevant medium-term plan, as referred to in Article 28, paragraph (2), item (v); provided, however, that the Institute may make short-term borrowings in excess of the limits if the authorization of the Minister of Health, Labour and Welfare is obtained on unavoidable grounds.
- (2) Short-term borrowings under the preceding paragraph must be redeemed within the relevant business year; provided, however, that, if short-term borrowings cannot be redeemed due to a shortage of funds, only the amount that cannot be redeemed may be refinanced, upon obtaining the authorization of the Minister of Health, Labour and Welfare.
- (3) Short-term borrowings that have been refinanced pursuant to the provisions of the proviso to the preceding paragraph must be redeemed within one year.
- (4) Upon obtaining the authorization of the Minister of Health, Labour and Welfare, the Institute may take out long-term borrowings or issue Japan Institute for Health Security bonds (referred to below as "bonds") in order to

allocate those borrowings or bonds for the expenses required in the installation or maintenance of facilities provided for by Cabinet Order or in the installation of equipment.

- (5) Beyond what is provided for in the preceding paragraph, the Institute may, upon obtaining the authorization of the Minister of Health, Labour and Welfare, take out long-term borrowings or issue bonds in order to allocate them for the redemption of the long-term borrowings or bonds provided for by Cabinet Order; provided, however, that those long-term borrowings and bonds to be taken out or issued for redemption are limited to those in which redemption periods are provided for by Cabinet Order.
- (6) Creditors holding bonds under the provisions of the preceding two paragraphs have the right to receive payment of their own claims in preference to other creditors regarding the assets of the Institute.
- (7) The order of statutory lien under the preceding paragraph is ranked next to the general statutory lien under the provisions of the Civil Code (Act No. 89 of 1896).
- (8) Upon obtaining the authorization of the Minister of Health, Labour and Welfare, the Institute may entrust a bank or trust company with all or part of affairs concerning the issuance of bonds.
- (9) The provisions of Article 705, paragraphs (1) and (2), and of Article 709 of the Companies Act apply mutatis mutandis to the bank or trust company entrusted pursuant to the provisions of the preceding paragraph.
- (10) Beyond what is provided for in paragraph (4) through the preceding paragraph, the necessary matters concerning long-term borrowings or bonds under the provisions of paragraph (4) or (5) are provided for by Cabinet Order.

(Guarantee of Obligations)

Article 37 Notwithstanding the provisions of Article 3 of the Act on Restrictions on Financial Assistance by the Government to Corporations (Act No. 24 of 1946), the government may, within the limits of the amount determined by a National Diet resolution, guarantee obligations relating to the Institute's long-term borrowings or bonds under the provisions of paragraph (4) or (5) of the preceding Article (excluding obligations for which the government may enter into guarantee contracts pursuant to the provisions of Article 2 of the Act on Special Measures Pertaining to the Acceptance of Foreign Capital from the International Bank for Reconstruction and Development, etc. (Act No. 51 of 1953)).

(Redemption Plan)

Article 38 When taking out long-term borrowings or issuing bonds pursuant to the provisions of Article 36, paragraph (4) or (5), the Institute must formulate

a redemption plan for its long-term borrowings and bonds for each business year and obtain the authorization of the Minister of Health, Labour and Welfare.

(Granting of Financial Resources)

- Article 39 (1) The government may, within the limits of budget, grant the Institute an amount of money equivalent to all or part of the amount required to be allocated to the financial resources for the operations of the Institute.
- (2) For the purpose of its operational management, the Institute must bear in mind that a grant provided under the provisions of the preceding paragraph is procured from taxes collected from the people and other invaluable financial resources, and must strive to use such a grant in an appropriate and efficient manner in accordance with the provisions of laws and regulations and the medium-term plan.

Chapter VI Supervision

(Orders in Emergencies)

- Article 40 If the Minister of Health, Labour and Welfare finds it necessary in handling a situation in which a disaster occurs or is imminent, or an emergency situation in which serious harm to public health occurs or is likely to occur in connection with any infectious and other diseases, the minister may order the Institute to take the necessary measures concerning the operations stated in Article 23, paragraph (1), items (i) through (x).

(Supervision Order)

- Article 41 Beyond what is provided for in the preceding Article, if the Minister of Health, Labour and Welfare finds it necessary for achievement of the medium-term objectives or for enforcement of this Act and the Act on Infectious Diseases, the minister may issue an order to the Institute as necessary for supervision of its operations.

(Report and Inspection)

- Article 42 (1) If the Minister of Health, Labour and Welfare finds it necessary for enforcement of this Act and the Act on Infectious Diseases, the minister may have the Institute report on the status of its operations, assets, and debts or have the ministry's employee enter the Institute's offices and other places of its operations, and inspect the status of its operations or its books, documents, and other necessary items.
- (2) When an employee of the competent ministry conducts an on-site inspection pursuant to the provisions of the preceding paragraph, the employee must

carry an identification card and present it to the person concerned.

- (3) The authority for the on-site inspection pursuant to the provisions of paragraph (1) must not be interpreted as having been accorded for the purpose of a criminal investigation.

Chapter VII Miscellaneous Provisions

(Application Mutatis Mutandis of the Provisions of the Act on General Rules for Incorporated Administrative Agencies)

Article 43 The provisions of Article 8, paragraphs (1) and (3), Articles 9, 19-2, 21-5, 24, 25, and 26, Article 36, paragraph (1), Article 37, Articles 39 through 43, Article 46-2, Articles 47 through 50, and Articles 50-3 through 50-9 of the Act on General Rules for Incorporated Administrative Agencies apply mutatis mutandis to the Institute, and the provisions of Article 12-2, paragraph (2) and Articles 28-2, 28-3, and 35-2 of that Act apply mutatis mutandis to the Institute's medium-term objectives and evaluation. In this case, the term "competent minister" in these provisions is deemed to be replaced with "Minister of Health, Labour and Welfare"; the term "order of the competent ministry" is deemed to be replaced with "Order of the Ministry of Health, Labour and Welfare"; and the terms listed in the middle column of the following Table and used in the provisions of that Act listed in the left-hand column of the Table are deemed to be replaced with the terms listed in the right-hand column of the Table, respectively.

Provisions of Act on General Rules for Incorporated Administrative Agencies to be Replaced	Terms to Be Replaced	Terms to Replace
Article 8, paragraph (3)	(meaning Cabinet Office Order or Ministerial Order of the Cabinet Office or each ministry that has jurisdiction over the relevant Incorporated Administrative Agency; provided, however, that the Rules of the NRA apply to Incorporated Administrative Agencies under the jurisdiction of the NRA; the same applies hereinafter)	Be specified in
	Article 46-2 Or Article 46-3.	Article 46-2

Article 12-2, paragraph (2)	The provisions prescribed in item (i) or (ii) of the preceding paragraph, or item (v) or (vi) of that paragraph	Article 28-2, paragraph (2) as applied mutatis mutandis pursuant to Article 43 of the Act on Japan Institute for Health Security (referred to below as the "Institute Act")
Article 19-2	This Act and the relevant Individual Act	Institute Act
	The Agency President	President
Article 24	The Agency President or any other officer with the authority of representation	President or Vice President
Article 25	The Agency President or any other officer with the authority of representation	President or Vice President
	Officers without the Authority to Represent	Directors (excluding external directors prescribed in the proviso to Article 7 of the Institute Act)
Article 26	The Agency President	President
Article 28-2, paragraph (1)	The establishment of the medium-term objectives referred to in Article 29, paragraph (1), the medium to long-term objectives referred to in Article 35-4, paragraph (1), and the annual objectives referred to in Article 35-9, paragraph (1), as well as the establishment of the medium-term objectives referred to in Article 32, paragraph (1), Article 35-6, paragraphs (1) and (2), and Article 35-11, paragraphs (1) and (2)	Formulation of the medium-term goals prescribed in Article 27, paragraph (1) of the Institute Act (referred to below as the "medium-term goals") (excluding formulation related to the matters stated in paragraph (2), item (i) of the same Article) and Article 30, paragraphs (1) and (2) of the Institute Act

Article 28-2, paragraph (3)	The medium-term objectives referred to in Article 29, paragraph (1), the medium to long-term objectives referred to in Article 35-4, paragraph (1), and the annual objectives referred to in Article 35-9, paragraph (1);	Medium-Term Goals
	Article 32, paragraph (1), Article 35-6, paragraphs (1) and (2), and Article 35-11, paragraphs (1) and (2)	Article 30, paragraphs (1) and (2) of the Institute Act
Article 35-2	Paragraph (4) of the preceding Article	Article 32, paragraph (5) of the Institute Act
Article 39, paragraph (2), item (ii)	Order of the Ministry of Internal Affairs and Communications	Order of the Ministry of Health, Labour and Welfare
Article 39, paragraph (3)	From a subsidiary	From a subsidiary corporation (meaning a subsidiary corporation prescribed in Article 7, item (i) of the Institute Act; the same applies below)
Article 39-2, paragraph (1)	This Act and the relevant Individual Act	Institute Act
Article 42	Date of approval of financial statements	The date of approval of the financial statements prescribed in Article 33, paragraph (1) of the Institute Act under the provisions of that paragraph;

Proviso to Article 46-2, paragraph (1)	When the plan referred to in Article 30, paragraph (2), item (v) is specified in the Medium-term Plan of an Agency Managed under the Medium-term Objectives, when the plan referred to in Article 35-5, paragraph (2), item (v) is specified in the Medium to Long-term Plan of a National Research and Development Agency, or when the plan referred to in Article 35-10, paragraph (3), item (v) is specified in the Annual Objective Plan of an Agency Engaged in Administrative Execution	In the medium-term plan prescribed in Article 28, paragraph (1) of the Institute Act (referred to below as the "medium-term plan"), the provisions of paragraph (2), item (vi) of that Article
	These	That
Proviso to Article 46-2, paragraph (2)	When the plan referred to in Article 30, paragraph (2), item (v) is specified in the Medium-term Plan of an Agency Managed under the Medium-term Objectives, when the plan referred to in Article 35-5, paragraph (2), item (v) is specified in the Medium to Long-term Plan of a National Research and Development Agency, or when the plan referred to in Article 35-10, paragraph (3), item (v) is specified in the Annual Objective Plan of an Agency Engaged in Administrative Execution	In the medium-term plan Article 28, paragraph (2), item (vi) of the DICJ Act
	These	That
Proviso to Article 48	When the plan referred to in Article 30, paragraph (2), item (vi) is specified in the Medium-term Plan of an Agency Managed under the Medium-term Objectives, when the plan referred to in Article 35-5, paragraph (2), item (vi) is specified in the Medium to Long-term Plan of a National Research and Development Agency, or when the plan referred to in Article 35-10, paragraph (3), item (vi) is specified in the Annual Objective Plan of an Agency Engaged in Administrative Execution	In the medium-term plan, Article 28, paragraph (2), item (vii) of the Institute Act
	These	That

Article 50-4, paragraph (2), item (i)	Cabinet Order	Order of the Ministry of Health, Labour and Welfare
Article 50-4, paragraph (2), item (iii)	Researcher of	A person who exclusively engages in research or education in
	In research	In research or education
Article 50-4, paragraph (2), item (iv)	Article 32, paragraph (1)	Article 30, paragraph (1) of the Institute Act
Article 50-4, paragraph (2), item (v)	Article 35, paragraph (1)	Article 32, paragraph (1) of the Institute Act
	Cabinet Order	Order of the Ministry of Health, Labour and Welfare
Article 50-4, paragraph (3)	Cabinet Order	Order of the Ministry of Health, Labour and Welfare
Article 50-4, paragraph (4)	Minister for Internal Affairs and Communications	Minister of Health, Labour and Welfare
Article 50-4, paragraph (5)	Cabinet Order	Order of the Ministry of Health, Labour and Welfare
Article 50-4, paragraph (6)	This Act and the relevant Individual Act	Institute Act
Article 50-6, Article 50-7, paragraph (1), Article 50-8, paragraph (3), and Article 50-9	Cabinet Order	Order of the Ministry of Health, Labour and Welfare

(Deliberation with the Minister of Finance)

Article 44 The Minister of Health, Labour and Welfare must deliberate with the Minister of Finance in any of the following cases:

- (i) when the minister intends to set or revise medium-term objectives pursuant to the provisions of Article 27, paragraph (1);
- (ii) when the minister intends to grant authorization under the provisions of Article 48 of the Act on General Rules for Incorporated Administrative

Agencies, as applied *mutatis mutandis* pursuant to Article 28, paragraph (1), the proviso to paragraph (1) or that to paragraph (2) of Article 36, Article 36, paragraph (4), (5), or (8), Article 38, or the preceding Article following the deemed replacement of terms;

- (iii) when the minister intends to grant approval under the provisions of Article 34, paragraph (3) or Article 35, paragraph (1);
- (iv) when the minister intends to grant authorization under the provisions of Article 46-2, paragraph (1) or (2), or the proviso to paragraph (3) of that Article of the Act on General Rules for Incorporated Administrative Agencies, as applied *mutatis mutandis* pursuant to the preceding Article following the deemed replacement of terms;
- (v) when the minister intends to designate as under the provisions of Article 47, item (i) or (ii) of the Act on General Rules for Incorporated Administrative Agencies, as applied *mutatis mutandis* pursuant to the preceding Article following the deemed replacement of terms.

(Financial Considerations)

Article 45 In light of the characteristics of the operations of the Institute and on the basis of the progress of research and development at the Institute, the national government is to give the financial consideration necessary to enhance the capability of the Institute to engage in its research and development, and to promote the effective implementation of its research and development and the dissemination of their results.

(Application *Mutatis Mutandis* of Other Laws and Regulations)

Article 46 The Medical Care Act (Act No. 205 of 1948) and other laws and regulations provided for by Cabinet Order are applied *mutatis mutandis* with the Institute deemed to be the national government, pursuant to the provisions of Cabinet Order.

(Dissolution)

Article 47 The dissolution of the Institute is provided for by a separate Act.

Chapter VIII Penal Provisions

Article 48 A person who has divulged or misappropriated any confidential information in violation of the provisions of Article 21 is punished by imprisonment for not more than one year or a fine of not more than five hundred thousand yen.

Article 49 If the Institute fails to make a report under the provisions of Article

42, paragraph (1), or makes a false report, or refuses, obstructs or avoids an inspection under the provisions of that paragraph, its officer or employee who has committed the violation in question is punished by a fine of not more than two hundred thousand yen.

Article 50 (1) If the Institute falls under any of the following items, its officer who has committed the violation in question is punished by a civil fine of not more than two hundred thousand yen:

- (i) the Institute fails to obtain the authorization or approval of the Minister of Health, Labour and Welfare when the authorization or approval is required pursuant to the provisions of this Act (including the provisions of Act on General Rules for Incorporated Administrative Agencies, as applied mutatis mutandis pursuant to Article 43 following the deemed replacement of terms; the same applies in the following item);
- (ii) the Institute fails to make a notification or makes a false notification to the Minister of Health, Labour and Welfare when a notification to the minister is required pursuant to the provisions of this Act;
- (iii) the Institute fails to make a public announcement or makes a false public announcement when a public announcement is required to be made pursuant to the provisions of this Act;
- (iv) the Institute obstructs an investigation under the provisions of Article 39, paragraph (3) of the Act on General Rules for Incorporated Administrative Agencies, as applied mutatis mutandis pursuant to Article 10, paragraph (5) or (6), or Article 43, following the deemed replacement of terms;
- (v) the Institute performs any operations other than those provided for in Article 23, paragraph (1) and Article 25;
- (vi) the Institute violates an order under the provisions of Article 28, paragraph (3), Article 30, paragraph (9), Article 40, or Article 41;
- (vii) the Institute fails to submit a report under the provisions of Article 30, paragraph (3) or (4), or fails to state any matters required to be stated in a report or submits a report with false statements;
- (viii) the Institute fails to keep in its principal office or make available for public inspection its financial statements, business reports, statements of accounts, audit reports, or financial audit reports, in violation of the provisions of Article 33, paragraph (3);
- (ix) the Institute fails to register in violation of Cabinet Order under the provisions of Article 9, paragraph (1) of the Act on General Rules for Incorporated Administrative Agencies, as applied mutatis mutandis pursuant to Article 43;
- (x) the Institute has invested surplus funds accrued in the course of its operations in violation of the provisions of Article 47 of the Act on General

Rules for Incorporated Administrative Agencies, as applied mutatis mutandis pursuant to Article 43 following the deemed replacement of terms; or

(xi) the Institute fails to make a report or makes a false report under Article 50-8, paragraph (3) of the Act on General Rules for Incorporated Administrative Agencies, as applied mutatis mutandis pursuant to Article 43 following the deemed replacement of terms.

(2) If an officer of a subsidiary corporation of the Institute obstructs an investigation under Article 39, paragraph (3) of the Act on General Rules for Incorporated Administrative Agencies, as applied mutatis mutandis pursuant to Article 10, paragraph (7), or Article 43, following the deemed replacement of terms, the officer is punished by a civil fine of not more than two hundred thousand yen.

Article 51 A person who has violated the provisions of Article 5 is punished by a civil fine of not more than one hundred thousand yen.

Supplementary Provisions

(Effective Date)

Article 1 This Act comes into effect on the date provided for by Cabinet Order within a period not exceeding three years from the date of promulgation; provided, however, that the provisions of the following Article through Article 4 of the Supplementary Provisions, and the provisions of Article 12, paragraphs (3) and (4), Article 16, paragraphs (4) and (5), Article 17, paragraphs (2) and (3), and Article 26 of the Supplementary Provisions come into effect on the date of promulgation.

(Nomination of Persons Who Are to Assume the Position of President and Other Positions)

Article 2 (1) The Minister of Health, Labour and Welfare nominates a person to serve as the president and those to serve as inspectors of the Institute before the date on which this Act comes into effect (referred to below as the "effective date").

(2) The person nominated to serve as the president pursuant to the provisions of the preceding paragraph nominates a person to serve as the vice president and those to serve as directors of the Institute, upon obtaining the authorization of the Minister of Health, Labour and Welfare.

(3) The persons who are nominated to serve as the president, vice president, directors, or inspectors pursuant to the provisions of the preceding two paragraphs are deemed to be appointed as the president, vice president, directors, or inspectors, respectively, at the time of incorporation of the

Institute pursuant to the provisions of Article 11, paragraphs (1) and (2).

- (4) Notwithstanding the provisions of Article 12, paragraph (1), if the Minister of Health, Labour and Welfare finds it particularly necessary in order to appoint a person considered more suitable for the position of president pursuant to the provisions of Article 11, paragraph (1), the minister may set the term of office of the president deemed to be appointed at the time of incorporation of the Institute pursuant to the provisions of the preceding paragraph so that it starts from the date of appointment and ends on the day on which three years have passed from the first day of the period for the medium-term objectives.

(Organizing Committee Members)

Article 3 (1) The Minister of Health, Labour and Welfare appoints organizing committee members to process affairs concerning the incorporation of the Institute.

- (2) Organizing committee members must prepare an operational method statement, disciplinary rules, and other rules provided for by Order of the Ministry of Health, Labour and Welfare, and obtain the authorization of the Minister of Health, Labour and Welfare.
- (3) Pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, the authorization of the Minister of Health, Labour and Welfare granted pursuant to the provisions of the preceding paragraph is deemed to be the authorization of the Minister granted on the effective date pursuant to the provisions of Article 22, paragraph (1), Article 26, paragraph (1), and other provisions provided for by Order of the Ministry of Health, Labour and Welfare.
- (4) Upon completing the preparation for incorporating the Institute, organizing committee members must, without delay, notify the Minister of Health, Labour and Welfare to that effect and hand over the affairs of the Institute to the person nominated to serve as the president pursuant to the provisions of paragraph (1) of the preceding Article.

(Hearing of Opinions from the Headquarters for Healthcare Policy and the Committee on the System of Evaluating Incorporated Administrative Agencies)

Article 4 As a necessary preparation for the formulation of the first medium-term objectives, the Minister of Health, Labour and Welfare may, even before the effective date, hear opinions from the Headquarters for Healthcare Policy, the Committee on the System of Evaluating Incorporated Administrative Agencies, and the research and development council and deliberate with the Minister of Finance.

(Incorporation of the Institute)

Article 5 (1) The Institute is incorporated at the time when this Act comes into effect.

(2) The Institute must register its incorporation without delay after its incorporation pursuant to the provisions of Cabinet Order.

(Succession of Employees)

Article 6 Persons who are actually employees of the organs of the Ministry of Health, Labour and Welfare provided by Cabinet Order at the time of incorporation of the Institute, except for those persons designated by the Minister of Health, Labour and Welfare, become employees of the Institute on the date of incorporation of the Institute unless any notice of appointment stating otherwise is issued.

Article 7 Concerning the application of the provisions of Article 82, paragraph (2) of the National Public Service Act (Act No. 120 of 1947) to a person who has become an employee of the Institute pursuant to the provisions of the preceding Article, the employee of the Institute is deemed to be a national public employee in the special service, etc. provided for in that paragraph, and the loss of status as a national public employee pursuant to the provisions of the preceding Article is deemed to be due to retirement upon the request of the relevant appointer for the person to become a national public employee in the special service, etc. provided for in that paragraph.

Article 8 (1) When an employee of the Ministry of Health, Labour and Welfare becomes an employee of the Institute pursuant to the provisions of Article 6 of the Supplementary Provisions, no retirement allowance under the Act on National Public Officers' Retirement Allowance (Act No. 182 of 1953) is paid to that employee.

(2) When the Institute intends to pay a retirement allowance to its employee to whom the provisions of the preceding paragraph have been applied upon that employee's retirement, the Institute is to handle the retirement allowance by deeming the employee's continuous period of service as an employee provided in Article 2, paragraph (1) of the Act on National Public Officers' Retirement Allowance (including a person who is deemed to be an employee pursuant to paragraph (2) of that Article) to be the employee's period of service as an employee of the Institute.

(3) In the case of a person who had been serving as an employee of the Ministry of Health, Labour and Welfare on the day before the date of incorporation of the Institute, who then became an employee of the Institute without interruption pursuant to the provisions of Article 6 of the Supplementary Provisions, and who has become, after serving as an employee of the Institute

without interruption, an employee provided in Article 2, paragraph (1) of the Act on National Public Officers' Retirement Allowance without interruption, the calculation of the length of service as the basis for calculation of the retirement allowance to be paid to that person in accordance with that Act deems the person's period of service as an employee of the Institute to be the continuous period of service as an employee provided in that paragraph; provided, however, that this does not apply if the person has received an retirement allowance (including any payment equivalent to this) due to retirement from the Institute.

- (4) Among persons who had been serving as employees of the Ministry of Health, Labour and Welfare on the day before the date of incorporation of the Institute, and who became employees of the Institute without interruption pursuant to the provisions of Article 6 of the Supplementary Provisions, a person who retired from the Institute during the period between the date of incorporation of the Institute and the time when the person was to become qualified for receiving benefits for unemployment, etc. under the Employment Insurance Act (Act No. 116 of 1974), and who would be able to receive a retirement allowance under the provisions of Article 10 of the Act on National Public Officers' Retirement Allowance if the person had served as an employee of the Ministry of Health, Labour and Welfare up until the day of retirement from the Institute, the Institute is to pay an amount equivalent to the retirement allowance calculated in accordance with the provisions of that Article to the person as a retirement allowance.

Article 9 If a person who became an employee of the Institute pursuant to the provisions of Article 6 of the Supplementary Provisions and who has been certified by the Minister of Health, Labour and Welfare or a person entrusted thereby under the provisions of Article 7, paragraph (1) of the Child Allowance Act (Act No. 73 of 1971) on the day before the date of incorporation of the Institute satisfies the requirements for receiving child allowances on the date of incorporation of the Institute, the certification of the mayor of the relevant municipality (including of the mayor of a special ward) is deemed to have been granted under the provisions of that paragraph on the date of incorporation of the Institute, regarding the payment of child allowances to the person. In this case, the payment of child allowances or special benefits for which the certification is deemed to have been granted starts in the month following that which includes the day before the date of incorporation of the Institute, notwithstanding the provisions of Article 8, paragraph (2) of that Act.

(Transitional Measures Concerning the Application of the National Public Officers Mutual Aid Association Act to Persons Who Had Been Employees of

the Organs of the Ministry of Health, Labour and Welfare Provided for by Cabinet Order and Who Subsequently Became Officers and Employees of the Institute Without Interruption)

- Article 10 (1) If a person who was serving, on the day before the effective date, as an employee of any of the organs of the Ministry of Health, Labour and Welfare provided for by Cabinet Order under Article 6 of the Supplementary Provisions (limited to a person who was, on that day, a member of a national public employee mutual aid association organized by employees provided for in Article 2, paragraph (1), item (i) of the National Public Officers Mutual Aid Association Act (Act No. 128 of 1958) and belonging to the Ministry of Health, Labour and Welfare pursuant to Article 3, paragraph (1) of that Act (referred to as the "MHLW mutual aid association" in this paragraph and paragraph (3) below)) becomes an officer or employee (limited to an officer or employee equivalent to what can be deemed to be an employee provided for in the above item pursuant to the provisions of Article 124-3 of that Act; referred to as an "officer or employee" in this Article below) of the Institute on the effective date without interruption and continues to be an officer or employee of the Institute on and after the effective date, and if this officer or employee makes a request to the MHLW mutual aid association by the day on which twenty days have passed from the effective date (if the MHLW mutual aid association finds that there are reasonable grounds, by the day authorized thereby), the officer or employee is to, concerning the application of the provisions of that Act, fall under the category of employees provided in that item and constituting the MHLW mutual aid association during the period that has continued since the effective date and in which the officer or employee has served.
- (2) If the officer or employee of the Institute referred to in the preceding paragraph dies without making the request under that paragraph by the time limit provided for in that paragraph, that request may be made by a surviving family member (limited to a person who is equivalent to a surviving family member provided for in Article 2, paragraph (1), item (iii) of the National Public Officers Mutual Aid Association Act; the same applies in the following paragraph) of the officer or employee within the time limit.
- (3) If a person who serves, on the day before the effective date, as an employee of any of the organs of the Ministry of Health, Labour and Welfare provided for by Cabinet Order under Article 6 of the Supplementary Provisions (limited to a person who is, on that day, a member of the MHLW mutual aid association) becomes an officer or employee of the Institute on the effective date without interruption, and if this officer or employee or their surviving family member does not make a request under the provisions of paragraph (1) by the time limit provided for by that paragraph, the officer or employee is, concerning the application of the National Public Officers Mutual Aid Association Act, deemed

to have retired on the day before the effective date as provided for by Article 2, paragraph (1), item (iv) of that Act.

(Transitional Measures on Employee Organizations of Persons to Be Employees of the Institute)

Article 11 (1) Any employee organization that is provided for in Article 108-2, paragraph (1) of the National Public Service Act and that actually exists at the time of incorporation of the Institute, and of which the majority of members are persons to be succeeded to by the Institute pursuant to the provisions of Article 6 of the Supplementary Provisions, is to become a labor union to which the Labor Union Act (Act No. 174 of 1949) applies upon the incorporation of the Institute. In this case, if the employee organization is a corporation, it is to become a corporate labor union.

(2) An employee organization that has become a corporate labor union pursuant to the provisions of the preceding paragraph is to obtain certification from the labor relations commission indicating that the organization conforms to the provisions of Article 2 and Article 5, paragraph (2) of the Labor Union Act by the day on which sixty days have passed from the date of incorporation of the Institute, and is to register at the location of its principal office, or else the organization is to dissolve upon the passage of that day.

(3) The proviso to Article 2 of the Labor Union Act (limited to the part relating to item (i)) does not apply to an employee organization that has become a labor union pursuant to the provisions of paragraph (1) until the day on which sixty days have passed from the date of incorporation of the Institute.

(Succession of Rights and Obligations)

Article 12 (1) At the time of its incorporation, the Institute succeeds to the rights and obligations which are actually held by the national government as of the incorporation in relation to the operations provided for in Article 23, paragraph (1) and which are provided for by Cabinet Order.

(2) When the Institute succeeds to the rights and obligations held by the national government pursuant to the provisions of the preceding paragraph, an amount equivalent to that obtained by deducting the total value of liabilities that are associated with the obligations succeeded to by the Institute and are provided for by Cabinet Order from the total value of assets that are associated with the rights succeeded to by the Institute and are provided pursuant to the provisions of Cabinet Order is deemed to have been contributed to the Institute by the government pursuant to the provisions of Cabinet Order.

(3) The value of assets referred to in the preceding paragraph is the value evaluated by evaluation committee members on the basis of the market value on the date of incorporation of the Institute.

- (4) The evaluation committee members referred to in the preceding paragraph and other necessary matters concerning evaluation are provided for by Cabinet Order.

(Succession of Rights and Obligations Related to Holders of Specified Class I Pathogens)

Article 13 (1) If, on the day before the effective date, any of the organs of the Ministry of Health, Labour and Welfare provided for by Cabinet Order under Article 6 of the Supplementary Provisions was designated as a holder of specified class I pathogens and toxins under the provisions of Article 56-3, paragraph (2) of the Act on Infectious Diseases (referred to as a "designated organ" in this Article below), the Institute is deemed to be designated as a holder of specified class I pathogens and toxins under the provisions of that paragraph at the time of incorporation of the Institute. In this case, the Institute is to take over, at the time of its incorporation, the specified class I pathogens and toxins (meaning specified class I pathogens and toxins provided in Article 56-3, paragraph (1), item (i) of the Act on Infectious Diseases; the same applies in the following paragraph) that the designated organ held, notwithstanding the provisions of Article 56-5 of that Act.

- (2) In the case referred to in the preceding paragraph, the Institute is to carry out, under the supervision and instructions of the national government, the tests and research that the designated organ had been carrying out in relation to specified class I pathogens and toxins under the responsibility of the national government before the enforcement of this Act, in light of the social necessity and importance of those tests and research.

(Gratuitous Use of National Government Assets)

Article 14 The national government may, pursuant to the provisions of Cabinet Order, allow the Institute to use, for its own purposes and without compensation, the national government assets that are actually used, at the time of incorporation of the Institute, by the organs of the Ministry of Health, Labour and Welfare provided for by Cabinet Order under Article 6 of the Supplementary Provisions and the national government assets that are used as the residences of persons belonging to the organs concerned and are provided by Cabinet Order.

(Transitional Measures Concerning the Act on the Authority of the Minister of Justice over Suits Relating to the Interests of the State)

Article 15 Concerning the suits or non-contentious cases that are actually pending at the time of incorporation of the Institute, that are related to the administrative functions under the jurisdiction of the organs of the Ministry of

Health, Labour and Welfare provided for by Cabinet Order under the provisions of Article 6 of the Supplementary Provisions, and that the Institute is to succeed to, the Act on the Authority of the Minister of Justice over Suits Relating to the Interests of the State (Act No. 194 of 1947) applies with the Institute deemed to be the national government or administrative authority provided for in that Act, pursuant to the provisions of Cabinet Order.

(Dissolution of the National Center for Global Health and Medicine)

Article 16 (1) The National Center for Global Health and Medicine (referred to below as "NCGM"), a national research and development agency, is to dissolve at the time of enforcement of this Act, and the Institute is to succeed to all the rights and obligations of NCGM at that time, excluding the assets to be succeeded to by the national government pursuant to the provisions of the following paragraph.

- (2) Of the rights actually held by NCGM at the time of enforcement of this Act, assets other than those necessary for the Institute to securely implement its operations are succeeded to by the national government at that time.
- (3) The scope of assets to be succeeded to by the national government pursuant to the provisions of the preceding paragraph and other necessary matters concerning the succession to those assets by the national government are provided for by Cabinet Order.
- (4) The business year of NCGM that includes the day before the date of its dissolution (excluding the business year for the case in which that day is March 31) is to end on the day before the date of dissolution of NCGM, notwithstanding the provisions of Article 36, paragraph (1) of the Act on General Rules for Incorporated Administrative Agencies.
- (5) The period for the medium to long-term objectives including the day before the date of dissolution of NCGM (meaning the period for the medium to long-term objectives provided for in Article 35-4, paragraph (2), item (i) of the Act on General Rules for Incorporated Administrative Agencies; the same applies in this Article below) is to end on that day.
- (6) The provisions of Article 35-6, paragraphs (1) and (3) and paragraphs (5) through (9) of the Act on General Rules for Incorporated Administrative Agencies apply to the evaluation of the operational performance during the business year including the day before the date of dissolution of NCGM and during the period for the medium to long-term objectives including that day. In this case, the Institute is to undergo an evaluation under the provisions of paragraph (1) of that Article and submit and make public a report under the provisions of paragraph (3) of that Article, and any notice under the provisions of the first sentence of paragraph (7) of that Article and any order under the provisions of paragraph (9) of that Article are deemed to be made to the

Institute.

- (7) The Institute is to carry out the preparation, etc. of financial statements, a business report, and a statement of accounts for the business year including the day before the date of dissolution of NCGM under the provisions of Article 38 of the Act on General Rules for Incorporated Administrative Agencies.
- (8) The Institute is to carry out operations concerning the processing of profits and losses for the business year including the day before the date of dissolution of NCGM under the provisions of Article 44, paragraphs (1) and (2) of the Act on General Rules for Incorporated Administrative Agencies.
- (9) In the processing under the provisions of the preceding paragraph, if there remain any reserve funds under the provisions of Article 44, paragraph (1) of the Act on General Rules for Incorporated Administrative Agencies after the settlement of accounts under the provisions of paragraph (1) or (2) of that Article, the Institute is to carry out the disposition of those reserve funds. In this case, the provisions of Article 20 (including penal provisions related to the provisions of this Article) of the Act on National Research and Development Agencies that Conduct Research Related to Advanced and Specialized Medical Care before amendment under the provisions of Article 13 of the Act on Development of Laws Related to Enforcement of the Act on the Japan Institute for Health Security (Act No. 47 of 2023) (referred to "Former Act on National Research and Development Agencies for Advanced and Specialized Medical Care" below) are to remain in force in relation to NCGM, and the term "the final business year of the period for the medium to long-term objectives provided for in Article 35-4, paragraph (2), item (i) of the Act on General Rules (referred to as the "period for the medium to long-term objectives" in this paragraph below)" is to be replaced with "the business year including the day before the date of dissolution of the National Center for Global Health and Medicine"; the term "the medium to long-term plan for which the authorization referred to in Article 35-5, paragraph (1) of the Act on General Rules has been obtained regarding the next period for the medium- to long-term objectives after the relevant period for the medium- to long-term objectives" is to be replaced with "the medium-term plan for which the authorization referred to in Article 28, paragraph (1) of the Act on Japan Institute for Health Security (Act No. 46 of 2023) has been obtained regarding the period for the medium-term objectives provided in Article 27, paragraph (1) of that Act and including the date on which that Act comes into effect"; and the term "Article 13 through the preceding Article (excluding Article 18-2) and implemented by the relevant highly specialized national medical research center during the next period for the medium to long-term objectives" is to be replaced with "Article 23, paragraph (1), and Article 25, of that Act during the period for the medium-term objectives."

- (10) The registration of dissolution when NCGM dissolves pursuant to the provisions of paragraph (1) is provided for by Cabinet Order.

(Contribution to the Institute)

Article 17 (1) When the Institute succeeds to the rights and obligations of NCGM pursuant to the provisions of paragraph (1) of the preceding Article, the amount obtained by deducting the amount of liabilities succeeded to by the Institute from the value of the assets succeeded to by the Institute (if there is any amount approved under the provisions of Article 20, paragraph (1) of the Former Act on National Research and Development Agencies for Advanced and Specialized Medical Care remaining in force with its relevant terms replaced pursuant to the provisions of paragraph (9) of the preceding Article, excluding an amount equivalent to the approved amount) is deemed to have been contributed by the government to the Institute at the time of succession. In this case, the Institute is to increase its stated capital by that amount.

- (2) The value of assets referred to in the preceding paragraph is the value evaluated by evaluation committee members on the basis of the market value on the effective date.

- (3) The evaluation committee members referred to in the preceding paragraph and other necessary matters concerning evaluation are provided for by Cabinet Order.

(Transitional Measures Concerning the Handling of Retirement Allowances for Persons Who Were Employees of NCGM and Who Subsequently Became Employees of the Institute Without Interruption)

Article 18 (1) When the Institute intends to pay a retirement allowance to a person, upon this person's retirement from the Institute, who had been serving as an employee of NCGM on the day before the effective date (limited to a person to whom the provisions of Article 5, paragraph (1) of the Supplementary Provisions of the Act on National Research and Development Agencies for Advanced and Specialized Medical Care were applied) and who subsequently became an employee of the Institute without interruption, the Institute is to handle the retirement allowance by deeming the person's continuous period of service as an employee provided in Article 2, paragraph (1) of the Act on National Public Officers' Retirement Allowance (including a person who is deemed to be an employee pursuant to paragraph (2) of that Article) to be the person's period of service as an employee of the Institute; provided, however, that this does not apply if the person has received a retirement allowance (including any payment equivalent to that) due to retirement from a highly specialized national medical research center provided in Article 3-2 of the Former Act on National Research and Development Agencies for Advanced and

Specialized Medical Care on or after the date on which the Act on National Research and Development Agencies for Advanced and Specialized Medical Care came into effect (referred to as a "highly specialized national medical research center" in the following paragraph).

- (2) In the case of a person who had been serving as an employee of NCGM on the day before the effective date (limited to a person to whom the provisions of Article 5, paragraph (1) of the Supplementary Provisions of the Act on National Research and Development Agencies for Advanced and Specialized Medical Care were applied and who continued to serve as an employee of a highly specialized national medical research center on and after the date on which the Act on National Research and Development Agencies for Advanced and Specialized Medical Care came into effect), who then became an employee of the Institute without interruption, and who has become, after serving as an employee of the Institute without interruption, an employee provided for in Article 2, paragraph (1) of the Act on National Public Officers' Retirement Allowance without interruption, the calculation of the length of service as the basis for calculation of the retirement allowance to be paid to that person in accordance with that Act deems the person's period of service as an employee of the highly specialized national medical research center on and after the date on which the Act on National Research and Development Agencies for Advanced and Specialized Medical Care came into effect, as well as the person's period of service as an employee of the Institute, to be the person's continuous period of service as an employee provided for in that paragraph; provided, however, that this does not apply if the person has received a retirement allowance (including any payment equivalent to that) due to retirement from the highly specialized national medical research center on or after the date on which the Act on National Research and Development Agencies for Advanced and Specialized Medical Care came into effect, or due to retirement from the Institute.

(Gratuitous Use of National Government Assets Used as the Residences of Persons Belonging to NCGM)

Article 19 The national government may, pursuant to the provisions of Cabinet Order, allow the Institute to use, for its own purposes and without compensation, the national government assets that are actually used at the time of incorporation of the Institute as the residences of persons belonging to NCGM and that are provided for by Cabinet Order.

(Transitional Measures Concerning the Application of the Act on General Rules for Incorporated Administrative Agencies to Officers or Employees of the Institute)

Article 20 In the application of the provisions of Article 50-4, paragraph (1), paragraph (2), item (iv), and paragraph (6), and Article 50-6 of the Act on General Rules for Incorporated Administrative Agencies to an officer or employee of the Institute, as applied mutatis mutandis pursuant to Article 43, the terms listed in the middle column of the following table and used in those provisions listed in the left-hand column of the table are deemed to be replaced with the terms listed in the right-hand column of the table, respectively.

Act on General Rules for Incorporated Administrative Agencies as applied mutatis mutandis pursuant to Article 43 Article 50-4, paragraph (1)	For the purpose of seeking a position with the closely-related corporation, etc.;	(including persons who were officers or employees (excluding part-time officers or employees) of the former National Center for Global Health and Medicine dissolved pursuant to the provisions of Article 16, paragraph (1) of the Supplemental Provisions of the Act on Japan Institute for Health Security (Act No. 46 of 2023; referred to below as the "Institute Act") (referred to below as the "Former National Center for Global Health and Medicine"); the same applies below) for the purpose of seeking a position with the closely-related corporation, etc.;
Act on General Rules for Incorporated Administrative Agencies as applied mutatis mutandis pursuant to Article 43 Article 50-4, paragraph (2), item (iv)	Organization of	Organization of the (including the Former National Center for Global Health and Medicine)

Act on General Rules for Incorporated Administrative Agencies as applied mutatis mutandis pursuant to Article 43 Article 50-4, paragraph (6)	Done	(including committing an act in the course of duties that violates the Act on National Research and Development Agencies that Conduct Research related to Advanced and Specialized Medical Care (Act No. 93 of 2008; referred to below as the "Act on National Research and Development Agencies for Advanced and Specialized Medical Care") or the operational method statement, rules prescribed in Article 49, or other rules established by the Former National Center for Global Health and Medicine (referred to below as the "Former Rules of the National Center for Global Health and Medicine" in this paragraph); the same applies in the following Article)
	Cause	(including causing an officer or employee of the Former National Center for Global Health and Medicine to engage in conduct in the course of duties that is in violation of the Act on National Research and Development Agencies for Advanced and Specialized Medical Care, other laws and regulations, or the Former Rules of the National Center for Global Health and Medicine; the same applies in the following Article)
	Person who was	(including those who was an officer or employee of the Former National Center for Global Health and Medicine)
Act on General Rules for Incorporated Administrative Agencies as applied mutatis mutandis pursuant to Article 43 Article 50-6, item (i)	Items to be specified	What is specified (including what is specified by Order of the Ministry of Health, Labour and Welfare as an internal organization of the OTIT that carries out the operations that were carried out by the organization specified by Order of the Ministry of Health, Labour and Welfare as an internal organization of the former National Center for Global Health and Medicine in which the relevant person had held office during the five years before the separation from service);

Act on General Rules for Incorporated Administrative Agencies as applied mutatis mutandis pursuant to Article 43 Article 50-6, item (ii)	Officer or Management of	Officer or Manager of (including Former National Center for Global Health and Medicine)
Act on General Rules for Incorporated Administrative Agencies as applied mutatis mutandis pursuant to Article 43 Article 50-6, item (iii)	And enterprise for profit	(including the Former National Center for Global Health and Medicine; the same applies below in this item) and enterprise for profit

(Transitional Measures Concerning Restriction on Use of the Name)

Article 21 The provisions of Article 5 do not apply for a period of six months from the enforcement of this Act to any person who actually uses the name “国立健康危機管理研究機構” (pronounced “kokuritsu kenkou kiki kanri kenkyu kikou” (“Japan Institute for Health Security (JIHS)”) at the time of enforcement of this Act.

(Transitional Measures Concerning the Appointment of Outside Directors)

Article 22 (1) Any person who served as an employee of any of the organs of the Ministry of Health, Labour and Welfare provided for by Cabinet Order under Article 6 of the Supplementary Provisions or as an officer (excluding an inspector) or employee of NCGM during the past ten years from the date of incorporation of the Institute is deemed to have been the Institute's officer or employee provided for in Article 7, item (i), and accordingly the provisions of that item and item (ii) of that Article apply to this person.

(2) Any person who served as an inspector or financial auditor of NCGM (for the case in which a corporation served as a financial auditor, its member who was responsible to perform the duties of a financial auditor) during the past ten years from the date of incorporation of the Institute is deemed to have been an inspector or financial auditor of the Institute provided for in Article 7, item (ii), and accordingly the provisions of that item apply to this person. In this case, the term "as the Institute's officer or employee or as an executive director, etc. of the Institute's subsidiary corporation" in the item is deemed to be replaced with "as the Institute's officer or employee, as an executive director, etc. of the Institute's subsidiary corporation, as an employee of any of the organs of the Ministry of Health, Labour and Welfare provided by Cabinet Order under the provisions of Article 6 of the Supplementary Provisions, or as an officer (excluding an inspector) or employee of the National Center for Global Health

and Medicine."

(Transitional Measures Concerning Business Years)

Article 23 Notwithstanding the provisions of Article 36, paragraph (1) of the Act on General Rules for Incorporated Administrative Agencies, as applied *mutatis mutandis* pursuant to Article 43, the first business year of the Institute begins on the date of its incorporation and ends on the first March 31 later.

(Transitional Measures Concerning Annual Plans)

Article 24 Regarding a plan for the operational management provided for in Article 29 for the first business year of the Institute, the term "before the start of each business year" in that Article is deemed to be replaced with "without delay after the incorporation of the Institute".

(Adjustment Provisions)

Article 25 If the date on which this Act comes into effect is earlier than the date on which the Act Partially Amending the Penal Code (Act No. 67 of 2022) comes into effect (referred to as the "Penal Code effective date" in this Article below), the provisions of Article 48 apply with the term "imprisonment under the new Penal Code" in that Article is deemed to be replaced with "imprisonment under the former Penal Code" during the period until the day before the Penal Code effective date. The same applies to the application of the provisions of that Article on or after the Penal Code effective date to acts committed before the Penal Code effective date.

(Delegation to Cabinet Order)

Article 26 Beyond what is provided for in these Supplementary Provisions, transitional measures necessary for the enforcement of this Act (including transitional measures concerning penal provisions) are provided for by Cabinet Order.

Supplementary Provisions [Act No. 47 of June 12, 2024] [Extract]

(Effective Date)

Article 1 This Act comes into effect on October 1, 2024; provided, however, that the provisions stated in the following items come into effect on the dates specified respectively in those items:

- (i) the provisions of Article 4 that amend Article 25-2 of the Child Welfare Act, the provisions of Article 20, and the provisions of Article 21 that amend Article 4, paragraph (1) of the Supplementary Provisions of the Act Partially Amending the Child and Childcare Support Act (limited to the part that

amend the phrase "the day on which five years have elapsed from the effective date" to "March 31, 2030"), and the provisions of Article 46 of the Supplementary Provisions: the date of promulgation of this Act.

(Transitional Measures Concerning Penal Provisions)

Article 45 Prior laws and regulations continue to govern the applicability of penal provisions to conduct that a person engages in before this Act comes into effect (for the provisions stated in Article 1, items (iv) through (vi) of the Supplementary Provisions, those provisions; the same applies in this Article below), and to conduct that a person engages in after this Act comes into effect but which, pursuant to Article 13, paragraph (1) of the Supplementary Provisions, is to continue to be governed by prior laws and regulations.

(Delegation of Other Transitional Measures to Cabinet Order)

Article 46 Beyond what is provided for in these Supplementary Provisions, transitional measures necessary for the enforcement of this Act (including transitional measures concerning penal provisions) are specified.