

Clinical Trials Act (Act No. 16 of April 14, 2017)

(Act No. 16 of 2017)

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Chapter I General Provisions

(Purpose)

Article 1 The purpose of this Act is to establish procedures for the implementation of clinical trials, measures for appropriately conducting operations for reviews and opinions by a certified review board, and systems for disclosure of information on provision of funds or other benefits for clinical trials and other matters, thereby promoting the implementation of clinical trials through ensuring the confidence in clinical trials of citizens including clinical trial subjects, and contributing to the improvement of public health and hygiene.

(Definitions)

Article 2 (1) The term "clinical trials" as used in this Act means research to demonstrate the efficacy or safety of pharmaceuticals, etc. by the use of pharmaceuticals, etc. in human bodies (excluding research involving testing of the efficacy or safety of pharmaceuticals, etc. falling under clinical trials provided for in Article 80-2, paragraph (2) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960; referred to below as the "Pharmaceuticals and Medical Devices Act" in this Article) and other types of research specified by Order of the Ministry of Health, Labour and Welfare, and including research involving additional examinations or other acts (limited to those specified by Order of the Ministry of Health, Labour and Welfare as acts that impose an extreme mental or physical burden on human bodies) required to demonstrate the efficacy or safety of the pharmaceuticals, etc. used to diagnose, treat, or prevent human diseases, or to affect the structure or functioning of the human body).

(2) The term "specified clinical trials" as used in this Act means clinical trials that fall under either of the following items:

(i) clinical trials implemented receiving research funds or other benefits (meaning funds for the implementation of clinical trials (including benefits

specified by Order of the Ministry of Health, Labour and Welfare); the same applies below) provided by a holder of marketing authorization for pharmaceuticals, etc. or a specially related person (meaning a person who has a special relationship with the holder of marketing authorization for pharmaceuticals, etc. as specified by Order of the Ministry of Health, Labour and Welfare; the same applies below) (limited to such clinical trials implemented using pharmaceuticals, etc. that are marketed (meaning marketing provided for in Article 2, paragraph (13) of the Pharmaceuticals and Medical Devices Act; the same applies below) or intended to be marketed by the holder of marketing authorization for pharmaceuticals, etc.); or

(ii) clinical trials implemented using pharmaceuticals, etc. stated in the following items (excluding the clinical trials that fall under the preceding item):

(a) pharmaceuticals stated in item (i) of the following paragraph, approval for which has not been obtained pursuant to Article 14, paragraph (1) or Article 19-2, paragraph (1) of the Pharmaceuticals and Medical Devices Act;

(b) pharmaceuticals stated in item (i) of the following paragraph, approval for which has been obtained pursuant to Article 14, paragraph (1) or Article 19-2, paragraph (1) of the Pharmaceuticals and Medical Devices Act (including approval for change pursuant to Article 14, paragraph (15) of that Act (including as applied mutatis mutandis pursuant to Article 19-2, paragraph (5) of that Act); the same applies below in this item) (limited to the case where it is used for dosage, administration, efficacy, or effects (referred to below as "dosage, etc." in this item) which is different from dosage, etc. concerning the approval (excluding any dosage, etc. specified by Order of the Ministry of Health, Labour and Welfare as posing the same or lower risk to human life and health compared to the approved dosage, etc.));

(c) medical devices stated in item (ii) of the following paragraph, approval for which has not been obtained pursuant to Article 23-2-5, paragraph (1) or Article 23-2-17, paragraph (1) of the Pharmaceuticals and Medical Devices Act, certification for which has not been received pursuant to Article 23-2-23, paragraph (1) of that Act, or notification of which has not been made as provided for in Article 23-2-12, paragraph (1) of that Act;

(d) medical devices stated in item (ii) of the following paragraph, approval for which has been obtained pursuant to Article 23-2-5, paragraph (1) or Article 23-2-17, paragraph (1) of the Pharmaceuticals and Medical Devices Act (including approval for change pursuant to Article 23-2-5, paragraph (15) of that Act (including as applied mutatis mutandis pursuant to Article 23-2-17, paragraph (5) of that Act); the same applies below in this item), certification for which has been received pursuant to Article 23-2-23, paragraph (1) of that Act (including certification for change pursuant to paragraph (7) of that Article; the same applies below in this item), or notification of which has been made as provided

for in Article 23-2-12, paragraph (1) of that Act (including notification of change under paragraph (2) of that Article; the same applies below in this item) (limited to the case where it is used in a usage, effect, and performance (referred to below as "usage, etc." in this item) which is different from the usage, etc. concerning the approval, certification or notification (excluding any usage, etc. specified by Order of the Ministry of Health, Labour and Welfare as posing the same or lower risk to human life and health compared to the usage, etc. allowed under the approval, certification, or notification));

(e) regenerative medicine products stated in item (iii) of the following paragraph, approval for which has not been obtained pursuant to Article 23-25, paragraph (1) or Article 23-37, paragraph (1) of the Pharmaceuticals and Medical Devices Act; or

(f) regenerative medicine products stated in item (iii) of the following paragraph, approval for which has been obtained pursuant to Article 23-25, paragraph (1) or Article 23-37, paragraph (1) of the Pharmaceuticals and Medical Devices Act (including approval for change pursuant to Article 23-25, paragraph (11) of that Act (including as applied mutatis mutandis pursuant to Article 23-37, paragraph (5) of that Act); the same applies below in this item) (limited to the case where it is used for dosage, administration, methods of usage, efficacy, effects, and performance (referred below to as "dosage, etc." in this item) which is different from dosage, etc. concerning the approval (excluding any dosage, etc. specified by Order of the Ministry of Health, Labour and Welfare as posing the same or lower risk to impact the life and health of a human life and health compared to than the approved dosage, etc.)).

(3) The term "pharmaceuticals, etc." as used in this Act means those stated in the following items:

(i) pharmaceuticals provided for in Article 2, paragraph (1) of the Pharmaceuticals and Medical Devices Act (excluding in-vitro diagnostics provided for in paragraph (14) of that Article);

(ii) medical devices provided for in Article 2, paragraph (4) of the Pharmaceuticals and Medical Devices Act; and

(iii) regenerative medicine products provided for in Article 2, paragraph (9) of the Pharmaceuticals and Medical Devices Act.

(4) The term "holder of marketing authorization for pharmaceuticals, etc." as used in this Act means a person who has obtained a license for pharmaceuticals, etc. pursuant to Article 12, paragraph (1), Article 23-2, paragraph (1), or Article 23-20, paragraph (1) of the Pharmaceuticals and Medical Devices Act.

Chapter II Implementation of Clinical Trials

(Clinical Trial Standards)

Article 3 (1) The Minister of Health, Labour and Welfare must establish standards for the implementation of clinical trials (referred to below as the

"clinical trial standards") by Order of the Ministry of Health, Labour and Welfare.

(2) In the clinical trial standards, matters stated in the following items are to be specified:

(i) matters concerning the system for implementing clinical trials;

(ii) matters concerning buildings and equipment at facilities where clinical trials are implemented;

(iii) matters concerning confirmation of the state of implementation of clinical trials;

(iv) matters concerning compensation and provision of medical care upon occurrence of health damage to clinical trial subjects;

(v) matters concerning involvement of a holder of marketing authorization for pharmaceuticals, etc. which markets or intends to market pharmaceuticals, etc. used for specified clinical trials (limited to those stated in paragraph (2), item (i) of the preceding Article) and their specially related person in the specified clinical trials; and

(vi) other necessary matters for the implementation of clinical trials.

(Compliance with Clinical Trial Standards)

Article 4 (1) A person who implements clinical trials (excluding specified clinical trials) must endeavor to implement the clinical trials in accordance with the clinical trial standards.

(2) A person who implements specified clinical trials must conduct the clinical trials in accordance with the clinical trial standards.

(Submission of Trial Plan)

Article 5 (1) A person who implements specified clinical trials must prepare a plan for the implementation of specified clinical trials stating matters listed in the following items for each specified clinical trials (referred to below as the "trial plan"), and submit the trial plan to the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare:

(i) the person's name and address, and the name of the representative in the case of a corporation;

(ii) the purpose and details of specified clinical trials, and the outline of pharmaceuticals, etc. used;

(iii) matters concerning the system for implementation of specified clinical trials;

(iv) matters concerning buildings and equipment at facilities where specified clinical trials are conducted;

(v) matters concerning confirmation of the state of implementation of specified clinical trials;

(vi) matters concerning compensation and provision of medical care upon occurrence of health damage to specified clinical trial subjects;

(vii) matters concerning involvement of a holder of marketing authorization for pharmaceuticals, etc. which markets or intends to market pharmaceuticals, etc. used for specified clinical trials (limited to those stated in Article 2, paragraph (2), item (i)) and their specially related person in the specified clinical trials;

(viii) the name of the certified review board provided for in Article 23, paragraph (5), item (ii) which performs operations for reviews and opinions as provided for in paragraph (1) of that Article for specified clinical trials (referred to below as the "certified review board" in this Chapter); and

(ix) other matters specified by Order of the Ministry of Health, Labour and Welfare.

(2) To the trial plan, the following documents must be attached:

(i) a document stating the details of opinions under the following paragraph; and

(ii) other documents specified by Order of the Ministry of Health, Labour and Welfare.

(3) When a person who implements specified clinical trials submits the trial plan pursuant to paragraph (1) of this Article, the person must hear the opinions of the certified review board stated in the trial plan about whether or not specified clinical trials are to be implemented in accordance with the trial plan and matters to be noted in the implementation of the specified clinical trials, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Changes in Trial Plan)

Article 6 (1) When a person who has submitted the trial plan pursuant to paragraph (1) of the preceding Article (referred to below as a "specified clinical trial conductor") intends to change the trial plan (excluding minor changes specified by Order of the Ministry of Health, Labour and Welfare; the same applies in the main clause of the following paragraph), the person must submit the trial plan so changed to the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) The provisions of paragraphs (2) and (3) of the preceding Article apply mutatis mutandis to changes in the trial plan under the preceding paragraph; provided, however, that the attachment of documents stated in item (ii) of paragraph (2) of that Article may be omitted when the details of the documents already submitted to the Minister of Health, Labour and Welfare are not changed.

(3) When a specified trial conductor has made minor changes to the trial plan as specified by Order of the Ministry of Health, Labour and Welfare under paragraph (1) of this Article, they must give notice of the details of the changes to the certified review board stated in the trial plan, and notify the Minister of Health, Labour and Welfare, within ten days from the date of change.

(Compliance with Trial Plan)

Article 7 A specified clinical trial conductor must implement specified clinical trials in accordance with the trial plan submitted pursuant to Article 5, paragraph (1) or paragraph (1) of the preceding Article (if minor changes have been made as specified by Order of the Ministry of Health, Labour and Welfare under that paragraph, the changed trial plan).

(Suspension of Specified Clinical Trials)

Article 8 When a specified clinical trial conductor suspends specified clinical trials, they must give notice to the certified review board stated in the trial plan of the specified clinical trials, and notify the Minister of Health, Labour and Welfare, within ten days from the date of suspension.

(Consent of Specified Clinical Trial Subjects, etc.)

Article 9 A person who implements specified clinical trials must explain in advance to the subjects of the specified clinical trials the purpose and details of the specified clinical trials, the overview of the pharmaceuticals, etc. used, and if the specified clinical trials are implemented receiving research funds or other benefits provided by the holder of marketing authorization for pharmaceuticals, etc. which markets or intends to market the pharmaceuticals, etc. or their specially related person, the details of a contract provided for in Article 32 and other matters specified by Order of the Ministry of Health, Labour and Welfare, and obtain their consent, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare; provided, however, that this does not apply to the case where it is difficult to obtain the consent of a specified clinical trial subject due to disease or for other reasons specified by Order of the Ministry of Health, Labour and Welfare, and explanations are made to the spouse of the subject, person who has parental authority over the subject or any other person specified by Order of the Ministry of Health, Labour and Welfare, and the consent of the spouse or person is obtained, or as otherwise specified by Order of the Ministry of Health, Labour and Welfare.

(Protection of Personal Information Concerning Specified Clinical Trials)

Article 10 A person who implements specified clinical trials must take necessary measures to prevent the leakage, loss, or damage of personal information or to otherwise appropriately manage personal information (meaning information relating to a living individual, containing a name, date of birth, or other identifier or equivalent which can be used to identify a specific individual (this includes any information that can be used to identify that

specific individual by collating with other information); the same applies below in this Article) of each subject of the specified clinical trials..

(Duty of Confidentiality)

Article 11 A person who is or was engaged in specified clinical trials must not divulge, without legitimate grounds, any confidential information of specified clinical trial subjects which may come to their knowledge in the course of the implementation of the specified clinical trials.

(Records Concerning Specified Clinical Trials)

Article 12 A person who implements specified clinical trials must prepare records of dates when and places where pharmaceuticals, etc. were used and other matters specified by Order of the Ministry of Health, Labour and Welfare for each subject of the specified clinical trials, and keep the records pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Report to Certified Review Board)

Article 13 (1) If a specified clinical trial conductor comes to know that any disease, disability, death, or infection (referred to as "disease, etc." in the following Article and Article 23, paragraph (1)) which is suspected of being due to the implementation of specified clinical trials has occurred, the specified clinical trial conductor must report the facts to the certified review board stated in the trial plan of the specified clinical trials pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) When the certified review board receiving the report pursuant to the preceding paragraph provides opinions to the specified clinical trial conductor, the specified clinical trial conductor must respect the opinions and take necessary measures.

(Report to Minister of Health, Labour and Welfare)

Article 14 If a specified clinical trial conductor comes to know matters specified by Order of the Ministry of Health, Labour and Welfare concerning the occurrence of any disease, etc. that is suspected of being due to the implementation of specified clinical trials, the specified clinical trial conductor must report the facts to the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Report to Health Science Council)

Article 15 (1) The Minister of Health, Labour and Welfare must provide the Health Science Council with the status of the report under the preceding Article each fiscal year and hear the opinions of the Health Science Council and take necessary measures to prevent the occurrence or spread of hazards to public health and hygiene caused by the implementation of specified clinical trials, if the Minister finds it necessary.

(2) In addition to the case referred to in the preceding paragraph, the Health Science Council may study and deliberate necessary measures to prevent the

occurrence or spread of hazards to public health and hygiene caused by the implementation of specified clinical trials and provide opinions to the Minister of Health, Labour and Welfare, if the Health Science Council finds it necessary.

(3) When providing the status report or taking measures under paragraph (1) of this Article, the Minister of Health, Labour and Welfare is to compile information on the report under the preceding Article and implement a study concerning the report under the preceding Article, if the Minister finds it necessary.

(Implementation of Compilation of Information and Study by PMDA)

Article 16 (1) The Minister of Health, Labour and Welfare may have the Pharmaceuticals and Medical Devices Agency (referred to below as the "PMDA" in this Article) compile information as provided for in paragraph (3) of the preceding Article.

(2) Upon request from the PMDA, the Minister of Health, Labour and Welfare may provide the PMDA with the details of specified clinical trials concerning the report under Article 14 and other information on matters specified by Order of the Ministry of Health, Labour and Welfare, in order for the PMDA to compile information under the preceding paragraph.

(3) If the Minister of Health, Labour and Welfare has the PMDA compile information under paragraph (1) of this Article, the Minister must give public notice of that fact.

(4) When the Minister of Health, Labour and Welfare has the PMDA compile information under paragraph (1) of this Article, a person who makes a report under Article 14 must provide the PMDA with the report pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, notwithstanding the provisions of that Article.

(5) If the PMDA has compiled information under paragraph (1) of this Article, the PMDA must report the result of compilation of the information to the Minister of Health, Labour and Welfare without delay.

(6) The provisions of paragraphs (1), (2) and the preceding paragraph apply mutatis mutandis to the study provided for in paragraph (3) of the preceding Article.

(Periodic Report to Certified Review Board)

Article 17 (1) A specified clinical trial conductor must regularly report the state of implementation of specified clinical trials to the certified review board stated in the trial plan of the specified clinical trials pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) When the certified review board that received the report pursuant to the preceding paragraph provides opinions to the specified clinical trial conductor, the specified clinical trial conductor must respect the opinions and take necessary measures.

(Periodic Report to Minister of Health, Labour and Welfare)

Article 18 (1) A specified clinical trial conductor must regularly report the state of implementation of specified clinical trials to the Minister of Health, Labour and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) When the Minister of Health, Labour and Welfare received the report pursuant to the preceding paragraph, the Minister must compile the report and make its overview public.

(Emergency Order)

Article 19 The Minister of Health, Labour and Welfare may order that a person who implements specified clinical trials should suspend the specified clinical trials and take other emergency measures to prevent the occurrence or spread of hazards to public health and hygiene, if it is found necessary to do so to prevent the occurrence or spread of hazards to public health and hygiene caused by the implementation of the specified clinical trials.

(Order for Improvement, etc.)

Article 20 (1) If the Minister of Health, Labour and Welfare finds that any provision of this Chapter or an order under any provision of this Chapter has been violated, the Minister may order that a person who implements specified clinical trials should cause the specified clinical trials to conform to the clinical trial standards, change the trial plan, or otherwise take necessary measures to rectify the violation.

(2) If a person who implements specified clinical trials fails to comply with the order issued under the preceding paragraph, the Minister of Health, Labour and Welfare may order that the person who implements the specified clinical trials should suspend the specified clinical trials, in whole or in part, specifying a certain period of time.

(Measures to Be Taken by Person Implementing Clinical Trials Other Than Specified Clinical Trials)

Article 21 A person who implements clinical trials (excluding specified clinical trials) must endeavor to prepare a plan for the implementation of the clinical trials in accordance with the provisions of Article 5, paragraph (1), and in addition, when preparing or changing the plan, endeavor to hear the opinions of the certified review board, as well as to take necessary measures in accordance with the provisions of Article 7 and Articles 9 through 12.

(Exclusion from Application)

Article 22 The provisions of this Chapter do not apply to the case where the use of pharmaceuticals, etc. for clinical trials falls under regenerative medicine provided for in Article 2, paragraph (1) of the Act on the Safety of Regenerative Medicine (Act No. 85 of 2013).

Chapter III Certified Review Board

(Certification of Clinical Trials Review Board)

Article 23 (1) A person (limited to an organizer of a hospital (meaning a hospital provided for in Article 1-5, paragraph (1) of the Medical Care Act (Act No. 205 of 1948)) or a clinic (meaning a clinic provided for in paragraph (2) of that Article, including the address of a physician or dentist provided for in Article 5, paragraph (1) of that Act), an academic society of medicine and medical science, or any other organization specified by Order of the Ministry of Health, Labour and Welfare (in the case of an organization without legal personality, limited to an organization for which a representative or an administrator has been designated)) that establishes a board composed of persons who have expert knowledge and experience concerning clinical trials that performs the operations stated in the following items (referred to below as "operations for reviews and opinions"; and this board is referred to below as a "clinical trials review board" in this Article) must obtain certification from the Minister of Health, Labour and Welfare with respect to the conformance of the clinical trials review board established to the requirements stated in the items of paragraph (4) of this Article:

(i) if opinions are requested pursuant to Article 5, paragraph (3) (including as applied *mutatis mutandis* pursuant to Article 6, paragraph (2)), operations to review the trial plan in light of the clinical trial standards and to provide opinions to a person who implements specified clinical trials about whether the specified clinical trials are appropriate and matters to be noted in the implementation of the specified clinical trials;

(ii) if a report is received pursuant to Article 13, paragraph (1), if it finds it necessary, operations to provide opinions to the specified clinical trial conductor about measures to be taken to investigate the cause or prevent recurrence of the disease, etc. related to the report;

(iii) if a report is received pursuant to Article 17, paragraph (1), if it finds it necessary, operations to provide opinions to the specified clinical trial conductor about matters to be noted or improved in the implementation of the specified clinical trials related to the report; and

(iv) in addition to the preceding three items, if it finds it necessary, operations to provide opinions to the person who implements specified clinical trials pursuant to the trial plan in which its name is stated as the certified review board under Article 5, paragraph (1), item (viii), about matters to be improved to cause the specified clinical trials to conform to the clinical trial standards, or measures to be taken to prevent the occurrence of disease, etc.

(2) A person who intends to obtain certification under the preceding paragraph must submit to the Minister of Health, Labour and Welfare a written application stating the matters listed in the following items and apply for

certification under that paragraph, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare:

(i) the person's name and address, and the name of the representative in the case of a corporation (or the representative or administrator in the case of an organization without legal personality);

(ii) the name of the clinical trials review board;

(iii) the names of members of the clinical trials review board;

(iv) matters concerning the system under which operations for reviews and opinions are performed; and

(v) other matters specified by Order of the Ministry of Health, Labour and Welfare.

(3) To the written application under the preceding paragraph, operational rules provided for in item (ii) of the following paragraph and other documents specified by Order of the Ministry of Health, Labour and Welfare must be attached.

(4) When an application for certification under paragraph (1) of this Article (simply referred to below as "certification" in this Article) is filed, and if the Minister of Health, Labour and Welfare finds that the clinical trials review board concerning the application conforms to the requirements stated in the following items, the Minister must approve the certification of the clinical trials review board:

(i) the clinical trials review board is composed of members who have expert knowledge and experience concerning clinical trials and the system specified by Order of the Ministry of Health, Labour and Welfare as being unlikely to adversely affect fair performance of operations for reviews and opinions has been established;

(ii) operational rules concerning the method of performance of operations for reviews and opinions, the method of management and confidentiality of information that may come to their knowledge in the course of the performance of operations for reviews and opinions, and other methods for the appropriate performance of operations for reviews and opinions have been established; and

(iii) in addition to those stated in the preceding two items, the clinical trials review board conforms to the standards specified by Order of the Ministry of Health, Labour and Welfare as being necessary for the appropriate performance of operations for reviews and opinions.

(5) When the Minister of Health, Labour and Welfare approved the certification for the clinical trials review board pursuant to the preceding paragraph, the Minister must give public notice of the matters stated in the following items:

(i) the name and address of a person who has obtained certification (referred to below as an "establisher of the certified board"); and

(ii) the name of the clinical trials review board concerning certification (referred to below as a "certified review board").

(Grounds for Disqualification)

Article 24 Notwithstanding the provisions of paragraph (4) of the preceding Article, an applicant for certification of a clinical trials review board may not obtain certification under paragraph (1) of that Article if they fall under any of the following items:

(i) if an applicant is a person who has been sentenced to imprisonment or a heavier punishment, and who has not yet finished serving the sentence or has not ceased to be subject to its enforcement;

(ii) if an applicant is a person who has been sentenced to a fine pursuant to the provisions of this Act or other laws concerning health and medical care for citizens as specified by Cabinet Order, and who has not yet finished serving the sentence or has not ceased to be subject to its enforcement;

(iii) if an applicant is a person whose certification under paragraph (1) of the preceding Article has been rescinded pursuant to Article 31, paragraph (1), and for whom three years have not elapsed from the date of rescission of the certification (including a person who was an officer (including a person who has authority or control equivalent to or greater than that of the officer, irrespective of their title; the same applies below in this Article) of a corporation whose certification has been rescinded within sixty days before the day on which a notice concerning the disposition of rescission of certification was given under Article 15, paragraph (1) of the Administrative Procedure Act (Act No. 88 of 1993) (referred to below as the "notice day" in this Article) and for whom three years have not elapsed from the date of rescission of the certification, and a person who was the representative or administrator of an organization, certification of which has been rescinded within sixty days before the notice day and for whom three years have not elapsed from the date of rescission of the certification); provided, however, that this excludes the case where the rescission of certification falls under the rescission of certification specified by Order of the Ministry of Health, Labour and Welfare, such that it is found that it is appropriate to handle the case as one not falling under the rescission of certification provided for in the main clause of this item, taking into account the facts that constitute the grounds for the disposition of rescission of certification, the status of initiatives for the establishment of the system to prevent the occurrence of the facts by the establisher of the certified board, and the level of other responsibilities for the facts of the establisher of the certified board;

(iv) if an applicant is a person who has filed a notification of abolition under Article 27, paragraph (1) in the period from the notice day concerning the disposition of rescission of certification under paragraph (1) of the preceding Article pursuant to Article 31, paragraph (1) to the day on which the disposition

is rendered or it is decided that the disposition is not rendered (excluding a person who has reasonable grounds for the abolition), and for whom three years have not elapsed from the date of the notification;

(v) if an applicant is a person who has committed a wrongful act or an extremely unjustifiable act concerning operations for reviews and opinions within three years before the filing of the application for certification under paragraph (1) of the preceding Article;

(vi) if an applicant is a corporation and any of its officers falls under any of the preceding items; or

(vii) if an applicant is an organization without legal personality and its representative or administrator falls under any of items (i) through (v) of this Article.

(Certification of Changes)

Article 25 (1) When an establisher of the certified board changes the matters stated in Article 23, paragraph (2), item (iii) or (iv) (excluding minor changes specified by Order of the Ministry of Health, Labour and Welfare), they must obtain certification from the Minister of Health, Labour and Welfare.

(2) When an establisher of the certified board made minor changes specified by Order of the Ministry of Health, Labour and Welfare referred to in the preceding paragraph, they must notify the Minister of Health, Labour and Welfare of their details without delay.

(3) The provisions of Article 23, paragraphs (2) through (5) apply mutatis mutandis to the certification of changes under paragraph (1) of this Article.

(4) When there is any change in the matters stated in Article 23, paragraph (2), item (i), (ii), or (v), or any matter stated in the document provided for in paragraph (3) of that Article (excluding the case where the changes are minor as specified by Order of the Ministry of Health, Labour and Welfare), the establisher of the certified board must notify the Minister of Health, Labour and Welfare of their details without delay.

(5) The provisions of Article 23, paragraph (5) apply mutatis mutandis to the case where a notification as to the matters stated in either of the items of that paragraph is made pursuant to the preceding paragraph.

(Effective Period of Certification)

Article 26 (1) The effective period of certification under Article 23, paragraph (1) is three years from the date of the certification.

(2) The establisher of the certified board who continues to have the certified review board after the expiration of the effective period under the preceding paragraph (if the effective period is renewed pursuant to this paragraph, meaning the renewed effective period; simply referred to below as the "effective period" in this Article) must obtain a renewal of the effective period.

(3) The establisher of the certified board who intends to obtain the renewal under the preceding paragraph must file an application for renewal under the preceding paragraph with the Minister of Health, Labour and Welfare, within the period from ninety days before the date of expiration of the effective period to sixty days before the date (referred to below as the "renewal application period"); provided, however, that this does not apply to the case where it is not possible to file an application for renewal in the renewal application period due to a disaster or for other unavoidable grounds.

(4) If an application under the preceding paragraph has been filed, but no disposition is rendered for the application by the date of expiration of the effective period, the former certification remains in force even after the expiration of the effective period until the disposition is rendered.

(5) In the case of the preceding paragraph, if renewal is granted under paragraph (2) of this Article, the effective period is to be calculated from the day following the date of expiration of the effective period before the renewal.

(6) The provisions of Article 23 (limited to paragraphs (2) through (4)) and Article 24 (excluding items (iii) through (v)) apply mutatis mutandis to renewal under paragraph (2) of this Article; provided, however, that the attachment of documents provided for in Article 23, paragraph (3) may be omitted if the details of the documents already submitted to the Minister of Health, Labour and Welfare are not changed.

(Abolition of Certified Review Board)

Article 27 (1) When an establisher of the certified board abolishes the certified review board that had been established, they must give prior notice to the person who implements specified clinical trials pursuant to the trial plan in which its name is stated as the certified review board under Article 5, paragraph (1), item (viii), and notify the Minister of Health, Labour and Welfare of the fact, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) When a notification under the preceding paragraph has been filed, the Minister of Health, Labour and Welfare must give public notice of that fact.

(Duty of Confidentiality)

Article 28 Members of the certified review board, persons engaged in operations for reviews and opinions, or persons who formerly held these positions must not divulge any confidential information that may come to their knowledge in the course of the performance of operations for reviews and opinions, without legitimate grounds.

(Report to Minister of Health, Labour and Welfare)

Article 29 When the certified review board provided opinions under Article 23, paragraph (1), items (ii) through (iv), it must report the details to the Minister of Health, Labour and Welfare without delay.

(Order for Improvement)

Article 30 (1) If the Minister of Health, Labour and Welfare finds that the certified review board ceases to conform to any of the requirements stated in the items of Article 23, paragraph (4), the Minister may order that the establisher of the certified board should take necessary measures to cause the board to conform to the requirements.

(2) In addition to what is provided for in the preceding paragraph, if the Minister of Health, Labour and Welfare finds that the establisher of the certified board has violated any provision of this Chapter or an order under any provision of this Chapter or otherwise it is necessary to ensure the appropriate performance of operations for reviews and opinions, the Minister may order that the establisher of the certified board should improve the system under which operations for reviews and opinions are performed, make changes in operational rules provided for in Article 23, paragraph (4), item (ii), and take other necessary measures.

(Rescission of Certification)

Article 31 (1) The Minister of Health, Labour and Welfare may rescind certification under Article 23, paragraph (1) if the establisher of the certified board falls under any of the following items:

(i) if the establisher of the certified board has obtained certification under Article 23, paragraph (1), certification for changes under Article 25, paragraph (1), or renewal under Article 26, paragraph (2) through deception or other wrongful means;

(ii) if the certified review board ceases to conform to any of the requirements stated in the items of Article 23, paragraph (4);

(iii) if the establisher of the certified board comes to fall under any of the items of Article 24 (excluding items (iii) and (iv));

(iv) if the establisher of the certified board has violated any provision of this Chapter or an order under any provision of this Chapter; or

(v) if the establisher of the certified board has failed to submit a report or any other item under Article 35, paragraph (1) without legitimate grounds or submitted a false report or item, has refused, obstructed, or evaded an inspection under that paragraph, or has failed to answer questions or made a false answer under that paragraph.

(2) When the Minister of Health, Labour and Welfare rescinds certification under Article 23, paragraph (1) pursuant to the preceding paragraph, the Minister must give public notice of that fact.

Chapter IV Provision of Funds or Other Benefits for Clinical Trials

(Conclusion of Contract)

Article 32 If a holder of marketing authorization for pharmaceuticals, etc. or their specially related person provides a person who implements specified

clinical trials with research funds or other benefits for the specified clinical trials for which pharmaceuticals, etc. marketed or intended to be marketed by the holder of marketing authorization for pharmaceuticals, etc. are used, they must enter into a contract specifying the amount and details of the research funds or other benefits, details of the specified clinical trials, and other matters specified by Order of the Ministry of Health, Labour and Welfare.

(Disclosure of Information, etc. on Provision of Research Funds or Other Benefits)

Article 33 In addition to information on the provision of research funds or other benefits for specified clinical trials for which pharmaceuticals, etc. marketed or intended to be marketed by the holder of marketing authorization for pharmaceuticals, etc. are used, a holder or their specially related person must, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, disclose information on the provision of money or other profits (excluding research funds or other benefits) to a person who implements specified clinical trials or a person who has a special relationship with that person as specified by Order of the Ministry of Health, Labour and Welfare, for which ensuring transparency contributes to obtaining the confidence of citizens in specified clinical trials as specified by Order of the Ministry of Health, Labour and Welfare, by the use of the Internet or other means specified by Order of the Ministry of Health, Labour and Welfare.

(Recommendations, etc.)

Article 34 (1) If a holder of marketing authorization for pharmaceuticals, etc. or their specially related person has violated the provisions of the preceding two Articles, the Minister of Health, Labour and Welfare may recommend that the holder or their specially related person enter into a contract provided for in Article 32 or to disclosure information provided for in the preceding Article in accordance with these provisions.

(2) If the holder of marketing authorization for pharmaceuticals, etc. or their specially related person who has received recommendations under the preceding paragraph fails to comply with the recommendations, the Minister of Health, Labour and Welfare may make the fact public.

Chapter V Miscellaneous Provisions

(Collection of Reports and On-site Inspections)

Article 35 (1) To the extent necessary for the enforcement of this Act, the Minister of Health, Labour and Welfare may request that a person who implements specified clinical trials, the establisher of the certified board, a holder of marketing authorization for pharmaceuticals, etc. (limited to the manufacturer marketing or intending to market pharmaceuticals, etc. used for specified clinical trials; the same applies in Article 42), or their specially related person should submit the necessary report, books, documents, or other items; or

have the Ministry's officials enter the workplace of the person to inspect books, documents, or other items or to question persons concerned.

(2) When the Ministry's officials enter a workplace pursuant to the preceding paragraph, they must carry their identification card and present it to persons concerned.

(3) The authority under paragraph (1) of this Article must not be construed as being granted for criminal investigation purposes.

(Hearing of Opinions of Health Science Council)

Article 35-2 In the following cases, the Minister of Health, Labour and Welfare must hear the opinions of the Health Science Council in advance:

(i) establishing, amending, or repealing Order of the Ministry of Health, Labour and Welfare that specifies the examinations or other acts in Article 2, paragraph (1), or Order of the Ministry of Health, Labour and Welfare in item (ii), (b), (d), or (f) of paragraph (2) of that Article; or

(ii) establishing or changing the clinical trial standards.

(Delegation of Authority)

Article 36 (1) The authority of the Minister of Health, Labour and Welfare provided for in this Act may be delegated to the Director-General of a Regional Bureau of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) The authority delegated to the Director-General of a Regional Bureau of Health and Welfare pursuant to the preceding paragraph may be delegated to the Director-General of a Regional Branch Bureau of Health and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Transitional Measures)

Article 37 If an order is established, amended, or repealed under the provisions of this Act, necessary transitional measures (including transitional measures concerning penal provisions) may be specified in the order to the extent determined to be reasonably necessary for the establishment, amendment, or repeal.

(Delegation to Order of the Ministry of Health, Labour and Welfare)

Article 38 In addition to what is provided for in this Act, procedures and other matters necessary for the enforcement of this Act are to be specified by Order of the Ministry of Health, Labour and Welfare.

Chapter VI Penal Provisions

Article 39 A person who has violated an order issued under Article 19 is punished by imprisonment for not more than three years or a fine of not more than three million yen, or both.

Article 40 A person who has divulged confidential information in violation of the provisions of Article 11 or 28 is punished by imprisonment for not more than one year or a fine of not more than one million yen.

Article 41 A person who implements specified clinical trials is punished by a fine of not more than five hundred thousand yen if they fall under any of the following items:

(i) a person who has failed to submit a trial plan without legitimate grounds, or submitted a trial plan without stating the matters to be stated or containing a false statement, and implemented specified clinical trials in violation of the provisions of Article 5, paragraph (1);

(ii) a person who has failed to submit the trial plan without legitimate grounds, or submitted a trial plan without stating the matters to be stated or containing a false statement, and implemented specified clinical trials in violation of the provisions of Article 6, paragraph (1);

(iii) a person who has failed to prepare or keep records without legitimate grounds, or prepared false records, in violation of the provisions of Article 12;

(iv) a person who has violated an order issued under Article 20, paragraph (2);
or

(v) a person who has failed to submit a report or any other item under Article 35, paragraph (1) without legitimate grounds, or submitted a false report or item, has refused, obstructed, or evaded an inspection under that paragraph, or has failed to answer questions under that paragraph or made a false answer.

Article 42 A holder of marketing authorization for pharmaceuticals, etc. or their specially related person is punished by a fine of not more than three hundred thousand yen if it failed to submit a report or any other item under Article 35, paragraph (1) without legitimate grounds or submitted a false report or item, refused, obstructed, or evaded an inspection under that paragraph, or failed to answer questions under that paragraph or made a false answer.

Article 43 (1) If a representative or administrator of a corporation (including an organization without legal personality for which a representative or an administrator has been designated; the same applies below in this Article), or an agent, employee, or other worker of a corporation or person has committed a violation under Article 39 or either of the preceding two Articles concerning the business of the corporation or person, not only the offender is punished but also the corporation or person is punished by a fine under each relevant Article.

(2) If the provisions of the preceding paragraph apply to an organization without legal personality, its representative or administrator represents the organization without legal personality with respect to its procedural acts, and the provisions of laws concerning criminal proceedings in the case where the organization is the accused or suspect apply *mutatis mutandis*.

Supplementary Provisions (Act No. 63 of December 4, 2019) (Extract)

(Effective Date)

Article 1 This Act comes into effect on the day specified by Cabinet Order within a period not exceeding one year from the date of promulgation; provided, however, that the provisions stated in each of the following items come into effect on the day specified in the respective items:

(i) omitted; or

(ii) the provisions of Article 2, the provisions of Article 4 (limited to the provisions revising Article 9, paragraph (1), item (ii) of the Stimulants Control Act), and the provisions of Article 6; the provisions of the following Article, the provisions of Articles 5, 6 and 8, Article 11, paragraph (2), Article 16, and Article 20 of the Supplementary Provisions, and the provisions of Article 22 of the Supplementary Provisions (limited to the provisions revising Article 115-5, paragraph (2) of the Self-Defense Forces Act (Act No. 165 of 1954)); and the provisions of Articles 23, 28, 31, 34, and 36 of the Supplementary Provisions: the day specified by Cabinet Order within a period not exceeding two years from the date of promulgation.

(Transitional Measures Concerning Penal Provisions)

Article 38 Prior laws and regulations continue to govern the applicability of penal provisions to any acts performed before this Act comes into effect, and any acts performed after this Act comes into effect in cases where this Act provides that those prior laws and regulations remain applicable.

Supplementary Provisions (Act No. 68 of June 17, 2022) (Extract)

(Effective Date)

(1) This Act comes into effect on the effective date of the Act Partially Amending the Penal Code; provided, however, that the provisions stated in each of the following items come into effect on the day specified in the respective items:

(i) the provisions of Article 509: the date of promulgation.

Supplementary Provisions (Act No. 51 of June 14, 2024) (Extract)

(Effective Date)

Article 1 This Act comes into effect on the day specified by Cabinet Order within a period not exceeding one year from the date of promulgation; provided, however, that the provisions of Articles 8, 9, 12, and 13 of the Supplementary Provisions come into effect on the date of promulgation.

(Review)

Article 2 (2) After approximately five years from the enforcement of this Act, the government is to review the provisions of the respective Acts that have been revised by this Act, taking into account the status, etc. of enforcement of those Acts and, if deemed necessary, take necessary measures based on the results of the review.

(Preparation Before Enforcement)

Article 9 (2) When the Minister of Health, Labour and Welfare intends to establish Order of the Ministry of Health, Labour and Welfare as provided for in Article 35-2, item (i) of the Clinical Trials Act that is revised under Article 2, the Minister may hear the opinions of the Health Science Council, even before the effective date.

(Transitional Measures Concerning Penal Provisions)

Article 10 Prior laws and regulations continue to govern the applicability of penal provisions to any acts performed before this Act comes into effect.

(Delegation to Cabinet Order)

Article 13 In addition to what is provided for in these Supplementary Provisions, necessary transitional measures for the enforcement of this Act (including transitional measures concerning penal provisions) are to be specified by Cabinet Order.