BIOETHICS AND SAFETY ACT

[Enforcement Date 12. Dec, 2017.] [Act No.15188, 12. Dec, 2017., Partial Amendment]

보건복지부 (생명윤리정책과-총괄, 기관생명윤리위원회)044-202-2619

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CHAPTER I GENERAL PROVISIONS

Article 1 (Purpose)

The purpose of this Act is to ensure bioethics and biosafety, thereby contributing to promoting citizens' health and improving their quality of life by preventing the violation of human dignity and values or the infliction of harm on human body in the course of researching on human beings and human materials or of handling embryos, genes, etc.

Article 2 (Definitions)

The terms used in this Act shall be defined as follows:<Amended by Act No. 13651, Dec. 29, 2015>

1. The term "human subjects research project" means a research project specified by Ordinance of the Minister of Health and Welfare, such as a research project physically involving a human being as a subject, a research project conducted through communication, physical contact or other means of interaction, a research project conducted by using information with which individuals can be identified;
2. The term "human subject of research" means a person who is the subject of a human subjects research project;
3. The term "embryo" means a fertilized human ovum or a group of cells divided during a period from the time such ovum is fertilized until the time all organs are embryologically formed;
4. The term "residual embryo" means an embryo remaining after embryos produced as a consequence of artificial insemination are used for pregnancy;
5. The term "residual ovum" means a human ovum left over after ova are used for artificial insemination;
6. The term "somatic-cell nuclear transplantation" means that a human somatic nucleus is transplanted into a human ovum with its own nucleus removed;

7. The term "parthenogenesis" means a process through which a human ovum is divided into cells aside from the process of fertilization;
8. The term "somatic-cell cloning embryo" means a group of cells produced by somatic-cell nuclear transplantation;
9. The term "parthenogenic embryo" means a group of cells produced by parthenogenesis;
10. The term "embryonic stem cell line" means a cell line derived from an embryo, somatic-cell cloning embryo, or parthenogenic embryo, which can constantly multiply in culturable conditions and can be divided into various cells;
11. The term "human material" means a component of the human body, such as a tissue, a cell, blood, or body fluid collected or extracted from the human body, or serum, plasma, chromosomes, DNA (Deoxyribonucleic Acid), RNA (Ribonucleic Acid), protein, etc. isolated from such component;
12. The term "human materials research project" means a research project on human materials through direct examination and analysis;
13. The term "human material bank" means an institution that extracts and preserves human materials or genetic information, relevant epidemiological information, and clinical information so as to directly use such derivatives or information or provide them to other persons;
14. The term "genetic information" means information obtained by analyzing the genetic characteristics of human materials of an individual;
15. The term "genetic test" means a test conducted to obtain genetic information from a human material for identifying an individual or for preventing, diagnosing, or treating a disease;
16. The term "gene therapy" means a series of procedures to alter genes in the body for the purpose of preventing or treating a disease, or to transfer hereditary substances or cells to which hereditary substances are introduced, to the body;
17. The term "personally identifiable information" means information with which an individual can be identified, such as the name, resident registration number, etc. of a human subject of research or the donor of an embryo, ovum, sperm, or human material (hereinafter referred to as "human subject of research or donor");
18. The term "personal information" means information about an individual, such as personally identifiable information, genetic information, or information about health;

19. The term "anonymization" means the deletion of personally identifiable information permanently or full or partial substitution of personally identifiable information with an identification code given by an institution involved.

Article 3 (Basic Principles) (1) No activity regulated under this Act shall be conducted in any manner that violates the dignity and values of a human being, and priority shall be given to human rights and welfare of each human subject of research or donor.

(2) Self-determination of each human subject of research or donor shall be respected, and the voluntary consent of a human subject of research or donor shall be supported by adequate information.

(3) Privacy of each human subject of research or donor shall be protected, and personal information likely to lead to the invasion of privacy shall be protected as confidential information, except where the relevant party consents to disclosure or an Act expressly permits disclosure.

(4) Full consideration shall be given to the safety of each human subject of research or donor, and risks shall be minimized.

(5) An individual or group in vulnerable conditions shall be specially protected.

(6) International cooperation shall be promoted as necessary to ensure bioethics and biosafety, and a person conducting such activities shall endeavor to adopt universal norms.

Article 4 (Scope of Application) (1) Except as otherwise expressly provided for in any other Act, bioethics and biosafety shall be governed by this Act.

(2) When it is intended to enact or amend any other Act providing for bioethics and biosafety, endeavors shall be made to ensure that such Act accords with this Act.

Article 5 (Responsibilities of State and Local Governments) (1) The State and local governments shall formulate policies necessary to efficiently address bioethics and biosafety issues.

(2) The State and local governments shall formulate schemes to provide administrative and financial support to research and activities relating to bioethics and biosafety.

(3) The State and local governments shall ensure that educational institutions at various levels provide educational programs for bioethics and biosafety, develop educational programs, and assist such educational programs in developing good educational conditions for such purpose.

Article 6 (Designation of Bioethics Policy Research Centers) (1) In order to conduct specialized surveys, research, education, etc. with respect to policies on bioethics, the Minister of Health and Welfare may designate an institution, organization, or facility as a bioethics policy research center, if he/she discovers that the institution, organization, or facility is capable of conducting such activities.

(2) Matters necessary for designating or operating a bioethics policy research center under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

CHAPTER II NATIONAL BIOETHICS COMMITTEE, INSTITUTIONAL BIOETHICS COMMITTEES, ETC.

SECTION 1 National Bioethics Committee

Article 7 (Establishment and Functions of National Bioethics Committee) (1) In order to deliberate on the following matters regarding bioethics and biosafety, the National Bioethics Committee (hereinafter referred to as the "National Committee") shall be established as a presidential committee:

1. Establishment of basic national policies on bioethics and biosafety;
2. Affairs assigned to joint institutional bioethics committees under Article 12 (1) 3;
3. Exemption from the examination of a human subjects research project under Article 15 (2);
4. Making and preservation of records and disclosure of information under Article 19 (3);
5. Research for which it is permitted to use residual embryos under Article 29 (1) 3;
6. Categories, subject-matter, and the scope of research under Article 31 (2);
7. Research for which it is permitted to use embryonic stem cell lines under Article 35 (1) 3;
8. Exemption from the examination of research on human materials under Article 36 (2);
9. Restrictions on genetic test under Article 50 (1);
10. Other matters tabled by the chairperson of the National Committee deemed likely to substantially affect society in connection with bioethics and biosafety.

(2) The chairperson of the National Committee shall introduce a bill, submitted by at least one-third of current members regarding a matter specified in any provision of paragraph (1) 1 through 9, to a meeting of the National Committee.

Article 8 (Composition of National Committee) (1) The National Committee shall be comprised of at least 16 and not more than 20 members, including one chairperson and one vice chairperson. <Amended by Act No. 11690, Mar. 23, 2013>

(2) The chairperson shall be appointed or commissioned by the President of the Republic of Korea from among members, and the vice chairperson shall be elected by and from among members.

(3) The National Committee shall be comprised of the following members:<Amended by Act No. 11690, Mar. 23, 2013; Act No. 12844, Nov. 19, 2014; Act No. 14839, Jul. 26, 2017>

1. The Minister of Education, the Minister of Science and ICT, the Minister of Education, the Minister of Justice, the Minister of Trade, Industry and Energy, the Minister of Health and Welfare, and the Minister of Gender Equality and Family;
2. Not more than seven persons commissioned by the President of the Republic of Korea from among persons who have abundant expertise and experience in research on bioscience, biomedical science, or social science;
3. Not more than seven persons commissioned by the President of the Republic of Korea from among representatives of religions, ethics circles, judicial circles, non-governmental organizations (referring to nonprofit non-governmental organizations defined in Article 2 of the Assistance for Non-Profit, Non-Governmental Organizations Act) or women.

(4) Each member specified in paragraphs (3) 2 and 3 shall hold office for a term of three years and may be appointed consecutively for further terms: Provided, That the term of office of a member newly commissioned to fill a vacancy shall be the remaining term of his/her predecessor.

(5) The National Committee shall have two secretaries, comprised of the Minister of Science and ICT and the Minister of Health and Welfare, and the Minister of Health and Welfare shall also serve as senior secretary.<Amended by Act No. 11690, Mar. 23, 2013; Act No. 14839, Jul. 26, 2017>

(6) In order to support the business affairs, including the management of administrative affairs, of the National Committee, the Minister of Health and Welfare may designate a specialized institution related to bioethics and safety and require the institution to serve as a secretariat, as prescribed by Ordinance of the Ministry of Health and Welfare.<Newly Inserted by Act No. 12447, Mar. 18, 2014>

Article 9 (Operation of National Committee) (1) The National Committee may organize specialized committees for its efficient operation.

(2) The senior secretary shall take charge of administrative affairs of the National Committee.

(3) Meetings and activities of the National Committee shall be independent and generally open to the public.

(4) The National Committee may request parties to a case to make an appearance and make oral statements or submit information. A person so demanded shall comply with such request, unless justifiable grounds exist.

(5) Except as provided for in this Act, the organization and operation of the National Committee and special committees and other necessary matters shall be prescribed by Presidential Decree.

SECTION 2 Institutional Bioethics Committees

Article 10 (Establishment and Functions of Institutional Bioethics Committees) (1) An institution specified in any of the following subparagraphs shall establish an institutional bioethics committee (hereinafter referred to as "institutional committee") so as to ensure bioethics and biosafety:

1. An educational institution, research institute, or hospital, to which a person who conducts a human subjects research project (hereinafter referred to as "human subjects researcher") belongs;
2. An educational institution, research institute, or hospital, to which a person who conducts a human materials research project (hereinafter referred to as "human materials researcher") belongs;
3. A medical institution designated under Article 22 (1) as specializing in producing embryos;
4. A research institute registered pursuant to Article 29 (2) as specializing in embryos;
5. A research institute registered pursuant to Article 31 (3) as specializing in somatic-cell cloning embryos, etc.;
6. A human material bank with permission from the Minister of Health and Welfare under Article 41 (1);

7. Other institutions specified by Ordinance of the Ministry of Health and Welfare as institutions likely to substantially affect society in connection with bioethics and biosafety.

(2) Notwithstanding paragraph (1), an institution shall be deemed to have an institutional committee, if it has entered into an agreement with the institutional committee of an institution or a joint institutional bioethics committee under Article 12 (1) to entrust the execution of affairs assigned to its institutional committee established pursuant to paragraph (3) and Article 11 (4), as prescribed by Ordinance of the Ministry of Health and Welfare.

(3) An institutional committee shall take charge of the following affairs:

1. Examination of the following matters:
   (a) Ethical and scientific validity of a research plan;
   (b) Whether consent has been duly obtained from human subjects of research or donors;
   (c) Matters regarding the safety of human subjects of research or donors;
   (d) Measures for protecting personal information of human subjects of research or donors;
   (e) Other matters regarding bioethics and biosafety in the relevant institution;
2. Inspection and supervision of the progress and outcomes of research projects executed by the relevant institution;
3. The following activities for bioethics and biosafety:
   (a) Education of researchers and employees of the relevant institution;
   (b) Formulation of measures for protecting human subjects of research or donors in a vulnerable position;
   (c) Establishment of ethical guidelines for researchers.

(4) An institution that has established an institutional committee pursuant to paragraph (1) shall register the institutional committee with the Minister of Health and Welfare.

(5) Functions of an institutional committee and matters necessary for the registration under paragraphs (3) and (4) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 11 (Composition, Operation, etc. of Institutional Committees) (1) An institutional committee shall be comprised of at least five members, including one chairperson, with mixed gender, and shall include at least one person who has sufficient experience and knowledge to evaluate social and ethical validity and at least one person from outside of

the relevant institution.

(2) Members of an institutional committee shall be commissioned by the head of the relevant institution specified in any subparagraph of Article 10 (1), and the committee chairperson shall be elected by and from among the members.

(3) No member involved in a case of research, development, or use subject to examination shall participate in the examination of the relevant case of research, development, or use.

(4) If the head of an institution specified in any subparagraph of Article 10 (1) discovers that a serious accident has occurred, or is likely to occur, to affect bioethics or biosafety, he/she shall convene a meeting of the competent institutional committee promptly for deliberation and shall report to the Minister of Health and Welfare on the results of the deliberation.

(5) The head of an institution specified in any subparagraph of Article 10 (1) shall ensure that the competent institutional committee maintains independence and shall provide administrative and financial support to the committee.

(6) An institution that has two or more institutional committees established pursuant to Article 10 (1) may integrate such institutional committees for efficient operation, as prescribed by Ordinance of the Ministry of Health and Welfare.

(7) Except as provided for in paragraphs (1) through (6), matters necessary for organizing and operating an institutional committee shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 12 (Designation of Joint Institutional Bioethics Committee and Joint Operation of Institutional Committees) (1) In order to permit an institutional committee established pursuant to Article 10 (1) to execute the following affairs, the Minister of Health and Welfare may designate such institutional committee as a joint institutional bioethics committee that institutions or researchers may jointly use (hereinafter referred to as "joint committee"):

1. Affairs entrusted by an institution under an agreement made with the joint committee pursuant to Article 10 (2);
2. Affairs requested by a human subjects researcher or human materials researcher affiliated with any educational institution, research institute, or hospital;
3. Other affairs specified by Ordinance of the Ministry of Health and Welfare through deliberation by the National Committee.

(2) Where two or more institutions execute a joint research project and it is found inappropriate for the institutional committee of each institution involved in the research project to examine the project separately, the institutions involved may select one of their institutional committees to authorize it to exclusively examine the research project.

(3) Matters necessary for the designation, functions, and operation of a joint committee and the joint operation of an institutional committee under paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 13 (Support, etc. to Institutional Committees) (1) In order to appropriately supervise and support the operation of institutional committees, the Minister of Health and Welfare shall take charge of the following affairs:

1. Inspection of institutional committees;
2. Education of members of institutional committees;
3. Other affairs specified by Ordinance of the Ministry of Health and Welfare as necessary to supervise and support institutional committees.

(2) Matters necessary for inspection of institutional committees and support to education shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 14 (Evaluation and Accreditation of Institutional Committees) (1) The Minister of Health and Welfare may evaluate and accredit the organization, operation performance, etc. of each institutional committee regularly.

(2) The Minister of Health and Welfare may publish the results of accreditation of an institutional committee accredited under paragraph (1) through a web-site or by other means.

(3) The head of a central administrative agency may subsidize an institution's budget or take a measure to restrict provision of subsidies for research expenses, based on the results of accreditation under paragraph (1).

(4) If an institutional committee accredited under paragraph (1) falls under any of the following subparagraphs, the Minister of Health and Welfare may revoke its accreditation: Provided, That the Minister of Health and Welfare shall revoke accreditation in cases falling under subparagraph 1:

1. If an institutional committee obtains accreditation by fraud or other misconduct;
2. If an institutional committee ceases to meet a standard for accreditation under paragraph (5) because of a significant change in the organization or operation of the

institutional committee.

(5) Matters necessary for the standards for accreditation referred to in paragraph (1) and the period for validity of such accreditation shall be prescribed by Ordinance of the Ministry of Health and Welfare.

CHAPTER III RESEARCH ON HUMAN SUBJECTS AND PROTECTION OF HUMAN SUBJECTS OF RESEARCH

Article 15 (Examination of Research on Human Subjects) (1) A person who intends to conduct research on human subjects shall prepare a research plan and submit it for examination by the competent institutional committee before commencing research on human subjects.

(2) Notwithstanding paragraph (1), a research project may be exempted from examination by the competent institutional committee, if a risk to human subjects of research and the general public is insignificant and the research project meets the standards prescribed by Ordinance of the Ministry of Health and Welfare through deliberation by the National Committee.

Article 16 (Consent to Research on Human Subjects) (1) A human subjects researcher shall obtain written consent (including consent by an electronic document; hereinafter the same shall apply) regarding the following matters from human subjects of research before commencing a human subjects research project:

1. Objectives of the human subjects research project;
2. Duration, procedure for, and methods of participation of human subjects of research;
3. Foreseen risks and benefits to human subjects of research;
4. Protection of personal information;
5. Compensation for losses incurred through participation in the research project;
6. Provision of personal information;
7. Withdrawal of consent;
8. Other matters the competent institutional committee deems necessary.

(2) Notwithstanding paragraph (1), where a research project is to involve a person incapable of, or incompetent for, giving consent as a human subject of research, as specified by Ordinance of the Ministry of Health and Welfare, his/her representative specified in any of the following subparagraphs shall give written consent thereto. A

representative's consent in such cases must not be contrary to the intention of the relevant human subject of research:

1. The legal representative;
2. If no legal representative is appointed, the spouse or a lineal ascendant or descendant shall act as an agent for such person in the abovementioned order, but if there are two or more lineal ascendants or descendants, the representative for such person shall be appointed under agreement by and between such ascendants or descendants, or the oldest person among them shall act as the representative for such person if they fail to reach an agreement.

(3) Notwithstanding paragraph (1), a research project may be exempted from obtaining written consent of a human subject of research, subject to approval from the competent institutional committee, if the research project satisfies all the following prerequisites. In such cases, a research project shall not be exempted from obtaining written consent of the representative under paragraph (2):

1. If it is determined that obtaining consent from a human subject of research is impracticable in the course of research or is likely to seriously affect the validity of research;
2. If there is no ground to find that a human subject of research will decline consent or the risk to a human subject of research is very low even if the project is exempted from consent.

(4) A human subjects researcher shall fully explain the matters specified in paragraph (1) to a person having the right to consent before obtaining written consent from him/her pursuant to paragraphs (1) and (2).

Article 17 (Measures for Safety of Human Subjects of Research) (1) A human subjects researcher shall assess the physical and mental impact of a research project and the research environment on human subjects of research and prepare safety measures before commencing the research project, and if he/she discovers that a research project in progress is likely to cause a serious harm to an individual or society, he/she shall immediately report thereon to the head of the institution, to which he/she belongs, and take appropriate measures therefor.

(2) No human subjects researcher shall delay medical treatment necessary to a human subject of research or deprive a human subject of research of an opportunity for diagnosis

or prevention of a disease in the course of research relating to the diagnosis, treatment, or prevention of a disease.

Article 18 (Provision of Personal Information) (1) When a human subject of research gives written consents to providing his/her personal information to a third party pursuant to Article 16 (1), the relevant human subjects researcher may provide his/her personal information to a third party, subject to examination thereof by the competent institutional committee.

(2) When a human subjects researcher intends to provide personal information about a human subject of research to a third party under paragraph (1), he/she shall anonymize such personal information: Provided, That the foregoing shall not apply where a human subject of research consents to leaving his/her personally identifiable information therein.

Article 19 (Preservation of Records and Disclosure of Information) (1) A human subjects researcher shall keep and preserve records about matters regarding a human subjects research project.

(2) A human subject of research may request the relevant human subjects researcher to disclose information about him/her, and the human subjects researcher so requested shall disclose relevant information, except in exceptional circumstances.

(3) Further details about the keeping and preservation of records and the disclosure of information under paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare, subject to prior deliberation by the National Committee.

CHAPTER IV PRODUCTION OF EMBRYOS, ETC. AND RESEARCH THEREON

SECTION 1 Protection of Human Dignity and Identity

Article 20 (Prohibition of Human Cloning) (1) No person shall implant a somatic-cell cloning embryo or parthenogenic embryo (hereinafter referred to as "somatic-cell cloning embryo") into a human or animal womb or keep such embryo implanted or bear a child therefrom.

(2) No person shall solicit another person to conduct an activity referred to in paragraph (1) or act as a broker for such activity.

Article 21 (Prohibition on Implantation between Different Species) (1) No person shall implant a human embryo into an animal womb or implant an animal embryo into a human womb.

(2) No person shall engage in the following activities:

1. Fertilizing a human ovum with an animal spermatozoon or an animal ovum with a human spermatozoon: Provided, That medical tests for examining the activity of human spermatozoa shall be excluded herefrom;
2. Implanting an animal somatic nucleus into a human ovum with its nucleus removed or a human somatic nucleus into an animal ovum with its nucleus removed;
3. Fusing a human embryo with an animal embryo;
4. Fusing human embryos with different genetic information.

(3) No person shall implant a thing produced from a procedure referred to in any subparagraph of paragraph (2) into a human or animal womb.

SECTION 2 Medical Institutions Producing Embryos

Article 22 (Designation, etc. of Medical Institutions Producing Embryos) (1) A medical institution that intends to extract and preserve ova or spermatozoa or to produce embryos through fertilization shall obtain designation as a medical institution producing embryos from the Minister of Health and Welfare.

(2) A medical institution that intends to be designated as a medical institution producing embryos shall secure facilities and secure human resources, as prescribed by Ordinance of the Ministry of Health and Welfare.

(3) Matters necessary for the standards and procedure for the designation of medical institutions producing embryos shall be prescribed by Ordinance of the Ministry of Health and Welfare.

(4) When a medical institution producing embryos designated under paragraph (1) (hereinafter referred to as "medical institution producing embryos") intends to change an important matter specified by Ordinance of the Ministry of Health and Welfare, it shall report to the Minister of Health and Welfare on such change.

(5) If a medical institution producing embryos temporarily or permanently closes its business, the head of such medical institution shall report thereon to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.

(6) When a medical institution producing embryos temporarily or permanently closes its business, the head of such medical institution shall transfer embryos, reproductive cells,

and relevant documents in its custody to the Korea Centers for Disease Control and Prevention or another medical institution producing embryos, as prescribed by Ordinance of the Ministry of Health and Welfare.

Article 23 (Rules on Production of Embryos) (1) No person shall produce an embryo for any purpose other than pregnancy.

(2) No person shall conduct any of the following procedures in producing an embryo:

1. Selecting an ovum and spermatozoon for fertilization with intent to choose a particular gender;
2. Fertilizing with a decedent's ovum or spermatozoon;
3. Fertilizing with a minor's ovum or spermatozoon: Provided, That cases where a married minor attempts to fertilize in order to have a child shall be excluded herefrom.

(3) No person shall provide or use an embryo, ovum, or spermatozoon for money, an interest in property, or any other consideration, solicit another person to provide or use an embryo, ovum, or spermatozoon for such consideration, or act as a broker for providing or using an embryo, ovum, or spermatozoon.

Article 24 (Consent to Production, etc. of Embryos) (1) When a medical institution producing embryos intends to extract ova or spermatozoa in order to produce embryos, it shall obtain written consent to the following matters from the donor of the ova or spermatozoa, the person into whom an externally fertilized ovum is to be implanted and the spouse of the donor or the person to undergo such implantation, if the donor or the person to undergo such implantation has a spouse: Provided, That if a person involved has a disability, heed shall be given to the person's particular conditions in seeking for consent to such activity:

1. Objectives of producing embryos;
2. Preservation period of embryos, ova, or spermatozoa and other matters regarding preservation;
3. Disuse of embryos, ova, or spermatozoa;
4. Use of residual embryos or ova for the purpose of research;
5. Alteration to, or withdrawal of, consent;
6. Protection of rights of the person with the right to consent and information about such person and other matters specified by Ordinance of the Ministry of Health and Welfare.

(2) A medical institution producing embryos shall fully explain matters specified in paragraph (1) to persons with the right to consent before obtaining written consent pursuant to paragraph (1).

(3) Matters necessary for the form of the written consent specified in paragraph (1) and the preservation of such consent shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 25 (Preservation and Discard of Embryos) (1) The period for preservation of embryos shall be five years: Provided, That if the period set by a person with a right to consent is less than five years, embryos shall be preserved only for such period.

(2) Notwithstanding paragraph (1), the person with a right to consent may extend the preservation period beyond five years in cases specified by Ordinance of the Ministry of Health and Welfare, such as an anticancer therapy.

(3) A medical institution producing embryos shall discard embryos that will not be used for the purpose of research pursuant to Article 29, among embryos for which the preservation period set under paragraph (1) or (2) ends.

(4) A medical institution producing embryos shall keep and preserve records of details about the discarding of embryos.

(5) The procedure and methods for discarding embryos under paragraphs (3) and (4) and matters necessary for the keeping and preservation of records of details about the discarding of embryos shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 26 (Provision of Residual Embryos or Ova) (1) Where a medical institution producing embryos provides residual embryos necessary to research to an embryo research institute with an embryo research plan approved pursuant to Article 30 (1) or residual ova to a research institute with a research plan approved regarding somatic-cell cloning embryos pursuant to Article 31 (4), it shall provide such research institute with embryos or ova free of charge: Provided, That a medical institution producing embryos may request a research institute, to whom residual embryos or ova are provided, to reimburse it for expenses incurred in preserving and providing such embryos or ova, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) The procedure for providing residual embryos or ova under paragraph (1), the calculation of expenses therefor, and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

(3) A medical institution producing embryos shall report details about the preservation and provision of residual embryos or ova to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.

Article 27 (Protection, etc. of Donors of Ova) (1) A medical institution producing embryos shall examine the health of an ova donor before it extracts ova from her, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) No medical institution producing embryos shall extract ova from a person whose health fails to meet a standard prescribed by Ordinance of the Ministry of Health and Welfare.

(3) No medical institution producing embryos shall extract ova from one and the same donor in excess of the frequency specified by Presidential Decree.

(4) A medical institution producing embryos may pay an ova donor an amount specified by Ordinance of the Ministry of Health and Welfare for the items specified by Ordinance of the Ministry of Health and Welfare, including compensation for the time required for the operation necessary to donate ova and for recovery from the operation and travel expenses.

Article 28 (Compliance of Medical Institutions Producing Embryos) (1) A medical institution producing embryos shall comply with the following rules:

1. A medical institution producing embryos shall comply with the terms and conditions of the written consent obtained pursuant to Article 24 in handling embryos, ova, or spermatozoa;
2. A medical institution producing embryos shall strictly adhere to the Ordinance of the Ministry of Health and Welfare in preserving, handling, discarding, and managing residual embryos or ova;
3. Other rules prescribed by Ordinance of the Ministry of Health and Welfare as necessary to ensure bioethics and biosafety.

(2) In order to appropriately manage consents to the production of embryos, the Minister of Health and Welfare shall determine guidelines for the standard operation of medical institutions producing embryos and advise the medical institutions producing embryos to

comply therewith.<Newly Inserted by Act No. 13651, Dec. 29, 2015>

SECTION 3 Research on Residual Embryos, etc.

Article 29 (Research on Residual Embryos) (1) A residual embryo for which the preservation period set under Article 25 ends may be used externally for any of the following purposes of research only until the primitive streak appears embryologically:

1. Research for the development of therapies for infertility and technology for contraception;
2. Research on therapies for muscular dystrophy or other rare or incurable diseases specified by Presidential Decree;
3. Research specified by Presidential Decree through deliberation by the National Committee.

(2) A person who intends to conduct research on residual embryos under paragraph (1) shall secure facilities and human resources specified by Ordinance of the Ministry of Health and Welfare and shall register his/her establishment as an embryo research institute with the Minister of Health and Welfare.

(3) If an embryo research institute registered pursuant to paragraph (2) (hereinafter referred to as "embryo research institute") intends to change an important matter specified by Ordinance of the Ministry of Health and Welfare or close its business permanently, it shall report thereon to the Minister of Health and Welfare.

Article 30 (Approval of Plans for Research on Embryos) (1) If an embryo research institute intends to conduct research on residual embryos, it shall submit a plan for research on embryos to the Minister of Health and Welfare for approval. The same shall apply when it intends to change an important matter specified in Presidential Decree and included in a plan for research on embryos.

(2) A plan for research on embryos under paragraph (1) shall be accompanied by documents about the results of examination by the competent institutional committee.

(3) Upon receipt of a plan for research on embryos from an embryo research institute that the head of any other central administrative agency subsidizes for research expenses, the Minister of Health and Welfare shall consult thereon with the head of the central administrative agency before determining whether to approve the plan.

(4) The standards and procedure for approval of a plan for research on embryos, documents required therefor, and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 31 (Research on Somatic-Cell Cloning Embryos, etc.) (1) No person shall engage in somatic-cell nuclear transplantation or parthenogenesis for any purpose other than research on a therapy for a rare or incurable disease under Article 29 (1) 2.

(2) The categories, targets, and scope of research under paragraph (1) shall be prescribed by Presidential Decree through deliberation by the National Committee.

(3) A person who intends to produce, or conduct research on, somatic-cell cloning embryos shall secure facilities and human resources specified by Ordinance of the Ministry of Health and Welfare and register its establishment with the Minister of Health and Welfare.

(4) If an institution registered pursuant to paragraph (3) (hereinafter referred to as "research institute for somatic-cell cloning embryos") intends to produce, or conduct research on, somatic-cell cloning embryos, it shall submit a research plan (hereinafter referred to as "plan for research on somatic-cell cloning embryos") to the Minister of Health and Welfare for approval, as prescribed by Ordinance of the Ministry of Health and Welfare.

(5) Article 30 shall apply mutatis mutandis to approval of a plan for research on somatic-cell cloning embryos. In such cases, the term "residual embryos" shall be construed as "somatic-cell cloning embryos", and the term "plan for research on embryos" as "plan for research on somatic-cell cloning embryos", respectively.

Article 32 (Compliance of Embryo Research Institutes) (1) When a serious accident occurs, or is likely to occur, to bioethics or biosafety as a consequence of research executed by an embryo research institute or a research institute for somatic-cell cloning embryos, the research institute shall discontinue research or take other appropriate measures.

(2) Article 25 (3) through (5) shall apply mutatis mutandis where an embryo research institute or a research institute for somatic-cell cloning embryos intends to disuse residual embryos or ova for the purpose of research after it acquires such embryos or ova. In such cases, the term "embryos" shall be construed as "residual embryos or ova".

(3) Article 28 shall apply mutatis mutandis where an embryo research institute manages residual embryos or where a research institute for somatic-cell cloning embryos manages residual ova or somatic-cell cloning embryos.

SECTION 4 Embryonic Stem Cell Lines

Article 33 (Registration of Embryonic Stem Cell Lines) (1) A person who establishes or imports embryonic stem cell lines shall either provide such embryonic stem cell lines to a third person pursuant to Article 34 or register such embryonic stem cell lines with the Minister of Health and Welfare pursuant to Article 35 before using them, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) If a person who applies for the registration of embryonic stem cell lines has successfully passed a scientific test conducted by the head of any other central administrative agency, the Minister of Health and Welfare shall utilize data from the test in accepting the registration under paragraph (1).

(3) The Minister of Health and Welfare may fully or partially subsidize a person who registers embryonic stem cell lines pursuant to paragraph (1) for expenses incurred in testing the embryonic stem cell lines.

Article 34 (Provision of Embryonic Stem Cell Lines) (1) When a person who has established an embryonic stem cell line intends to provide it to a third person, he/she shall undergo examination by the competent institutional committee, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) A person who provides an embryonic stem cell line to a third person pursuant to paragraph (1) shall report the current status of the provided embryonic stem cell line to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.

(3) An embryonic stem cell line provided pursuant to paragraph (1) shall be free of charge: Provided, That a person who provides an embryonic stem cell line may demand the person to whom it is provided to reimburse him/her for expenses incurred in preserving and providing the embryonic stem cell line, as prescribed by Ordinance of the Ministry of Health and Welfare.

(4) Matters necessary for providing and reporting embryonic stem cell lines under paragraphs (1) through (3) and the method for calculating expenses therefor shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 35 (Use of Embryonic Stem Cell Lines) (1) Embryonic stem cell lines registered pursuant to Article 33 (1) may be used externally only for any of the following research objectives:

1. Research for diagnosis, prevention, or treatment of a disease;
2. Basic research on characteristics and division of stem cells;
3. Other objectives of research specified by Presidential Decree through deliberation by the National Committee.

(2) A person who intends to use an embryonic stem cell line pursuant to paragraph (1) shall submit the relevant research plan to be examined by the competent institutional committee and obtain approval thereof from the head of the relevant institution, as prescribed by Ordinance of the Ministry of Health and Welfare. The same shall also apply where it is intended to change an important matter specified by Presidential Decree in the details of an approved research plan.

(3) A person who has obtained approval of a plan or revised a plan pursuant to paragraph (2) shall report relevant facts to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.

(4) A person who has obtained approval of a plan pursuant to paragraph (2) shall prepare a plan for the use of the provided embryonic stem cell line and shall submit the plan to the person who has provided the embryonic stem cell line.

(5) The head of the institution who approves a research project pursuant to paragraph (2) shall supervise the person who executes the research project so as to ensure that the person complies with the relevant plan in executing the research project.

CHAPTER V RESEARCH ON HUMAN MATERIALS AND HUMAN MATERIAL BANKS

SECTION 1 Research on Human Materials

Article 36 (Examination of Research on Human Materials) (1) A person who intends to conduct research on human materials shall undergo examination of the relevant research plan by the competent institutional committee before commencing the research on human

materials.

(2) Notwithstanding paragraph (1), if a hazard that is likely to be caused by a research project to donors of a human material and to the general public is insignificant and if the research project meets the standards prescribed by Ordinance of the Ministry of Health and Welfare through deliberation by the National Committee, such research project may be exempted from examination by the competent institutional committee.

Article 37 (Consent to Research on Human Materials) (1) A human materials researcher shall obtain written consent regarding the following matters from donors of a human material before commencing the research on human materials:

1. Objectives of the research on human materials;
2. Protection and management of personal information;
3. Preservation and discarding of human materials;
4. Provisions of human materials and genetic information obtained from human materials (hereinafter referred to as "human materials, etc.");
5. Withdrawal of consent, disposal of human materials if consent is withdrawn, the right of the donor of a human material, change of objectives, and other matters specified by Ordinance of the Ministry of Health and Welfare.

(2) Notwithstanding paragraph (1), if a human materials researcher conducts research with a human material provided by a person who is not a human materials researcher, but extracted the human material, the human materials researcher shall be deemed to have obtained written consent pursuant to paragraph (1) at the time the person who extracted the human material obtained written consent from the donor of the human material regarding matters specified in paragraph (1).

(3) Article 16 (3) shall apply to the exemption of research on human materials from written consent. In such cases, the term "human subject of research" shall be construed as "donor of a human material".

(4) A human materials researcher shall fully explain the matters specified in paragraph (1) to a donor of a human material before obtaining written consent from him/her pursuant to paragraph (1).

(5) Matters necessary for the form of written consent under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 38 (Provision of Human Materials, etc.) (1) If a human materials researcher has obtained written consent from a donor of a human material, etc. pursuant to Article 37 (1) regarding the provision of human materials, he/she may provide the human material, etc. to a human material bank or another researcher, subject to examination thereof by the competent institutional committee.

(2) When a human materials researcher provides a human material, etc. to another researcher pursuant to paragraph (1), he/she shall anonymize the human material, etc.: Provided, That the foregoing shall not apply where the donor of the human material consents to leaving personally identifiable information therein.

(3) A human material, etc. provided pursuant to paragraph (1) shall be free of charge: Provided, That the institution to which the researcher providing a human material, etc, may demand the person who conducts research with the provided human material, etc. to reimburse it for expenses incurred in preserving and providing the human material, etc., as prescribed by Ordinance of the Ministry of Health and Welfare.

(4) If a human materials researcher provides a human material, etc. to any person or acquires a human material, etc. provided by any person pursuant to paragraph (1), he/she shall keep and preserve records about the provision of the human material, etc., as prescribed by Ordinance of the Ministry of Health and Welfare.

(5) The method and procedure for providing human materials, etc., the calculation of expenses therefor, and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 39 (Preservation and Discarding of Human Materials, etc.) (1) A human materials researcher shall discard a human material, etc. at the lapse of the duration set in the relevant written consent: Provided, That if a donor of a human material requests the relevant human materials researcher to amend the duration of preservation or discard the human material, the human materials researcher shall comply with such request.

(2) A human materials researcher shall keep and preserve records of details about the discarding of human materials, etc. under paragraph (1), as prescribed by Ordinance of the Ministry of Health and Welfare.

(3) If a human materials researcher is unable to preserve human materials, etc. due to inevitable circumstances, he/she shall dispose of, or transfer, human materials, etc., subject to examination thereof by the competent institutional committee.

(4) Matters necessary for the preservation, discarding, disposal, or transfer of human materials, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 40 (Compliance by Human Materials Researchers)

@Article 17 and 19 shall apply mutatis mutandis to measures for safety of donors of a human material by human materials researchers and preservation of records and disclosure of information of donors of a human material by human materials researchers, respectively. In such cases, the term "human subjects research project" shall be construed as "human materials research project", and the term "human subject of research" as "donors of a human material", respectively.

SECTION 2 Human Material Banks

Article 41 (Permission for, and Reporting of, Human Material Banks) (1) A person who intends to establish a human material bank shall obtain permission therefor from the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare: Provided, That the foregoing shall not apply to a state agency that intends to directly establish a human material bank.

(2) Notwithstanding paragraph (1), if a person who intends to establish a human material bank with approval from the head of a central administrative agency for subsidizing research expenses pursuant to any other Act and subordinate statutes reports thereon to the Minister of Health and Welfare after he/she obtains the approval from the head of the central administrative agency for subsidizing research expenses, such person shall be deemed to have obtained the permission required under paragraph (1). In such cases, the head of the competent central administrative agency shall consult thereon with the Minister of Health and Welfare in advance.

(3) If a human material bank established pursuant to paragraphs (1) and (2) intends to change any important matter specified by Presidential Decree or temporarily or permanently closes its business, it shall report thereon to the Minister of Health and Welfare.

(4) The standards for facilities and equipment of human material banks, the procedures for the permission for, and the reporting of, a human material bank, and other necessary matters shall be prescribed by Presidential Decree.

Article 42 (Consent to Extraction of Human Materials) (1) When a human material bank intends to directly extract a human material for research on the human material or request a third person to extract a human material for such purpose, it shall obtain written consent regarding the following matters from the donor of the human material:

1. Objectives of research on the human material (only applicable where a human material bank directly conduct research on the human material);
2. Protection and disposal of personal information;
3. The scope of researchers and institutions to which the human material, etc. shall be provided;
4. Preservation, management, and discarding of the human material, etc.;
5. Withdrawal of consent, disposal of the human material, etc. when consent is withdrawn, rights of the donor of the human material, and other matters specified by Ordinance of the Ministry of Health and Welfare.

(2) A human material bank shall fully explain the matters specified in paragraph (1) to a donor of a human material before obtaining written consent pursuant to paragraph (1).

(3) Matters necessary for the form of the written consent pursuant to paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 43 (Provision of Human Materials, etc.) (1) The head of a human material bank shall require a person who intends to acquire a human material, etc. to submit a plan for the use of the human material, etc. and examine the plan to determine whether to provide the human material, etc.

(2) Where the head of a human material bank provides a human material, etc. to a person, he/she shall anonymize the human material, etc.: Provided, That the foregoing shall not apply where the donor of a human material consents to leaving his/her personally identifiable information therein.

(3) A human material, etc. provided to a person by the head of a human material bank shall be free of charge: Provided, That the head of a human material bank may demand a person, to whom a human material, etc. are provided, to reimburse him/her for expenses incurred in preserving and providing the human material, etc., as prescribed by Ordinance of the Ministry of Health and Welfare.

(4) An institutional committee shall formulate guidelines necessary to provide human materials, etc. and shall regularly review whether human materials, etc. are provided

properly in compliance with the guidelines.

(5) Descriptions of a plan for the use of human materials, etc. the procedure for the submission of such plan, the guidelines to provide human materials, etc., the review by an institutional committee, and other matters necessary for providing and managing human materials, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 44 (Compliance of Human Material Banks) (1) The head or an employee of a human material bank shall not use, discard, or destroy human materials, etc. in its custody without justification.

(2) When a human material bank receives a human material, etc. provided pursuant to Article 38 (1) or 53 (1), it shall anonymize the human material, etc.

(3) Article 39 shall apply mutatis mutandis to the preservation and discarding of human materials, etc. by a human material bank.

(4) The head of a human material bank shall formulate guidelines for the protection of personal information, including schemes for anonymizing human materials, etc., as prescribed by Ordinance of the Ministry of Health and Welfare, and shall designate a manager in charge of the management and security of personal information.

Article 45 (Support to Human Material Banks)

The State or a local government may subsidize a human material bank, within the budget, for expenses incurred in operation.

CHAPTER VI GENE THERAPY, TESTING, ETC.

Article 46 (Prohibition, etc. of Discrimination Based on Genetic Information) (1) No person shall discriminate against any person on the ground of genetic information in education, employment, promotion, insurance, or any other social activity.

(2) Except as otherwise expressly provided for in any other Act, no person shall compel any person to undergo a genetic test or to submit the results of a genetic test.

(3) No medical institution shall include genetic information in medical records or therapy records provided to any person other than the patient him/herself pursuant to Article 21 (3) of the Medical Service Act: Provided, That the foregoing shall not apply where another medical request to provide such records for the purpose of diagnosis or treatment of the

same disease as the disease of the patient involved and measures for protecting personal information are taken.<Amended by Act No. 14438, Dec. 20, 2016>

Article 47 (Gene Therapy) (1) Research on a gene therapy that falls into a series of procedures to alter genes in the body may be conducted in cases that meet both of the following conditions: <Amended by Act No. 13651, Dec. 29, 2015>

1. Research on a therapy for a hereditary disease, Acquired Immune Deficiency Syndrome (AIDS), or any other disease that threatens one's life or causes a severe disability;
2. Research on a therapy where there is no applicable therapy at present or the effect of a gene therapy is expected to be significantly better than other therapies.

(2) Research on a gene therapy that falls into a series of procedures to transfer hereditary substances or cells to which hereditary substances are introduced, to the body may be conducted only when falling under either paragraph (1) 1 or 2.<Newly Inserted by Act No. 13651, Dec. 29, 2015>

(3) No gene therapy shall be applied to an embryo, ovum, or fetus.

Article 48 (Gene Therapy Institutions) (1) A medical institution that intends to apply a gene therapy shall report thereon to the Minister of Health and Welfare. The same shall also apply where it is intended to change an important matter specified by Presidential Decree.

(2) A medical institution that reported on its business to the Minister of Health and Welfare pursuant to paragraph (1) (hereinafter referred to as "gene therapy institution") shall explain the following matters to each patient to whom it intends to apply a gene therapy and shall obtain written consent thereto:

1. Objectives of the therapy;
2. Expected results and side-effects of the therapy;
3. Other matters specified by Ordinance of the Ministry of Health and Welfare.

(3) The conditions and procedure for the reporting of gene therapy institutions, the form of the written consent, and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 49 (Genetic Testing Institutions) (1) A person who intends to conduct genetic tests shall secure facilities, human resources, etc. specified by Ordinance of the Ministry of Health and Welfare and report his/her business to the Minister of Health and Welfare: Provided, That the foregoing shall not apply to a State agency that intends to conduct

genetic tests.

(2) A change to any important matters specified by Presidential Decree, among matters reported pursuant to paragraph (1), shall be also reported.

(3) The Minister of Health and Welfare may require a genetic testing institution that reported on its business pursuant to paragraph (1) (hereinafter referred to as "genetic testing institution") to undergo the evaluation of accuracy of genetic tests, as prescribed by Ordinance of the Ministry of Health and Welfare, and may disclose the results thereof to the public.

(4) Where a genetic testing institution intends to close its genetic testing business temporarily or permanently, it shall report thereon to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.

(5) If a genetic testing institution has filed a business closure report with the head of the competent tax office pursuant to Article 8 of the Value-Added Tax Act or if the head of the competent tax office has cancelled the business registration of a genetic testing institution, the Minister of Health and Welfare may ex officio delete records of the reporting of the genetic testing institution.<Amended by Act No. 15188, Dec. 12, 2017>

(6) The Minister of Health and Welfare may, where necessary to delete the reported matters ex officio under paragraph (5), request the head of the competent tax office to furnish information on whether the genetic testing institution has permanently closed its business. In this case, the head of the competent tax office in receipt of the request shall provide the information in accordance with Article 36 (1) of the Electronic Government Act. <Newly Inserted by Act No. 15188, Dec. 12, 2017>

Article 50 (Restrictions, etc. on Genetic Tests) (1) No genetic testing institution shall conduct any genetic test for physical appearance or character, which has no reliable scientific proof and is likely to mislead the testee, or any other genetic test specified by Presidential Decree through deliberation by the National Committee.

(2) A genetic testing institution may conduct a genetic test for an embryo or fetus only for diagnosing muscular dystrophy or any other hereditary disease specified by Presidential Decree.

(3) No genetic testing institution, other than a medical institution, shall conduct a genetic test in connection with the prevention, diagnosis, or treatment of a disease unless it falls under the following cases:<Amended by Act No. 13651, Dec. 29, 2015>

1. Where it is requested by a medical institution;
2. Where it conducts a genetic test related to the prevention of a disease, the necessity of which is recognized by the Minister of Health and Welfare.

(4) No genetic testing institution shall make a misrepresentation or an exaggerative advertisement regarding genetic tests. The standards and procedure for judgment on misrepresentation or exaggerative advertising and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 51 (Consent to Genetic Testing) (1) When a genetic testing institution intends to extract a material to be used for a genetic test on a testee or request a third person to extract such material from a testee, it shall obtain written consent from the testee regarding the following matters before extracting the material for testing: Provided, That if a testee has a disability, heed shall be given to the person's particular conditions in seeking for consent:

1. Objectives of the genetic test;
2. Management of the material for testing;
3. Withdrawal of consent, the protection of rights and information of the test, and other matters specified by Ordinance of the Ministry of Health and Welfare.

(2) If a genetic testing institution intends to provide a material for testing to a human material researcher or a human material bank, it shall obtain written consent regarding the following matters in addition to the consent under paragraph (1):

1. Protection and disposal of personal information;
2. Preservation, management, and discarding of the material for testing;
3. Provision of the material for testing;
4. Withdrawal of consent, disposal of the material for testing when consent is withdrawn, rights of the testee, and other matters specified by Ordinance of the Ministry of Health and Welfare.

(3) When any person, other than a genetic testing institution, extracts a material for testing and requests a genetic testing institution to conduct a genetic test, he/she shall present written consent obtained for the test to the genetic testing institution pursuant to paragraph (1) and shall take measures for protecting personal information, as prescribed by Ordinance of the Ministry of Health and Welfare.

(4) Article 16 (2) shall apply mutatis mutandis to consent by an agent where a testee is incompetent or quasi-incompetent to consent. In such cases, the term "human subject of research" shall be construed as "testee", and the term "research" as "testing", respectively.

(5) Consent is not required for genetic testing in either of the following cases:

1. Where it is urgently or specially required to identify who is a corpse or an unconscious person;
2. Where any other Act requires genetic testing.

(6) A person who intends to obtain written consent pursuant to paragraphs (1) through (4) shall fully explain the objectives and method of the genetic test and the expected results and significance of the genetic test to the testee or his/her representative by law.

(7) The method for consenting to a genetic test, the exemption from consent, and other necessary matters shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 52 (Preservation of Records and Disclosure of Information) (1) A genetic testing institution shall record and preserve the following documents, as prescribed by Ordinance of the Ministry of Health and Welfare:

1. A written consent under Article 51;
2. Reports on the results of genetic tests;
3. Records about the provision of materials for testing under Article 53 (2).

(2) Where a testee or his/her legal representative requests a genetic testing institution to allow him/her to inspect the records specified in paragraph (1) or provide copies of such records, the genetic testing institution shall comply with such request.

(3) The procedure for applying for the inspection of records or the issuance of copies under paragraph (2) and the form of such application shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 53 (Provision, Discarding, etc. of Materials for Testing) (1) If a genetic testing institution obtains written consent to the provision of a material for testing from a testee under Article 51 (2), it may provide the material for testing to a human material researcher or human material bank.

(2) Article 38 (2) through (5) shall apply mutatis mutandis to the provision of materials for testing under paragraph (1). In such cases, the term "human materials, etc." shall be construed as "materials for testing", and "donor of a human material" as "testee",

respectively.

(3) Except materials for testing to be provided under paragraph (1), a genetic testing institution shall discard materials for testing after it obtains results of a genetic test.

(4) A genetic testing institution shall make and preserve records of the details about the discarding of materials for testing.

(5) If a genetic testing institution is unable to preserve materials for testing due to temporary or permanent closure of business or other inevitable circumstances, it shall dispose of materials for testing, or transfer such materials to other person, as prescribed by Ordinance of the Ministry of Health and Welfare.

(6) Matters necessary for the discarding of materials for testing, the making and preservation of records of discarding, the disposal or transfer of materials for testing shall be prescribed by Ordinance of the Ministry of Health and Welfare.

CHAPTER VII SUPERVISION

Article 54 (Reporting and Inspection) (1) If the Minister of Health and Welfare deems it necessary to ensure bioethics and biosafety, he/she may order an institution specified in any subparagraph of Article 10 (1) or a genetic testing institution (hereinafter referred to as "institution subject to supervision") or an employee of any of such institutions to submit a report or data necessary to the enforcement of this Act, as prescribed by Ordinance of the Ministry of Health and Welfare, and may order any of such institutions to discontinue research or the use of outcomes of research, or may take other necessary measures, if a serious accident to bioethics or biosafety has occurred or is likely to occur.

(2) If the Minister of Health and Welfare deems it necessary to ascertain compliance with the provisions of this Act or a violation of any provision of this Act, the Minister of Health and Welfare may authorize an appropriate public official to enter an institution subject to supervision or its office to inspect its facilities, equipment, relevant accounting books or documents, or other things or to query persons involved, and may collect the minimum quantity of samples necessary for testing. In such cases, public officials shall carry an identification certificate indicating their authority and present it to persons involved.

(3) An institution subject to supervision or an employee of such institution shall comply with an order issued, an inspection conducted, or a query raised under paragraph (1) or

(2), unless justification to the contrary is provided.

Article 55 (Order for Discarding or Improvement) (1) The Minister of Health and Welfare may order an institution subject to supervision or any of its employees and a person who registers, provides, or uses an embryonic stem cell line pursuant to Articles 33 through 35 to discard each of the following materials. In such cases, Articles 25 (5), 39 (4), and 53 (6) shall apply mutatis mutandis to the procedure and methods for the discarding:

1. An embryo, somatic-cell cloning embryo, embryonic stem cell line, or ovum extracted, produced, preserved, used for research, or provided in violation of Articles 22 (1) through (3), 23, 24 (1), 25 (3) (including cases to which the aforesaid paragraph shall apply mutatis mutandis under Article 32 (2)), 26 (1), 27 (1) through (3), 29 (1) and (2), 30 (1) through (3), 31 (1), (3), and (4), 33 (1), 34 (1) and (3), and 35 (2);
2. A material for testing or a human material, extracted, preserved, or provided in violation of Articles 39 (1), 41 (1), 43 (2), 49 (1), 50 (1) through (3), 51 (1), (2), and (4), and 53 (1) through (3).

(2) If the Minister of Health and Welfare discovers that an institution subject to supervision fails to meet the standards prescribed in Article 22 (2), 29 (2), 31 (3), or 41 (4) for facilities, human resources, etc. and has caused or is likely to cause serious harm to bioethics or biosafety if it continues research, extraction, preservation, or production of embryos, he/she may order the institution subject to supervision to improve its facilities or discontinue the use of its facilities entirely or partially.

Article 56 (Revocation of Registration, etc. and Suspension of Operation) (1) In any of the following cases, the Minister of Health and Welfare may revoke the designation or registration of an institution subject to supervision or the permission granted to an institution subject to supervision or may order an institution subject to supervision to completely or partially suspend its operation for a specified period not exceeding one year:

1. If an institution subject to supervision violates Articles 10 (1) (excluding cases where an institution falls under subparagraphs 1 and 2 of the aforesaid paragraph), 20, 21, 22 (1) through (3), 23, 24 (1) and (2), 25 (3) and (4) (including cases to which the aforesaid paragraph shall apply mutatis mutandis pursuant to Article 32 (2)), 26 (1) and (3), 27 (1) through (3), 28 (including cases to which the aforesaid Article shall apply mutatis mutandis pursuant to Article 32 (3)), 29 (2), 30 (1), 31 (1), 32 (1), 43 (2), and 44 (1), the

latter part of Article 48 (1), Articles 48 (2), 50, 51 (1) through (4), 52 (1) and (2), 53 (2) through (5);

2. If an institution subject to supervision fails to comply with an order issued under Article 54 (1) or 55;
3. If an institution subject to supervision fails to cooperate in an inspection conducted, a query raised, or collection executed pursuant to Article 54 (2).

(2) Detailed guidelines for administrative actions under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare, taking into consideration the type and degree of each violation.

Article 57 (Hearings)

When the Minister of Health and Welfare intends to revoke the designation or registration of an institution or the permission granted to an institution under Article 56, he/she shall hold a hearing.

Article 58 (Penalty Surcharges) (1) If the Minister of Health and Welfare discovers that an institution subject to supervision falls under any of the following subparagraphs and he/she shall order it to suspend its operation but suspending its operation is likely to cause severe inconvenience to users of its business or undermine public interests, he/she may impose a penalty surcharge not exceeding 200 million won upon such institution in lieu of suspending its operation, as prescribed by Presidential Decree:

1. If an institution subject to supervision violates Articles 22 (1) through (3), 24 (1) and (2), 25 (3) and (4) (including cases to which the aforesaid paragraph shall apply mutatis mutandis under Article 32 (2)), and 27 (1) through (3);
2. If an institution subject to supervision violates any rule prescribed in Article 28 (including cases to which the aforesaid paragraph shall apply mutatis mutandis under Article 32 (3)) or 32 (1);
3. If an institution subject to supervision fails to comply with an order issued under Article 54 (1) or 55;
4. If an institution subject to supervision fails to cooperate in an inspection conducted, a query raised, or collection executed under Article 54 (2).

(2) The amount of a penalty surcharge to be imposed under paragraph (1), based on the type and degree of each violation, shall be prescribed by Ordinance of the Ministry of

Health and Welfare.

(3) If a person obligated to pay a penalty surcharge imposed under paragraph (1) fails to pay it by the payment deadline, such penalty surcharge shall be collected in the same manner as delinquent national taxes are collected.

Article 59 (Fees)

The Minister of Health and Welfare may require a person who intends to obtain designation, permission, registration, or approval under the provisions of this Act, who files a report, or who intends to revise a report to pay fees, as prescribed by Ordinance of the Ministry of Health and Welfare.

CHAPTER VIII SUPPLEMENTARY PROVISIONS

Article 60 (Subsidies from National Treasury)

In order to develop and support research projects and education that can contribute to securing bioethics and biosafety pursuant to this Act, the Minister of Health and Welfare may fully or partially subsidize an appropriate institution or an employee of such institution for expenses incurred in such projects or education, as prescribed by Ordinance of the Ministry of Health and Welfare.

Article 61 (Delegation, Entrustment, etc.) (1) The Minister of Health and Welfare may partially delegate his/her authority granted under this Act to the head of an affiliated agency, as prescribed by Presidential Decree.

(2) The Minister of Health and Welfare may partially entrust any of the following affairs to an appropriate specialized institution or organization, as prescribed by Presidential Decree:

1. Education of members of an institutional committee established pursuant to Article 13 (1) 2;
2. Evaluation and accreditation of an institutional committee established pursuant to Article 14;
3. Evaluation of the accuracy of genetic tests referred to in Article 49 (3).

(3) Where the Minister of Health and Welfare entrusts affairs to an appropriate specialized institution or organization pursuant to paragraph (2), he/she may subsidize such institution or organization for necessary budgetary funding.

(4) Matters necessary for the provision of subsidies of an appropriate specialized institution or organization under paragraph (2) for its budget, the recouping of subsidies, the ban on provision of subsidies, etc. shall be prescribed by Presidential Decree.

Article 62 (Legal Fiction as Public Officials for Purposes of Penalty Provisions)
Executive officers and employees of an institution or organization that engages in affairs entrusted pursuant to Article 61 shall be deemed public officials for the purposes of Articles 129 through 132 of the Criminal Act thereto.

Article 63 (Prohibition of Divulgence, etc. of Confidential Information)
An institution subject to supervision or an employee or former employee of such institution shall not divulge personal information or other confidential information which it or he/she has learned in the course of conducting duties or use such information without authorization.

CHAPTER IX PENALTY PROVISIONS

Article 64 (Penalty Provisions) (1) Any person who implants a somatic-cell cloning embryo to a womb, maintains the state of implantation, bears a child, in violation of Article 20 (1), shall be punished by imprisonment with labor for not more than ten years.
(2) Any person who attempts to commit a crime specified in paragraph (1) shall also be punished.

Article 65 (Penalty Provisions) (1) Any person who implants a human embryo into an animal womb or implants an animal embryo into a human womb, in violation of Article 21 (1), or any person who implants a thing produced from an activity referred to in any subparagraph of Article 21 (2) into a human or animal womb, in violation of Article 21 (3), shall be punished by imprisonment with labor for not more than five years.
(2) Any person who attempts to commit a crime specified in paragraph (1) shall also be punished.

Article 66 (Penalty Provisions) (1) Any of the following persons shall be punished by imprisonment with labor for not more than three years:

1. A person who solicits another person to implant a somatic-cell cloning embryo into a womb or to keep such embryo implanted or to bear a child therefrom or who acts as a broker for such activity, in violation of Article 20 (2);
2. A person who conducts an activity specified in any subparagraph of Article 21 (2);
3. A person who produces an embryo for any purpose other than pregnancy, in violation of Article 23 (1);
4. A person who provides or uses an embryo, ovum, or spermatozoon for money, an interest in property, or any other consideration, who solicits another person to provide or use an embryo, ovum, or spermatozoon for such consideration, or who acts as a broker for providing or using an embryo, ovum, or spermatozoon, in violation of Article 23 (3);
5. A person who engages in somatic-cell nuclear transplantation or parthenogenesis for any purpose other than research on a therapy for a rare or incurable disease, in violation of Article 31 (1);
6. A person who divulges confidential information or who uses confidential information without authorization, in violation of Article 63.

(2) Any person who uses a residual embryo, in violation of Article 29 (1), shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding 50 million won.

(3) Any person who attempts to commit a crime specified in paragraph (1) or (2) shall also be punished.

Article 67 (Penalty Provisions) (1) Any of the following persons shall be punished by imprisonment with labor for not more than two years or by a fine not exceeding 30 million won: <Amended by Act No. 13651, Dec. 29, 2015>

1. A person who conducts an activity referred to in any subparagraph of Article 23 (2) in producing an embryo;
2. A person who extracts ova or spermatozoa without written consent, in violation of Article 24 (1);
3. A person who to examine the health of a an ova donor, in violation of Article 27 (1), or who extracts ova in violation of Article 27 (2) or (3);
4. A person who discriminates against another person on the ground of genetic information, who compels another person to undergo a genetic test or to submit the results of a genetic test, or who leaves genetic information in records provided to any

person other than the patient, in violation of Article 46 (1) through (3);

5. A person who conducts research on a gene therapy or practices a gene therapy, in violation of Article 47 (1) through (3);
6. A person who conducts a genetic test, in violation of Article 50 (1) through (3);
7. A person who fails to comply with an order issued for discarding or improvement under Article 55.

(2) Any person who fails to transfer embryos or reproductive cells, in violation of Article 22 (6), shall be punished by imprisonment with labor for not more than two years or by a fine not exceeding ten million won.

Article 68 (Penalty Provisions)

Any of the following persons shall be punished by imprisonment with labor for not more than one year or by a fine not exceeding 20 million won:

1. A person who extracts and preserves ova or spermatozoa or produces embryos through fertilization without designation, in violation of Article 22 (1) through (3);
2. A person who fails to discard embryos, in violation of Article 25 (3) (including cases to which the aforesaid paragraph shall apply mutatis mutandis pursuant to Article 32 (2));
3. A person who provides residual embryos or ova for consideration, in violation of Article 26 (1);
4. A person who fails to report relevant details to the Minister of Health and Welfare, in violation of Article 26 (3);
5. A person who conducts research on residual embryos without registering his/her establishment as an embryo research institute, in violation of Article 29 (2);
6. A person who conducts research on embryos without obtaining approval of the relevant plan for research on embryos, in violation of Article 30 (1) (including cases to which the aforesaid paragraph shall apply mutatis mutandis pursuant to Article 31 (5));
7. A person who produces, or conducts research on, somatic-cell cloning embryos without registering his/her establishment with the Minister of Health and Welfare, in violation of Article 31 (3);
8. A person who establishes a human material bank without permission, in violation of Article 41 (1);
9. A person who directly extracts a human material, or requests another person to extract a human material, without written consent, in violation of Article 42 (1);

10. A person who makes a misrepresentation or an exaggerative advertisement regarding genetic tests, in violation of Article 50 (4);
11. A person who extracts a material to be used for a genetic test without written consent to the genetic test, in violation of Article 51 (1), (2), or (4), or a person who requests a genetic testing institution to conduct a genetic test without presenting written consent or without taking measures for protecting personal information, in violation of Article 51 (3).

Article 69 (Joint Penalty Provisions) (1) If the representative of a legal entity or an agent, employee, or worker of a legal entity or individual commits an offense specified in any provision of Articles 64 through 66 in the course of business of the legal entity or individual, not only shall such an offender be punished accordingly, but the legal entity or individual also shall be punished by a fine not exceeding 50 million won: Provided, That the foregoing shall not apply where the legal entity or individual has not neglected due care and supervision over the business to prevent such offense.

(2) If the representative of a legal entity or an agent, employee, or worker of a legal entity or individual commits an offense specified in Article 67 or 68 in the course of business of the legal entity or individual, not only shall such an offender be punished accordingly, but the legal entity or individual also shall be punished by the fine specified in the relevant Article: Provided, That the foregoing shall not apply where the legal entity or individual has not neglected due care and supervision over the business to prevent such offense.

Article 70 (Administrative Fines) (1) Any of the following persons shall be punished by an administrative fine not exceeding five million won:

1. A person who fails to establish an institutional committee, in violation of Article 10 (1);
2. A person who provides or uses an embryonic stem cell line without registration, in violation of Article 33 (1);
3. A person who uses an embryonic stem cell line, in violation of Article 35 (1);
4. A person who provides a human material, etc. to any other researcher without anonymizing the human material, etc., in violation of Article 38 (2);
5. A person who fails to discard, dispose of, or transfer a human material as referred to in the main sentence of Article 39 (1) or Article 39 (3) (including cases to which any of the aforesaid paragraphs shall apply pursuant to Article 44 (3));

6. A person who fails to report his/her establishment as required in Article 41 (2);
7. A person who fails to formulate guidelines for the protection of personal information, including schemes for anonymizing human materials, etc., or fails to designate a manager to be in charge of the management and security of personal information, in violation of Article 44 (4);
8. A person who practices a gene therapy without reporting his/her practice, in violation of Article 48 (1);
9. A person who fails to report his/her business pursuant to the main sentence of Article 49 (1);
10. An institution subject to supervision or its employee who fails to comply with an order issued, an inspection conducted, or a query raised by the Minister of Health and Welfare, in violation of Article 54 (3).

(2) Any of the following persons shall be punished by an administrative fine not exceeding three million won:

1. A person who fails to report a change to the Minister of Health and Welfare, in violation of Article 22 (4) or (5) or 29 (3);
2. A person who fails to transfer relevant documents, in violation of Article 22 (6).

(3) Any of the following persons shall be punished by an administrative fine not exceeding two million won:

1. A person who fails to register an institutional committee with the Minister of Health and Welfare, in violation of Article 10 (4);
2. A person who fails to report to the Minister of Health and Welfare on the results of deliberation, in violation of Article 11 (4);
3. A person who provides an embryonic stem cell line for consideration, in violation of Article 34 (3);
4. A person who provides a human material, etc. for consideration, in violation of Article 38 (3);
5. A person who fails to report as required under Article 41 (3);
6. A person who fails to report as required under Article 49 (2) or (4).

(4) Administrative fines specified in paragraphs (1) through (3) shall be imposed and collected by the Minister of Health and Welfare, as prescribed by Presidential Decree.