BIOETHICS AND SAFETY ACT

Wholly Amended by Act No. 11250, Feb. 1, 2012
Amended by Act No. 11690, Mar. 23, 2013
Act No. 12447, Mar. 18, 2014
Act No. 12844, Nov. 19, 2014
Act No. 13651, Dec. 29, 2015
Act No. 14438, Dec. 20, 2016
Act No. 14839, Jul. 26, 2017
Act No. 15188, Dec. 12, 2017
Act No. 15888, Dec. 11, 2018
Act No. 16372, Apr. 23, 2019

CHAPTER I GENERAL PROVISIONS

Article 1 (Purpose)

The purpose of this Act is to ensure bioethics and safety, 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, human materials, etc. or of handling embryos, genes, etc.

Article 2 (Definitions)

The definitions of the terms used in this Act are as follows: *<Amended by Act No. 13651, Dec. 29, 2015>*

1. The term "human subjects research" means research performed through interactions including physical intervention, communication, and interpersonal contact or a study using personally identifiable information, as determined by the Ordinance of the Ministry of Health and Welfare;
2. The term "human subject of research" means a person who is the subject of a human subjects research;
3. The term "embryo" means a fertilized human egg or a group of cells divided from the moment of fertilization at the point of time at which all organs of the given organism have developed in the embryo logically;

4. The term "residual embryo" means an embryo remaining after embryos produced as a consequence of in vitro fertilization are used for pregnancy;
5. The term "residual egg" means a human egg remaining after use for in vitro fertilization;
6. The term "somatic-cell nuclear transplantation" means that a human somatic nucleus is transplanted into a human egg from which the nucleus has been removed;
7. The term "parthenogenesis" means making a human egg divide and develop without a fertilization process;
8. The term "somatic-cell cloning embryo" means an embryo formed by the act of a somatic-cell nuclear transplantation;
9. The term "parthenogenic embryo" means an embryo formed by the act of parthenogenesis;
10. The term "embryonic stem cell line" means a cell line derived from an embryo, somatic-cell cloning embryo, and parthenogenic embryo and which can proliferate continuously and differentiate to various cells;
11. The term "human material" means human constitutes, including tissues, cells, blood, and body fluid obtained or collected from the human body; or serum, plasma, chromosomes, DNA (Deoxyribonucleic Acid), RNA (Ribonucleic Acid), protein, etc. separated from them;
12. The term "human materials research" means a study to investigate and analyze human materials directly;
13. The term "Human Material Bank" means an institution that collects and stores human materials or genetic information, and epidemiologic information and clinical information concerning them to use directly or provide to others;
14. The term "genetic information" means information regarding the genetic characteristics of an individual, obtained by analyzing human materials of such 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 involve genetic mutations in the body or to transfer hereditary substances or cells to which hereditary substances are introduced, to the body, for the purpose of preventing or treating a disease;
17. The term "personally identifiable information" means information with which an individual can be identified, such as the name and resident registration number of a human subject of research or the donor of an embryo, egg, 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 permanent deletion of personally identifiable information or full or partial substitution of personally identifiable information with an identification code given by an institution involved.

Article 3 (Basic Principles)

(1) No act 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) Autonomy 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 based on sufficient 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 except as otherwise provided in any other statute.

(4) Safety of each human subject of research or donor shall be considered sufficiently, 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 secure bioethics and safety, and common international standards shall be accepted.

Article 4 (Scope of Application)

(1) Except as otherwise provided in any other statute, bioethics and safety shall be governed by this Act.

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

Article 5 (Responsibilities of the State and Local Governments)

(1) The State and local governments shall formulate policies necessary to efficiently address bioethics and safety issues.

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

(3) The State and local governments shall ensure that educational institutions at various levels provide education about bioethics and safety and shall offer support for laying educational foundations, such as developing educational programs.

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, as a bioethics policy research center, an institution, organization, or facility deemed to be capable of conducting such activities.

(2) Details necessary for the designation, operation, etc. of 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 AND INSTITUTIONAL BIOETHICS COMMITTEE

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 safety, a National Bioethics Committee (hereinafter referred to as the "National Committee") shall be established as a presidential committee:

1. Establishment of basic policies on national bioethics and safety;
2. Affairs assigned to public institutional bioethics committees under Article 12 (1) 3;
3. Exemption from the deliberation on human subjects research under Article 15 (2);
4. Keeping and storing of records and disclosure of information under Article 19 (3);
5. Research 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 permitted to use embryonic stem cell lines under Article 35 (1) 3;
8. Exemption from the deliberation on human materials research under Article 36 (2);
9. Restrictions on genetic tests under Article 50 (1);
10. Other matters submitted by the chairperson of the National Committee, deemed likely to substantially affect society in connection with bioethics and safety.

(2) The chairperson of the National Committee shall introduce a bill, submitted by at least 1/3 of current members regarding a matter specified in 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 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 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 from among persons who have abundant expertise and experience in research on biological science, medical science, or social science;

3. Not more than seven persons commissioned by the President from among representatives of representatives of religious circles, ethical circles, judicial circles, civic groups (referring to nonprofit, non-governmental organizations defined in Article 2 of the Assistance for Non-Profit, Non-Governmental Organizations Act) or women's organizations.

(4) Each member specified in paragraph (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 or her predecessor.

(5) The National Committee shall have two secretaries, who are 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 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, so that the institution serves 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 open to the public, in principle.

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

(5) Except as provided 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 Committee

Article 10 (Establishment and Functions of Institutional Bioethics Committee)

(1) Any of the following institutions shall establish an institutional bioethics committee (hereinafter referred to as "institutional committee") so as to ensure bioethics and safety:

1. An educational institution, research institute, hospital, or similar institution, to which a person who conducts human subjects research(hereinafter referred to as "human subjects researcher") belongs;
2. An educational institution, research institute, hospital, or similar institution, to which a person who conducts human materials research (hereinafter referred to as "human materials researcher") belongs;
3. An embryo-producing medical institution designated pursuant to Article 22 (1);
4. An embryo research institute registered pursuant to Article 29 (2);

5. A research institute for somatic-cell cloning embryos, etc. registered pursuant to Article 31 (3);

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 safety.

(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 any other institution or a public institutional bioethics committee under Article 12 (1), to entrust the affairs assigned to its institutional committee specified in 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. Deliberation on 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 safety in the relevant institution;

2. Inspection and supervision of the progress and outcomes of research conducted by the relevant institution;

3. The following activities for bioethics and safety:

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

Article 11 (Composition and Operation 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 the subparagraphs 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 deliberation shall participate in the deliberation of the relevant case of research, development, or use.

(4) If the head of an institution specified in the subparagraphs of Article 10 (1) discovers that a research conducted by his or her institution has posed or is likely to pose a grave danger to bioethics or safety, he or she shall convene a meeting of the competent institutional committee without delay 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 the subparagraphs 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 in paragraphs (1) through (6), details necessary for organizing and operating an institutional committee shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 12 (Designation of Public Institutional Bioethics Committees and Joint Operation of Institutional Committees)

(1) The Minister of Health and Welfare may designate a public institutional bioethics committee (hereinafter referred to as "public committee") that institutions or researchers may jointly use among institutional committee established pursuant to Article 10 (1) to conduct the following:

1. Affairs entrusted by an institution under an agreement made with the public committee pursuant to Article 10 (2);
2. Affairs requested by a human subjects researcher or human materials researcher not affiliated with any educational institution, research institute, hospital, or similar institution;
3. Other affairs specified by Ordinance of the Ministry of Health and Welfare after deliberation by the National Committee.

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

(3) Details necessary for the designation, functions, and operation of a public 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 to Institutional Committees)

(1) In order to appropriately supervise and support the operation of IRBs, 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) Details necessary for inspection of institutional committees and educational support 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 on a regular basis.

(2) The Minister of Health and Welfare may publish the results of accreditation of an institutional committee under paragraph (1) on a website or by other means.

(3) The head of a central administrative agency may subsidize an institution's budget or take measures 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, the Minister of Health and Welfare may revoke its accreditation: Provided, That the Minister of Health and Welfare shall revoke the accreditation in cases falling under subparagraph 1:

1. If an institutional committee obtains accreditation by fraud or other improper means;

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) Details necessary for the standards for accreditation referred to in paragraph (1) and the period for validity of such accreditation shall be prescribed by Presidential Decree.

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

Article 15 (Deliberation on Human Subjects Research)

(1) A person who intends to conduct a human subjects research shall prepare a research plan and submit it for deliberation by the institutional committee before commencing such human subjects research.

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

Article 16 (Consent to Human Subjects Research)

(1) A human subjects researcher shall obtain written consent (including consent given in an electronic document; hereinafter the same shall apply) regarding the following matters from human subjects of research before commencing human subjects research:

1. The objectives of the human subjects research;
2. The duration, procedures 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 ;
6. Provision of personal information;
7. Withdrawal of consent;
8. Other matters the competent institutional committee deems necessary.

(2) Notwithstanding paragraph (1), where research 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 or her representative specified in the following 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 there is no legal representative, 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), research may be exempted from obtaining written consent of a human subject of research, subject to approval from the institutional committee, if the research satisfies all the following prerequisites. In such cases, research shall not be exempted from obtaining written consent of the representative under paragraph (2):

1. If it is deemed 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 or her pursuant to paragraphs (1) and (2).

Article 17 (Safety Measures for Human Subjects of Research)

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

(2) No human subjects researcher shall delay medical treatment necessary to a human subject of research or deprive such person 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) Where a human subjects researcher obtains written consent from a human subject of research for the provision of such subject's personal information to a third party pursuant to Article 16 (1), the researcher may provide the personal information to a third party, after deliberation thereon by the competent institutional committee.

(2) Where a human subjects researcher provides personal information about a human subject of research to a third party under paragraph (1), he or she shall anonymize such personal information: Provided, That the foregoing shall not apply where a human subject of research consents to the inclusion of his or her personally identifiable information.

Article 19 (Records Storage and Disclosure of Information)

(1) A human subjects researcher shall keep and store records about matters regarding a human subjects research.

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

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

CHAPTER IV EMBRYO, PRODUCTION AND RESEARCH

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, etc.") into a human or animal uterus, keep such embryo implanted, or bear a child therefrom.

(2) No person shall induce or assist in the activities defined in paragraph (1).

Article 21 (Prohibition on Implantation between Different Species)

(1) No person shall implant a human embryo into an animal uterus or implant an animal embryo into a human uterus.

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

1. Fertilizing a human egg with an animal sperm or an animal egg with a human sperm: Provided, That medical tests for examining the activity of a human sperm shall be excluded herefrom;
2. Implanting an animal somatic nucleus into a human egg which is enucleated or implanting a human somatic nucleus into an animal egg which is enucleated;
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 uterus.

SECTION 2 Embryo-Producing Medical Institutions

Article 22 (Designation of Embryo-Producing Medical Institutions)

(1) A medical institution that intends to collect and store eggs or sperm or to produce embryos through fertilization for purposes of in vitro fertilization shall be designated as an embryo-producing medical institution by the Minister of Health and Welfare.

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

(3) Details necessary for the standards and procedures for the designation of embryo-producing medical institutions shall be prescribed by Ordinance of the Ministry of Health and Welfare.

(4) When an embryo-producing medical institution designated under paragraph (1) (hereinafter referred to as "embryo-producing medical institution") 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 an embryo-producing medical institution suspends or closes its business operations, 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 an embryo-producing medical institution suspends or closes its business operations, the head of such medical institution shall transfer embryos, reproductive cells, and relevant documents in its custody to the Korea Disease Control and Prevention Agency or another embryo-producing medical institution, as prescribed by Ordinance of the Ministry of Health and Welfare.

Article 23 (Obligations regarding 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 acts in producing an embryo:

1. Selecting an egg and sperm for fertilization with intent to choose a particular sex;
2. Fertilizing with a decedent's egg or sperm;
3. Fertilizing with a minor's egg or sperm: 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 utilize embryos, sperms or eggs, or induce or assist in providing or utilizing them for the purpose of receiving monetary benefits, property interests or other personal benefits in return.

Article 24 (Consent to Production of Embryos)

(1) When an embryo-producing medical institution intends to collect eggs or sperm in order to produce embryos, it shall obtain written consent to the following matters from the donor of the eggs or sperm, the person subject to in vitro fertilization and the spouse, if any, of the donor or the person to undergo IVF: 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 acts:

1. The objectives of producing embryos;
2. The storage period of embryos, eggs, or sperm and other matters regarding storage;
3. Disposal of embryos, eggs, or sperm;
4. Use of residual embryos or eggs 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) An embryo-producing medical institution shall fully explain matters specified in the subparagraphs of paragraph (1) to persons with the right to consent before obtaining written consent pursuant to paragraph (1).

(3) Details 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 (Storage and Disposal of Embryos)

(1) The storage period of embryos shall be five years: Provided, That if the period set by a person with the right to consent is less than five years, embryos shall be stored only for such period.

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

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

(4) An embryo-producing medical institution shall keep and store records of details about the disposal of embryos.

(5) The procedures and methods of disposing of embryos and details necessary for keeping and storing records of details about the disposal of embryos under paragraphs (3) and (4) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 26 (Provision of Residual Embryos or Eggs)

(1) Where an embryo-producing medical institution provides residual embryos necessary for research to an embryo research institute with an embryo research plan approved pursuant to Article 30 (1) or offers residual eggs to a research institute with a research plan approved regarding somatic-cell cloning embryos, etc. pursuant to Article 31 (4), such provision or offer shall be made free of charge: Provided, That an embryo-producing medical institution may request a research institute to which residual embryos or eggs are provided, to reimburse it for expenses incurred in storing and providing such embryos or eggs, as prescribed by Ordinance of the Ministry of Health and Welfare.

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

(3) An embryo-producing medical institution shall report details about the storage, provision, etc. of residual embryos or eggs to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.

Article 27 (Protection of Donors of Eggs)

(1) An embryo-producing medical institution shall examine the health of an egg donor before it collects eggs from her, as prescribed by Ordinance of the Ministry of Health and Welfare.

(2) No embryo-producing medical institution shall collect eggs from a person whose health fails to meet a standard prescribed by Ordinance of the Ministry of Health and Welfare.

(3) No embryo-producing medical institution shall collect eggs from the same donor in excess of the frequency specified by Presidential Decree.

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

Article 28 (Obligations of Embryo-Producing Medical Institutions)

(1) An embryo-producing medical institution shall comply with the following: *<Amended by Act No. 13651, Dec. 29, 2015>*

1. An embryo-producing medical institution shall comply with the terms and conditions of the written consent obtained pursuant to Article 24 in handling embryos, eggs, or sperm;
2. An embryo-producing medical institution shall strictly adhere to the Ordinance of the Ministry of Health and Welfare in storing, handling, disposing of, and managing residual embryos or eggs;
3. Other detai prescribed by Ordinance of the Ministry of Health and Welfare as deemed necessary to ensure bioethics and safety.

(2) In order to appropriately manage consents, etc. to the production of embryos, etc., the Minister of Health and Welfare shall establish guidelines for the standard operation of embryo-producing medical institutions and recommend they comply therewith. *<Newly Inserted by Act No. 13651, Dec. 29, 2015>*

SECTION 3 Residual Embryos Research

Article 29 (Residual Embryos Research)

(1) A residual embryo for which the storage period set under Article 25 ends may be used in vitro for any of the following purposes of research only before the primitive streak appears during embryonic development:

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 after 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 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 to close its business operations, it shall report thereon to the Minister of Health and Welfare.

Article 30 (Approval of Embryo Research Plans)

(1) If an embryo research institute intends to conduct research on residual embryos, it shall, in advance, submit a plan for embryo research to the Minister of Health and Welfare for approval. The same shall also apply to the change of an important matter specified by Presidential Decree in the details of the approved plan for embryo research.

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

(3) Where an embryo research institute that is funded by another central administrative agency submits a plan for embryo research, the Minister of Health and Welfare shall cdiscuss the matter with the head of the central administrative agency before determining whether to approve the plan.

(4) The standards and procedures for approval of a plan for embryo research, 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)

(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 after deliberation by the National Committee.

(3) A person who intends to produce, or conduct research on, somatic-cell cloning embryos, etc. shall secure facilities and human resources specified by Ordinance of the Ministry of Health and Welfare and fregister 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, etc.") intends to produce, or conduct research on, somatic-cell cloning embryos, etc., it shall, in advance, submit a research plan (hereinafter referred to as "plan for research on somatic-cell cloning embryos, etc.") 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, etc. In such cases, "residual embryos" shall be construed as "somatic-cell cloning embryos, etc.", and "plan for embryo research" as "plan for research on somatic-cell cloning embryos, etc.", respectively.

Article 32 (Obligations of Embryo Research Institutes)

(1) Where research conducted by an embryo research institute or a research institute for somatic-cell cloning embryos, etc. has posed or is likely to pose a grave danger to bioethics or safety, such institute shall discontinue the 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, etc. intends to disuse residual embryos or eggs for the purpose of research after it acquires such embryos or eggs. In such cases, "embryos" shall be construed as "residual embryos or eggs".

(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, etc. manages residual eggs or somatic-cell cloning embryos, etc.

SECTION 4 Embryonic Stem Cell Lines

Article 33 (Registration of Embryonic Stem Cell Lines)

(1) A person who has established or imported embryonic stem cell lines shall register such embryonic stem cell lines with the Minister of Health and Welfare as prescribed by Ordinance of the Ministry of Health and Welfare before he or she provides them pursuant to Article 34 or uses them pursuant to Article 35.

(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 granting the registration under paragraph (1).

(3) The Minister of Health and Welfare may fully or partially reimburse a person whoregisters 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) If a person who has established an embryonic stem cell line intends to provide it to a third person, he or she shall undertake deliberation 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 under paragraph (1) shall be provided free of charge: Provided, That a person who provides an embryonic stem cell line may demand the third person to whom it is provided, to reimburse him or her for expenses incurred in storing and providing the embryonic stem cell line, as prescribed by Ordinance of the Ministry of Health and Welfare.

(4) Details necessary for providing and reporting embryonic stem cell lines and the method of calculating expenses therefor under paragraphs (1) through (3) 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 in vitro only for the purpose of conducting the following research:

1. Research for diagnosis, prevention, or treatment of a disease;
2. Basic research on characteristics and differentiation of stem cells;
3. Other research specified by Presidential Decree after 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 deliberated on by the institutional committee and shall obtain the approval of

the head of the relevant institution for the plan, as prescribed by Ordinance of the Ministry of Health and Welfare. The same shall also apply to the change of an important matter specified by Presidential Decree in the details of the approved research plan.

(3) A person who has obtained approval of a plan or approval for change of such 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 research pursuant to paragraph (2) shall supervise the person who conducts the research so as to ensure that the person complies with the relevant plan in conducting the research.

CHAPTER V HUMAN MATERIALS RESEARCH AND HUMAN MATERIAL BANKS

SECTION 1 Human Materials Research

Article 36 (Deliberation on Human Materials Research)

(1) A person who intends to conduct human materials research shall undertake deliberation on the relevant research plan by the competent institutional committee before commencing such research.

(2) Notwithstanding paragraph (1), where research poses an insignificant danger to donors of a human material and to the general public and meets the standards prescribed by Ordinance of the Ministry of Health and Welfare after deliberation by the National Committee, such research project may be exempted from deliberation by the institutional committee.

Article 37 (Consent to Human Materials Research)

(1) A human materials researcher shall obtain written consent regarding the following matters from donors of a human material before commencing the human materials research:

1. The objectives of the human materials research;
2. Protection and management of personal information;
3. Storage and disposal 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, treatment of human materials, etc. if consent is withdrawn, rights of donors of a human material, change of the objectives, and other matters specified by Ordinance of the Ministry of Health and Welfare.

(2) Article 16 (2) shall apply mutatis mutandis to the consent of a representative in cases where the donor of a human material is incapable of, or incompetent for, giving consent. In such cases, “human subject of research” shall be construed as “donor of a human material”. *<Newly Inserted by Act No. 15888, Dec. 11, 2018>*

(3) Notwithstanding paragraphs (1) and (2), if a human materials researcher conducts research with a human material provided by a person who is not a human materials researcher but collected 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 collected the human material obtained written consent from the donor (including the representative prescribed in Article 16 (2), which applies mutatis mutandis under paragraph (2); hereafter in this Article and Article 38 the same shall apply) of the human material regarding matters specified in paragraph (1). *<Amended by Act No. 15888, Dec. 11, 2018>*

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

(5) A human materials researcher shall fully explain the matters specified in paragraph (1) to the donor of a human material before obtaining written consent under paragraphs (1) and (2) from him or her. *<Amended by Act No. 15888, Dec. 11, 2018>*

(6) Details necessary for the form, etc. of the written consent under paragraphs (1) and (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare. *<Amended by Act No. 15888, Dec. 11, 2018>*

Article 38 (Provision of Human Materials)

(1) If a human materials researcher has obtained written consent from the donor of a human material regarding the provision of human materials, etc. pursuant to Article 37 (1) and (2), such researcher may provide the human material, etc. to a Human Material Bank or another researcher, after deliberation thereon by the competent institutional committee. *<Amended by Act No. 15888, Dec. 11, 2018>*

(2) When a human materials researcher provides a human material, etc. to another researcher pursuant to paragraph (1), such researcher shall anonymize the human material, etc.: Provided, That the foregoing shall not apply where the donor of the human material agrees to the inclusion of his or her personally identifiable information.

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

(4) If a human materials researcher provides or receives human materials pursuant to paragraph (1), such researcher shall prepare and keep records about the provision of the human material, etc., as prescribed by Ordinance of the Ministry of Health and Welfare.

(5) The methods and procedures 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 (Storage and Disposal of Human Materials)

(1) A human materials researcher shall dispose of a human material, etc. at the lapse of the duration set in the relevant written consent: Provided, That if such researcher receives a request from the donor of the human material, while storing the human material, etc., to amend the duration of storage or to dispose of the human material, etc., the researcher shall comply with such request.

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

(3) Where a human materials researcher is unable to store human materials, etc. due to inevitable circumstances, such researcher shall treat, or transfer, the human materials, etc., after deliberation thereon by the competent institutional committee.

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

Article 40 (Obligations of Human Materials Researchers)

@Articles 17 and 19 shall apply mutatis mutandis to the safety measures for donors of a human material taken by human materials researchers and the storage of records and disclosure of information, respectively. In such cases, “human subjects research” shall be construed as “human materials research”, and “human subject of research” as “donor 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 Presidential Decree: 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 statute or regulation reports thereon to the Minister of Health and Welfare after obtaining approval from the head of the central administrative agency for subsidizing research expenses, such person shall be deemed to have obtained 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 suspends or closes its business operations, it shall report thereon to the Minister of Health and Welfare.

(4) The standards for facilities and equipment of a Human Material Bank, the procedures for permission for, and reporting of, a Human Material Bank, and other necessary matters shall be prescribed by Presidential Decree.

Article 42 (Consent to Collection of Human Materials)

(1) When a Human Material Bank intends to directly collect a human material for human materials research or to request a third person to collect a human material for such purpose, it shall obtain written consent regarding the following matters from the donor of the human material, prior to such collection:

1. The objectives of the human materials research (only applicable where the Human Material Bank directly conducts the human materials research);
2. Protection and disposal of personal information;
3. The scope of researchers and institutions that are provided with the human material, etc.;
4. Storage, management, and disposal 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 the donor of a human material before obtaining written consent pursuant to paragraph (1).

(3) Details necessary for the form, etc. of the written consent under paragraph (1) shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 42-2 (Provision of Residual Samples)

(1) Notwithstanding Article 42, a Human Material Bank can be provided from a medical institution (referring to any medical institution established under the Medical Service Act; hereafter in this Article the same shall apply) with any human material remaining after the medical institution has used for the purpose of treatment or diagnosis (hereinafter referred to as “residual sample”) only for research purposes in compliance with the manner and procedures provided in paragraphs (2) through (6). In such cases, medical institutions shall not collect any human material in excess of the volume necessary for treatment or diagnosis for the purpose of providing residual samples.

(2) A medical institution that intends to provide residual samples for Human Material Banks shall give the donor written notice stating the following information before the medical institution collects the human materials it intends to provide. In such cases, the medical institution shall also explain the information referred to in subparagraph 1 orally to the donor:

1. The fact that the residual samples can be provided to Human Material Banks unless the donor expresses his or her opposition;
2. The manner and procedures in which the donor expresses his or her opposition under subparagraph 1;

3. The method of anonymizing the residual samples;

4. Matters about the storage, management, disposal, and use of the residual samples;

5. Other matters prescribed by Ordinance of the Ministry of Health and Welfare.

(3) In receipt of written notice under paragraph (2), a donor who intends to oppose to the provision of residual samples, shall express his or her opposition in writing form signed or sealed by himself or herself or in other manners prescribed by Ordinance of the Ministry of Health and Welfare. In such cases, a refusal to accept written notice given under paragraph (2) shall be construed as expression of opposition under the former part.

(4) A medical institution shall not provide Human Material Banks with any residual samples to which the donor has expressed his or her opposition under paragraph (3).

(5) A medical institution shall determine the purposes and objects for which residual samples are provided and the method of anonymizing such residual samples, and shall obtain approval from its institutional committee in advance, before providing the residual samples.

(6) A medical institution shall anonymize residual samples when it provides such samples for Human Material Banks under paragraph (1).

(7) Provision of residual samples by medical institutions under paragraph (1) shall be free of charge: Provided, That if any expenses are incurred by a medical institution in storing and providing residual samples, the medical institution may request reimbursement of the expenses from Human Materials Banks, as prescribed by Ordinance of the Ministry of Health and Welfare.

(8) Upon provision of a residual sample, a medical institution shall prepare and keep records on the provision of the residual sample, as prescribed by Ordinance of the Ministry of Health and Welfare.

(9) Article 43 shall apply mutatis mutandis to the provision of residual samples by Human Material Banks. In such cases, “human material, etc.” shall be construed as “residual sample”.

(10) Details necessary for the methods and procedures of written notice pursuant to paragraph (2), the method and procedure for expressing opposition under paragraph (3), and items and procedures for approval granted by the institutional committee pursuant to paragraph (5), etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 42-3 (Management of Residual Samples)

(1) The head of a Human Material Bank or its employees shall not use, dispsoe of, or damage any residual samples stored by the Human Material Bank without good cause.

(2) Article 39 shall apply mutatis mutandis to the storage and disposal of residual samples by Human Material Banks. In such cases, “human materials researcher” shall be construed as “Human Material Bank”, and “human material, etc.” as “residual sample”.

(3) If a Human Material Bank is provided with a residual sample under Article 42-2 (1), it shall anonymize the residual sample.

(4) The head of a Human Material Bank shall establish personal information protection guidelines, including schemes for anonymizing residual samples, 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 43 (Provision of Human Materials)

(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 shall 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 any other person, he or she shall anonymize the human material, etc.: Provided, That the foregoing shall not apply where the donor of a human material has agreed to the inclusion of his or her personally identifiable information therein.

(3) Where the head of a Human Material Bank provides a human material, etc. to any other person, such provision shall be made free of charge: Provided, That the head of a Human Material Bank may demand a person who is provided with a human material, etc., to reimburse him or her for expenses incurred in storing and providing the human material, etc., as prescribed by Ordinance of the Ministry of Health and Welfare.

(4) An institutional committee shall establish guidelines necessary to provide human materials, etc. and shall regularly review whether human materials, etc. are provided properly in compliance with the guidelines.

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

Article 44 (Obligations of Human Material Banks)

(1) The head or an employee of a Human Material Bank shall not use, dispose of, or destroy human materials, etc. that are stored without good cause.

(2) When a Human Material Bank receives human materials, etc. provided pursuant to Article 38 (1) or 53 (1), it shall anonymize the human materials, etc.

(3) Article 39 shall apply mutatis mutandis to the storage and disposal of human materials, etc. by a Human Material Bank.

(4) The head of a Human Material Bank shall establish personal information protection guidelines, 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 for expenses incurred in operation, within the budget.

CHAPTER VI GENE THERAPY AND TESTING

Article 46 (Prohibition 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 provided in any other statute, no person shall compel any other 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, therapy records, etc. provided to any person other than the patient himself or herself pursuant to Article 21 (3) of the Medical Service Act: Provided, That the foregoing shall not apply where another medical institution requests 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 Therapies)

(1) Research on a gene therapy that falls into a series of procedures to involve genetic mutations in the body may be conducted only 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 subparagraph 1 or 2 of paragraph (1). *<Newly Inserted by Act No. 13651, Dec. 29, 2015>*

(3) No gene therapy shall be applied to an embryo, egg, sperm, or fetus. *<Amended by Act No. 13651, Dec. 29, 2015>*

Article 48 (Gene Therapy Institutions)

(1) A medical institution that intends to apply a gene therapy shall report to the Minister of Health and Welfare. The same shall also apply where such institution intends to change an important matter specified by Presidential Decree.

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

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

(3) The conditions and procedures for reporting 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 such facilities, human resources, etc. required depending on genetic test items as prescribed by Ordinance of the Ministry of Health and Welfare and shall report on his or 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 matter 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 has reported on its business pursuant to paragraph (1) (hereinafter referred to as "genetic testing institution") to undergo the evaluation of the 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 suspend or close its business operations of genetic testing, it shall report to the Minister of Health and Welfare, as prescribed by Ordinance of the Ministry of Health and Welfare.

(5) Where a genetic testing institution has reported on its business closure to the head of the competent tax office pursuant to Article 8 of the Value-Added Tax Act or where the head of the competent tax office has canceled the business registration of a genetic testing institution, the Minister of Health and Welfare may ex officio cancel records of the reporting of the genetic testing institution. *<Amended by Act No. 15188, Dec. 12, 2017>*

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

Article 50 (Restrictions 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 other genetic tests specified by Presidential Decree after 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 other hereditary diseases 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 except in 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, which is deemed necessary by the Minister of Health and Welfare.

(4) No genetic testing institution shall make a misrepresentation or an exaggerated advertisement regarding genetic tests. The standards and procedures for judgment on misrepresentation or exaggerated advertisement 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 directly collects or requests collection of test materials to be used for genetic testing, it shall obtain written consent from the testee regarding the following, before collecting the test material: Provided, That if a testee has a disability, heed shall be given to the person's particular conditions in seeking for consent:

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

(2) If a genetic testing institution intends to provide a test material to a human material researcher or a Human Material Bank, it shall obtain written consent from the testee regarding the following in addition to the consent under paragraph (1):

1. Protection and disposal of personal information;
2. Storage, management, and disposal of the test material;
3. Provision of the test material;
4. Withdrawal of consent, treatment of the test material 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, collects a test material and requests a genetic testing institution to conduct a genetic test thereon, he or she shall present written consent obtained from the testee 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, "human subject of research" shall be construed as "testee", and "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 a corpse or an unconscious person;
2. Where it is provided in any other statute.

(6) A person who intends to obtain written consent pursuant to paragraphs (1) through (4) shall, in advance, give sufficient explanation the objectives and methods of the genetic test and the expected results and significance of the genetic test, to the testee or his or her legal representative.

(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 (Records Storage and Disclosure of Information)

(1) A genetic testing institution shall record and keep 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 or her legal representative requests a genetic testing institution to allow him or her to access the records specified in paragraph (1) or to issue copies of such records, the genetic testing institution shall comply with such request.

(3) Details necessary for the procedures for applying for the access of records or the issuance of copies under paragraph (2), the form of such application, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

Article 53 (Provision and Disposal of Materials for Testing)

(1) Where a genetic testing institution obtains written consent to the provision of a test material from a testee under Article 51 (2), such institution may provide the test material 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, "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 dispose of materials for testing after it obtains the result of a genetic test.

(4) A genetic testing institution shall keep and store records of the details about the disposal of materials for testing.

(5) Where a genetic testing institution is unable to store materials for testing due to suspension or closure of its business operations or other inevitable circumstances, such institution shall treat materials for testing or transfer such materials to any other person, as prescribed by Ordinance of the Ministry of Health and Welfare.

(6) Details necessary for the disposal of materials for testing, the recording and keeping of records of disposal, the treatment 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) Where deemed necessary to ensure bioethics and safety, the Minister of Health and Welfare may order an institution specified in the subparagraphs 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 for enforcing 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 bioethics or safety is or is likely to be in grave danger.

(2) Where deemed 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 a relevant public official to enter an institution subject to supervision or its office to inspect its facilities, equipment, relevant accounting books or documents, or other articles or to inquire of interested persons; and may collect the minimum quantity of samples necessary for testing. In such cases, a public official shall carry an identification certificate indicating his or her authority and present it to interested persons.

(3) An institution subject to supervision or its employees shall comply with an order issued, an inspection conducted, or an inquiry made under paragraph (1) or (2), except in extenuating circumstances.

Article 55 (Orders for Disposal 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 dispose of the following materials. In such cases, Articles 25 (5), 39 (4), and 53 (6) shall apply mutatis mutandis to the procedures and methods for the disposal:

1. An embryo, somatic-cell cloning embryo, embryonic stem cell line, or eggs collected, produced, stored, 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 pursuant to 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 test material or a human material collected, stored, 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) Where it is deemed 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 therefore has posed or is likely to pose a grave danger to bioethics or safety if it conducts research, collection, storage, or production of embryos, the Minister of Health and Welfare may order such institution to improve its facilities or to prohibit the use of all or part of its facilities.

Article 56 (Revocation of Registration and Suspension of Operation)

(1) In any of the following cases, the Minister of Health and Welfare may revoke the designation or registration of, or permission granted to, an institution subject to supervision; or may order such institution to completely or partially suspend its operation for a specified period not exceeding one year: *<Amended by Act No. 16372, Apr. 23, 2019>*

1. Where an institution subject to supervision violates Articles 10 (1) (excluding 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), 42-3 (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), and 53 (2) through (5);

2. Where an institution subject to supervision fails to comply with an order issued under Article 54 (1) or 55;

3. Where an institution subject to supervision fails to cooperate in an inspection conducted, an inquiry made, or collection conducted under Article 54 (2).

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

Article 57 (Hearings)

Where the Minister of Health and Welfare intends to revoke the designation or registration of, or permission granted to, an institution under Article 56, he or 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 and therefore he or 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; the Minister 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 pursuant to 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 Article shall apply mutatis mutandis pursuant to 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, an inquiry made, or collection conducted 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; reports; or intends to modify the details of any of the aforesaid acts in accordance with this Act, to pay fees, as prescribed by Ordinance of the Ministry of Health and Welfare.

CHAPTER VIII SUPPLEMENTARY PROVISIONS

Article 60 (National Fund Support)

In order to promote and support research and education that can contribute to securing bioethics and safety in accordance with this Act, the Minister of Health and Welfare may fully or partially subsidize a relevant organization or institution or their employees for expenses incurred in such research or education, as prescribed by Presidential Decree.

Article 61 (Delegation and Entrustment)

(1) The Minister of Health and Welfare may delegate part of his or her authority 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 a related specialized institution or organization, as prescribed by Presidential Decree:

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

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

(4) Details necessary for budget subsidies, subsidy redemptions, and prohibition of support to related institutions and organizations pursuant to paragraph (2) shall be prescribed by Presidential Decree.

Article 62 (Legal Fiction as Public Officials in Application of Penalty Provisions)

The executive officers and employees of an institution or organization that engages in affairs entrusted by the Minister of Health and Welfare pursuant to Article 61 shall be deemed public officials in applying Articles 129 through 132 of the Criminal Act.

Article 63 (Prohibition of Confidential Information)

An institution subject to supervision or an employee or former employee of such institution shall neither divulge personal information or other confidential information that such institution or such employee has learned in the course of conducting duties nor use such information without authorization.

CHAPTER IX PENALTY PROVISIONS

Article 64 (Penalty Provisions)

(1) Any person who implants a somatic-cell cloning embryo to an uterus, keeps such embryo implanted, or gives birth therefrom, in violation of Article 20 (1), shall be punished by imprisonment with labor for not more than 10 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 uterus or implants an animal embryo into a human uterus, in violation of Article 21 (1), or any person who implants a thing produced by conducting an act referred to in any subparagraph of Article 21 (2) into a human or animal uterus, 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 induces or assists to implant a somatic-cell cloned embryo, etc. into the uterus, to maintain the implanted state, or give birth, in violation of Article 20 (2);

2. A person who conducts an act 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, egg, or sperm for money, an interest in property, or any other consideration; induces or assists another person to conduct such act; acts as a broker for conducting such act, in violation of Article 23 (3);

5. A person who engages in somatic-cell nuclear transplantation or parthenogenesis for any purpose other than research purposes for therapy of a rare or incurable disease, in violation of Article 31 (1);

6. A person who divulges confidential information or 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) 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 act specified in any subparagraph of Article 23 (2) in producing an embryo;

2. A person who collects eggs or sperm without written consent, in violation of Article 24 (1);

3. A person who does not conduct a medical examination of an egg donor, in violation of Article 27 (1), or who collects eggs, in violation of Article 27 (2) or (3);

4. A person who discriminates against another person on the ground of genetic information; compels another person to undergo a genetic test or to submit the results of a genetic test; or includes genetic information in records, etc. 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 disposal 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 10 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: *<Amended by Act No. 16372, Apr. 23, 2019>*

1. A person who collects and stores eggs or sperm or produces embryos therefrom through fertilization without being designated as an embryo-producing medical institution, in violation of Article 22 (1) through (3);

2. A person who fails to dispose of 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 eggs for monetary compensation, 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 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 therefor, 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, etc. without registering 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 collects a human material or requests another person to collect a human material, without written consent, in violation of Article 42 (1);

9-2. A person who provides a Human Material Bank with any residual sample without giving the donor written notice required under Article 42-2 (2);

9-3. A person who provides a Human Material Bank with a residual sample collected from a donor who expressed his or her opposition, in violation of Article 42-2 (4);

10. A person who makes a misrepresentation or an exaggerated advertisement regarding genetic tests, in violation of Article 50 (4);

11. A person who collects 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 corporation or an agent, employee, or worker of a corporation or individual commits an offense specified in any provision of Articles 64 through 66 in the course of business of the corporation or individual, not only shall such an offender be punished accordingly, but the corporation or individual also shall be punished by a fine not exceeding 50 million won: Provided, That the foregoing shall not apply where the corporation or individual has not neglected due care and supervision over the business to prevent such offense.

(2) If the representative of a corporation or an agent, employee, or worker of a corporation or individual commits an offense specified in Article 67 or 68 in the course of business of the corporation or individual, not only shall such an offender be punished accordingly, but the corporation or individual also shall be punished by a fine specified in the relevant Article: Provided, That the foregoing shall not apply where the corporation 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 subject to an administrative fine not exceeding five million won: *<Amended by Act No. 16372, Apr. 23, 2019>*

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 registering, 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 dispose of, treat, or transfer a human material as referred to in the main clause of Article 39 (1) or Article 39 (3) (including cases to which any of the aforesaid paragraphs shall apply mutatis mutandis pursuant to Article 42-3 (2) and Article 44 (3));
6. A person who fails to report as required in Article 41 (2);
6-2. A person who provides a residual sample for a Human Material Bank without anonymizing the residual sample, in violation of Article 42-2 (6);
6-3. A person who provides a residual sample for any other person without anonymizing the residual sample, in violation of Article 42-2 (9);
6-4. A person who fails to establish personal information protection guidelines, including schemes for anonymizing residual samples or fails to designate a manager in charge of the management and security of personal information, in violation of Article 42-3 (4);
7. A person who fails to establish personal information protection guidelines, including schemes for anonymizing human materials, etc., or fails to designate a manager 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 thereon, in violation of Article 48 (1);
9. A person who fails to report pursuant to the main clause of Article 49 (1);
10. An institution subject to supervision or its employee that fails to comply with an order issued, an inspection conducted, or an inquiry, etc. made by the Minister of Health and Welfare, without good cause, in violation of Article 54 (3).

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

1. A person who fails to report with 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 subject to an administrative fine not exceeding two million won: *<Amended by Act No. 16372, Apr. 23, 2019>*

1. A person who fails to register with the Minister of Health and Welfare, in violation of Article 10 (4);

2. A person who fails to report with the Minister of Health and Welfare, 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);

5-2. A person who provides a residual sample for consideration, in violation of Article 42-2 (7);

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.

ADDENDA *<Act No. 11250, Feb. 1, 2012>*

Article 1 (Enforcement Date)

This Act shall enter into force one year after the date of its promulgation.

Article 2 (Transitional Measures concerning Consent to Human Materials Research)

Human materials that have been already used in human materials research, other than research on genes, before this Act enters into force, may be continuously used in such research without written consent otherwise required under Article 37 (1): Provided, That the foregoing shall not apply where such human materials are provided to any third person.

Article 3 (Transitional Measures concerning Permission for Human Material Banks)

A gene bank with permission granted under the previous provisions before this Act enters into force shall be construed as a Human Material Bank with permission granted under this Act.

Article 4 (Transitional Measures concerning Administrative Dispositions)

The previous provisions shall apply to administrative dispositions (including the imposition of penalty surcharges) to be taken against violations committed before this Act enters into force.

Article 5 (Transitional Measures concerning Administrative Fines)

The previous provisions shall apply to administrative fines to be imposed for violations committed before this Act enters into force.

Article 6 Omitted.

Article 7 (Relationship to Other Statutes)

A citation of any provision of the previous Bioethics and Safety Act by any other statute in force as at the time this Act enters into force shall be construed as a citation of the relevant provision of this Act in lieu of the previous provision, if this Act contains such relevant provision.

ADDENDA <*Act No. 11690, Mar. 23, 2013*>

Article 1 (Enforcement Date)

(1) This Act shall enter into force on the date of its promulgation.

(2) Omitted.

Articles 2 through 7 Omitted.

ADDENDUM <*Act No. 12447, Mar. 18, 2014*>

This Act shall enter into force three months after the date of its promulgation.

ADDENDA <*Act No. 12844, Nov. 19, 2014*>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation: Provided, That the amendments to the statutes to be amended pursuant to Article 6 of the Addenda, which were promulgated before this Act enters into force but the enforcement dates of which have yet to arrive, shall enter into force on the enforcement date of the relevant statute.

Articles 2 through 7 Omitted.

ADDENDUM <*Act No. 13651, Dec. 29, 2015*>

This Act shall enter into force on the date of its promulgation: Provided, That the amended provisions of Articles 28 (2) and 50 (3) 2 shall enter into force six months after the date of the promulgation.

ADDENDA <*Act No. 14438, Dec. 20, 2016*>

Article 1 (Enforcement Date)

This Act shall enter into force on the date of its promulgation. (Proviso Omitted.)

Articles 2 through 5 Omitted.

ADDENDA <*Act No. 14839, Jul. 26, 2017*>

Article 1 (Enforcement Date)

(1) This Act shall enter into on the date of its promulgation: Provided, That the amendments to the statutes to be amended pursuant to Article 5 of the Addenda, which were promulgated before this Act

enters into force but the enforcement dates of which have yet to arrive, shall enter into force on the enforcement date of the relevant statute.

Articles 2 through 6 Omitted.

ADDENDUM <*Act No. 15188, Dec. 12, 2017*>

This Act shall enter into force on the date of its promulgation.

ADDENDUM <*Act No. 15888, Dec. 11, 2018*>

This Act shall enter into force three months after the date of its promulgation.

ADDENDUM <*Act No. 16372, Apr. 23, 2019*>

This Act shall enter into force six months after the date of its promulgation.

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