

Act No.9100

Bioethics and Safety Act

[Revised as of June 5, 2008]

Chapter 1

General Provisions

Article 1 - Purpose

This act aims to enhance the health of human beings and the quality of human life by creating conditions that allow for the development of life sciences and biotechnologies that can be used to prevent or cure human diseases. Additionally, this act aims to protect human dignity and to prevent harm to human beings by ensuring that these life sciences and biotechnologies are developed safely and in accordance with the principles of bioethics.

Article 2 – Definitions

The following definitions apply in this Act:

1. “Life Sciences and biotechnologies” refers to the sciences and technologies that study and utilize human embryos, cells, and genes.
2. “Embryo” refers to a fertilized oocyte (or segmented cells) from the moment of fertilization to the point of time at which all organs of the given organism have developed embryologically.
3. “Spare embryo” refers to an embryo that is created through *in vitro* fertilization procedures and remains after fertility treatment.
4. “Somatic cell nuclear transfer” refers to the transfer of a human somatic cell nucleus to a human oocyte from which the nucleus has been removed.
5. “Somatic cell cloning embryo” refers to an embryo formed by the act of somatic cell nuclear transfer.
6. “Genetic test” refers to the act of analyzing chromosomes and genes derived from the blood, hair, saliva, or any other bodily part or a person for the purpose of identifying that individual or examining his or her health status or predisposition to acquire certain diseases.
7. “Genetic information” refers to the information obtained through genetic tests.
8. “Gene Bank” refers to an institution which either directly uses or provides others with the genetic information, including specimens, genes or personal

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information (hereafter referred to as “genetic information, etc”) which the institution collects and maintains in purpose of obtaining genetic information.

9. “Gene therapy” refers to procedures involving genetic mutation that are intended to prevent or treat certain diseases.
10. “Stem cell lines” refers to a population of cells that can be grown indefinitely and has the ability to differentiate into various types of cells if the culture conditions are met.

Article 3 – Extent of Application

Unless there are other provisions from other laws concerning bioethics and the safety of life sciences and biotechnologies, this act will be relied upon solely.

Article 4 – Obligations

- ① National or regional governments shall arrange all necessary measures to deal effectively with problems concerning bioethics and safety that may arise during the process of developing and utilizing life sciences and biotechnologies.
- ② Anyone who intends to study, develop or utilize life sciences and biotechnologies shall endeavor to safeguard human dignity and the value of human life and to carry out their work in accordance with the principles of bioethics and safety.

Article 5 – Right to Self-Determination

Anyone who becomes a subject of research or experimentation in the area of life sciences and biotechnologies shall have the right to be fully informed of his or her involvement in the research and shall also have the right to consent, or refuse consent, after being fully informed of his or her involvement in the research.

Chapter 2

National Bioethics Committee and Institutional Bioethics Committees

Article 6 – The Establishment and Functions of the National Bioethics Committee

- ① There shall exist a National Bioethics Committee (hereafter called the ‘National Committee’), responsible to the President, whose function it is to review the following subparagraphs concerning bioethics and safety in the life sciences and biotechnologies:

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1. Establishing policies concerning national bioethics and safety;
 2. The type, subject, and extent of research involving spare embryos under article 17-3;
 3. The type, subject, and extent of research involving somatic cell nuclear transfer under article 22-②;
 4. The types of genetic tests that are prohibited under article 25-①;
 5. The types of diseases for which gene therapy can be performed under article 36-①-3; and
 6. Other issues of social or moral significance concerning the research, development, and utilization of life sciences and biotechnologies that the Chairperson of the National Committee formally submits to the National Committee for its deliberation.
- ② The Chairperson of the National Committee shall submit to the National Committee for its deliberation any issue related to paragraphs ①-1 through ①-5 that has been proposed by at least one third of the members of the National Committee.

Article 7 – Composition of the National Committee

- ① The National Committee will be composed of between 16 and 21 persons, including one Chairperson and one Vice-Chairperson.
- ② The President shall appoint the Chairperson of the National Committee; the Vice-Chairperson of the National Committee shall be elected by a majority vote of the National Committee members.
- ③ Membership in the National Committee shall be as follows:
 1. The following ministers will all be members of the National Committee: the Minister of Education, Science and Technology, the Minister of Justice, the Minister of Knowledge Economy, the Minister of Health, Welfare and Family Affairs, the Minister of Gender Equality, and the Minister of Government Legislation.
 2. The president will appoint not more than seven representatives of the academic, scientific, and industrial spheres, each of whom have professional knowledge and experience in the fields of life science or medical science.
 3. The president will appoint not more than seven representatives of the fields of religion, philosophy, ethics, social science, law, NGO groups (nonprofit civil organizations under article 2 of the Nonprofit Civil Organization Support Act), or gender equality.
- ④ Members appointed under paragraphs ③-2 and ③-3 shall serve on the National Committee for a term 3 years and may be reappointed for additional terms.
- ⑤ The National Committee shall have two executive secretaries: the Minister of Education, Science and Technology and the Minister of Health, Welfare and Family Affairs. The Chief Executive Secretary shall be the Minister of Health, Welfare and Family Affairs.

Article 8 – Operation of the National Committee

- ① In order to ensure the effective operation of the National Committee, specialized subcommittees may be formed.
- ② The Chief Executive Secretary shall oversee all affairs of the National Committee.
- ③ The conferences and activities of the National Committee shall be open to the public.
- ④ Other matters concerning the composition and administration of the National Committee and subcommittees that are not stated in this Act shall be decided by the Presidential Decree.

Article 9 – The Establishment of Institutional Bioethics Committees

- ① In order to ensure bioethics and bioethical safety in the life sciences and biotechnologies, each of the following institutions shall set up its own Institutional Bioethics Committee (hereafter called an “Institutional Committee”):
 1. Medical institution designated as an Embryo Producing Medical Institution by the Minister of Health, Welfare and Family Affairs according to article 14-①;
 2. Embryo research institutions registered with the Minister of Health, Welfare and Family Affairs according to article 18;
 3. Somatic Cell Cloning Embryo Research Institutions registered with the Minister of Health, Welfare and Family Affairs according to article 23;
 4. Genetic Testing Institutions reported to the Minister of Health, Welfare and Family Affairs according to article 24-①;
 5. Gene Bank permitted by the Minister of Health, Welfare and Family Affairs according to the provisions of article 32-①;
 6. Gene Therapy Institution reported to the Minister of Health, Welfare and Family Affairs according to article 37-①; and
 7. Other research institutions designated by the Ordinance of the Ministry for Health, Welfare and Family Affairs that study, develop or utilize life sciences and biotechnologies that may have significant moral or social consequences.
- ② The Institutional Committee of each institution mentioned in article 9-① shall review the following matters related to the research, development, and utilization of life sciences and biotechnologies carried out by its institution:
 1. The ethical and scientific validity of its research protocols in the life sciences and biotechnologies;
 2. Whether or not consent was obtained, with appropriate measures, from all patients and donors of sperm, oocytes and specimens;
 3. The safety measures undertaken for patients, subjects of genetic information, and donors of sperm, oocytes, or specimens, and safeguards to protect personally identifiable information such as the donor's name and resident registration number (hereafter called ‘personal information’) where sperm, oocytes, or specimens are provided to others; and

4. Other matters concerning the research, development, or utilization of life sciences and biotechnologies carried out by the institutions listed in paragraph ①.
 - ③ Where there is a serious threat or a potential threat to bioethics and safety due to the research, development, or utilization of the life sciences and biotechnologies at any of the institutions listed in paragraph ①, the head of that institution must summon its Institutional Committee immediately to review the relevant details of the threat or potential threat and must also report the results of the Institutional Committee's meeting to the Minister of Health, Welfare and Family Affairs.
 - ④ Among the institutions mentioned in paragraph ①, when an institution is below the standard set by the Ordinance of the Ministry for Health, Welfare and Family Affairs, in size or number of researchers, and when that institution has agreed to cooperate in the review of activities listed in paragraphs ② and ③ with a similar institution that does have an Institutional Committee, then such an institution will be regarded as having an Institutional Committee, notwithstanding the provisions of paragraph ①.

Article 10 – Organization and Administration of Institutional Committees

- ① Each Institutional Committee shall consist of more than 5 persons, including one chairperson. Each Institutional Committee should also include more than one person not engaged in the fields of life science or medical science, as well as more than one person external to the institution.
- ② The head of each institution listed in article 9-① shall appoint the members of that institution's Institutional Committee, and the chairperson shall be elected by a majority vote of the members of that Institutional Committee.
- ③ Members involved in research, development, or utilization of life sciences and biotechnologies that needs to be reviewed by the Institutional Committee shall not participate in the review process.
- ④ Other matters related to the Institutional Committee's composition and operation not covered by this Act shall be decided by the Presidential Decree.

Article 10.2 – Support for the Institutional Committee

- ① In order to oversight and support the operation of the Institutional Committee appropriately, the Minister of Health, Welfare and Family Affairs shall conduct the following activities:
 1. Inspection of the Institutional Committee;
 2. Evaluation of the Institutional Committee;
 3. Education for the Institutional Committee members; and
 4. Other activities necessary to oversight and support the Institutional Committee, as stipulated in the Ordinance of the Ministry for Health, Welfare and Family Affairs.

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- ② The Minister of Health, Welfare and Family Affairs may evaluate the operation of the Institutional Committee and disclose the results according to paragraph ①-2.
- ③ Other matters concerning evaluation of the Institutional Committee, disclosure of the results and education of Institutional Committee members shall be stipulated in the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Chapter 3

Embryo Production and Research

Section 1 – Prohibitions on Human Cloning

Article 11 – Prohibition on Human Cloning

- ① No one shall implant a somatic cell cloning embryo into a uterus, maintain a cloned embryo within a uterus, or give birth when the pregnancy results from the act of implanting a somatic cell cloning embryo into a uterus.
- ② No one shall induce or assist in the activities defined in paragraph ①.

Article 12 – Prohibition on the Transfer of Embryos between Two Different Species

- ① No one shall implant a human embryo in the uterus of an animal; nor shall anyone implant an animal embryo into a human uterus.
- ② No one shall perform any of the following acts:
 - 1. The act of fertilizing a human oocyte with an animal sperm, or vice versa, for any purpose other than that of testing human sperm cells;
 - 2. The act of implanting an animal somatic cell nucleus into an enucleated human oocyte, or a human somatic cell nucleus into an enucleated animal oocyte;
 - 3. The act of fusing a human embryo with an animal embryo; or
 - 4. The act of fusing a human embryo with another embryo of non-identical genetic information.
- ③ No one shall transfer the products of any of the acts described in paragraph ② into the uterus of a human being or animal.

Section 2 – Embryos Produced through Artificial Fertilization

Article 13 – Producing Embryos

- ① No one shall produce embryos other than for the purpose of pregnancy.
- ② In producing embryos for the purpose of pregnancy, no one shall perform any of the following acts:
 1. Fertilizing an oocyte, when the oocyte and/or sperm have been specially selected for the purpose of producing offspring of a particular gender;
 2. Fertilizing an oocyte, when the oocyte and/or sperm are those of a non-living human; or
 3. Fertilizing an oocyte, when the oocyte and/or sperm are those of an under-aged human. However, this shall be allowed when married under-aged parents wish to conceive a child.
- ③ No one shall provide or utilize sperm or oocytes, 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 14 – Embryo Producing Medical Institutions

- ① Any medical institution that wishes to collect and preserve sperm or oocytes for artificial fertilization or to generate embryos through fertilization should be designated as an Embryo Producing Medical Institution by the Minister of Health, Welfare and Family Affairs.
- ② Any medical institution that wishes to be designated as an Embryo Producing Medical Institution should meet the facility and manpower requirements set by the Ordinance of the Ministry for Health, Welfare and Family Affairs.
- ③ The Ordinance of the Ministry for Health, Welfare and Family Affairs is to decide on the criteria, process, documents, and any other requirements of institutions seeking designation as Embryo Producing Medical Institutions.

Article 15 – Consent to the Production of Embryos

- ① When a medical institution, designated as an Embryo Producing Medical Institution by article 14, collects sperm or oocytes in order to produce an embryo, they shall obtain written consent from both the sperm and oocyte donors as well as the artificial insemination patient and her spouse (hereafter called the 'Consenters').
- ② In the written consent described in paragraph ①, the following shall be included:
 1. The details of the purpose of producing an embryo;
 2. The details of the deposit period and maintenance of embryos;
 3. The details of the disposal of embryos;
 4. Indication of whether or not consent is given to utilize the spare embryos for purposes other than pregnancy; and

5. Information on the procedures for the withdrawal of consent, the protection of consenters' rights and information, and other necessary information set by the Ordinance of the Ministry for Health, Welfare and Family Affairs.
- ③ Embryo Producing Medical Institutions shall explain in detail the contents of paragraph ② before obtaining a written consent under the provisions of paragraph ①.
- ④ Any other details or procedures required for the written consent outlined in paragraph ①, such as the consent form and record keeping, will be decided by the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Article 15.2 – Physical Examination of Oocyte Donors

- ① Embryo Producing Medical Institution shall conduct a physical examination of oocyte donors prior to oocyte collection as provided in the Ordinance of the Ministry for Health, Welfare and Family Affairs.
- ② Embryo Producing Medical Institution shall not collect oocytes from a person who is below health standards set by the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Article 15.3 – Limit of Collection Frequency

When Embryo Producing Medical Institution collects oocytes from the same donor, it shall comply with the limit of collection frequency set by the Presidential Decree.

Article 15.4 – Compensation for the Actual Cost

Embryo Producing Medical Institution may pay oocyte donors for their time needed for oocyte collection procedure and recovery, and transportation fare as determined by the Ordinance of the Ministry for Health and Welfare.

Article 16 – Storage and Disposal of Embryos

- ① The storage period of embryos shall be 5 years; shorter storage periods are possible when the Consenters request it.
- ② Embryo Producing Medical Institutions shall dispose of all embryos approaching the end of their period of storage, except for those that are to be utilized for the purpose of research outlined in article 17.
- ③ Embryo Producing Medical Institutions shall keep records and preserve details concerning the disposal of all embryos.
- ④ The correct processes and procedures of embryo disposal and the necessary details concerning record keeping will be further outlined by the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Article 17 – Research on Spare Embryos

Spare embryos that have passed the storage period outlined in article 16 may be utilized for any of the following purposes, but only until the embryological primitive streaks appear in their developmental process:

1. To conduct research aimed at developing contraception and infertility treatments;
2. To conduct research aimed at curing rare or incurable diseases including muscle dystrophy, as decided by the Presidential Decree; or
3. To conduct other research that is pursuant to subparagraphs 1 and 2, and approved by the Presidential Decree.

However, in order to utilize a spare embryo that has been stored for less than 5 years, a new consent, for this new purpose, is required from the Consenters.

Article 18 – Embryo Research Institutions

Any one who wishes to do research on spare embryos under the provisions of article 17 should meet the facility and manpower requirements set by the Ordinance of the Ministry for Health, Welfare and Family Affairs and be registered with the Minister of Health, Welfare and Family Affairs as an Embryo Research Institution.

Article 19 – Approval of Embryo Research Protocol

- ① When an Embryo Research Institution, registered with the Minister of Health, Welfare and Family Affairs under article 18, wishes to do research on embryos under the provisions of article 17, it shall submit an Embryo Research Protocol for the approval of the Minister of Health, Welfare and Family Affairs. The same requirement applies even in the event of making changes to the important contents covered by the Presidential Decree.
- ② The Embryo Research Protocol mentioned in paragraph ① should include documents showing the review results of that Embryo Research Institution's Institutional Committee.
- ③ When an Embryo Research Institution submits a research protocol that is funded by a central government agency, the Minister of Health, Welfare and Family Affairs should discuss the matter with the head of that agency before granting approval.
- ④ The approval criteria, processes, documents, and any other relevant details shall be decided by the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Article 20 – Supplying and Maintaining Spare Embryos

- ① When an Embryo Producing Institution supplies a spare embryo to an Embryo Research Institution for research approved under article 19-①, it shall be supplied for free. However, the Embryo Producing Institution may, under the Ordinance of the Ministry for Health, Welfare and Family Affairs, request that the Embryo Research Institution provide reimbursement for the expenses of storing and providing the spare embryo.
- ② The supply procedures, the calculation of expenses, and any other details concerning the spare embryos mentioned in paragraph ① shall be decided by the Ordinance of the Ministry for Health, Welfare and Family Affairs.
- ③ The Embryo Producing Institution and Embryo Research Institution shall report all details concerning the storage and supply of spare embryos to the Minister of Health, Welfare and Family Affairs in accordance with the Ordinance of the Ministry for Health, Welfare and Family Affairs.
- ④ The provisions of article 16-② through 16-④ shall apply to the disposal of spare embryos that are received by an Embryo Research Institution in accordance with paragraph ① but are not utilized for research. In such cases, the Embryo Producing Medical Institution will be regarded as the Embryo Research Institution.

Article 20.2 – Registration of stem cell lines

- ① Anyone who has established or imported stem cell lines shall register those lines with the Minister of Health, Welfare and Family Affairs as provided in the Ordinance of the Ministry for Health, Welfare and Family Affairs before he/she provides them pursuant to article 20.3 or uses them pursuant to article 20.4.
- ② If a person applies for registration of stem cell lines which have been scientifically validated by the heads of other government agencies, the Minister of Health, Welfare and Family Affairs shall utilize those validation resources in registration process pursuant to paragraph ①.
- ③ The Minister of Health, Welfare and Family Affairs may reimburse a person who registered stem cell lines pursuant to paragraph ① for all or part of the cost of validation of those lines.

Article 20.3 – Distribution of stem cell lines

- ① If a person who has established or imported the stem cell lines in accordance with article 20.2 plans to provide those lines, he/she shall undergo the Institutional Committee review as provided in the Ordinance of the Ministry for Health, Welfare and Family Affairs.
- ② A person who provided the stem cell lines pursuant to paragraph ① should report a supply status to the Minister of Health, Welfare and Family Affairs as provided in the Ordinance of the Ministry for Health, Welfare and Family Affairs.

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- ③ When a person supplies stem cell lines in accordance with paragraph ①, it shall be supplied for free. However, the provider may be reimbursed for the expenses for storage and distribution by the recipient.
- ④ Any details concerning distribution and report procedures, and the calculation of expenses mentioned from paragraphs ① through ③ shall be provided in the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Article 20.4 – Utilization of stem cell lines

- ① The stem cell lines registered in accordance with article 20.2 shall be used in vitro for the following research purposes:
 - 1. Research to diagnose, prevent or treat diseases;
 - 2. Basic research to study characteristics and differentiation of stem cells; or
 - 3. Other research decided by the Presidential Decree after it has been reviewed by the National Committee.
- ② A person who wishes to use stem cell lines under paragraph ① shall obtain approval of the head of the institution for a research protocol after it has been reviewed by the Institutional Committee as provided in the Ordinance of the Ministry for Health, Welfare and Family Affairs. The same requirement applies even in the event of making changes to the important contents in the approved protocol, which are decided by the Presidential Decree.
- ③ A person who obtained approval or modification approval under paragraph ② shall report this fact to the Minister of Health, Welfare and Family Affairs as stipulated in the Ordinance of the Ministry for Health, Welfare and Family Affairs.
- ④ A person who has obtained approval under paragraph ② shall submit a plan for utilization of stem cell lines to the provider.
- ⑤ The head of the institution who has approved research under paragraph ② shall conduct oversight to ensure that the investigators conduct research by following the protocol.

Article 21 – Compliance of Embryo Producing Medical Institutions and Embryo Research Institutions

Embryo Producing Medical Institutions and Embryo Research Institutions shall do the following:

- 1. Deal with embryos in accordance with what is written in the relevant consent forms, as outlined in article 15;
- 2. Exercise care in storing, handling, and disposing of spare embryos;
- 3. Cease all relevant research or take appropriate measures when the research poses a significant or potential threat to bioethics or safety; and

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4. Follow other regulations or guidelines set by the Ordinance of the Ministry for Health, Welfare and Family Affairs in order to ensure bioethics and safety in accordance with subparagraphs 1 through 3.

Section 3 – Somatic Cell Cloning Embryos

Article 22 – The Act of Somatic Cell Nuclear transfer

- ① No one shall conduct somatic cell nuclear transfer other than for the purpose of conducting research aimed at curing rare or currently incurable diseases, as described in article 17-②.
- ② The type, subject, and extent of allowed research on somatic cell nuclear transfer guided by the purpose stated in paragraph ① shall be decided by the Presidential Decree after it has been reviewed by the National Committee.

Article 23 – Production and Research of Somatic Cell Cloning Embryos

- ① Any one wishing to produce or research somatic cell cloning embryos shall register with the Minister of Health, Welfare and Family Affairs only after satisfying the requirements concerning facilities and personnel set by the Ministry for Health, Welfare and Family Affairs.
- ② Articles 19 through 21 shall apply also to research on somatic cell cloning embryos. In this case, “spare embryo” is regarded as “somatic cell cloning embryos”.

Chapter 4

Genetic Test

Article 24 – Genetic Testing Institutions

- ① Anyone who wishes to conduct genetic tests or directly obtain the specimens and do genetic research on them should report the following details to the Minister of Health, Welfare and Family Affairs: the location of the institution in which the tests or research are carried out, the name of the head of the institution, the type of genetic tests or research topics carried out, and other details required by the Ordinance of the Ministry for Health, Welfare and Family Affairs. Government agencies that conduct genetic tests or engage in gene research are not required to report these details to the Minister of Health, Welfare and Family Affairs.

- ② The provisions of paragraph ① will apply even in the event of making changes to the important contents covered by the Presidential Decree.
- ③ The Minister of Health, Welfare and Family Affairs may require any institution wishing to conduct genetic tests in accordance with paragraph ① (hereafter called a Genetic Testing Institution) to be evaluated for the accuracy of its genetic tests and make the results of this evaluation public.
- ④ If a Genetic Testing Institution ceases operations, either permanently or temporarily, it should report to the Minister of Health, Welfare and Family Affairs, in accordance with the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Article 25 – Restrictions on Genetic Tests

- ① Genetic Testing Institutions shall not conduct genetic tests concerning physical characteristics or personality traits that may mislead subjects due to a lack of scientific evidence; nor shall they conduct tests that have been prohibited by the Presidential Decree after being reviewed by the National Committee.
- ② Genetic Testing Institutions shall not conduct genetic tests on embryos or fetuses for purposes other than that of diagnosing muscle dystrophy or other gene-related diseases as stipulated by the Presidential Decree.
- ③ No Genetic Testing Institution shall conduct genetic tests for the diagnosis of disease, unless it either is a medical institution or is requested by a medical institution to conduct such tests.

Article 26 – Consenting to Genetic Tests

- ① Before a Genetic Testing Institution or anyone conducting gene research obtains, either directly or indirectly, specimens or materials to be utilized in the research, a written consent, which includes the following details, should be obtained from the test subject:
 - 1. The purpose of the genetic test or gene research;
 - 2. Indication of whether or not consent is given for the use or provision of specimens and their extent other than for purposes mentioned in paragraph ①-1;
 - 3. Indication of whether or not personal information will be revealed when specimens are provided to others, in accordance with paragraph ①-2;
 - 4. Information on the maintenance and storage period of specimens; and
 - 5. Information on the right and manner of withdrawing consent, the rights and protection of test subjects, and any other details stipulated by the Ordinance of the Ministry for Health, Welfare and Family Affairs.
- ② When anyone other than a Genetic Testing Institution requests a genetic test, a written consent, as outlined in paragraph ①, should be obtained from the test subject and attached to the request. In this case, all necessary steps must be taken

to protect personal information, as guided by the Ordinance of the Ministry for Health, Welfare and Family Affairs.

- ③ If the test subject is a minor, a quasi-incompetent, or an incompetent, the consent outlined in paragraph ①, as well as an additional consent by his or her legal guardian, should be obtained. However, in the case of conducting genetic tests for the purpose of diagnosing or treating a disease, if consent cannot be obtained from the test subject due to his or her quasi-incompetence or incompetence, consent from the test subject may be waived.
- ④ Notwithstanding paragraphs ① through ③, a genetic test may be conducted without written consent in either of the following cases:
 1. When there is an urgent or a special reason to identify an individual who is either deceased or unconscious; or
 2. When special provisions exist under other Acts.
- ⑤ Anyone wishing to obtain a written consent, as outlined in paragraphs ① through ③ shall thoroughly explain the purpose and procedures of the genetic test as well as the meanings of its possible results to the test subject or his or her legal guardian beforehand.
- ⑥ The consent procedures, the format of the consent documents, and any other necessary details related to paragraphs ① through ③ shall be stipulated in the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Article 27 – Providing Specimens

- ① When a Genetic Testing Institution obtains a written consent from a test subject concerning the use of specimens for research purpose as guided by article 26, it may provide the specimens to either a person conducting research on genes or an institution licensed to open a Gene Bank under article 32.
- ② Genetic Testing Institution shall not include personal information in the specimens mentioned in paragraph ①. However, personal information may be included when the test subject or his or her legal guardian has agreed to it in a written consent and a copy of the written consent is attached.
- ③ When a Genetic Testing Institution, any institution conducting gene research, or any institution licensed to open a Gene Bank (hereafter called Genetic Testing Institutions) provide, or are provided with, specimens as guided by paragraph ①, a record of the process shall be kept, as stipulated in the Ordinance of Ministry for Health, Welfare and Family Affairs.
- ④ Paragraphs ① through ③ shall apply when an institution that has received specimens wishes to provide them to other researchers or Gene Banks.

Article 28 – Disposal of Specimens

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- ① The storage period of specimens shall be five years, unless the test subject or his or her legal guardian states otherwise in the written consent outlined in article 26-①.
- ② Genetic Testing Institutions shall dispose of specimens immediately after the storage period expires, unless the test subject or his or her legal guardian submits a written request not to dispose of the specimens.
- ③ If the test subject or his or her legal guardian requests the disposal of his or her specimens at any point during the storage period, the Genetic Testing Institutions shall comply with the request.
- ④ Genetic Testing Institutions shall keep records and file documentation concerning the disposal of all specimens.
- ⑤ If Genetic testing Institutions close, temporarily or permanently, or cannot store specimens for unavoidable reasons, they shall handle or transfer the specimens in accordance with the Ordinance of the Ministry for Health, Welfare and Family Affairs.
- ⑥ Other necessary details concerning the disposal procedures and methods, the keeping and filing of records, and the handling and transferring of the specimens described in paragraph ⑤ shall be stipulated in the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Article 29 – Filing and Reading Records

- ① Genetic Testing Institutions shall file the following documents in accordance with the Ordinance of the Ministry for Health, Welfare and Family Affairs:
 1. A signed consent form, as outlined in article 26;
 2. The results of the genetic tests; and
 3. The records of providing specimens in accordance with article 27-③.
- ② Genetic Testing Institutions shall comply with all requests made by the test subject or his or her legal guardian to access to or obtain copies of the records described in paragraph ①.
- ③ Other necessary details concerning the request procedures and forms to access to or obtain copies of records shall be stipulated in the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Article 30 – Obligations of Genetic Testing Institutions

- ① Genetic Testing Institutions shall observe the following:
 1. The details of informed consent outlined in article 26;
 2. The protection of genetic information; and
 3. Other details related to subparagraphs 1 and 2 that the Ordinance of the Ministry for Health, Welfare and Family Affairs stipulates to ensure bioethics and safety.

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- ② Genetic Testing Institutions shall not make false statements or exaggerated advertisements about genetic tests.
- ③ The extent of false statements or exaggerated advertisements, and other relevant details concerning paragraph ② shall be stipulated in the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Chapter 5

Protection and Use of Genetic Information, etc

Article 31 – Prohibitions on Discrimination Based on Genetic Information

- ① No one shall be discriminated against in educational opportunities, in employment or promotion, or in eligibility for insurance coverage on the basis of his or her genetic information.
- ② Unless specifically stated otherwise in a different law, no one shall force others to take genetic tests or to submit genetic test results.

Article 32 – Gene Bank Licensing and Registration

- ① Any one who wishes to establish a Gene Bank must receive licensing of the Minister of Health, Welfare and Family Affairs, as stipulated in the Presidential Decree. However, it does not apply to a government agency which wishes to establish a Gene Bank.
- ② Notwithstanding paragraph ② if anyone wishes to establish a Gene Bank with a research grant from the head of a central government agency under other Acts, he/she is regarded to receive licensing of the Minister of Health, Welfare and Family Affairs when he/she obtains the approval for research grant from the head of that agency. In this case, the head of the central government agency shall consult with the Minister of Health, Welfare and Family Affairs before granting license.
- ③ Before moving the location of a Gene Bank, under article 32-①, or making other important changes stipulated in Presidential Decree, the head of the Gene Bank should report to the Minister of Health, Welfare and Family Affairs as stipulated in the regulations of Ministry for Health, Welfare and Family Affairs.
- ④ If a Gene Bank is closed, temporarily or permanently, the head of the Gene Bank should report to the Minister of Health, Welfare and Family Affairs, in accordance with the Ordinance of the Ministry for Health, Welfare and Family Affairs.

- ⑤ Facilities and equipment standards, licensing procedures, and other necessary details concerning Gene Banks, under article 32-①, shall be stipulated in the Presidential Decree.

Article 33 – Providing Genetic Information

- ① Any one wishing to use genetic information from a Gene Bank shall submit a plan on how the genetic information is to be used to the head of the Gene Bank.
- ② The head of the Gene Bank shall decide whether or not to release genetic information only after that institution's Institutional Committee, under article 9, reviews the plan on how the information will be used. Furthermore, the head of the Gene Bank must report the results of the Institutional Committee's review to the Minister of Health, Welfare and Family Affairs.
- ③ Details of the items to be included in the plan, submission procedures, and guidelines for providing and maintaining genetic information will be stipulated in the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Article 34 – Obligations of Heads of Gene Banks

- ① The head of a Gene Bank shall not include personal information when providing others with the genetic information mentioned in article 33.
- ② When the head of Gene Bank provides others with genetic information, it shall be provided free of charge. However, the head of Gene Bank may request compensation for the cost of maintaining and providing genetic information, as stipulated in the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Article 35 – Protection of Genetic Information

- ① In the absence of legitimate reasons for doing so, neither the head of a Gene Bank nor its employees shall provide others with genetic information obtained through their work; nor shall they use such genetic information for inappropriate purposes.
- ② In accordance with the provisions of article 20-① of the Medical Act, medical institutions shall not include genetic information when disclosing patient information to persons other than the patient. However, disclosure of a patient's genetic information is allowed when it is requested by another medical institution seeking to diagnose and cure the same disease as the patient's and when appropriate measures are taken to protect the patient's personal information.

Article 35.2 – Management of genetic information

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- ① A Gene Bank shall render all of the genetic information collected anonymous before storage and maintenance.
- ② A Gene Bank shall designate an officer responsible for maintenance and security of information to protect personal information.
- ③ Other matters concerning storage and maintenance of genetic information under paragraph ① and responsibilities of security officer under paragraph ② shall be provided in the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Article 35.3 – Support for the operation of a Gene Bank

The national or regional governments may provide financial support for the operation of a Gene Bank within the budget.

Chapter 6

Gene Therapy

Article 36 – Gene Therapy

- ① Gene therapy is allowed only in any of the following cases:
 1. To treat or cure genetic disorders, cancer, Acquired Immune Deficiency Syndrome, and other life threatening or seriously damaging diseases;
 2. To treat diseases for which there currently is no cure or when the expected results of gene therapy outweigh those of other therapies; or
 3. To prevent or cure diseases that the Minister of Health, Welfare and Family Affairs, after a review by the Institutional Committee, targets for treatment by means of gene therapy.
- ② Notwithstanding paragraph ①, gene therapy on sperm, oocytes, embryos, or fetuses is prohibited.

Article 37 – Gene Therapy Institutions

- ① Any medical institutions wishing to conduct gene therapy should register with the Minister of Health, Welfare and Family Affairs. This condition will apply even in the event of making changes to the important contents covered by the Presidential Decree.
- ② Any medical institution (hereafter called a 'Gene Therapy Institution') that has registered with the Minister of Health, Welfare and Family Affairs according to the provisions of paragraph ① shall obtain a written consent from patients

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wishing to undergo gene therapy only after it provides them sufficient information, including the following:

1. The purpose of the therapy;
 2. The predicted results and side effects of the therapy; and
 3. Other details stipulated in the Ordinance of the Ministry for Health, Welfare and Family Affairs.
- ③ The reporting requirements and procedures that each Gene Therapy Institution shall follow, the written consent forms that they are to use, and other relevant details shall be stipulated in the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Chapter 7

Supervision

Article 38 – Report and Inspection

- ① The Minister of Health, Welfare and Family Affairs may order Embryo Producing Medical Institutions, Embryo Research Institutions, Genetic Testing Institutions, Gene Therapy Institutions (hereafter called the ‘institutions subject to inspection’) and their employees to report or submit any details concerning the enforcement of this Act when it is deemed necessary to ensure bioethics and safety. The Minister may also order any research or development or use of biotechnology to stop or may take any other precautionary measures when there is either a serious or a potential threat to bioethics or safety.
- ② Whenever the Minister of Health, Welfare and Family Affairs believes there is a need to confirm that the provisions of this Act are being followed, the Minister may send a government official to any of the institutions subject to inspection or their offices in order to inspect facilities and documents, to ask questions of the institution’s employees, and to collect minimum amounts of specimens needed for inspection. In this case, the government official shall carry proof of his or her authority and show it to the relevant representatives of the institution under inspection.
- ③ Institutions subject to inspection and their employees shall comply with all orders, inspection requests, and questions under paragraphs ① and ②, unless there is a legitimate reason not to do so.

Article 39 – Disposal Orders

The Minister of Health, Welfare and Family Affairs may order institutions subject to inspection, their employees and the persons who registered, provided or used stem cell lines in accordance with articles 20.2 through 20.4 to dispose of embryo, somatic cell

cloning embryos, stem cell lines, or oocytes that have been created, stored, or provided in breach of articles 13, 14, 15-①, 15.2, 15.3, 16-②, 17 through 19, 20-①, 20-④, 20.2-①, 20.3-①, 20.3-③, 20.4-②, 22-① and 23 as well as specimens that have been collected, stored, and provided in breach of articles 24-①, 25, 26-① through ③, 27-①, 27-②, 27-④, 28-②, 28-③, 32-①, 32-②. The procedures and methods of disposal shall comply with provisions of article 16-④ or article 28-⑥.

Article 40 – Improvement Orders

When the Minister of Health, Welfare and Family Affairs concludes that the research being carried out at an institution subject to inspection, or its collection, storage, or creation procedures for embryos, poses a serious threat to bioethics or safety, in virtue of the fact that the facility fails to meet the standards set in articles 14-②, 18, 23 or 32-⑤, the Minister may either order the institution to improve its facilities or close the facility, either partially or fully.

Article 41 – License Revocation and Facility Closure

- ① If any of the following conditions apply to an Embryo Producing Medical Institution, an Embryo Research Institutions, a Genetic Testing Institution, a Gene Bank, or a Gene Therapy Institution, the Minister of Health, Welfare and Family Affairs may revoke the authorization, registration, or license of that institution or order it to close its facilities, partially or fully, for a maximum of one year:
 1. It is in breach of articles 9-①, 9-③, 10-①, 10-③, 11 through 14, 15-①, 15-③, 15.2, 15.3, 16-②, 16-③, 17, 19-①, 20, 22, 24-②, 24-④, 25, 26-① through ③, 26-⑤, 27, 28-② through ⑤, 29-①, 29-②, 32-③, 32-④, 33-②, 35, 35.2-①, 35.2-②, 36, 37-① or 37-②;
 2. It does not comply with articles 21, 30, or 34;
 3. It fails to carry out the orders of articles 38-①, 39, or 40; or
 4. It does not comply with inspections, questions, and collection requirements stated in article 38-②.
- ② Details on the administrative action under paragraph ① shall be stipulated in the Ordinance of the Ministry for Health, Welfare and Family Affairs, which will take into consideration the type and degree of the violation.

Article 42 – Hearing

Whenever the Minister of Health, Welfare and Family Affairs wishes to revoke the authorization, registration, or license of an institution under article 41-①, a hearing shall be held.

Article 43 – Issuing of Fines

- ① If, for any of the following reasons, an order by the Minister of Health, Welfare and Family Affairs to shut down an Embryo Producing Medical Institution or a Genetic Therapy Institution either causes serious inconveniences to the users of the facility or poses threats to the public interest, the Minister of Health, Welfare and Family Affairs may instead fine the institution a maximum amount of 200 million Korean won as stipulated in the Presidential Decree.
1. It is in breach of articles 14, 15-①, 15-③, 16-②, 16-③ or 36;
 2. It is in breach of article 21;
 3. It fails to carry out the orders stated in articles 38-①, 39, or 40; or
 4. It fails to comply with the inspection, questioning, or collection requirement mentioned in article 38-②.
- ② The amount of the fines levied, which will depend on the type and degree of the violations under paragraph ①, and other necessary details will be stipulated in the regulations of Ministry for Health, Welfare and Family Affairs.
- ③ When a person who is charged with a fine does not pay it on time, the Minister of Health, Welfare and Family Affairs may collect the full amount of the fine under the disposition of national taxes in arrears.

Article 44 – Commission Fee

When anyone wishes to be authorized, registered, licensed or approved, or wishes to file a report or make changes to filed documents under the provisions of this Act, the Minister of Health, Welfare and Family Affairs may make them subject to such commission fees as provided by the Ordinance of the Ministry for Health, Welfare and Family Affairs.

Chapter 8

Supplementary Rules

Article 45 – Support for Adult Stem Cell Research

The national and regional governments may both provide financial support for adult stem cell research.

Article 46 – National Fund Support

To promote and support research and education concerning bioethics and safety in the life sciences and biotechnologies, the Minister of Health, Welfare and Family Affairs may offer either partial or full financial support to organizations, research institutions, and life science professionals, as stipulated in the Presidential Decree.

Article 47 – Delegating Responsibilities

- ① The Minister of Health, Welfare and Family Affairs may delegate part of his authority in this Act to the head of other institutions, as stipulated in the Presidential Decree.
- ② The Minister of Health, Welfare and Family Affairs may entrust part of the following duties to the relevant institutions or organizations, as stipulated in the Presidential Decree:
 1. Evaluating the Institutional Committee and educating the Institutional Committee members mentioned in article 10-2;
 2. Managing the Embryo Producing Medical Institutions mentioned in article 14;
 3. Managing the Embryo Research Institutions mentioned in article 18;
 4. Registering the stem cell lines mentioned in article 20.2-①
 5. Managing the Genetic Testing Institutions mentioned in article 24;
 6. Managing the Gene Banks mentioned in article 32; and
 7. Managing the Gene Therapy Institutions mentioned in article 37.
- ③ When the Minister of Health, Welfare and Family Affairs entrusts institutions and organizations with any of the duties described in article 47-②, he may reward those institutions or organizations with financial compensation for such work.

Article 48 – Prohibition on Disclosure of Secret Information

Neither the institutions subject to inspection nor their employees shall disclose or misappropriate secret information that they come across *ex officio*.

Chapter 9

Penal Clause

Article 49 – Penal Clause

- ① Anyone who, in violation of article 11-①, implants a somatic cell cloning embryo into a uterus, maintains a cloned embryo within a uterus, or gives birth when the

pregnancy results from the act of implanting a somatic cell cloning embryo into a uterus shall be sentenced to up to 10 years of imprisonment.

- ② Anyone who attempts any of the actions described in paragraph ① shall be punished accordingly.

Article 50 – Penal Clause

Anyone who, in violation of article 12-①, implants a human embryo into an animal's uterus or an animal embryo into a human's uterus and any one who, in violation of article 12-③, implants the products of the acts described in article 12-② into the uterus of an animal or a human shall be sentenced to up to 5 years of imprisonment.

Article 51 – Penal Clause

- ① Sentences of up to 3 years of imprisonment shall be given to a person described in any of the following:
1. Anyone who, in violation of article 11-②, either induces, or assists in, the act of implanting a somatic cell cloning embryo into a uterus, maintaining a cloned embryo within a uterus, or giving birth when the pregnancy results from the act of implanting a somatic cell cloning embryo into a uterus;
 2. Anyone who performs any of the actions described in article 12-②;
 3. Anyone who, in violation of article 13-①, produces an embryo for a purpose other than pregnancy;
 4. Anyone who performs any of the actions described in article 13-②;
 5. Anyone who, in violation of article 13-③, either induces or assists in providing or utilizing sperm or oocytes for monetary benefits, property interests or other personal benefits in return;
 6. Anyone who, in violation of article 13-③, either induces or assists in providing sperm or oocytes for monetary benefits, property interests or other personal benefits in return;
 7. Anyone who, in violation of article 22-①, conducts somatic cell nuclear transfer for a purpose other than that of engaging in research aimed at curing rare or incurable diseases; or
 8. Anyone who, in violation of article 48, discloses or misappropriates secret information that they come across *ex officio*.
- ② Anyone who, in violation of article 17, utilizes spare embryos shall either be sentenced to up to 3 years of imprisonment or pay a fine of up to 50 million Korean won.
- ③ Anyone who attempts any of the actions described in paragraph ①-1 shall be punished accordingly.

Article 52 – Penal Clause

Sentences of up to 3 years of imprisonment or fines of up to 30 million Korean won shall be given to a person described in any of the following:

1. [deleted]
2. Anyone who, in violation of article 15-①, harvests sperm and oocytes without obtaining a written consent concerning embryo creation;
- 2-2. Anyone who, in violation of article 15.2-②, does not conduct a physical examination of oocyte donors; and
- 2-3. Anyone who, in violation of article 15.2-②, collects oocytes, and
- 2-4. Anyone who, in violation of article 15-③, collects oocytes.
3. Anyone who, in violation of article 25, conducts a genetic test;
4. Anyone who, in violation of article 26-① through ③, collects specimens without a written consent for a genetic test or requests a genetic test without attaching a written consent;
5. Anyone who, in violation of article 31-① or ②, discriminates against other people by using genetic information or forces others to either take a genetic test or submit the results of a genetic test;
6. Anyone who, in violation of article 34, includes personal information when providing others with genetic information;
7. Anyone who, in violation of article 35-①, provides others with genetic information without a legitimate reason for doing so or who uses such information for an illegitimate purposes;
8. Anyone who, in violation of article 36-① or ②, performs gene therapy; or
9. Anyone who fails to comply with the Disposal Orders mentioned in article 39.

Article 53 – Penal Clause

Sentences of up to 1 year of imprisonment or fines of up to 20 million Korean won shall be given to a person described in any of the following:

1. Anyone who, in violation of article 14, harvests and stores human sperm or oocytes or creates embryos in places not licensed as Embryo Producing Medical Institutions;
2. Anyone who, in violation of article 16-② or ③ (including the application of article 20-④), does not dispose of embryos in accordance with the Ordinance of the Ministry for Health, Welfare and Family Affairs or does not record or store information about the embryo disposal;
3. Anyone who, in violation of article 18, conducts research on spare embryos without being registered as an Embryo Research Institution;
4. Anyone who, in violation of article 19-① (including the application of article 23-②), conducts research on embryos without the expressed approval of the Minister of Health, Welfare and Family Affairs;
5. Anyone who, in violation of article 20-① or ③, provides spare embryos for monetary compensation or does not report the details of the storage and provision of spare embryos to the Minister of Health, Welfare and Family

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Affairs, as stipulated in the Ordinance of Ministry for Health, Welfare and Family Affairs;

6. Anyone who, in violation of article 23-①, creates a somatic cell cloning embryo or conducts research on such a clone, without being registered with the Minister of Health, Welfare and Family Affairs;
7. Anyone who violates article 30-① or who, in violation of article 30-②, makes false statements or exaggerated advertisements about genetic tests;
8. Anyone who, in violation of article 32-①, opens a Gene Bank without being licensed by the Minister of Health, Welfare and Family Affairs; or
- 8-2. Anyone who, in violation of article 35-2-①, does not render the genetic information anonymous before storage and maintenance.
9. Anyone who violates the Improvement Orders described in article 40.

Article 54 – Provision of Dual Punishment

When the head of a corporation, a representative or an employee of a corporation or an individual, or its other employee violates any of the articles 49 through 53, a fine shall be imposed upon the agent who commits the act as well as on the corporation or the individual for whom the agent works.

Article 55 – Fines of Negligence

- ① Fines of up to 5 million Korean won shall be given to a person described in any of the following:
 1. Anyone who, in violation of article 20.2-①, provides or utilizes stem cell lines which have not been registered;
 2. Anyone who, in violation of the provisions of article 20.3-③, provides the stem cell lines for monetary compensation;
 3. Anyone who, in violation of article 20.4-①, utilizes the stem cell lines;
 4. Anyone who fails to report details mentioned in article 24-①, ② or ④;
 5. Anyone who violates any of the article 28-② through ⑤;
 6. Anyone who, in violation of article 29-①, fails to store documents or who, in violation of article 29-②, denies access to, or the copying of, records;
 7. Anyone who fails to report the details mentioned in article 32-③ or ④;
 8. Anyone who, in violation of article 35-②, provides records including a patient's genetic information to someone other than the patient;
 9. Anyone who, in violation of article 35.2-②, does not designate an officer responsible for maintenance and security of information; or
 10. Anyone who, in violation of article 37-①, conducts Gene Therapy without being registered with the Minister of Health, Welfare and Family Affairs.

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- ② The negligence fine under paragraph ① shall be levied and imposed by the Minister of Health, Welfare and Family Affairs, as stipulated in the Presidential Decree.
- ③ Anyone who objects to the negligence fine imposed upon him or her under paragraph ② may submit a demurrer to the Minister of Health, Welfare and Family Affairs within 30 days of receiving notice of the fine.
- ④ When a person, imposed with a negligence fine under paragraph ②, submits a demurrer under paragraph ③, the Minister of Health, Welfare and Family Affairs should report the matter immediately to a competent court, and the court shall open a trial following non-litigation case procedures.
- ⑤ When no demurrer is submitted within the time period stated in paragraph ③, and when the fine remains unpaid, it will be collected under the disposition of national taxes in arrears.

Additional Provisions

[Act No. 7150 enacted on January 29, 2004]

- ① **(Date of Effect)** This Act shall take effect on 1 January 2005. However, articles 11, 12, 49, 50, 51-①-1 and 2 shall become effective on the day of promulgation.
- ② **(Interim Measures on Spare Embryo Research)** Until the embryological primitive streaks emerge, spare embryos may be utilized for any of the purposes mentioned in article 17 on the following conditions:
 1. The spare embryos was produced before this Act takes effect;
 2. A period of 5 years has passed since the spare embryos were created; and
 3. A written consent was obtained from the consenters. However this requirement does not apply in case that it is impossible to receive consents because consenter's whereabouts is unknown.
- ③ **(Interim Measures on Embryonic Stem Cell Research)** Anyone who is engaged in embryonic stem cell research for the purposes mentioned in article 17-2 at the time this Act takes effect may continue his or her research, with the approval of the Minister of Health, Welfare and Family Affairs, on the following conditions:
 1. The researcher has been engaged in embryonic stem cell research for at least 3 years; and
 2. The researcher has published at least one research paper on embryonic stem cell research in a related academic periodical.
- ④ **(Revision of Other Acts)** The Organ Transplantation Act is revised as follows: The term "Bioethics Committee" in the title of Chapter 2 is revised as "Organ Transplantation Ethics Committee". The title of article 7, "Bioethics

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Committee” is revised as “Organ Transplantation Ethics Committee,” and the term “Bioethics Committee” in article 7-① is revised as “Organ Transplantation Ethics Committee.”

Additional Provisions

[Act No. 9100 revised on June 5, 2008]

- ① (Date of Effect) This Act shall take effect six months after promulgation. However, revised articles 20.2 through 20.4 shall become effective on the day of 1 January 2010.
- ② (Interim Measures on registration of established or imported stem cell lines) The stem cell lines established or imported before the effective date of revised articles 20.2 through 20.4 shall be regarded as established or imported in accordance with the revised provision of article 20.2. In this case, application for registration shall be submitted no later than 30 June 2010.