

Act No.7150

# Bioethics and Biosafety Act

## 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 DNA.
2. “Embryo” refers to a fertilized egg (or segmented cell) from the moment of fertilization to the point of time at which all organs of the given organism have developed embryologically.
3. “Remaining Embryo” refers to an embryo that is created through *in vitro* fertilization procedures but is not implanted in the womb of any woman.
4. “Somatic Cell Nucleus Transfer” refers to the transfer of a human somatic cell nucleus to a human or animal oocyte from which the nucleus has been removed.
5. “Somatic Cell Embryo Clone” refers to an embryo formed by the act of somatic cell nucleus transfer.
6. “DNA Test” refers to the act of analyzing chromosomes and DNA 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 DNA tests.
8. “DNA Bank” refers to an institution which either directly uses or provides others with preserved samples of genes or personal genetic information.
9. “Gene Therapy” refers to procedures involving genetic mutation that are intended to prevent or treat certain diseases.

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### **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 biosafety 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 biosafety.

### **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 Review Boards**

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

- ① There shall exist a National Bioethics Committee (hereafter called the ‘Committee’), responsible to the President, whose function it is to review the following items concerning bioethics and biosafety in the life sciences and biotechnologies:
  1. Policies concerning national bioethics and biosafety;
  2. The type, subject, and extent of research involving remaining embryos under Article 17-3;
  3. The type, subject, and extent of research involving somatic cell nucleus transfer under Article 22-②;
  4. The types of DNA 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

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6. Other issues of social or moral significance concerning the research, development, and utilization of life sciences and biotechnologies that the Chairperson of the Committee formally submits to the Committee for its deliberation.
- ② The Chairperson of the Committee shall submit to the Committee for its deliberation any issue related to items ①-1 through ①-5 that has been proposed by at least one third of the members of the Committee.

#### **Article 7 – Composition of the Committee**

- ① The 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 Committee; the Vice-Chairperson of the Committee shall be elected by a majority vote of the Committee members.
- ③ Membership in the Committee shall be as follows.
  1. The following ministers will all be members of the Committee: the Minister of Education and Human Resources Development, the Minister of Justice, the Minister of Science and Technology, the Minister of Commerce, the Minister of Industry and Energy, the Minister of Health and Welfare, 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 clause ③-2 and ③-3 shall serve on the Committee for a term 3 years and may be reappointed for additional terms.
- ⑤ The Committee shall have two executive secretaries: the Minister of Science and Technology and the Minister of Health and Welfare. The Chief Executive Secretary shall be the Minister of Health and Welfare.

#### **Article 8 – Operation of the Committee**

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

## **Article 9 – The Establishment of Institutional Review Boards**

- 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 Review Board (hereafter called a “Board”):
  1. Embryo research institutions registered with the Ministry of Health and Welfare according to Article 18;
  2. DNA banks approved by the Minister of Health and Welfare under Article 32-①;
  3. Gene therapy institutions, under Article 37-②; and
  4. Other research institutions appointed by the Minister of Health and Welfare that research, develop, or utilize life sciences and biotechnologies that may have significant moral or social consequences.
  
- ② The Board 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 and whether or not the research conforms to protocols in the life sciences and biotechnologies;
  2. Whether or not consent was obtained, with appropriate measures, from all patients and donors of sperm, eggs, and test samples;
  3. The safety measures undertaken for patients, subjects of genetic information, and donors of sperm, eggs, or test samples. Where sperm, eggs, or test samples are provided to others, information such as the donors' name and identification number (hereafter called ‘personal information’), which can be used to identify individuals, must be protected.
  4. Other matters concerning the research, development, or utilization of life sciences and biotechnologies carried out by the institutions listed in Article 9-①.
  
- ③ Where there is a serious threat or a potential threat to bioethics and biosafety due to the research, development, or utilization of the life sciences and biotechnologies at any of the institutions listed in Article 9-①, the head of that institution must summon its Board immediately to review the relevant details of the threat or potential threat and must also report the results of the Board's meeting to the Minister of Health and Welfare.
  
- ④ Among the institutions mentioned in Article 9-①, when an institution is below the standard set by the Ministry of Health and Welfare, in size or number of researchers, and when that institution has agreed to cooperate in the review of items listed in Articles 9-② and 9-③ with a similar institution that does have a Board, then such an institution will be regarded as having a Board.

### **Article 10 – Organization and Administration of Boards**

1. Each Board shall consist of between 5 and 9 persons, including one chairperson. Each Board should also include one person not engaged in the fields of life science or medical science, as well as 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 Board, and the chairperson shall be elected by a majority vote of the members of that Board.
3. Members involved in research, development, or utilization of life sciences and biotechnologies that needs to be reviewed by the Board shall not participate in the review process.
4. Other matters related to the Board's composition and operation not covered by this Act shall be decided by the President.

## **Chapter 3 Embryo Production and Research**

### **Paragraph 1 – Prohibitions on Human Cloning**

#### **Article 11 – Prohibition on Human Cloning**

- ① No one shall implant a somatic cell embryo clone 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 embryo clone into a uterus.
- ② No one shall induce or assist in the activities defined in Article 11-①.

#### **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's somatic cell nucleus into a human oocyte whose nucleus has been removed;
  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 Article 12-② into the uterus of a human being or animal.

## Paragraph 2 – Embryos Produced through Artificial Insemination

### 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 induce or assist in providing or utilizing sperm or oocytes for the purpose of receiving financial reward, property, or any other personal benefits.

### 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 authorized to do by the Minister of Health and Welfare and designated as an Embryo Producing Medical Institution.
- 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 Ministry of Health and Welfare.
- ③ The Ministry of Health and Welfare 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 Article 15-①, the following shall be included:
  1. The details of the purpose of producing an embryo;
  2. The details of the period of depositing embryos;
  3. The details of the disposal of all embryos;

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4. Indication of whether or not consent is given to utilize the remaining 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 Ministry of Health and Welfare.
- ③ Embryo Producing Medical Institutions shall explain in detail the contents of Article 15-② before obtaining a written consent under the provisions of Article 15-①.
- ④ Any other details or procedures required for the written consent outlined in Article 15-①, such as the consent form and record keeping, will be decided by the Ministry of 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 agree to 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 Ministry of Health and Welfare.

#### **Article 17 – Research on Remaining Embryos**

Remaining Embryos that have passed the storage period outlined in Article 16 may be utilized for 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, as decreed by the President.
3. To conduct other research approved by the President after being reviewed by the Committee.

However, in order to utilize a remaining 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 remaining embryos under the provisions of Article 17 should meet the facility and manpower requirements set by the Ministry of Health and Welfare and be registered with the Ministry as an Embryo Research Institution.

#### **Article 19 – Approval of Embryo Research Protocol**

- ① When an embryo research institution, registered with the Ministry of Health and Welfare 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 and Welfare. The same requirement applies even in the event of significant changes to the Presidential orders that support this Act.
- ② The Embryo Research Protocol mentioned in Article 19-① should include documents showing the review results of that Embryo Research Institution's Board.
- ③ When an Embryo Research Institution submits a research protocol that is funded by a central government agency, the Minister of Health and Welfare 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 Ministry of Health and Welfare.

#### **Article 20 – Supplying and Maintaining Remaining Embryos**

- ① When an Embryo Producing Institution supplies a remaining 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, with the approval of the Ministry of Health and Welfare, request that the Embryo Research Institution provide reimbursement for the expenses of storing and providing the remaining embryo.
- ② The supply procedures, the calculation of expenses, and any other details concerning the remaining embryos mentioned in Article 20-① shall be decided by the Ministry of Health and Welfare.
- ③ The Embryo Producing Institution and Embryo Research Institution shall report all details concerning the storage and supply of remaining embryos to the Minister of Health and Welfare in accordance with the regulations of the Ministry of Health and Welfare.
- ④ The provisions of Article 16-② through 16-④ shall apply to the disposal of remaining embryos that are received by an Embryo Research Institution in accordance with Article 20-① but are not utilized for research. In such cases, the Embryo Producing Medical institution will be regarded as the Embryo Research Institution.

**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 remaining embryos;
3. Cease all relevant research or take appropriate measures when the research poses a significant or potential threat to bioethics or biosafety; and
4. Follow other regulations or guidelines set by the Ministry of Health and Welfare in order to ensure bioethics and biosafety.

**Paragraph 3 – Somatic Cell Embryo Clones**

**Article 22 – The Act of Somatic Cell Nucleus Transfer**

- ① No one shall conduct somatic cell nucleus 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 nucleus transfer guided by the purpose stated in Article 22-① shall be decided by the President after it has been reviewed by the Committee.

**Article 23 – Production and Research of Somatic Cell Embryo Clones**

- ① Any one wishing to produce or research somatic cell embryo clones shall register with the Ministry of Health and Welfare only after satisfying the Ministry's requirements concerning facilities and personnel.
- ② Articles 19 through 21 shall apply also to research on somatic cell embryo clones.

**Chapter 4  
DNA Testing**

**Article 24 – DNA Testing Institutions**

- ① Anyone who wishes to conduct DNA tests or do research on material directly obtained from DNA tests should report the following details to the Minister of Health and Welfare: the location of the institution in which the tests or research

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are carried out, the name of the head of the institution, the type of DNA tests or research topics carried out, and other details required by the Ministry of Health and Welfare. Government agencies that conduct DNA tests or engage in DNA research are not required to report these details to the Minister.

- ② The provisions of Article 24-① will apply even in the event of changes being made to the Presidential orders that support this Act.
- ③ The Minister of Health and Welfare may require any institution wishing to conduct DNA tests in accordance with Article 24-① (hereafter called a DNA Testing Institution) to be evaluated for the accuracy of its DNA tests and make the results of this evaluation public.
- ④ If a DNA Testing Institution ceases operations, either permanently or temporarily, it should report to the Minister of Health and Welfare, in accordance with the regulations of the Ministry of Health Welfare.

#### **Article 25 – Restrictions on DNA Tests**

- ① DNA Testing Institutions shall not conduct DNA 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 President after being reviewed by the Committee.
- ② DNA Testing Institutions shall not conduct DNA tests on embryos or fetuses for purposes other than that of diagnosing muscular dystrophy or other DNA-related diseases as stipulated by the President.
- ③ No DNA Testing Institution shall conduct DNA 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 DNA Tests**

- ① Before a DNA Testing Institution or anyone conducting DNA research obtains, either directly or indirectly, test materials 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 DNA test or DNA research;
  - 2. Indication of whether or not consent is given for the use of test materials other than for purposes mentioned in 26-①-1;
  - 3. Indication of whether or not personal information will be revealed when test materials are provided to others, in accordance with Article 26-①-2;
  - 4. Information on the maintenance and storage period of test materials; 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 Ministry of Health and Welfare.

- ② When anyone other than a DNA Testing Institution requests a DNA test, a written consent, as outlined in Article 26-①, 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 Ministry of Health and Welfare.
- ③ If the test subject is a minor, a quasi-incompetent, or an incompetent, the consent outlined in Article 26-①, as well as an additional consent by his or her legal guardian, should be obtained. However, in the case of conducting DNA 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 Articles 26-① and 26-③ notwithstanding, a DNA 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 Article 26-① through ③ shall thoroughly explain the purpose and procedures of the DNA 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 Articles 26-① through ③ shall be stipulated in the regulations of the Ministry of Health and Welfare.

#### **Article 27 – Providing Test Materials**

- ① When a DNA Testing Institutions obtains a written consent from a test subject concerning the use of test materials for research purpose as guided by Article 26, it may provide the test materials to either a person conducting research on DNA or an institution licensed to open a DNA bank under Article 32.
- ② DNA Testing Institutions shall not include personal information in the test materials mentioned in Article 27-①. 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 DNA Testing Institution, any institution conducting DNA research, or any institution licensed to open a DNA bank (hereafter called DNA Test Institutions) provide, or are provided with, test materials as guided by Article 27-①, a record of the process shall be kept, as stipulated in the regulations of Ministry of Health and Welfare.
- ④ Articles 27-① through 27-③ shall apply when an institution that has received test materials wishes to provide them to other researchers or DNA banks.

#### **Article 28 – Disposal of Test Materials**

- ① The storage period of test materials 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 DNA Testing Institutions shall dispose of test materials 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 test materials.
- ③ If the test subject or his or her legal guardian requests the disposal of his or her test material at any point during the storage period, the DNA Testing Institutions shall comply with the request.
- ④ DNA Testing Institutions shall keep records and file documentation concerning the disposal of all test materials.
- ⑤ If a DNA Testing Institution closes, temporarily or permanently, for unavoidable reasons and cannot store test materials, they shall handle or transfer the test materials in accordance with the guidelines of the Ministry of Health and Welfare.
- ⑥ Other necessary details concerning the disposal procedures and methods, the keeping and filing of records, and the handling and transferring of the test materials described in Article 28-⑤ shall be stipulated in the regulations of the Ministry of Health and Welfare.

#### **Article 29 – Filing and Reading Records**

- ① DNA Testing Institutions shall file the following documents in accordance with the guidelines of the Ministry of Health and Welfare:
  1. A signed consent form, as outlined in Article 26;
  2. The results of the DNA tests; and
  3. The records of providing test materials in accordance with Article 27-③.
- ② DNA Testing Institutions shall comply with all requests made by the test subject or his or her legal guardian to read the records described in Article 29-① or to obtain copies of them.
- ③ Other necessary details concerning the request procedures and forms and the issuing of copies of records shall be stipulated in the regulations of the Ministry of Health and Welfare.

#### **Article 30 – Obligations of DNA Testing Institutions**

- ① DNA Testing Institutions shall observe the following:
  1. The details of informed consent outlined in Article 26;
  2. The protection of DNA information;

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3. Other details related to Articles 30-①-1 and 30-①-2 that the Ministry of Health and Welfare stipulates to ensure bioethics and biosafety.
- ② DNA Testing Institutions shall not make false statements or exaggerated advertisements about DNA tests.
- ③ Other relevant details concerning Article 30-② shall be stipulated in the regulations of the Ministry of Health and Welfare.

## **Chapter 5**

### **Protection and Use of Genetic Information**

#### **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 DNA tests or to submit DNA test results.

#### **Article 32 – DNA Bank Licensing and Registration**

- ① Any non-government institution wishing to open a DNA bank must receive the approval of the Minister of Health and Welfare, as stipulated in the Presidential orders that support this Act.
- ② Anyone wishing to open a DNA bank with a research grant from some other central government agency must receive licensing from the Minister of Health and Welfare. In this case, however, the head of the central government agency shall consult with the Minister of Health and Welfare before licensing is granted.
- ③ Before moving the location of a DNA bank, under Article 32-①, or making other important changes stipulated in Presidential orders, the head of the DNA bank should report to the Minister of Health and Welfare as stipulated in the regulations of Ministry of Health and Welfare.
- ④ If a DNA bank is closed, temporarily or permanently, the head of the DNA bank should report to the Minister of Health and Welfare, in accordance with the regulations of the Ministry of Health and Welfare.
- ⑤ Facilities and equipment standards, licensing procedures, and other necessary details concerning DNA banks, under Article 32-①, shall be stipulated in the Presidential orders that support this Act.

### **Article 33 – Providing Genetic Information**

- ① Any one wishing to use genetic information from a DNA Bank shall submit a plan on how the genetic information is to be used to the head of the DNA Bank.
- ② The head of the DNA Bank shall decide whether or not to release genetic information only after that institution's Board, under Article 9, reviews the plan on how the information will be used. Furthermore, the head of the DNA bank must report the results of the Board's review to the Minister of Health and Welfare.
- 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 regulations of the Ministry of Health and Welfare.

### **Article 34 – Obligations of Heads of DNA Banks**

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

### **Article 35 – Protection of Genetic Information**

- ① In the absence of legitimate reasons for doing so, neither the head of a DNA 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 cure and diagnose the patient's disease and when appropriate measures are taken to protect the patient's personal information.

## **Chapter 6 Gene Therapy**

### **Article 36 – Gene Therapy**

- ① Gene therapy is allowed only in the following cases:

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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 and Welfare, after a review by the Board, targets for treatment by means of gene therapy.
- ② Notwithstanding Article 36-①, 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 Ministry of Health and Welfare. This condition will apply even in the event of significant changes to the Presidential orders that support this Act.
- ② Any medical institution (hereafter called a 'Gene Therapy Institution') that has registered with the Ministry of Health and Welfare according to the provisions of Article 37-① shall obtain a written consent from patients 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 regulations of the Ministry of Health and Welfare.
- ③ The reporting 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 regulations of the Ministry of Health and Welfare.

## **Chapter 7 Supervision**

### **Article 38 – Report and Inspection**

- ① The Minister of Health and Welfare may order Embryo Producing Medical Institutions, Embryo Research Institutions, DNA 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 biosafety. 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 biosafety.

- ② Whenever the Minister of Health and Welfare 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 test material 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 from the Minister, under Articles 38-① and 38-②, unless there is a legitimate reason not to do so.

### **Article 39 – Disposal Orders**

The Minister of Health and Welfare may order institutions subject to inspection and their employees to dispose of embryo and somatic cell embryo clones that have been created, stored, or provided in breach of Articles 13, 14, 15-①, 16-②, 17 through 19, 20-①, 20-④, 22-① and 23 as well as test materials that have been collected, stored, and provided in breach of Articles 24-①, 25, 26-① through 26-③, 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 28-⑥.

### **Article 40 – Improvement Orders**

When the Minister of Health and Welfare 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 biosafety, in virtue of the fact that the facility fails to meet the standards set in Articles 14-②, 18, 23, 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 one of the following conditions apply to an Embryo Producing Medical Institution, an Embryo Research Institutions, a DNA Test Institution, a DNA Bank, or a Gene Therapy Institution, the Minister of Health and Welfare 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:

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1. It is in breach of Articles 9-①, 9-③, 10-①, 10-③, 11, 14, 15-①, 15-③, 16-②, 16-③, 17, 19-①, 20, 22, 24-②, 24-④, 25, 26-①, 26-③, 26-⑤, 27, 28-②, 28-⑤, 29-①, 29-②, 32-③, 32-④, 33-②, 35, 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 Article 41-① shall be stipulated in the regulations of the Ministry of Health and Welfare, which will take into consideration the type and degree of the violation.

#### **Article 42 – Hearing**

Whenever the Minister of Health and Welfare 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 one of the following reasons, an order by the Minister of Health and Welfare 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 and Welfare may instead fine the institution a maximum amount of 200 million Korean won as stipulated in the Presidential orders that support this Act.
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 Article 43-①, and other necessary details will be stipulated in the regulations of Ministry of Health and Welfare.
- ③ When a person who is charged with a fine does not pay it on time, the Minister of Health and Welfare may collect the full amount of the fine under the disposition of national taxes in arrears.

#### **Article 44 – Commission Fee**

Under the provisions of this Act, anyone who wishes to be authorized, registered, licensed or approved, or who wishes to file a report with the Ministry of Health and

Welfare, as well as anyone who wishes to make changes to documents filed with the Ministry, may be subject to a commission fee, as guided by the Ministry of Health and Welfare.

## **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 biosafety in the life sciences and biotechnologies, the Minister of Health and Welfare may offer either partial or full financial support to organizations, research institutions, and life science professionals, as stipulated in the Presidential orders that support this Act.

### **Article 47 – Delegating Responsibilities**

- ① The Minister of Health and Welfare may delegate part of his authority in this Act to the head of other institutions, as stipulated in the Presidential orders that support this Act.
- ② The Minister of Health and Welfare may entrust the following duties to the relevant institutions or organizations, as stipulated in the Presidential orders that support this Act:
  1. Managing the Embryo Producing Medical Institutions mentioned in Article 14;
  2. Managing the Embryo Research Institutions mentioned in Article 18;
  3. Managing the DNA Testing Institutions mentioned in Article 24;
  4. Managing the DNA Banks mentioned in Article 32; and
  5. Managing the Gene Therapy Institutions mentioned in Article 37.
- ③ When the Minister of Health and Welfare 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 that are 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 embryo clone 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 embryo clone into a uterus shall be sentenced to up to 10 years of imprisonment.
- ② Anyone who attempts any of the actions described in Article 49-① 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 the following:
  1. Anyone who, in violation of Article 11-②, either induces, or assists in, the act of implanting a somatic cell embryo clone 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 embryo clone into a uterus;
  2. Anyone who performs one 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 one 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 eggs for monetary reward, capital gain, or other personal benefits;
  6. 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; and

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7. 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 remaining 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 Article 51-①-1 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 the following:

- a. Anyone who, in violation of Article 13-③, induces or assists in providing or utilizing sperm or eggs for monetary reward, capital gain, or other personal benefits;
- b. Anyone who, in violation of Article 15-①, harvests sperm and oocytes without obtaining a written consent concerning embryo creation;
- c. Anyone who, in violation of Article 25, conducts a DNA Test;
- d. Anyone who, in violation of Article 26-① through Article 26-③, collects test materials without a written consent for a DNA Test or requests a DNA Test without attaching a written consent;
- e. Anyone who, in violation of Article 31-① or Article 31-②, discriminates against other people by using genetic information or forces others to either take a DNA Test or submit the results of a DNA Test;
- f. Anyone who, in violation of Article 34, includes personal information when providing others with genetic information;
- g. 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;
- h. Anyone who, in violation of Article 36-① or Article 36-②, performs gene therapy; and
- i. 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 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 16-③ (including the application of Article 20-④), does not dispose of embryos in accordance with the regulations of

- the Ministry of Health and Welfare or does not record or store information about the embryo disposal;
3. Anyone who, in violation of Article 18, conducts research on remaining 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 and Welfare;
  5. Anyone who, in violation of Article 20-① or 20-③, provides remaining embryos for monetary compensation or does not report the details of the storage and provision of remaining embryos to the Minister of Health and Welfare, as stipulated in the regulations of Ministry of Health and Welfare;
  6. Anyone who, in violation of Article 23-①, creates a somatic cell embryo clone or conducts research on such a clone, without being registered with the Ministry of Health and Welfare;
  7. Anyone who violates Article 30-① or who, in violation of Article 30-②, makes false statements or exaggerated advertisements about DNA Tests;
  8. Anyone who, in violation of Article 32-①, opens a DNA Bank without being licensed by the Minister of Health and Welfare; and
  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 of a corporation, or an individual, an employer, or an employee of a corporation 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 the following:
  1. Anyone who fails to report details mentioned in Articles 24-①, 24-② or 24-④;
  2. Anyone who violates any of the Articles 28-② through 28-⑤;
  3. 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;
  4. Anyone who fails to report the details mentioned in Articles 32-③ or 32-④;
  5. Anyone who, in violation of Article 35-②, provides records including a patient's genetic information to someone other than the patient; and
  6. Anyone who, in violation of Article 37-①, conducts Gene Therapy without being registered with the Ministry of Health and Welfare.

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- ② The negligence fine under Article 55-① shall be levied and imposed by the Minister of Health and Welfare, as stipulated in the Presidential orders that support this Act.
- ③ Anyone who objects to the negligence fine imposed upon him or her under Article 55-② may submit a demurrer to the Minister of Health and Welfare within 30 days of receiving notice of the fine.
- ④ When a person, imposed with a negligence fine under Article 55-②, submits a demurrer under Article 55-③, the Minister of Health and Welfare 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 Article 55-③, and when the fine remains unpaid, it will be collected under the regulations of the National Tax Collection Law.

### **Additional Provisions**

- ① **(Date of Effect)** This Act shall take effect on 1 January 2005. However, Articles 11, 12, 49, 50, 51-①-1, and 51-①-2 shall become effective on the day of promulgation.
- ② **(Interim Measures on Remaining Embryo Research)** Until the embryological primitive streaks emerge, remaining embryos may be utilized for the purposes mentioned in Article 17 on any of the following conditions:
  1. If the remaining embryos are produced before this Act takes effect;
  2. If a period of 5 years has passed since the remaining embryos were created; or
  3. A written consent was obtained from the consenters, but the 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 and Welfare, on either the following conditions:
  1. The researcher has been engaged in embryonic stem cell research for at least 3 years; or
  2. The researcher has published at least one research paper on embryonic stem cell research in a related academic periodical.

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