(Tentative Translation)

Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and Ministry of Health, Labor and Welfare (MHLW)

Guidelines for Research Using Gene-altering Technologies on Human Fertilized Embryos are established as follows, and shall come into force as from the date of promulgation.

April 1st, 2019

Minister of Education, Culture, Sports, Science and Technology

Minister of Health, Labor and Welfare

Guidelines for Research Using Gene-altering Technologies on Human Fertilized Embryos

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Chapter I General Provisions

Section 1 Purpose

These Guidelines pertain to basic research using gene-altering technologies in Human Fertilized Embryos (except for paragraphs 1(1)(i) and (ii), 3(1)(ii), and 4(5)(i)A(b) of Section 1, Chapter IV; hereinafter referred to as "research"); the purpose of these Guidelines is for this research to be conducted appropriately by stipulating the matters to be observed by persons involved in such research, based on such ethical viewpoints as the respect for Human Fertilized Embryos and impact on genetic information.

Section 2 Definitions

In these Guidelines, each of the following terms shall be defined as follows.

(1) Gene-altering Technologies

Genome editing and other nucleic acid manipulation technologies.

(2) Genetic Information

Information possibly inherited by descendants which reflects the genetic characteristics or constitution of an individual person, which is obtained in the course of research or which is already contained in Human Fertilized Embryos.

(3) Human Fertilized Embryo

An Embryo produced by fertilization between a human Sperm and a human Unfertilized Egg (including each Embryo which is produced successively by single or multiple splitting of such an Embryo and is not a Human Split Embryo)

(4) Donor

A couple (including those who are in a de facto state of marriage, even if it has not been legally registered, and those who were already divorced (including those who were in a de facto state of marriage, even if it were not legally registered, and whose situation has changed to a de facto state of divorce) at the time of obtaining Informed Consent; hereinafter the same) who donated a Human Fertilized Embryo created for the purpose of using it in assisted reproductive technology, but is no longer planned to be used for the purpose.

However, this term shall mean a surviving spouse if one spouse was dead at the time of obtaining Informed Consent.

(5) Informed Consent

Consent regarding the provision and handling of a Human Fertilized Embryo, which a Donor gives on the basis of his/her discretion after receiving adequate prior explanations from a researcher, etc. with regard to the research and after understanding the significance, objectives and method of the research, the expected results and the disadvantages.

(6) Research Institution

An organization conducting research using Human Fertilized Embryos obtained from Donors. When research is conducted collaboratively among multiple institutions, the term shall mean each institution.

(7) Donor Facility

An organization receiving donation of a Human Fertilized Embryo used in research from a Donor.

(8) Research Director

A person at a Research Institution who carries out research as well as supervises the operations related to the research.

(9) Researcher

A person at a Research Institution who is involved in research, receiving direction from the Research Director.

(10) Ethics Review Committee

A council-type body established for the purposes of discussing the propriety of conducting, continuing or changing research and other related matters, involving both ethical viewpoints and scientific viewpoints.

(11) Personal Information

Information relating to a living individual Donor which corresponds to any of the following:

(i) Those containing a name, date of birth or other descriptions etc. (meaning any and all matters (excluding an individual identification code) stated, recorded or otherwise expressed using voice, movement or other methods in a document, drawing or electromagnetic record (meaning a record kept in an electromagnetic form (meaning an electronic, magnetic or other forms that cannot be recognized through the human senses; the same shall apply in paragraph (12)(ii)); hereinafter the same) whereby a specific individual Donor can be identified (including those which can be readily collated with other information and thereby identify a specific individual Donor); where information related to a deceased person is, at the same time, information about a living individual such as a surviving family member, it should be considered the Personal Information about the living individual Donor in question).

(ii) Those containing an individual identification code.

(12) Individual Identification Code

Those prescribed by the Order for Enforcement of the Act on the Protection of Personal Information (Cabinet Order No. 507 of 2003) or by other Laws and ordinances which are any character, letter, number, symbol or other codes falling under any of each following item.

(i) Those able to identify a specific individual that are a character, letter, number, symbol or other codes into which a bodily partial feature of the specific individual has been converted in order to be provided for use by computers

(ii) Those characters, letters, numbers, symbols or other codes which are assigned in regard to the use of services provided to an individual or to the purchase of goods sold to an individual, or which are stated or electromagnetically recorded in a card or other document issued to an individual so as to be able to identify a specific user or purchaser, or recipient of issuance by having made the codes differently assigned or, stated or recoded for the user or purchaser, or recipient of issuance.

(13) Anonymization

To delete, in part or in whole, descriptions, etc. (including Individual Identification Codes) which are contained in Personal Information accompanying a donated Human Fertilized Embryo (including replacement of all or part of the descriptions, etc. with descriptions, etc. that are unrelated to the specific individual in question).

(14) Decoding Index

A table or other similar format which enables a Donor to be identified where necessary from anonymized information, by allowing that Donor to be matched against the replacement descriptions, etc. that were substituted during the Anonymization process.

Section 3　Requirements for Research

For the time being, the research shall be limited to that pertaining to development, growth and implantation of embryos, that pertaining to improvement of preservation techniques for Human Fertilized Embryos, and other research that contributes to improvement of assisted reproductive technology.

Section 4　Consideration for Human Fertilized Embryos

A person handling Human Fertilized Embryos should handles such Human Fertilized Embryos conscientiously and carefully so as not to violate human dignity, taking into consideration that Human Fertilized Embryos are the emerging potential of human life.

Chapter II　Handling of Human Fertilized Embryos

Section 1　Acquisition of Human Fertilized Embryos

A Human Fertilized Embryo used in research may be accepted for donation, but only those comply with the following requirements:

(1) A Human Fertilized Embryo that has been produced for use in assisted reproductive technology, but is no longer planned to be used for the purpose, when the intention of the Donor has been confirmed with regard to destruction of the Human Fertilized Embryo.
(2) A Human Fertilized Embryo for which appropriate Informed Consent has been given by the Donor with regard to the use for research.
(3) A Human Fertilized Embryo that has been stored frozen.
(4) A Human Fertilized Embryo within 14 days from fertilization (excluding the period of being stored frozen).
(5) A Human Fertilized Embryo that has been donated voluntarily, except for necessary expenses.

Section 2 Period of Handling

A Human Fertilized Embryo may be handled, but only during the period until the primitive streak starts to form. However, with regard to Human Fertilized Embryos in which the primitive streak does not start to form during the 14-day period from fertilization, these shall not be handled after the 14 days have elapsed. In cases where a Human Fertilized Embryo is stored frozen, this period of frozen storage shall not be included in the period of handling.

Section 3 Prohibition of Transplantation into Uteri

(1) Human Fertilized Embryos used in research shall not be transplanted into a human or animal uterus.
(2) Research shall not be conducted in a room that is equipped with facilities allowing Human Fertilized Embryos to be transplanted into a human or animal uterus.

Section 4 Transfer to Other Institutions

A Research Institution shall not transfer Human Fertilized Embryos used in research to other institutions. However, in cases where research is conducted collaboratively at multiple Research Institutions, Human Fertilized Embryos used in research may be transferred, but only between these Research Institutions.

Section 5 Disposal at the Completion of Research

When a research has been completed or when the period of handling for a Human Fertilized Embryo set forth in Section 2 has elapsed, the Research Institution shall promptly dispose of the Human Fertilized Embryo.

Chapter III Procedures for Informed Consent

Section 1 Informed Consent

(1) A Research Institution shall accept the donation of a Human Fertilized Embryo upon

obtaining the Informed Consent of the Donor in writing.

(2) Informed Consent pertaining to the donation of a Human Fertilized Embryo shall not be acquired at a stage when a concrete research protocol has not yet been established.

Section 2 Consideration for Donors, etc.

When obtaining Informed Consent, a Donor Facility shall satisfy the following requirements, while giving sufficient consideration to feelings of the Donors.

(1) The Donor Facility should not take unfair advantage of the situation of the Donors.

(2) The Donor Facility should not request a person who is judged objectively that he/she is not capable of giving Informed Consent to donate Human Fertilized Embryos.

(3) The Donor Facility should have confirmed the intention of the Donor in advance with regard to destruction of the Human Fertilized Embryos.

(4) The Donor Facility should allow sufficient time for the Donor to determine whether or not to donate.

(5) The Donor Facility should preserve the Human Fertilized Embryos for at least 30 days after the Informed Consent has been obtained.

Section 3 Explanation on Informed Consent

The explanation on Informed Consent shall be provided to Donors in writing, in an easy-to-understand manner, in order to obtain an adequate understanding regarding the research objectives and method, handling of donated Human Fertilized Embryos, methods for protecting Personal Information and other necessary matters. The Written Information shall include the following items.

(1) Objective, method and implementation system of research

(2) Destruction of Human Fertilized Embryos and other handling of donated Human Fertilized Embryos

(3) Expected results of research

(4) The fact that the conformity of research protocol with these Guidelines has been confirmed by the Research Institution(s), the Donor facilities, the Minister of MEXT and the Minister of MHLW.

(5) Specific methods for protecting Personal Information (including Anonymization method)

(6) The fact that the Donors will receive no reward in the future

(7) In case that there is a possibility of genetic analysis, a statement to that effect, a method for disclosing the Genetic Information by the Research Institution to the Donors, etc.

(8) The possibility that results of research will be disclosed at such occasions as academic meetings

(9) The facts that, in case where useful results have been obtained from research, patent rights, copyrights or other intangible property rights or economic interests may arise from those

results, and that they will not belong to the Donors

(10) The fact that the statement of an intention to donate or not to donate Human Fertilized Embryos does not bring any advantage or disadvantage to the Donors of the Human Fertilized Embryos

(11) The following matters regarding withdrawal of Informed Consent:

(i) Human Fertilized Embryos shall be preserved at the Donor facilities for at least 30 days after the Informed Consent has been obtained

(ii) The fact that the Donor may revoke his/her Informed Consent at any time even if he/she has given his/her consent to research implementation

(iii) When it can be difficult to take measures that follow the withdrawal made by the Donor, a statement to that effect and the reason for the difficulty

(iv) The fact that Informed Consent can be revoked as proposed by either or both of the Donor.

Section 4　Issue of Written Information, etc.

When giving explanations regarding Informed Consent, a Donor of a Human Fertilized Embryo shall be provided with a document indicating that appropriate measures have been taken to protect Donor's Personal Information, and that sufficient information have been made in writing as stipulated in Section 3.

Section 5　Withdrawal of Informed Consent

(1) Either or both of the Donor may revoke Informed Consent by applying to the Donor Facility for withdrawal.

(2) Upon receipt of an application from a Donor for withdrawal set forth in (1), the Head of the Donor Facility shall notify the Head of the Research Institution of that effect.

(3) Upon receipt of a notification set forth in (2), the Head of Research Institution to which the Donor donated the Human Fertilized Embryo shall dispose of the donated Human Fertilized Embryo, and shall notify the Head of the Donor Facility in writing of that effect. This shall, however, not apply to any of the following cases. In such cases, the Donor shall be explained the fact that and the reason why measures according to the content of withdrawal are not taken, and endeavor shall be made to obtain the Donor's understanding.

(i) When the Human Fertilized Embryo has been anonymized (limited to case where a Decoding Index has not been created)

(ii) When continuation of the research has been approved by the Head of the Research Institution, based on the opinion of the ethics review committee of the Research Institution (including the ethics review committee established at another institution in case that the ethics review committee was requested to review; the same applies to the ethics review committee set forth in Section 6 (1)).

Section 6　Confirmation of Informed Consent concerning Donation of Human Fertilized Embryos

(1) Regarding appropriately obtaining the Informed Consent based on the research protocol, the Head of the Donor Facility shall confirm the document set forth in Section 1 (1) and a document indicating that the explanation have been made as stipulated in Section 3, and seek opinion of the ethics review committee of the Donor Facility.

(2) The Head of the Donor Facility, when transferring the Human Fertilized Embryos to a Research Institution, shall notify the Research Institution in writing about the confirmation set forth in (1).

(3) Upon transfer of Human Fertilized Embryos to the Research Institution, the Donor Facility shall produce and keep a record of the transfer.

Chapter IV　Research System

Section 1　Research Institutions

1. Criteria for Research Institutions

(1) A Research Institution shall conform to the following criteria:

(i) The Research Institution should have necessary facilities and equipment for research using Human Fertilized Embryos.

(ii) The Research Institution should have a sufficient track record and technical capability in the handling of Human Fertilized Embryos and in research on assisted reproductive technology and research using Gene-altering Technologies on human or animal fertilized embryos.

(iii) The Research Institution should have in place a management system concerning the handling of Human Fertilized Embryos.

(iv) The Research Institution should have taken adequate measures for the protection of Personal Information and Genetic Information of Donors.

(v) The Research Institution should have taken measures for persons involved in such research to receive an education and training program needed to maintain and improve its ethics as well as knowledge and technical capability needed to conduct the research.

(vi) At least one medical doctor should participate in the research.

(2) A Research Institution shall produce and keep records on the handling of Human Fertilized Embryos.

2. Head of Research Institutions

(1) The Head of a Research Institution shall perform the following duties:

(i) Confirm the propriety of a research protocol and any change to a research protocol, and approve the implementation thereof.

(ii) Ascertain the research progress and results and the handling of Human Fertilized Embryos, and where necessary, give instructions to the Research Director regarding any matters such as relevant points of concern and points for improvement.

(iii) Conduct education and training.

(2) The Head of a Research Institution may not simultaneously hold the position of a Research Director or Researcher; provided, however, this shall not apply to cases where a person who performs the duties of the Head of the Research Institution has been appointed.

3. Research Director and Researchers.

(1) A Research Director shall be a person meeting the following requirements:

(i) To have sufficient ethical insight regarding the handling of Human Fertilized Embryos and research on assisted reproductive technologies using Gene-altering Technologies on Human Fertilized Embryos.

(ii) To have sufficient expert knowledge and experience regarding the handling of Human Fertilized Embryos and research on assisted reproductive technology and related research using Gene-altering Technologies on human or animal fertilized embryos.

(2) A Researcher shall be a person who has sufficient ethical insight and experience in the handling of human or animal fertilized embryos.

4. Research Institution ethics review committees

(1) A Research Institution shall establish the ethics review committee to perform the following duties.

(i) To comprehensively review the scientific and ethical propriety of a research protocol, and to provide the Head of a Research Institution with opinions regarding suitability, relevant points of concern, points for improvement, etc., in accordance with these Guidelines.

(ii) To receive reports on the research progress and results, and where necessary, to conduct an investigation to provide the Head of a Research Institution with opinions regarding any matters such as relevant points of concern and points for improvement.

(2) Despite of the regulations set forth in (1), in the case that the ethics review committee established by another institution is capable of conducting an appropriate review, the ethics review committee may be used as a replacement of the ethics review committee set forth in (1).

(3) The ethics review committee of a Research Institution shall produce and keep records on the review process.

(4) Members of the ethics review committee of a Research Institution as well as related clerical workers must receive education and training to acquire necessary knowledge for reviewing, etc. from both ethical viewpoints and scientific viewpoints, prior to taking on reviewing and related duties. Afterwards, too, continued training and education must be received appropriately.

(5) The ethics review committee of a Research Institution shall satisfy all of the following requirements.

(i) In order to be able to comprehensively review of scientific and ethical propriety of a

research protocol, all following requirements must be satisfied. The same shall apply to the requirements for meetings held by the ethics review committee of a Research Institution (referred to as "review board" in (ii) and (iii)).

A The ethics review committee should consist of the following members. Respective members cannot be the same person.

(a) An expert in reproductive medicine

(b) An expert in research using Gene-altering Technologies

(c) A person having adequate insight to state opinions on bioethics

(d) An expert in law as well as humanities and social sciences

(e) A person capable of stating opinions from the standpoint of the general public

B The member of the ethics review committee should include two or more persons who do not belong to the organization to which the Research Institution belongs.

C The member of the ethics review committee should include two or more men and two or more women.

D Any interested persons of the Research Director or Researcher as well as doctors in charge of assisted reproductive technology of Donors (hereinafter referred to as "attending physician") and any other persons involved in donation of Human Fertilized Embryos should not take part in the review.

(ii) The Research Director and Researcher shall not be present when review and adoption of opinions are made. However, when requested by the ethics review committee, they can attend the review board to give explanations about the research protocol.

(iii) The Head of the Research Institution that requested the review shall not be present when review and adoption of opinions are made. However, when necessary for understanding of the content of the review in the ethics review committee, the director may attend the review board by obtaining the committee's consent.

(iv) The ethics review committee may seek advice from experts depending on subject and content, etc. of the review.

(v) The ethics review committee shall review research protocols involving donation of Human Fertilized Embryos from socially vulnerable persons who need special consideration, and where necessary, seek advice from those having an insight about such persons when providing opinions.

(vi) The ethics review committee shall endeavor to adopt its opinions by consensus of all members.

(vii)The ethics review committee shall establish rules concerning its organization and operation as well as disclosure of details of its proceedings, and shall disclose these rules.

(6) As regards the review pertaining to minor change to a research protocol, the ethics review committee of a Research Institution can nominate its members for reviewing and presenting their opinions. Results of this review shall be treated as opinions of the ethics

review committee, and must be reported to all members.

(7) The proceedings of ethics review committee meetings shall be disclosed, except in cases where doing so would impede the protection of intellectual property rights and Personal Information, etc.

Section 2 Donor Facilities

1. Criteria, etc. for Donor facilities

A Donor Facility shall conform to the following criteria:

(1) The Donor Facility should be either a hospital as prescribed in Article 1-5(1) of the Medical Care Act (Act No. 205 of 1948) or a clinic as prescribed in Article 1-5(2).

(2) The Donor Facility should have taken adequate measures for the protection of Personal Information and Genetic Information of Donors.

(3) The Donor Facility should have a sufficient track record and technical capability in the handling of Human Fertilized Embryos.

(4) The Donor Facility should have in place a management system concerning the preservation of Human Fertilized Embryos.

(5) The Donor Facility should have taken measures for persons involved in such research to receive an education and training program needed to maintain and improve its ethics as well as knowledge needed to conduct the research.

(6) The number of Human Fertilized Embryos donated by the Donor Facility to a Research Institution shall be limited to the number absolutely essential for research.

2. Donor Facility directors

The Head of a Donor Facility shall perform the following duties:

(1) With regard to a research protocol, in addition to the procedures for Informed Consent, the Head of the Donor Facility should confirm the propriety of the research protocol from the perspective of the Donor Facility, and should approve the implementation thereof.

(2) The Head of the Donor Facility should ascertain the provision of a Human Fertilized Embryo, and, where necessary, should provide guidance and supervision to the attending physician and to other persons involved in the provision of the Human Fertilized Embryo.

(3) The Head of the Donor Facility should conduct education and training.

3. Donor Facility ethics review committees

The regulations set forth in paragraph 4 of Section 1 (except for (1)(ii)) shall apply to ethics review committees of Donor facilities. In this case, “Research Institution” set forth in paragraph 4 of Section 1 shall be replaced with “Donor Facility”.

Section 3 Requirements where the Research Institution and the Donor Facility are the Same

In cases where the Research Institution and the Donor Facility are the same, the Head of the institution, the Research Director and the Researchers shall not serve concurrently as the attending

primary care physician of the Donor.

Chapter V　Procedure of Research

Section 1　Implementation of Research Protocols

1. Approval of the directors of Research Institutions

(1) When conducting research, a Research Director shall prepare a research protocol, and shall seek the approval of the Head of the Research Institution for implementation of the research protocol.

(2) The Head of the Research Institution shall seek the opinion of the ethics review committee of the Research Institution on the propriety of implementing the research protocol, whose approval is sought in paragraph (1), and shall confirm the conformity of the research protocol with these Guidelines with respect for that opinion.

(3) With regard to the implementation of a research protocol, of which conformity with these Guidelines has been confirmed pursuant to paragraph (2), the Head of the Research Institution shall obtain the approval of the Head of the Donor Facility; provided, however, that this shall not apply to cases where the Research Institution and the Donor Facility are one and the same.

(4) When giving approval for the implementation of a research protocol set forth in paragraph (3), the Head of the Donor Facility shall hear the opinion of the ethics review committee of the Donor Facility. When giving approval to the implementation of a research protocol, the Head of the Donor Facility shall notify the Head of the Research Institution by attaching documents indicating the process and results of the review by the ethics review committee of the Donor Facility.

2. Confirmation by the Minister of MEXT and the Minister of MHLW

(1) When giving approval for implementation of a research protocol, the Head of the Research Institution shall receive confirmation from the Minister of MEXT and the Minister of MHLW with regard to the conformity of the research protocol with these Guidelines.

(2) When seeking the confirmation set forth in paragraph (1), the Head of the Research Institution shall submit the following documents:

(i) The research protocol

(ii) A copy of the Research Institution's rules concerning the handling of Human Fertilized Embryos

(iii) Documents indicating the process and results of the review by the ethics review committee of the Research Institution, and documents describing matters pertaining to the ethics review committee

(iv) A copy of the Donor Facility's rules concerning the preservation of Human Fertilized Embryos

(v) Documents indicating the process and results of the review by the ethics review

committee of the Donor Facility, and documents describing matters pertaining to the ethics review committee of the institution

3. Research protocols

A research protocol shall contain the following matters:

(1) The name of the research protocol

(2) The name and address of the Research Institution, and the name of the Head of the Research Institution

(3) The name, brief background, research achievements and records of education and training of the Research Director, and his/her role to be played in the research

(4) The name, brief background, research achievements and records of education and training of the Researchers, and their respective roles to be played in the research

(5) The Human Fertilized Embryos used in the research and the method of their acquisition

(6) The purpose and necessity of the research

(7) The method of the research (including the type of Gene-altering Technologies used in the research) and the period of the research

(8) An explanation concerning the criteria of the Research Institution

(9) An explanation concerning Informed Consent

(10) The name and address of the Donor Facility, and the name of the Head of the Donor Facility

(11) An explanation concerning the criteria of the Donor Facility

(12) Handling of Personal Information (including the method of Anonymization)

(13) Handling of Genetic Information

Section 2 Changes in Research Protocols

(1) When intending to change a research protocol (excluding the matters prescribed in paragraphs 3(2), (4) and (10) of Section 1), the Research Director shall first prepare a written amendment to the research protocol, and shall seek the approval of the Head of the Research Institution. The same shall also apply when making changes pertaining to the addition of Donor facilities.

(2) The Head of the Research Institution shall, when requested to give approval for an change set forth in paragraph (1), seek the opinion of the ethics review committee of the institution on the propriety of the change, and shall confirm the conformity of the change with these Guidelines with respect for that opinion.

(3) When confirming the conformity with these Guidelines pursuant to paragraph (2), in cases where the contents of the change to the research protocol pertain to a Donor Facility, the Head of the Research Institution shall obtain the approval of the Head of the Donor Facility for the change.

(4) When giving the approval set forth in paragraph (3), the Head of the Donor Facility shall

hear the opinion of the ethics review committee of the institution.

(5) When giving approval for a change set forth in paragraph (1), the Head of the Research Institution shall receive confirmation from the Minister of MEXT and the Minister of MHLW with regard to the conformity of the change with these Guidelines.

(6) When proposing to receive the confirmation set forth in paragraph (5), the Head of the Research Institution shall submit the following documents to the Minister of MEXT and the Minister of MHLW:

(i) A written amendment to the research protocol

(ii) Documents indicating the process and results of the review by the ethics review committee of the Research Institution regarding the change

(iii) In cases that fall under paragraph (3), documents indicating the process and results of the review by the ethics review committee of the Donor Facility regarding the change

(7) When any changes have been made to the matters listed in paragraphs 3(2) or (10) of Section 1, the Head of the Research Institution shall notify the Minister of MEXT and the Minister of MHLW to that effect.

Section 3 Reports on Research Progress

(1) During the period in which research is conducted, the Research Director shall, after the end of each fiscal year, prepare a research progress report that describes the progress of the research (including the handling of Human Fertilized Embryos), and shall submit this to the Head of the Research Institution.

(2) Upon receiving the submission of a report set forth in paragraph (1), the Head of the Research Institution shall promptly submit a copy thereof to the ethics review committee of the Research Institution and to the Minister of MEXT and the Minister of MHLW.

(3) The Research Institution shall cooperate in submitting materials, accepting investigations and any other measures found to be necessary by the Minister of MEXT and the Minister of MHLW concerning the research.

Section 4 Completion of Research

(1) When the research is completed, the Research Director shall promptly prepare a research completion report including a statement to that effect and describing the results of the research (including the disposal of Human Fertilized Embryos), and shall submit this to the Head of the Research Institution.

(2) Upon receiving the submission of a report set forth in paragraph (1), the Head of the Research Institution shall promptly submit a copy thereof to the ethics review committee of the Research Institution and to the Minister of MEXT and the Minister of MHLW.

Section 5 Protection of Personal Information

(1) With regard to measures concerning the protection of the Personal Information of Donors, the Head of the Research Institution and the Head of the Donor Facility shall take measures corresponding to the Ethical Guidelines for Medical and Health Research Involving Human Subjects (Public Notice of MEXT and the MHLW, No. 3 of 2014) (in cases when conducting human genome/gene analysis research based on the Ethical Guidelines for Human Genome/Gene Analysis Research (Public Notice No. 1 of the MEXT and the MHLW, and the METI, 2013), those guidelines).

(2) In cases where Personal Information is handled when receiving the provision of Human Fertilized Embryos in accordance with these Guidelines, the Head of the Research Institution and the Head of the Donor Facility shall designate a privacy officer within the organizations for the protection of that Personal Information.

(3) The privacy officer shall take measures for Anonymization before transferring the donated Human Fertilized Embryos to a Research Institution (in cases where the Research Institution and the Donor Facility are one and the same, before the donated Human Fertilized Embryos are handled by a research division within the organization).

Section 6 Handling of Genetic Information

When handling Genetic Information, the Head of the Research Institution and the Head of the Donor Facility shall take measures corresponding to the Ethical Guidelines for Human Genome/Gene Analysis Research in order to appropriately handle the Genetic Information.

Section 7 Disclosure of Research Results, etc.

(1) A Research Institution shall disclose its research results unless this would impede the protection of intellectual property rights and Personal Information, etc.

(2) The Researchers shall take every opportunity to raise public awareness of the research through delivery of information, etc.

Chapter VI Miscellaneous Provisions

Section 1 Public Announcement of Nonconformity to the Guidelines

The Minister of MEXT and the Minister of MHLW shall make a public announcement when research is found to have been conducted at variance with the criteria provided by the Guideline.

Section 2 Revision

These Guidelines shall, where necessary, be revised by taking into consideration such factors as the progress of related research and changes in social circumstances regarding the handling of Human Fertilized Embryos.