(Tentative Translation)

Guidelines on the Derivation of Human Embryonic Stem Cells

Public Notice of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Health, Labour and Welfare (MHLW) No. 2 of November 25, 2014

Chapter I General Provisions

(Purpose)

Article 1 The purpose of these Guidelines is to provide fundamental matters to be observed in handling human embryonic stem (ES) cells from bioethical viewpoints in order that human dignity may never be violated in such activity, in an effort to secure the proper handling of human ES cells. The Guidelines fully take into consideration that human ES cells involve bioethical issues, including the use of human embryos, which are the emerging potential of human life, and the fact that human ES cells are derived by destroying human embryos and have the potential to differentiate into any type of human cell while they have the potential to contribute significantly to the development of medicine and biology.

(Definitions)

Article 2 In these Guidelines, the meanings of the terms listed should be as prescribed in the following items:

(i) Embryo	An embryo prescribed in Article 2, Paragraph (1), Item (i) of the Act on Regulation of Human Cloning Techniques (Act No. 146 of 2000; hereinafter referred to as the "Act")
(ii) Human embryo	An embryo of a human being (including an embryo with the genetic information of a human being)
(iii) Human fertilized embryo	A human fertilized embryo prescribed in Article 2, Paragraph (1), Item (vi) of the Act
(iv) Human somatic cell nuclear transfer (SCNT) embryo	A human somatic cell nuclear transfer embryo prescribed in Article 2, Paragraph (1), Item (x) of the Act
(v) Human embryonic stem (ES) cell	A cell obtained from a human embryo or produced by the division of such a cell, excluding an embryo, which has pluripotency (the capability to differentiate into endodermal, mesodermal and ectodermal cells) and retains the ability to proliferate by itself or is presumed to have an ability similar thereto
(vi) Differentiated cell	A cell differentiated from a human ES cell, which results in the cell no longer having the property of a human ES cell
(vii) Germ cell	Any cell from a primordial germ cell to a spermatozoon or an ovum
(viii) Derivation	Production of cells with a specific property
(ix) First category derivation	Derivation of human ES cells by using human fertilized embryos (except as listed in the next item)
(x) Second category derivation	Production of human SCNT embryos and derivation of human ES cells by using produced human SCNT embryos
(xi) Deriving institute	An institute that derives human ES cells
(xii) First category deriving institute	A deriving institute that carries out first category derivation
(xiii) Second category deriving institute	A deriving institute that carries out second category derivation

(xiv) First category donor medical facility

A medical facility that receives donations of human fertilized embryos to be used for first category derivation and transfers such embryos to first category deriving institutes

(xv) Second category donor medical facility

A medical facility that receives donations of unfertilized eggs or human fertilized embryos (hereinafter referred to as "unfertilized eggs, etc.") necessary for producing human SCNT embryos to be used for second category derivation and transfers such unfertilized eggs, etc. to second category deriving institutes

(xvi) Somatic cell donor facility — A facility that receives donations of human somatic cells (hereinafter simply referred to as "somatic cells") necessary for producing human SCNT embryos to be used for second category derivation and transfers such cells to second category deriving institutes

(xvii) Distributing institute — An institute that distributes and maintains human ES cells (limited to those intended to be used for basic research) deposited by deriving institutes for the purpose of distributing such human ES cells to third parties

(xviii) Utilizing institute — An institute that utilizes human ES cells to carry out basic research (except overseas utilizing institutes)

(xix) Utilizing clinical institute — An institute that utilizes human ES cells following procedures established for the utilization of such cells for the purpose to use such in medical care (including clinical research and trials) in accordance with laws and regulations. An institute that utilizes human ES cells for basic research, however, is not considered as a utilizing clinical institute

(xx) Overseas utilizing institute — An institute that utilizes human ES cells for basic research at their places of business outside Japan

(xxi) Derivation plan — A plan concerning the derivation and distribution (except distribution to overseas utilizing institutes) of human ES cells by a deriving institute

(xxii) Overseas distribution plan	A plan concerning the distribution of human ES cells (limited to those intended to be used for basic research) to an overseas utilizing institute by a deriving institute
(xxiii) Utilization plan	A plan concerning the utilization of human ES cells by a utilizing institute
(xxiv) Derivation director	A person in a position to oversee the derivation and distribution of human ES cells in a deriving institute
(xxv) Informed consent	Consent given out of one's own free will based on the provision of sufficient explanation

(Scope of Application)

Article 3 These Guidelines shall apply to the derivation and distribution of human ES cells (limited to derivation and distribution carried out by deriving institutes).

(Consideration for Human Embryos and Human ES Cells)

Article 4 A person handling human embryos and human ES cells should handle such embryos and cells conscientiously and carefully so as not to violate human dignity, by taking into consideration that human embryos are the emerging potential of human life and that human ES cells have been derived by destroying human embryos and have the potential to differentiate into any type of human cell.

(Voluntary Donation of Human Embryos)

Article 5 A human embryo used for the derivation of human ES cells should be donated voluntarily except for necessary expenses.

Chapter II Derivation of Human Embryonic Stem Cells

Section 1 Requirements for Derivation

(Requirements for Derivation of Human ES Cells)

Article 6 (1) The first category derivation of human ES cells should be allowed only when the following requirements are satisfied:

(i) A policy concerning the utilization of human ES cells corresponding to any of the following is established to ensure compliance with laws and regulation or other national government guidelines:

(a) A policy on the utilization of human ES cells that satisfies the requirements for the utilization of such cells prescribed in Article 21, Paragraph (1), Item (i) of the Guidelines

on the Distribution and Utilization of Human Embryonic Stem Cells (Public Notice of MEXT No. 174 of 2014; hereinafter referred to as the "ES Distribution and Utilization Guidelines").

(b) A policy on the utilization of human ES cells for the purpose of medical care (including clinical research and trials).

(ii) The derivation of new human ES cells has scientific rationality and is necessary in light of the policy on utilization prescribed in the preceding item.

(2) The second category derivation of human ES cells can be allowed only when the following requirements are satisfied:

(i) A policy on the utilization of human ES cells that satisfies the requirements for the utilization of such cells prescribed in Article 21, Paragraph (2), Item (i) of the ES Distribution and Utilization Guidelines.

(ii) The derivation of new human ES cells has scientific rationality and is necessary in light of the policy on utilization prescribed in the preceding item.

(Requirements for Human Embryos Used for Derivation)

Article 7 (1) A human fertilized embryo used for first category derivation should satisfy the following requirements:

(i) The human fertilized embryo should be a human fertilized embryo that has been produced for use in assisted reproductive technology, but is no longer planned to be used for the said purpose, where the intention of the donor has been confirmed with regard to destroying the said human fertilized embryo.

(ii) The human fertilized embryo should be one for which appropriate informed consent has been given with regard to its use for the derivation of human ES cells.

(iii) The human fertilized embryo should be stored frozen.

(iv) The human fertilized embryo should be one within 14 days from fertilization (excluding the period during which it has been stored frozen).

(2) The number of human fertilized embryos donated by a first category donor medical facility to a first category deriving institute should be limited to the number absolutely essential for deriving the human ES cells.

(3) A first category deriving institute should use the donated human fertilized embryo for deriving the human ES cells without delay.

(4) Human SCNT embryos used for second category derivation should be limited to those that have been produced based on the Guidelines on the Handling of Specified Embryos (Public Notice of MEXT No. 83 of 2009; hereinafter referred to as the "Guidelines on Specified Embryos").

(Handling of Human Embryos within Deriving Institute)

Article 8 Human embryos and unfertilized eggs should be appropriately handled in a deriving institute by a medical doctor or under his/her guidance.

Section 2 Derivation System

(Criteria for Deriving Institute)

Article 9 A deriving institute should satisfy the following requirements:

(i) The deriving institute should have sufficient facilities, personnel, financial basis and technical capability for the derivation, maintenance and distribution of human ES cells.

(ii) The deriving institute should have in place rules on technical and ethical matters to be observed with regard to the derivation, maintenance and distribution of human ES cells.

(iii) The deriving institute should have an ethical review board.

(iv) The deriving institute should have in place a plan (hereinafter referred to as the "education and training plan") for providing the necessary education and training for improving technical capability and ethical awareness concerning the derivation, maintenance and distribution of human ES cells.

(Operations of Deriving Institute)

Article 10 (1) In addition to the derivation of human ES cells, a deriving institute should carry out the following operations:

(i) Distribute and maintain human ES cells that have been derived by the said deriving institute (including the case of depositing such human ES cells to a distributing institute for distribution and maintenance).

(ii) Receive already-distributed human ES cells that have been processed by a utilizing institute, and distribute and maintain such processed human ES cells (limited to cases that are reasonable for the development of research utilizing human ES cells).

(iii) Provide technical training on the handling of human ES cells to researchers who implement a utilization plan (limited to those in which human ES cells derived by the said deriving institute are utilized through distribution from the said deriving institute).

(2) The deriving institute should prepare and keep records on the derivation, maintenance, distribution, deposit, return and receipt of human ES cells.

(3) The deriving institute should cooperate in submitting materials, accepting investigations and any other measures found to be necessary by the competent minister concerning the derivation, maintenance, distribution, deposit, return and receipt of human ES cells.

(Head of Deriving Institute)

Article 11 (1) The head of a deriving institute should perform the following duties:

(i) Confirm the propriety of the derivation plan and any change to the derivation plan and

approve the implementation thereof pursuant to Articles 14 through 17.
(ii) Confirm the propriety of the overseas distribution plan and approve the implementation thereof pursuant to Article 44.
(iii) Ascertain the progress and/or results of the derivation of human ES cells as well as the status of the maintenance, distribution, deposit, return and receipt of human ES cells and, if necessary, give instructions to the derivation director regarding matters such as any relevant points of concern and points for improvement.
(iv) Supervise the derivation, maintenance, distribution and deposit of human ES cells.
(v) Communicate these Guidelines widely and thoroughly within the deriving institute and ensure the observance thereof.
(vi) Formulate an education and training plan on the derivation, maintenance and distribution of human ES cells and implement education and training based on this plan.
(vii) Establish an implementation system for the technical training prescribed in Paragraph (1), Item (iii) of the preceding article.
(2) The head of a deriving institute may not serve concurrently as the derivation director; provided, however, that this should not apply to the case where a person who acts for the head of the deriving institute in performing the duties set forth in the preceding paragraph has been appointed pursuant to the rules prescribed in Article 9, Item (ii).
(3) In the case referred to in the proviso to the preceding paragraph, the term "the head of a/the deriving institute" in the provisions of these Guidelines (excluding the preceding paragraph) should be deemed to be replaced with "a person who acts for the head of a/the deriving institute in performing the duties of the head of the deriving institute" and the term "the head of the deriving institute" in Article 44, Paragraph (1) with "the head of the deriving institute (including a person who acts for the head of the deriving institute in performing the duties of the head of the deriving institute)".

(Derivation Director)
Article 12 (1) The derivation director should perform the following duties:
(i) Examine the scientific and ethical propriety of the derivation plan or any change thereto based on the materials and information available in Japan and/or abroad concerning the derivation of human ES cells.
(ii) Prepare a document containing the derivation plan (hereinafter referred to as the "written derivation plan") or a document containing the contents of and reasons for any change to the derivation plan (referred to as the "written amendment to the derivation plan" in Article 17, Paragraphs (1), (3) and (7)) based on the results of the examination set forth in the preceding item.
(iii) Prepare a document containing the overseas distribution plan (hereinafter referred to as the "written overseas distribution plan").

(iv) Oversee the derivation, maintenance, distribution and deposit of human ES cells, and give the necessary instructions to researchers.
(v) Confirm as needed that the derivation of human ES cells is appropriately implemented in accordance with the written derivation plan.
(vi) Confirm as needed that the maintenance, distribution and deposit of human ES cells are appropriately implemented.
(vii) Take the procedures prescribed in Article 18, Paragraphs (1) and (2) and Article 19, Paragraph (1).
(viii) Order researchers who implement the derivation plan or overseas distribution plan to participate in education and training based on the education and training plan on the derivation, maintenance and distribution of human ES cells and, if necessary, provide any other education and training on the derivation, maintenance and distribution of human ES cells.
(ix) Provide the technical training prescribed in Article 10, Paragraph (1), Item (iii).
(x) In addition to what is prescribed in the preceding items, take any necessary measures for overseeing the derivation, maintenance, distribution and deposit.
(2) One derivation director should be assigned to each derivation plan, and should have ethical awareness regarding human ES cells, have experience in deriving ES cells from animal embryos as well as any other sufficient expert knowledge and technical capability on the derivation of human ES cells, and be capable of performing precisely the duties listed in the items of the preceding paragraph.

(Ethical Review Board of Deriving Institute)
Article 13 (1) The ethical review board of a deriving institute should carry out the following operations:
(i) Comprehensively review the scientific and ethical propriety of the derivation plan or any change thereto and submit opinions to the head of the deriving institute on matters such as the appropriateness of the plan or the change thereto and any relevant points of concern and points for improvement, in conformity with these Guidelines.
(ii) Comprehensively review the propriety of the overseas distribution plan and submit opinions to the head of the deriving institute on matters such as the appropriateness of the plan and any relevant points of concern and points for improvement, in conformity with these Guidelines.
(iii) Receive reports on the progress and the results of the derivation and the status of the maintenance, distribution, deposit, return and receipt, carry out investigations if necessary, and submit opinions to the head of the deriving institute on matters such as any relevant points of concern and points for improvement.
(2) The ethical review board of a deriving institute should prepare and keep records on the

process of the review set forth in Items (i) and (ii) of the preceding paragraph.
(3) The ethical review board of a deriving institute should satisfy the following requirements:
(i) The ethical review board should consist of experts in biology, medicine and law, persons having adequate insight to state opinions on bioethics and persons capable of stating opinions from the standpoint of the general public so as to be able to comprehensively review the scientific and ethical propriety of the derivation plan and the propriety of the overseas distribution plan.
(ii) The members of the ethical review board should include two or more persons who do not belong to the juridical entity to which the said deriving institute belongs.
(iii) The members of the ethical review board should include two or more men and two or more women.
(iv) Any researcher who implements the said derivation plan or overseas distribution plan, any interested persons of the derivation director or any relatives of the derivation director up to the third degree of kinship should not take part in the review.
(v) An appropriate administrative procedure that can guarantee the freedom and independence of the activities of the ethical review board should be set in place.
(vi) Rules on the constitution, organization and administration of the ethical review board, disclosure of the contents of its meetings and other necessary procedures required for reviewing a derivation plan and overseas distribution plan should be set in place and disclosed.
(4) In addition to items listed in the preceding paragraph, the ethical review board of a second category deriving institute should satisfy the following requirements:
(i) The experts in medicine set forth in Item (i) of the preceding paragraph should include persons having insight into regenerative medicine and medical doctors having excellent insight into the medical care which the donors of unfertilized eggs, etc. receive.
(ii) The majority of the members of the ethical review board should consist of those who do not belong to the second category deriving institute.
(5) When administering the ethical review board, the contents of its meetings should be disclosed except for the matters that are specified to be kept undisclosed pursuant to the rules prescribed in Paragraph (3), Item (vi).

Section 3 Derivation Procedure

(Approval of Head of Deriving Institute)
Article 14 (1) When deriving human ES cells, the derivation director should prepare a written derivation plan in advance and seek the approval of the head of the deriving institute for the implementation of the derivation plan.

(2) The written derivation plan should contain the following matters:
(i) The name of the derivation plan.
(ii) The name and address of the deriving institute and the name of its head.
(iii) The names, brief backgrounds, research achievements and records of education and training of the derivation director and researchers, and their respective roles to be played in the derivation plan.
(iv) An explanation concerning the human embryos used for the derivation.
(v) The policy on the utilization of human ES cells after the derivation.
(vi) The purpose and necessity of the derivation.
(vii) The method and period of the derivation.
(viii) An explanation concerning the distribution (including the case of entrusting the distribution work to a distributing institute).
(ix) An explanation concerning the criteria for the deriving institute.
(x) An explanation concerning informed consent (including the method of anonymization).
(xi) An explanation concerning the cell donor facility (a first category donor medical facility in the case of carrying out first category derivation and a second category donor medical facility and somatic cell donor facility in the case of carrying out second category derivation; the same should apply hereinafter).
(xii) An explanation concerning the ethical review board of the cell donor facility.
(xiii) Any other necessary matters.
(3) The written explanation set forth in Article 25, Paragraph (3) should be attached to the written derivation plan in the case of carrying out first category derivation, and the written explanations set forth in Article 31, Paragraph (3) and Article 37, Paragraph (3) in the case of carrying out second category derivation, respectively.

(Hearing of Opinion of Ethical Review Board of Deriving Institute)
Article 15 (1) The head of a deriving institute should, when requested by the derivation director to give approval for the implementation of the derivation plan pursuant to Paragraph (1) of the preceding article, seek the opinion of the ethical review board of the deriving institute on the scientific and ethical propriety of the plan and confirm the conformity of the plan with these Guidelines based on the said opinion.
(2) With regard to the derivation plan of which conformity with these Guidelines has been confirmed pursuant to the provisions of the preceding paragraph, the head of a deriving institute should obtain the consent of the heads of all of the cell donor facilities pertaining to the said derivation plan.
(3) When giving consent to the derivation plan, the head of a cell donor facility should seek the opinion of the ethical review board of the said facility.
(4) The head of a cell donor facility should, when giving consent to the derivation plan,

notify the head of the deriving institute by attaching documents indicating the process and results of the review by the ethical review board of the said facility.

(Confirmation by Competent Minister)

Article 16 (1) When giving approval for the implementation of the derivation plan, the head of a deriving institute should receive confirmation from the competent minister with regard to the conformity of the said derivation plan with these Guidelines after the termination of the procedures set forth in the preceding article.

(2) In the case referred to in the preceding paragraph, the head of the deriving institute should submit to the competent minister the following documents:

(i) A written derivation plan to which the written explanation set forth in Article 14, Paragraph (3) is attached.

(ii) Documents indicating the process and results of the review by the ethical review board of the deriving institute and the ethical review boards of all of the cell donor facilities pertaining to the said derivation plan, documents containing matters concerning the ethical review boards of such institute and facilities, and copies of the rules on the constitution, organization and administration of the ethical review boards of such institute and facilities, disclosure of the contents of their meetings and other necessary procedures required for reviewing a derivation plan.

(iii) A copy of the rules on technical and ethical matters to be observed with regard to the derivation, maintenance and distribution of human ES cells.

(3) The Minister of Education, Culture, Sports, Science and Technology should, when requested to provide the confirmation set forth in Paragraph (1), seek the opinion of the Bioethics and Biosafety Commission under the Council for Science and Technology on the conformity of the derivation plan with these Guidelines, and provide confirmation based on the said opinion.

(4) The Minister of Health, Labour and Welfare should, when requested to provide the confirmation set forth in Paragraph (1), seek the opinion of the Review Committee for Regenerative Medicine under the Health Science Council on the conformity of the derivation plan with these Guidelines, and provide confirmation based on the said opinion.

(Change to Derivation Plan)

Article 17 (1) The derivation director should, when intending to change any of the matters listed in Article 14, Paragraph (2), Items (i) and (iii) through (xii), prepare a written amendment to the derivation plan and seek the approval of the head of the deriving institute in advance. In this case, the head of the deriving institute who has been requested to give the approval should seek the opinion of the ethical review board of the deriving institute on the scientific and ethical propriety of the said change and confirm the conformity of the said

change with these Guidelines based on the said opinion.
(2) The head of a deriving institute should, when the contents of the change to the derivation plan for which confirmation set forth in the preceding paragraph has been provided, relate to the cell donor facility, obtain the consent of the head of the said cell donor facility with regard to the said change. In this case, the head of the cell donor facility who has been requested to give consent should seek the opinion of the ethical review board of the said facility and, when the head approves change to the derivation plan, the head of the said cell donor facility should notify the director of deriving institute to the effect, attaching a document indicating the process and results of the review by the said ethical review board.
(3) When giving the approval set forth in Paragraph (1), the head of a deriving institute should receive confirmation from the competent minister with regard to the conformity of the said change with these Guidelines. In this case, the head of the deriving institute should submit to the competent minister the following documents in addition to the written amendment to the derivation plan:
(i) Documents indicating the process and results of the review by the ethical review board of the deriving institute pertaining to the said change.
(ii) In the case prescribed in the preceding paragraph, documents indicating the process and results of the review by the ethical review board of the cell donor facility pertaining to the said change.
(4) The Minister of Education, Culture, Sports, Science and Technology should, when requested to provide the confirmation set forth in the preceding paragraph, seek the opinion of the Bioethics and Biosafety Commission under the Council for Science and Technology on the conformity of the said change with these Guidelines, and provide confirmation based on the said opinion.
(5) The Minister of Health, Labour and Welfare should, when requested to provide the confirmation set forth in Paragraph 3, seek the opinion of the Review Committee for Regenerative Medicine under the Health Science Council on the conformity of the said change with these Guidelines, and provide confirmation based on the said opinion.
(6) The head of a deriving institute should, when any change has been made to the matters listed in Article 14, Paragraph (2), Item (ii), promptly notify the competent minister to that effect.
(7) The derivation director should, when intending to change any of the matters listed in Article 14, Paragraph (2), Item (xiii), prepare a written amendment to the derivation plan and seek the approval of the head of the deriving institute in advance.
(8) The head of a deriving institute should, when having given the approval set forth in the preceding paragraph, promptly report the ethical review board of the deriving institute to that effect, and notify the competent minister to that effect.
(9) The Minister of Education, Culture, Sports, Science and Technology should, when the

notification set forth in the preceding paragraph has been given, report on the matters pertaining to the said notification to the Bioethics and Biosafety Commission under the Council for Science and Technology.
(10) The Minister of Health, Labour and Welfare should, when the notification set forth in Paragraph 8 has been given, report on the matters pertaining to the said notification to the Review Committee for Regenerative Medicine under the Health Science Council.

(Report on Progress of Derivation)
Article 18 (1) The derivation director should report on the progress of the derivation of human ES cells, the status of the maintenance, distribution, deposit, return and receipt of human ES cells and the status of the handling of the donated unfertilized eggs, etc. and somatic cells as needed to the head of the deriving institute and the ethical review board of the deriving institute.
(2) The derivation director should, when human ES cells have been derived, promptly prepare and submit to the head of the deriving institute a document containing that fact and the names of the human ES cell lines derived (referred to as a "written derivation report" in the next paragraph).
(3) The head of a deriving institute should, having received the submission of a written derivation report, promptly submit a copy thereof to the ethical review board of the deriving institute and the competent minister.
(4) The head of a deriving institute should, during the period in which the deriving institute maintains the human ES cells it has derived, report on the status of the maintenance, distribution, deposit, return and receipt of the said human ES cells to the competent minister at least once a year.

(Termination of Derivation Plan)
Article 19 (1) The derivation director should, when a derivation plan has been terminated, promptly prepare and submit to the head of the deriving institute a document containing that fact and the results of the derivation (referred to as a "written derivation plan completion report" in the next paragraph).
(2) The head of a deriving institute should, having received the submission of a written derivation plan completion report, promptly submit a copy thereof to the ethical review board of the deriving institute and the competent minister.
(3) A deriving institute should, when a derivation plan has been terminated, achieve appropriate handling of human ES cells by such means as transferring the human ES cells it possesses to a distributing institute.

(Disclosure of Research Results)

Article 20 (1) The research results obtained through the derivation of human ES cells should be disclosed, in principle.
(2) A deriving institute should, when disclosing the research results obtained through the derivation of human ES cells, clearly indicate that the said derivation of human ES cells has been carried out in conformity with these Guidelines.

(Coordination of Operations Concerning Deriving Institute)
Article 21 (1) Two or more institutes may carry out the operations of a deriving institute in collaboration with each other.
(2) In the case referred to in the preceding paragraph, each institute should include in its written derivation plan explanations on the role-sharing and the responsibilities of the respective institutes, and each institute should seek the opinion of the ethical review board established in the said institute with regard to the derivation plan or any change thereto (except changes pertaining to the matters listed in Article 14, Paragraph (2), Items (ii) and (xiii)).

Chapter III Donation of Human Fertilized Embryos Necessary for Deriving Human Embryonic Stem Cells

Section 1 Donation of Human Fertilized Embryos Necessary for First Category Derivation

(Criteria for First Category Donor Medical Facility)
Article 22 A first category donor medical facility should satisfy the following requirements:
(i) The first category donor medical facility should have sufficient track record and abilities concerning the handling of human fertilized embryos.
(ii) The first category donor medical facility should have established an ethical review board.
(iii) The first category donor medical facility should have taken sufficient measures to protect the personal information of the donors of human fertilized embryos.
(iv) The first category donor medical facility should have clearly established methods to confirm the donors' intention with regard to destroying the human fertilized embryos and other procedures concerning the handling of human fertilized embryos.

(Ethical Review Board of First Category Donor Medical Facility)
Article 23 (1) The ethical review board of a first category donor medical facility should carry out the operations to comprehensively review the scientific and ethical propriety of the derivation plan or any change thereto and submit opinions to the head of the first category donor medical facility on matters such as the appropriateness of the plan or the change thereto and any relevant points of concern and points for improvement, in conformity with

these Guidelines.
(2) The ethical review board of a first category donor medical facility should prepare and keep records on the process of the review set forth in the preceding paragraph.
(3) The ethical review board of a first category donor medical facility should satisfy the following requirements:
(i) The ethical review board should consist of experts in biology, medicine and law, persons having adequate insight to state opinions on bioethics and persons capable of stating opinions from the standpoint of the general public so as to be able to comprehensively review the scientific and ethical propriety of a derivation plan.
(ii) The members of the ethical review board should include two or more persons who do not belong to the juridical entity to which the said first category donor medical facility belongs.
(iii) The members of the ethical review board should include two or more men and two or more women.
(iv) Any researcher who implements the said derivation plan, any interested persons of the derivation director or any relatives of the derivation director up to the third degree of kinship should not take part in the review.
(v) An appropriate administrative procedure that can guarantee the freedom and independence of the activities of the ethical review board should be set in place.
(vi) Rules on the constitution, organization and administration of the ethical review board, disclosure of the contents of its meetings and other necessary procedures required for reviewing a derivation plan should be set in place and disclosed.
(4) When administering the ethical review board, the contents of its meetings should be disclosed except for the matters that are specified to be kept undisclosed pursuant to the rules prescribed in Item (vi) of the preceding paragraph.

(Procedures for Informed Consent Concerning the Donation of Human Fertilized Embryos Necessary for First Category Derivation)
Article 24 (1) A first category donor medical facility should obtain the informed consent of the donors of the human fertilized embryos necessary for first category derivation (husband and wife [not including those who are in a de facto relationship similar to husband and wife without having given the notification of marriage] who have donated the germ cells necessary for producing the said human fertilized embryos; hereinafter the same should apply in this section) with regard to using the human fertilized embryos for the said first category derivation.
(2) The informed consent set forth in the preceding paragraph should be indicated in writing.
(3) When obtaining the informed consent set forth in Paragraph (1), the first category donor medical facility should satisfy the following requirements, while giving sufficient consideration to the feelings of the donors of the human fertilized embryos:

(i) The first category donor medical facility should not take unfair advantage of the situation of the donors of human fertilized embryos.
(ii) The first category donor medical facility should not request a person who lacks the capability to consent to donate human fertilized embryos.
(iii) The first category donor medical facility should have confirmed the intention of the donors of human fertilized embryos in advance with regard to destroying the human fertilized embryos.
(iv) The first category donor medical facility should allow the donors of human fertilized embryos the necessary time for determining whether or not to donate.
(v) The first category donor medical facility should preserve the said human fertilized embryos for at least 30 days after the informed consent has been obtained.
(4) The donors of human fertilized embryos may revoke their informed consent during the period when the said human fertilized embryos are being preserved.
(5) A first category donor medical facility should not try to obtain informed consent again, after having obtained informed consent from a donor of human fertilized embryos (hereinafter referred to as "re-consent"). When, however, the procedures for obtaining informed consent again are based on Paragraph (3), Item (xv) of the following article, the donor of such embryos has so agreed and the ethical review board of the first category donor medical facility has given approval, the above should not apply.

(Explanation on Informed Consent Concerning the Donation of Human Fertilized Embryos Necessary for First Category Derivation)
Article 25 (1) The explanation pertaining to the informed consent prescribed in Paragraph (1) of the preceding article should be given by the first category deriving institute.
(2) A first category deriving institute should have a person who is nominated by the head of the said first category deriving institute from amongst persons belonging to the said first category deriving institute (except the derivation director) provide the explanation set forth in the preceding paragraph.
(3) The person who has been nominated by the head of a first category deriving institute pursuant to the provisions of the preceding paragraph should, when providing the explanation set forth in Paragraph (1), give the explanation to the donors of human fertilized embryos in an easy-to-understand manner by presenting a written explanation containing the following matters:
(i) The purpose and method of the derivation of human ES cells.
(ii) The fact that the human fertilized embryos will be destroyed in the derivation process and any other matters on the handling of the donated human fertilized embryos.
(iii) The expected utilization method of the human ES cells and the results thereof.
(iv) The fact that the conformity of the derivation plan with these Guidelines has been

confirmed by the first category deriving institute, the first category donor medical facility and the competent minister.

(v) The fact that the personal information of the donors of the human fertilized embryos will not be transferred to the first category deriving institute and any other concrete methods for protecting such personal information (including the method of anonymization).

(vi) The fact that, because human fertilized embryos are donated voluntarily, the donors will receive no reward in the future.

(vii) In cases where there is a possibility that the human ES cells may be analyzed genetically, a statement to that effect and the fact that those genetic analyses will not identify specific individuals.

(viii) In cases where there is a possibility that germ cells will be produced from human ES cells, a statement to that effect and the fact that human embryos will not be produced using the said germ cells.

(ix) The fact that information on human ES cells derived from donated human fertilized embryos will not be disclosed to the donor.

(x) The possibility that the process of deriving the human ES cells and the research results obtained from the research utilizing the human ES cells may be disclosed at such occasions as academic meetings.

(xi) The fact that the human ES cells will be maintained at the first category deriving institute for a long period and are distributed gratis to utilizing institutes or utilizing clinical institutes.

(xii) The possibility that, in the case where useful results have been obtained from the human ES cells (including the differentiated cells), patent rights, copyrights or other intangible property rights or economic interests may arise from those results and the fact that they will not belong to the donors of the human fertilized embryos.

(xiii) The fact that the statement of an intention to donate or not to donate does not bring any advantage or disadvantage to the donors of the human fertilized embryos.

(xiv) The fact that the human fertilized embryos will be preserved at the first category donor medical facility for at least 30 days after the consent has been obtained as well as the method of preservation, and the fact that the consent can be revoked during the period when the said human fertilized embryos are preserved as well as the method of revocation. (The fact that, when obtaining informed consent again, human fertilized embryos or human ES cells relevant to the re-consent will not be utilized for at least 30 days after the previous consent has been obtained.)

(xv) When there is a possibility to implement re-consent because it is necessary to utilize the human ES cells to the extent of requirement prescribed in Article 6, Paragraph (1), Item (i) for any reason or in any manner which could not been predicted at the time the previous informed consent was obtained, the following matters should be explained:

(a) The fact that there is a possibility to implement the procedures for obtaining informed consent again.
(b) The fact such procedures will be implemented along with the method, only when a prior agreement has been given to such re-consent.
(c) The fact that the agreement given to the implementation of the re-consent can be revoked and the method.

(xvi) Any other necessary matters

(4) A first category deriving institute should, when providing the explanation set forth in Paragraph (1), take appropriate measures to protect the personal information of the donors of human fertilized embryos, and should deliver respectively the written explanation set forth in the preceding paragraph and a document indicating that the said explanation has been provided (referred to as the "explanation certificate" in Paragraph (1) of the next article) to the donors of the human fertilized embryos and copies thereof to the first category donor medical facility.

(5) A first category deriving institute should give the explanation set forth in Paragraph (1) accurately based on the latest scientific knowledge.

(Confirmation of Informed Consent Concerning the Donation of Human Fertilized Embryos Necessary for First Category Derivation)

Article 26 (1) The head of a first category donor medical facility should confirm the document set forth in Article 24, Paragraph (2), the written explanation set forth in Paragraph (3) of the preceding article and the explanation certificate, and should seek the opinion of the ethical review board of the said first category donor medical facility with regard to the appropriate receipt of the informed consent based on the derivation plan.

(2) The head of a first category donor medical facility should, when transferring human fertilized embryos to a first category deriving institute, notify the first category deriving institute in writing that the head has carried out the confirmation set forth in the preceding paragraph.

(3) When the head of a first category deriving institute has received the notice set forth in the preceding paragraph, the head should submit a copy of the said notice to the competent minister.

(Protection of Personal Information of Donors of Human Fertilized Embryos)

Article 27 (1) Persons engaged in first category derivation should make their utmost efforts to protect the personal information of the donors of human fertilized embryos.

(2) Following the intention of the preceding paragraph, a first category donor medical facility should, when transferring human fertilized embryos to a first category deriving institute, take all necessary measures so that the said human fertilized embryos cannot be

identified with the personal information of the donors of the human fertilized embryos.

Section 2 Donation of Unfertilized Eggs Necessary for Second Category Derivation

(Criteria for Second Category Donor Medical Facility)

Article 28 (1) A second category donor medical facility should satisfy the following requirements:

(i) The second category donor medical facility should have sufficient track record and abilities concerning the handling of unfertilized eggs, etc.

(ii) The second category donor medical facility should have established an ethical review board.

(iii) The second category donor medical facility should have taken sufficient measures to protect the personal information of the donors of unfertilized eggs, etc.

(iv) The second category donor medical facility should have clearly established methods to confirm the donors' intention with regard to donating unfertilized eggs, etc. and other procedures concerning the handling of human fertilized embryos.

(2) When the donors of unfertilized eggs, etc. are receiving medical care at a second category donor medical facility, the second category donor medical facility should allocate a medical doctor in charge of explanation (a medical doctor who gives the donors of unfertilized eggs, etc. an explanation on the method of the said donation and the handling after the donation and has excellent insight into medical care in the field of obstetrics and gynecology) and a coordinator (a person who provides the donors of unfertilized eggs, etc. with information and consultation services and coordinates among the persons concerned with regard to the said donation, is not an interested person of the donors and has excellent insight into second category derivation and medical care in the field of obstetrics and gynecology).

(Ethical Review Board of Second Category Donor Medical Facility)

Article 29 (1) The ethical review board of a second category donor medical facility should carry out the operations to comprehensively review the scientific and ethical propriety of the derivation plan or any change thereto and submit opinions to the head of the second category donor medical facility on matters such as the appropriateness of the plan or the change thereto and any relevant points of concern and points for improvement, in conformity with these Guidelines.

(2) The ethical review board of a second category donor medical facility should prepare and keep records on the process of the review set forth in the preceding paragraph.

(3) The ethical review board of a second category donor medical facility should satisfy the following requirements:

(i) The ethical review board should consist of experts in biology, medicine and law, persons having adequate insight to state opinions on bioethics and persons capable of stating opinions from the standpoint of the general public so as to be able to comprehensively review the scientific and ethical propriety of the derivation plan.
(ii) The members of the ethical review board should include two or more persons who do not belong to the juridical entity to which the said second category donor medical facility belongs.
(iii) The members of the ethical review board should include two or more men and two or more women.
(iv) Any researcher who implements the said derivation plan, any interested persons of the derivation director or any relatives of the derivation director up to the third degree of kinship should not take part in the review.
(v) An appropriate administrative procedure that can guarantee the freedom and independence of the activities of the ethical review board should be set in place.
(vi) Rules on the constitution, organization and administration of the ethical review board, disclosure of the contents of its meetings and other necessary procedures required for reviewing a derivation plan should be set in place and disclosed.
(vii) The experts in medicine set forth in Item (i) should include persons having insight into regenerative medicine and medical doctors having excellent insight into the medical care which the donors of unfertilized eggs, etc. receive.
(viii) The majority of the members of the ethical review board should consist of those who do not belong to the second category deriving institute.
(4) When administering the ethical review board, the contents of its meetings should be disclosed except for the matters that are specified to be kept undisclosed pursuant to the rules prescribed in Item (vi) of the preceding paragraph.

(Procedures for Informed Consent Concerning the Donation of Unfertilized Eggs, etc. Necessary for Second Category Derivation)
Article 30 (1) A second category donor medical facility should obtain the informed consent of the donors of the unfertilized eggs, etc. necessary for second category derivation and any other persons whose intention to donate should be confirmed (hereinafter referred to as the "donors, etc." in this section) with regard to using the unfertilized eggs, etc. for the said second category derivation.
(2) The informed consent set forth in the preceding paragraph should be indicated in writing.
(3) When obtaining the informed consent set forth in Paragraph (1), the second category donor medical facility should satisfy the following requirements, while giving sufficient consideration to the feelings of the donors, etc.:
(i) The second category donor medical facility should not take unfair advantage of the

situation of the donors, etc.
(ii) The second category donor medical facility should not request a person who lacks the capability to consent, a person who carries out second category derivation or any other person concerned to donate unfertilized eggs, etc.
(iii) The second category donor medical facility should have confirmed the intention of the donors, etc. in advance with regard to destroying the unfertilized eggs, etc.
(iv) The second category donor medical facility should allow the donors, etc. the necessary time for determining whether or not to donate.
(v) The second category donor medical facility should not transfer the said unfertilized eggs, etc. to a second category deriving institute for at least 30 days after the informed consent has been obtained.
(vi) The second category donor medical facility should, when receiving the donation of unfertilized eggs, etc. listed in Article 9, Paragraph (5), Item (ii) or (iii) of the Guidelines on Specified Embryos (except those in a frozen state), confirm that the donors of the unfertilized eggs, etc. are those who have received assisted reproductive technology in the past and that the donors of the unfertilized eggs, etc. have offered to donate in advance.
(vii) A member of the ethical review board or a person designated by the ethical review board (limited to those who do not participate in the said second category derivation and are not the interested persons of the donors of the unfertilized eggs, etc.) should have confirmed the appropriateness of the procedure pertaining to the consent to donate through an interview with the donors of the unfertilized eggs, etc. (except when receiving the donation of frozen unfertilized eggs and when receiving the donation of human fertilized embryos after the termination of assisted reproductive technology provided to the donors of the unfertilized eggs, etc.).

(Explanation on Informed Consent Concerning the Donation of Unfertilized Eggs, etc. Necessary for Second Category Derivation)
Article 31 (1) The explanation pertaining to the informed consent set forth in Paragraph (1) of the preceding article should be given pursuant to Article 10, Paragraph (2) of the Guidelines on Specified Embryos.
(2) A second category deriving institute should have a person who is nominated by the head of the said second category deriving institute from amongst persons belonging to the said second category deriving institute (except the derivation director) provide the explanation set forth in the preceding paragraph.
(3) The person who has been nominated by the head of a second category deriving institute pursuant to the provisions of the preceding paragraph should, when providing the explanation set forth in Paragraph (1), give the explanation to the donors, etc. in an easy-to-understand manner by presenting a written explanation containing the matters listed in the

items of Article 10, Paragraph (2) of the Guidelines on Specified Embryos.
(4) A second category deriving institute should, when providing the explanation set forth in Paragraph (1), take appropriate measures to protect the personal information of the donors of unfertilized eggs, etc., and should deliver respectively the written explanation set forth in the preceding paragraph and a document indicating that the said explanation has been provided (referred to as the "explanation certificate" in Paragraph (1) of the next article) to the donors, etc. and copies thereof to the second category donor medical facility.
(5) A second category deriving institute should give the explanation set forth in Paragraph (1) accurately based on the latest scientific knowledge.

(Confirmation of Informed Consent Concerning the Donation of Unfertilized Eggs, etc. Necessary for Second Category Derivation)
Article 32 (1) The head of a second category donor medical facility should confirm the document set forth in Article 30, Paragraph (2), the written explanation set forth in Paragraph (3) of the preceding article and the explanation certificate, and should seek the opinion of the ethical review board of the said second category donor medical facility with regard to the appropriate receipt of the informed consent based on the derivation plan.
(2) The head of a second category donor medical facility should, when transferring unfertilized eggs, etc. to a second category deriving institute, notify the second category deriving institute in writing that the head has carried out the confirmation set forth in the preceding paragraph.
(3) When the head of a second category deriving institute has received the notice set forth in the preceding paragraph, the head should submit a copy of the said notice to the Minister of Education, Culture, Sports, Science and Technology.

(Protection of Personal Information of Donors of Unfertilized Eggs, etc.)
Article 33 (1) Persons engaged in second category derivation should make their utmost efforts to protect the personal information of the donors of unfertilized eggs, etc.
(2) Following the intention of the preceding paragraph, a second category donor medical facility should, when transferring unfertilized eggs, etc. to a second category deriving institute, take the necessary measures so that the said unfertilized eggs, etc. cannot be identified with the personal information of the donors of the unfertilized eggs, etc.

Section 3 Donation of Human Somatic Cells Necessary for Second Category Derivation

(Criteria for Somatic Cell Donor Facility)
Article 34 (1) A somatic cell donor facility should satisfy the following requirements:
(i) The somatic cell donor facility should have established an ethical review board.

(ii) The somatic cell donor facility should have taken sufficient measures to protect the personal information of the donors of somatic cells.
(iii) The somatic cell donor facility that receives the donation of the somatic cells listed in Article 9, Paragraph (6), Item (i) or (iii) of the Guidelines on Specified Embryos should be a medical facility.
(iv) The somatic cell donor facility that receives the donation of the somatic cells listed in Article 9, Paragraph (6), Item (iii) of the Guidelines on Specified Embryos should include medical doctors who have considerable experience in taking somatic cells and who are not the interested persons of the donors.

(Ethical Review Board of Somatic Cell Donor Facility)
Article 35 (1) The ethical review board of a somatic cell donor facility should carry out operations to comprehensively review the scientific and ethical propriety of the derivation plan or any change thereto and submit opinions to the head of the somatic cell donor facility on matters such as the appropriateness of the plan or the change thereto and any relevant points of concern and points for improvement, in conformity with these Guidelines.
(2) The ethical review board of a somatic cell donor facility should prepare and keep records on the process of the review set forth in the preceding paragraph.
(3) The ethical review board of a somatic cell donor facility should satisfy the following requirements:
(i) The ethical review board should consist of experts in medicine and law, persons having adequate insight to state opinions on bioethics and persons capable of stating opinions from the standpoint of the general public so as to be able to comprehensively review the scientific and ethical propriety of the derivation plan.
(ii) The members of the ethical review board should include one or more men and one or more women.
(iii) Any researcher who implements the said derivation plan should not take part in the review.
(iv) An appropriate administrative procedure that can guarantee the freedom and independence of the activities of the ethical review board should be set in place.
(v) Rules on the constitution, organization and administration of the ethical review board, disclosure of the contents of its meetings and other necessary procedures required for reviewing a derivation plan should be set in place and disclosed.
(4) When administering the ethical review board, the contents of its meetings should be disclosed except for the matters that are specified to be kept undisclosed pursuant to the rules prescribed in Item (v) of the preceding paragraph.

(Procedure of Informed Consent Concerning the Donation of Somatic Cells)

Article 36 (1) A somatic cell donor facility should obtain the informed consent of the donors of the somatic cells necessary for second category derivation and any other persons whose intention to donate the said somatic cells should be confirmed (hereinafter referred to as the "donors, etc." in this section) with regard to using the said somatic cells for the said second category derivation; provided, however, that this should not apply to the case where the somatic cell donor facility receives the donation of the somatic cells listed in Article 9, Paragraph (6), Item (ii) of the Guidelines on Specified Embryos for which information pertaining to the donors of the said somatic cells is not available.

(2) The informed consent set forth in the preceding paragraph should be indicated in writing.

(3) When obtaining the informed consent set forth in Paragraph (1), the somatic cell donor facility should satisfy the following requirements, while giving sufficient consideration to the feelings of the donors, etc.:

(i) The somatic cell donor facility should not request a person who lacks the capability to consent, a person who carries out second category derivation or any other person concerned to donate somatic cells.

(ii) The somatic cell donor facility should allow the donors, etc. the necessary time for determining whether or not to donate.

(iii) The somatic cell donor facility should not transfer the said somatic cells to a second category deriving institute for at least 30 days after the informed consent has been obtained.

(iv) The somatic cell donor facility should, when receiving the donation of the somatic cells listed in Article 9, Paragraph (6), Item (iii) of the Guidelines on Specified Embryos, confirm that all of the following requirements are satisfied:

(a) The donors of the somatic cells have offered to donate in advance.

(b) A member of the ethical review board of the somatic cell donor facility or a person designated by the said ethical review board (limited to those who do not participate in the said second category derivation and are not the interested persons of the donors of the somatic cells) has confirmed the appropriateness of the procedure pertaining to the consent to donate through interview with the donors of the somatic cells.

(Explanation on Informed Consent Concerning the Donation of Somatic Cells)

Article 37 (1) The explanation pertaining to the informed consent set forth in Paragraph (1) of the preceding article should be given pursuant to Article 10, Paragraph (2) of the Guidelines on Specified Embryos as applied mutatis mutandis by replacing terms pursuant to the provisions of Article 11, Paragraph (1) of the Guidelines on Specified Embryos, as well as pursuant to Article 11, Paragraphs (2) and (3) of the Guidelines on Specified Embryos.

(2) A second category deriving institute should, when giving the explanation set forth in the preceding paragraph, have a person who is nominated by the head of the said second category deriving institute from amongst persons belonging to the said second category

deriving institute (except the derivation director) provide the explanation set forth in the preceding paragraph.
(3) The person of a somatic cell donor facility who provides the explanation and the person who has been nominated by the head of a second category deriving institute pursuant to the provisions of the preceding paragraph should, when providing the explanation set forth in Paragraph (1), give the explanation to the donors, etc. in an easy-to-understand manner by presenting a written explanation containing the matters listed in the items of Article 10, Paragraph (2) of the Guidelines on Specified Embryos as applied mutatis mutandis by replacing terms pursuant to the provisions of Article 11, Paragraph (1) of the Guidelines on Specified Embryos, and in the items of Article 11, Paragraph (2) of the Guidelines on Specified Embryos.
(4) A second category deriving institute should, when providing the explanation set forth in Paragraph (1), take appropriate measures to protect the personal information of the donors of somatic cells, and should deliver respectively the written explanation set forth in the preceding paragraph and a document indicating that the said explanation has been provided (referred to as the "explanation certificate" in Paragraph (1) of the next article) to the donors, etc. and copies thereof to the somatic cell donor facility.
(5) A somatic cell donor facility and second category deriving institute should give the explanation set forth in Paragraph (1) accurately based on the latest scientific knowledge.

(Confirmation of Informed Consent Concerning the Donation of Somatic Cells)
Article 38 (1) The head of a somatic cell donor facility should confirm the document set forth in Article 36, Paragraph (2), the written explanation set forth in Paragraph (3) of the preceding article and the explanation certificate, and should seek the opinion of the ethical review board of the said somatic cell donor facility with regard to the appropriate receipt of the informed consent based on the derivation plan.
(2) The head of a somatic cell donor facility should, when transferring somatic cells to a second category deriving institute, notify the second category deriving institute in writing that the head has carried out the confirmation set forth in the preceding paragraph.
(3) Having received the notice set forth in the preceding paragraph, the head of a second category deriving institute should submit a copy of the said notice to the Minister of Education, Culture, Sports, Science and Technology.

(Protection of Personal Information of Donors of Somatic Cells)
Article 39 (1) Persons engaged in second category derivation should make their utmost efforts to protect the personal information of the donors of somatic cells.
(2) Following the intention of the preceding paragraph, a somatic cell donor facility should, when transferring somatic cells to a second category deriving institute, take the necessary

measures so that the said somatic cells cannot be identified with the personal information of the donors of the somatic cells; provided, however, that this should not apply to the case where the second category deriving institute requires information pertaining to the diseases of the donors of the somatic cells and the somatic cell donor facility has obtained the consent of the donors, etc. and the approval of the ethical review board of the somatic cell donor facility.

Chapter IV Distribution of Human Embryonic Stem Cells

Section 1 Requirements for Distribution

(Requirements for Human ES Cells to be Distributed)

Article 40 Human ES cells to be distributed should be limited to those that satisfy the following requirements:

(i) The human ES cells should be those that have been derived based on these Guidelines.

(ii) The human ES cells should be those that have been transferred gratis, except for necessary expenses.

(Requirements for Distribution)

Article 41 (1) The distribution of human ES cells (except distribution to overseas utilizing institutes) may be carried out only when the following requirements are satisfied:

(i) Human ES cells should be distributed only to utilizing institutes that implement a utilization plan based on the ES Distribution and Utilization Guidelines.

(ii) Human ES cells should be distributed gratis, except for necessary expenses.

(2) A deriving institute should, when a request for the distribution of human ES cells has been made by a utilizing institute that implements a utilization plan based on the ES Distribution and Utilization Guidelines, distribute the human ES cells unless there are unavoidable circumstances.

(Requirements for Distribution to Overseas Utilizing Institute)

Article 42 The distribution of human ES cells to an overseas utilizing institute may be carried out only when the following requirements are satisfied:

(i) Human ES cells should be distributed only to overseas utilizing institutes that have concluded a contract based on an overseas distribution plan that has been confirmed by the Minister of Education, Culture, Sports, Science and Technology as prescribed in Article 44, Paragraph (5).

(ii) Human ES cells should be distributed gratis except for necessary expenses.

Section 2 Distribution to Overseas Utilizing Institutes

(Criteria for Overseas Utilizing Institute)

Article 43 For the time being, an overseas distribution plan should be formulated for distribution to an overseas utilizing institute that satisfies the following requirements:

(i) The overseas utilizing institute should observe the national laws and regulations or guidelines equivalent thereto of the country where such overseas utilizing institute is located with regard to the handling of human ES cells and differentiated cells.

(ii) The overseas utilizing institute should not redistribute or transfer the human ES cells that it has received by distribution to any other institutes.

(iii) The overseas utilizing institute should, when it has terminated the utilization of human ES cells, dispose of the remaining human ES cells based on the agreement with the deriving institute that has distributed the said human ES cells, or return or transfer them to the deriving institute that has distributed the said human ES cells.

(iv) The overseas utilizing institute should not create an individual through the transplantation of embryos produced by utilizing human ES cells into a human or animal uterus or through any other method, introduce human ES cells into a human embryo or human fetus, or produce human embryos using germ cells produced from human ES cells.

(v) The overseas utilizing institute should not utilize human ES cells for a commercial purpose.

(vi) The overseas utilizing institute should not carry out clinical research applying human ES cells or cells originating therefrom to the human body or utilize human ES cells in medicine and in its related fields.

(vii) The overseas utilizing institute should have taken sufficient measures to protect personal information.

(viii) The overseas utilizing institute should take any other necessary measures for the appropriate handling of human ES cells.

(ix) The overseas utilizing institute should, in the event of violating the criteria for an overseas distribution plan prescribed in this article, return or transfer human ES cells to the deriving institute that has distributed the human ES cells.

(Procedure for Distribution to Overseas Utilizing Institute)

Article 44 (1) When distributing human ES cells to an overseas utilizing institute, the derivation director should prepare a written overseas distribution plan in advance and seek the approval of the head of the deriving institute for the implementation of the overseas distribution plan.

(2) The written overseas distribution plan should contain the following matters:

(i) The name of the overseas distribution plan.

(ii) The name and address of the deriving institute and its head.

(iii) The name of the derivation director.
(iv) The name and address and the name of the country of the location of the overseas utilizing institute to which human ES cells are to be distributed.
(v) The method of distribution.
(vi) The period of utilization by the overseas utilizing institute to which human ES cells are to be distributed.
(vii) The source of supply of the human ES cells to be distributed and the name of the human ES cell line.
(viii) An explanation concerning the criteria for the overseas utilizing institute.
(ix) Any other necessary matters.
(3) The derivation director should attach to the written overseas distribution plan a copy of a document indicating that the utilization of human ES cells by the overseas utilizing institute to which the cells will be distributed has been approved based on the national laws and regulations or guidelines equivalent thereto of the country where such overseas utilizing institute is located, and Japanese translations thereof.
(4) The head of a deriving institute should, when requested to give the approval set forth in Paragraph (1), seek the opinion of the ethical review board of the deriving institute on the propriety of the plan and confirm the conformity of the plan with these Guidelines based on the said opinion.
(5) When giving approval for the implementation of an overseas distribution plan, the head of a deriving institute should receive confirmation from the Minister of Education, Culture, Sports, Science and Technology with regard to the conformity of the said overseas distribution plan with these Guidelines after the termination of the procedures set forth in the preceding paragraph.
(6) In the case referred to in the preceding paragraph, the head of the deriving institute should submit to the Minister of Education, Culture, Sports, Science and Technology the following documents:
(i) The written overseas distribution plan.
(ii) Documents indicating the process and results of the review by the ethical review board of the deriving institute.
(7) The Minister of Education, Culture, Sports, Science and Technology should seek the opinion of the Bioethics and Biosafety Commission under the Council for Science and Technology on the conformity of the overseas distribution plan with these Guidelines, and provide confirmation based on the said opinion.

Chapter V Miscellaneous Provisions

(Competent Minister)

Article 45 For the purpose of these Guidelines, requirements concerning human ES cells prescribed in Article 6, Paragraph (1), Item (i) (a) and Paragraph (2), Item (i) of these Guidelines are in the charge of the Minister of Education, Culture, Sports, Science and Technology, while those concerning human ES cells prescribed in Article 6, Paragraph (1), item (i) (b) are in the charge of the Minister of Health, Labour and Welfare.

(Coordination with Relevant Administrative Organs)

Article 46 The Minister of Education, Culture, Sports, Science and Technology and the Minister of Health, Labour and Welfare should closely coordinate with the Minister of Economy, Trade and Industry by such means as providing information, by taking into consideration that the handling of human ES cells is closely connected to the related fields.

(Public Announcement of Nonconformity to Guidelines)

Article 47 The Minister of Education, Culture, Sports, Science and Technology and the Minister of Health, Labour and Welfare should, when there has been a person or entity whose handling of human ES cells was found not to conform to the criteria provided by these Guidelines, make a public announcement to that effect.

Supplementary Provisions

(Effective Date)

Article 1 These Guidelines shall come into effect as of November 25, 2014.

(Repeal of Guidelines on the Derivation and Distribution of Human Embryonic Stem Cells)

Article 2 The Guidelines on the Derivation and Distribution of Human Embryonic Stem Cells (Public Notice of MEXT No. 156 of 2009; referred to as the “old Guidelines” in the next article) should be repealed.

(Transitional Measures)

Article 3 A derivation plan or overseas distribution plan that has been confirmed by the Minister of Education, Culture, Sports, Science and Technology pursuant to the provisions of the old Guidelines at the time of the enforcement of these Guidelines should be deemed to have received the confirmation set forth in Article 16, Paragraph (1) or Article 44, Paragraph (5), respectively.

(Review of Guidelines)

Article 4 (1) The Minister of Education, Culture, Sports, Science and Technology and the Minister of Health, Labour and Welfare should review the provisions of these Guidelines if necessary, by taking into consideration such factors as the progress of research in life

sciences and trends of society.

(2) The review set forth in the preceding paragraph should be carried out based on the opinion of the Council for Science, Technology and Innovation.