

# The Guidelines for Derivation and Utilization of Human Embryonic Stem Cells

## Preface

Although derivation and utilization of human embryonic stem (ES) cells has the potential to bring to us great progress in medicine and biology, we need to give careful consideration to these activities because ethical issues do exist: a human embryo, which is the beginning of a human life, is required for deriving human ES cells; human ES cells are capable of differentiating into any type of human cell, and so on.

Based upon the 'Report on the Human Embryo Research Focusing on the Human Embryonic Stem Cells' (March 6, 2000, the Subcommittee of Human Embryo Research, Bioethics Committee, Council for Science and Technology), the Minister of Education, Culture, Sports, Science and Technology has established the Guidelines in attempt to appropriately promote research on human ES cells, by providing fundamental rules to be observed from bioethical points of view so that human dignity may never be violated in association with derivation or utilization of human ES cells.

## Section I. General Rules

(Definitions)

### Article 1

In the Guidelines, those terms stated in the following paragraphs have their meanings as defined therein:

1. *Embryo*  
A cell (except for a germ cell) or cells which has/have the potential to grow into an individual through the process of development in utero of a human or an animal and has/have not yet begun the formation of a placenta;
2. *Human embryo*  
An embryo of a human being, including an embryo with genetic information as a human being;
3. *Human fertilized embryo*  
An embryo produced by fertilization between a human spermatozoon and a human unfertilized egg;
4. *Human embryonic stem (ES) cell*  
A cell collected from an embryo or a cell produced by division of such a cell, (excluding the embryo), which has pluripotency and retains ability to proliferate by itself, or is considered to have such ability;
5. *Pluripotency*  
Capability to differentiate into ectodermal, endodermal and mesodermal cells;
6. *Derivation*  
Production of cells with a specific property;
7. *Differentiated cell*  
A cell differentiated from the ES cell, which results in not having the property of an ES cell;
8. *Deriving institute (DI)*  
An institute where human ES cells are derived;
9. *Donating Medical facilities (DMFs)*  
Medical facilities that receive donation of human fertilized embryos used for deriving human ES cells and then transfer them to DI;
10. *Utilizing institute (UI)*  
An institute where human ES cells are utilized;
11. *Derivation director (DD)*  
A person in charge directing derivation of human ES cells;
12. *Utilization director (UD)*  
A person in charge directing utilization of human ES cells; and
13. *Informed consent (IC)*  
A consent given out of one's own free will based upon sufficient explanation provided.

(Range of Application)

### Article 2

- (1) Derivation and utilization of human ES cells shall always be carried out appropriately in

accordance with the Guidelines.

(2) Derivation and utilization of ES cells shall be limited to basic research for the present. Again, the following activities shall not be carried out, until specific criteria other than the Guidelines have been established: i.e., clinical research applying human ES cells or cells originated from them to the human body, and utilization of them in medicine and in its related fields.

(Respect for Human Embryo and ES Cells)

#### **Article 3**

Human embryos and ES cells shall be handled carefully and conscientiously without violating human dignity, taking it into consideration that a human embryo is the beginning of a human life and that human ES cells have the potential to differentiate into any type of human cell.

(Gratuitous Donation of a Human Embryo)

#### **Article 4**

A human embryo shall be donated for derivation of human ES cells gratuitously, except for necessary expenses.

### **Section II. Derivation of Human ES Cells**

#### **Paragraph I. Requirements for Derivation and Distribution**

(Requirements for Derivation of Human ES Cells)

#### **Article 5**

Derivation of human ES cells shall be allowed only when the following requirements are satisfied:

1. A plan for utilization of human ES cells in accordance with the requirements for the utilization prescribed in Article 26(1) is explicitly indicated; and
2. The plan of utilization prescribed in 1 above is both scientifically necessary and rational.

(Requirements for Human Embryos Used for Derivation of Human ES Cells)

#### **Article 6**

A human embryo used for derivation of human ES cells shall

1. be the human fertilized embryo which has initially been created for the purposes of fertility treatment, but is planned not to be used any longer for the purposes, and, hence, is surely intended to be discarded by its donors,
2. be accompanied by an appropriate IC concerning its use for the derivation of human ES cells,
3. have been stored frozen, and
4. be used within 14 days after the fertilization, not counting any time during which it has been stored frozen.

(Handling of Human Fertilized Embryos in Deriving Institute)

#### **Article 7**

The human fertilized embryo shall be appropriately handled in the DI by a medical doctor or under his/her guidance.

(Requirements for Distribution)

#### **Article 8**

(1) Distribution of human ES cells shall be allowed

1. when limited to the UI which undertakes the utilization protocol accepted by the Minister of Education, Culture, Sports, Science and Technology (hereinafter referred to as the "Minister") in accordance with the provisions in Article 36, and
2. when distributed gratuitously, except for necessary expenses.

(2) The DI shall distribute human ES cells at request of the UI which undertakes the utilization protocol accepted by the Minister in accordance with the provisions in Article 36, except under unavoidable circumstances.

### **Paragraph II. Derivation System**

(Criteria for Deriving Institute)

**Article 9**

The DI shall satisfy the following requirements:

1. It has equipment, facilities, financial foundation, staffs and technical ability sufficient for deriving and distributing human ES cells;
2. Rules on ethical and technical matters to be observed in derivation and distribution of human ES cells are established; and
3. An institutional review board (IRB) is set in it.

(Tasks of Deriving Institute)

**Article 10**

- (1) The DI shall have the obligation to
  1. derive and distribute human ES cells, and
  2. get assigned and distribute the human ES cells, which was once distributed to and then processed in the UI (restricted to the cases reasonable for development of research utilizing human ES cells).
- (2) The DI shall prepare and keep records on derivation, maintenance and distribution of human ES cells.
- (3) The DI shall cooperate in presenting data on derivation, maintenance and distribution, arranging for accepting investigations and any other measures recognized necessary by the Minister.

(President of Deriving Institute)

**Article 11**

The president of the DI shall have the obligation to

1. confirm the propriety of the submitted derivation protocol and approve it for undertaking,
2. survey and grasp the progress and/or results of the derivation of human ES cells and, if necessary, provide the DD appropriate directions on any items to be paid attention to, improved and so on,
3. supervise derivation and distribution of human ES cells, and
4. inform of the Guidelines widely and thoroughly within the DI and make certain the Guidelines are to be observed there.

(Derivation Director)

**Article 12**

- (1) The DD shall have the obligation to
  1. examine ethical and scientific propriety of the derivation protocol based upon the information and materials available on deriving human ES cells at home and/or abroad,
  2. prepare a document on the derivation protocol (DDP) based upon the results of the examination prescribed in 1 above,
  3. direct derivation of human ES cells, and give any necessary directions to researchers,
  4. confirm on occasion that the derivation of human ES cells is appropriately carried out in accordance with the DDP,
  5. report to the president of the DI and the IRB in the DI on any items necessary to mention on the progress and the results of derivation of human ES cells, and
  6. take any measures necessary to direct the derivation protocol, in addition to the measures prescribed in 1 to 5 above.
- (2) One DD shall be assigned to each derivation protocol, and he/she shall have experience in deriving ES cells from an animal embryo, sufficient expert skills and knowledge on deriving human ES cells, and ability to carry out precisely the tasks set forth in (1)1 to 6 above.

(Institutional Review Board in Deriving Institute)

**Article 13**

- (1) The IRB in the DI shall have the obligation to
  1. review the overall ethical and scientific propriety of the submitted derivation protocol and advise the president of the DI on the approval/disapproval of the protocol and any related items to be paid attention to, improved and so on, together with preparing and keeping records on the process of the review, in conformity with the Guidelines, and

2. receive a report on the progress and the results of derivation, investigate if necessary, and advise the president of the DI on any related items to be paid attention to, improved and so on.
- (2) The IRB in the DI shall satisfy the following requirements:
1. It consists of an expert in biology, medicine and law, a person qualified to give his/her opinions on bioethics and a person able to give his/her opinions as a representative member for the general public;
  2. Among members there are included two or more persons not belonging or relating to the DI;
  3. There are included two or more men and two or more women;
  4. The person who carries out the derivation protocol does not take part in its review;
  5. There is an established appropriate procedure to manage the IRB so that independence and freedom in its activity will be guaranteed; and
  6. There are established and disclosed to the public rules on management, organization and system of the IRB, public disclosure of its proceedings and procedures required in reviewing a derivation protocol.

### **Paragraph III. Procedure of Derivation**

(Document on Derivation Protocol)

#### **Article 14**

- (1) For deriving human ES cells, the DD shall prepare a DDP in advance and request the president of the DI to approve it.
- (2) The DDP in (1) above shall include the following items:
  1. The name of the DDP;
  2. The name of the DI and its address;
  3. The name, the brief history, the achievement in research of the DD and researchers and their roles taken by each in the derivation protocol;
  4. Explanation concerning the human fertilized embryos used for the derivation;
  5. A plan for utilization of human ES cells after the derivation;
  6. The necessity of the derivation;
  7. The method and term of the derivation;
  8. Explanation concerning the distribution;
  9. Explanation concerning the criteria of the DI;
  10. Explanation concerning the IC;
  11. Explanation concerning the DMFs;
  12. Explanation concerning the IRB in the DMFs; and
  13. Any other items necessary to mention.
- (3) An executive summary of the DDP expressed in terms as simple as possible and the document explaining on the IC prescribed in Article 23(1) shall be attached to the DDP.

(Procedure of Derivation)

#### **Article 15**

- (1) The president of the DI, when requested by the DD to give approval of undertaking the derivation protocol, shall consult the IRB in the DI on the propriety of the protocol and shall confirm the compliance of the protocol with the Guidelines based upon recommendations submitted by the IRB.
- (2) The president of the DI shall obtain agreement of the president of the DMFs to undertake the derivation protocol.
- (3) The president of the DMFs shall consult the IRB in the DMFs for agreeing to undertake the derivation protocol.

(Acceptance of Derivation Protocol by the Minister)

#### **Article 16**

- (1) Prior to the approval of undertaking the derivation protocol, the president of the DI shall be given by the Minister acceptance to the compliance of the protocol with the Guidelines.
- (2) In the case of (1) above, the president of the DI shall present to the Minister the following documents, concerning the derivation protocol upon which the president of the DMFs has agreed:
  1. The DDP;
  2. Each document representing the process and results of reviewing by the IRB in the DI or

DMFs, respectively; and

3. Each document representing items on the IRB in the DI or the DMFs, respectively, and each copy of the rules prescribed in Article 13(2)6 and of those applied with substituting a few terms in accordance with Article 21(2).

(3) The Minister shall consult the Bioethics and Biosafety Commission under the Council for Science and Technology, the Ministry of Education, Culture, Sports, and Science and Technology (hereinafter referred to as the "B&BC") on the propriety of the derivation protocol, and shall accept the protocol based upon recommendations submitted by the B&BC.

(4) The Minister shall report on the results of the acceptance of derivation protocols to the Council for Science and Technology Policy, the Cabinet Office (hereinafter referred to as the "CSTP").

(Report)

#### **Article 17**

(1) The DD shall report on occasion to the president of the DI and the IRB in the DI on the progress and/or completion of the derivation of human ES cells, and the situation of the distribution of the ES cells and of the donated human fertilized embryos as well.

(2) The DD shall prepare and present to the president of the DI a document representing the results of derivation (hereinafter referred to as a "Derivation Report (DR)") immediately after completing the derivation of human ES cells.

(3) When the DR has been presented to the president of the DI, he/she shall present a copy of the DR to the IRB in the DI and the Minister.

(4) While human ES cells are maintained after completing the derivation, the president of the DI shall report to the Minister on the situation of the distribution of these human ES cells at least once a year.

(Public Disclosure of Outcomes from the Research)

#### **Article 18**

(1) In principle, outcomes from the derivation of human ES cells shall be disclosed to the public.

(2) In disclosing to the public the outcomes from the derivation of human ES cells, the DI shall point it out clearly that the derivation of human ES cells has been carried out in accordance with the Guidelines.

(Special Case Concerning Deriving Institute)

#### **Article 19**

(1) Two or more institutes in cooperation shall be allowed to assume their obligation as one DI entity.

(2) In the case of (1) above, each institute shall prepare their DDP to mention the role share and the responsibility taken by each institute, and consult each IRB set in these institutes on their derivation protocol, respectively.

### **Section III. Donation of Human Fertilized Embryos**

#### **Paragraph I. Donating Medical Facilities**

(Criteria for Donating Medical Facilities)

#### **Article 20**

DMFs shall satisfy the following requirements:

1. They have prior achievements in and sufficient ability for handling of a human fertilized embryo;
2. An IRB is set in them;
3. Measures are taken sufficiently for protecting personal information of the donors of a human fertilized embryo; and
4. There is clearly established methods to make sure of the will of the donors to discard their human fertilized embryo and, procedures concerning the handling of a human fertilized embryo as well.

(Institutional Review Board in Donating Medical Facilities)

#### **Article 21**

(1) The IRB in the DMFs shall have the obligation to review the overall ethical and scientific

propriety of the submitted derivation protocol and advise the president of the DMFs on approval/disapproval of the protocol and any related items to be paid attention to, improved and so on, together with preparing and keeping records on the process of the review, in conformity with the Guidelines.

(2) The provisions in Article 13(2) shall be applied as the requirements for the IRB in the DMFs, with substituting 'DMFs' for 'DI'.

## **Paragraph II. Informed Consent**

(Procedure of Informed Consent)

### **Article 22**

(1) On using donated human fertilized embryos for the derivation of human ES cells, DMFs shall be given the IC by the donors of the human fertilized embryos necessary to derive human ES cells, who are a married couple (excluding common-law couples without registering their marriage) donating gametes necessary to create these fertilized embryos (hereinafter referred to as the "donors").

(2) The IC in (1) above shall be expressed in writing.

(3) DMFs shall satisfy the following requirements, out of sufficient regard for the feelings of the donors for receiving IC as prescribed in (1) above:

1. No situations of the donors is unfairly taken advantage of;
2. A person who does not have the capacity to consent is not requested to donate a human fertilized embryo;
3. The will of the donors to discard their human fertilized embryos is confirmed in advance;
4. There is sufficient time necessary to decide whether the donors donate a human fertilized embryo or not; and
5. Donated fertilized embryos are stored for at least one month after the IC is given.

(4) The donors shall be able to withdraw the IC as long as their donated human fertilized embryos are still being stored.

(Explanation on Informed Consent)

### **Article 23**

(1) The explanation on IC shall be given by a member of the DI.

(2) The DI shall have the person, who is designated by the president of the DI from among persons belonging to the DI (excluding DD), give such explanation as prescribed in (1) above

(3) The person designated by the president of the DI in accordance with the provision in (2) above shall present to the donors a document including the following items (hereinafter referred to as an "Explanation Document (ED)"), and shall explain simply when giving the explanation prescribed in (1) above:

1. The purposes and methods for deriving human ES cells;
2. Loss of the donated human fertilized embryos in derivation process and procedures of handling those embryos;
3. The anticipated method to utilize human ES cells and outcomes from it;
4. The fact that the compliance of the derivation protocol with the Guidelines is confirmed by the DI and the DMFs, and is accepted by the Government;
5. The process to remove personal information of the donors in the transfer of the human embryo to the DI, and other concrete measures taken for protecting personal information;
6. The fact that the donors are offered no compensation throughout the future because human fertilized embryos are donated gratuitously;
7. Likelihood that human ES cells may be analyzed genetically and the fact that those genetic analyses never intend to identify a specific person;
8. The fact that the outcomes from the research and information on the human ES cells cannot be shown to the donors because the donors are not identified from the human ES cells;
9. Likelihood that the process of deriving human ES cells and outcomes from the research utilizing the cells may be published in academic meetings and on other occasions;
10. The fact that human ES cells are maintained in the DI for a long time and are distributed to the UI gratuitously;
11. Likelihood that, in the case that a valuable outcome has been obtained from human ES cells, intangible rights such as a copyright and/or a patent right or economic benefits arise from the outcomes (including differentiated cells), and the fact that such rights and benefits

do not belong to the donors;

12. The fact that expression of consent/dissent on the donation does not bring to the donors any advantage/disadvantage; and

13. The fact that donated human fertilized embryos are stored for at least one month after the consent has been given and that the consent can be withdrawn while those human fertilized embryos are still stored, and the method to withdraw the consent.

(4) The DI shall take appropriate measures to protect personal information of the donors, and shall provide an ED prescribed in (3) above and a certificate representing that such explanation has been given (hereinafter referred to as an "Explanation Certificate (EC)") to the donors and each copy of those two papers to the DMFs, respectively, when giving explanation as prescribed in (1) above.

(5) The DI shall give precise explanation as prescribed in (1) above based upon the latest scientific knowledge.

(Confirmation of Informed Consent)

Article 24

(1) The president of the DMFs shall confirm the document prescribed in Article 22(2), the ED and the EC, and shall consult the IRB in the DMFs, concerning the appropriate receipt of the IC based upon the derivation protocol.

(2) The president of the DMFs shall notify the DI in writing that he/she has carried out the confirmation prescribed in (1) above when human fertilized embryos have been transferred to the DI.

(3) When the president of the DI receives the notice prescribed in (2) above, he/she shall present a copy of the notice to the Minister.

(Protection of Personal Information of Donors)

Article 25

(1) The person involved in the derivation or utilization of human ES cells shall make his/her best efforts in order to protect personal information of the donors.

(2) Taking the meaning of (1) above into consideration, DMFs shall take any necessary measures so that no one can relate the donated human fertilized embryos with personal information of the donors when human fertilized embryos are transferred to the DI.

Section IV. Utilization of Human ES Cells

Paragraph I. Requirements for Utilization

(Requirements for Utilization)

Article 26

(1) Utilization of human ES cells shall be allowed only when the following requirements are satisfied:

1. Its purpose is basic research contributing to

(a) clarification of the function of human development, differentiation and regeneration, and

(b) development of a new method to diagnose, prevent or treat diseases or of medicines, drugs and so on; and

2. The utilization of human ES cells in the research prescribed in 1 above is both scientifically necessary and rational.

(2) The human ES cells to be utilized shall be limited to the cells derived in accordance with the Guidelines.

(3) Regardless of the provision in (2) above, the UI shall be able to utilize the human ES cells distributed from institutes in foreign countries, when the Minister recognizes that such cells have been appropriately derived on the basis of the Guidelines.

(Prohibitions)

Article 27

The person who handles human ES cells shall not perform the following acts:

1. Creation of an individual from human ES cells with such methods as implantation of an embryo created using human ES cells into the uterus of a human or an animal;

2. Introduction of human ES cells into a human embryo;

3. Introduction of human ES cells into a human fetus; and
4. Production of germ cells from human ES cells.

(Distribution of Human ES Cells)

Article 28

- (1) No UI shall distribute or assign human ES cells.
- (2) The provision in (1) above shall not be applied in the following cases:
  1. The case that it is necessary to distribute the human ES cells processed in the UI to another UI for the purpose of confirming reproducibility of research results; and
  2. The case that it is necessary to assign the human ES cells processed in the UI to DI for the purpose of developing basic research.

(Handling of Differentiated Cells)

Article 29

- (1) Utilization of differentiated cells shall be regarded as part of the utilization of human ES cells for the present.
- (2) Distribution of differentiated cells shall be allowed only when the Minister recognizes it to be in accordance with the fundamental principles shown in the Guidelines.

(Criteria for Utilizing Institute)

Article 30

- (1) The UI shall satisfy the following requirements:
  1. It has equipment, facilities, staffs and technical ability sufficient for utilizing human ES cells;
  2. Rules on ethical and technical matters to be observed in utilization of human ES cells are established; and
  3. An IRB is set in it.
- (2) The UI shall prepare and keep records on utilization of human ES cells.
- (3) The UI shall cooperate in presentation of data on utilization, arrangement for accepting investigations and any other measures recognized necessary by the Minister.

(President of Utilizing Institute)

Article 31

The president of the UI shall have the obligation to

1. confirm the propriety of the submitted utilization protocol and approve it for undertaking,
2. survey and grasp the progress and/or results of the utilization of human ES cells and, if necessary, give to the UD directions on any items to be paid attention to, improved and so on,
3. supervise utilization of human ES cells, and
4. inform of the Guidelines widely and thoroughly within the UI and make certain the Guidelines are to be observed there.

(Utilization Director)

Article 32

- (1) The UD shall have the obligation to
  1. examine ethical and scientific propriety of the utilization protocol based upon the information and materials available on utilizing human ES cells at home and/or abroad,
  2. prepare a document on the utilization protocol (DUP) based upon the results of the examination prescribed in 1 above,
  3. direct utilization of human ES cells and give any necessary directions to researchers,
  4. confirm on occasion that the utilization of human ES cells is appropriately carried out in accordance with the DUP,
  5. report to the president of the UI and the IRB in the UI on any items necessary to mention on the progress and the results of utilization of human ES cells, and
  6. take any measures necessary to direct the utilization protocol, in addition to the measures prescribed in 1 to 5 above.
- (2) One UD shall be assigned to each utilization protocol, and he/she shall have sufficient expert skills and knowledge on utilizing human ES cells, and ability to carry out precisely the tasks set

forth in (1)1 to 6 above.

(Institutional Review Board in Utilizing Institute)

Article 33

- (1) The IRB in the UI shall have the obligation to
  1. review the overall ethical and scientific propriety of the submitted utilization protocol and advise the president of the UI on the approval/disapproval of the protocol and any related items to be paid attention to, improved and so on, together with preparing and keeping records on the process of the review, in conformity with the Guidelines, and
  2. receive a report on the progress and the results of utilization, investigate if necessary and advise the president of the UI on any related items to be paid attention to, improved and so on.
- (2) The provisions in Article 13(2) shall be applied as the requirements for the IRB in the UI, with substituting 'UI' for 'DI' and 'utilization protocol' for 'derivation protocol', respectively.

Paragraph III. Procedure of Utilization

(Document on Utilization Protocol)

Article 34

- (1) For utilizing human ES cells, the UD shall prepare a DUP in advance and request the president of the UI to approve it.
- (2) The DUP in (1) above shall include the following items:
  1. The name of the DUP;
  2. The name of the UI and its address;
  3. The name, the brief history, the achievement in research of the UD and researchers and their roles taken by each in the utilization protocol;
  4. The purpose and necessity of utilization;
  5. The method and term of the utilization;
  6. The supplier of utilized human ES cells;
  7. The process and procedures of handling of human ES cells and differentiated cells after completing the utilization;
  8. Explanation concerning the criteria of the UI;
  9. In case the utilized human ES cells are offered from abroad, explanation concerning derivation of such human ES cells and any conditions for offering those cells ;
  10. In case the distribution of differentiated cells is planned, explanation concerning those differentiated cells and their distribution; and
  11. Any other items necessary to mention.
- (3) An executive summary of the DUP, which is mentioned in terms as simple as possible, shall be attached to the DUP.

(Procedure of Utilization)

Article 35

The president of the UI, when requested by the UD to give approval of undertaking the utilization protocol, shall consult the IRB in the UI on the propriety of the protocol and shall confirm the compliance of the protocol with the Guidelines based upon recommendations submitted by the IRB.

(Acceptance of Utilization Protocol by the Minister)

Article 36

- (1) Prior to the approval of undertaking the utilization protocol, the president of the UI shall be given by the Minister acceptance to the compliance of the protocol with the Guidelines.
- (2) In the case of (1) above, the president of the UI shall present to the Minister the following documents:
  1. The DUP;
  2. The document representing the process and results of reviewing by the IRB in the UI; and
  3. The document representing items on the IRB in the UI and a copy of the rules prescribed in Article 13(2) applied with substituting a few terms in accordance with Article 33(2).
- (3) The Minister shall consult the B&BC on the propriety of the utilization protocol, and shall accept the protocol based upon recommendations submitted by the B&BC.

(4) The Minister shall report on the results of acceptance of utilization protocols to the CSTP.

(Report)

Article 37

(1) The UD shall report on occasion to the president of the UI and the IRB in the UI on the progress and/or completion of the utilization of human ES cells.

(2) The UD shall prepare and present to the president of the UI a document representing the results of utilization (hereinafter referred to as a "Utilization Report (UR)") immediately after completing the utilization of human ES cells.

(3) When the UR has been presented to the president of the UI, he/she shall present a copy of the UR to the IRB in the UI and the Minister.

(4) The president of the UI shall notify the DI from which the utilized human ES cells were distributed of the completion of the utilization of the human ES cells and of the method of handling those cells thereafter.

(Public Disclosure of Outcomes of the Research)

Article 38

(1) In principle, the outcomes from the utilization of human ES cells shall be disclosed to the public.

(2) In disclosure to the public the outcomes from the utilization of human ES cells, the UI shall point it out clearly that the utilization of human ES cells has been carried out in accordance with the Guidelines.

Section V. Other Rules

(Cooperation with Administrative Organs Concerned)

Article 39

The Minister shall cooperate closely with the Minister of Economy, Trade and Industry and the Minister of Health, Labor and Welfare, - for example, offering information - , taking into consideration that derivation and utilization of human ES cells are closely connected with medicine and its related fields.

(Official Announcement of Offense against the Guidelines)

Article 40

The Minister shall announce officially if there is a certain instance of derivation or utilization of human ES cells that is recognized by the Minister of its non-compliance with the Guidelines.

Additional Rules

(Date of Enforcement)

Article 1

The Guidelines shall come into force from the date of the proclamation.

(Reexamination of guidelines)

Article 2

(1) The Minister shall take into consideration the progress of research in life science, social trends and so on, investigate in addition the implementation situation of the Guidelines, and reexamine them if necessary based upon the results of consideration and investigations, within three years of their enforcement.

(2) The reexamination prescribed in (1) above shall be based upon recommendations of the CSTP.

# Derivation/Utilization Scheme of Human ES Cells

Derivation : ~ , Utilization : (1) ~ (11)

