The Guidelines for Handling of a Specified Embryo

Section I. Requirements for Production of a Specified Embryo

(Requirements for Production of a Specified Embryo)

Article 1

Production of a Specified Embryo shall be allowed only when the following requirements are satisfied:

1. Scientific knowledge, which cannot be acquired from research with only animal embryos or cells or other research without a Specified Embryo, is acquired from production of such a Specified Embryou; and
2. A person who is going to produce a Specified Embryo (hereinafter referred to as a "Producer") has technical ability sufficient to study with such a Specified Embryo.

(Limitation of a Category of Specified Embryos Allowed to Be Produced)

Article 2

(1) Regardless of the provisions in Article 1 above, only an animal-human chimeric embryo shall be allowed to be produced among nine categories of Specified Embryos, and the purpose of its production shall be limited to the research concerning production of human cells-derived organs transplantable to a human being.

(2) A Producer shall not use any human fertilized embryos or human unfertilized eggs in order to produce an animal-human chimeric embryo.

(Consent from Donors of Cells)

Article 3

(1) A Producer shall obtain the consent, on using human cells for production of a Specified Embryo, from donors of cells necessary for production of such a Specified Embryo (hereinafter referred to as "Donors").

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

(3) A Producer shall take the following items into consideration when obtainig the consent prescribed in (1):

1. Donors are not treated to their disadvantage for the reason that they do not consent;
2. A Producer respects intention of Donors and give the explanation prescribed in (4) below fairly and appropriately from the standpoint of Donors; and
3. There is sufficient time necessary for Donors to decide whether they consent or not.

(4) A Producer shall present in advance to Donors the document including the following items, and shall give to them explanation on items represented in it:

1. The category of Specified Embryos to be produced;
2. The purpose and method of production;
3. Handling procedures of donated cells;
4. Handling procedures of the Specified Embryo after its production;
5. The method to protect personal information of Donors;
6. Explanation that cells are donated gratuitously;
7. Explanation that Donors are not treated to their disadvantage for the reason that they do not consent; and
8. Explanation that Donors can withdraw the consent.

(5) Donors shall be able to withdraw the consent prescribed in (1).

(Gratuitous Donation of Human Cells)

Article 4

Human cells used for production of a Specified Embryo shall be donated gratuitously, except for transportation expenses and other necessary expenses.

Section II. Requirements for Assignment and Other Handlings of a Specified Embryo

(Requirements for Assignment of a Specified Embryo)

Article 5

Assignment of a Spesified Embryo shall be allowed only when the following requirements

are satisfied:

1. A Specified Embryo, which is going to be assigned, has been produced in accordance with the provisions from Article 1 to 4;
2. Handling of the Specified Embryo after its assignment is carried out in accordance with the requirement prescribed in Article 1-1 and for the purpose of the research prescribed in Article 2(1);
3. A person who is going to be assigned a Specified Embryo has technical ability sufficient to study with such a Specified Embryo; and
4. A Specified Embryo is assigned gratuitously, except for transportation expenses and other necessary expenses.

(Import of a Specified Embryo)

Article 6

A Specified Embryo shall not be imported for the present.

(Requirements for Handling of the Specified Embryo after Its Production or Assignment)

Article 7

(1) Handling of the Specified Embryo after its production or assignment shall be allowed until the primitive streak appears since such a Specified Embryo has been produced. Here, handling of a Specified Embryo, in which the premitive streak does not appear until the fourteenth day from the date of production of such a Specified Embryo (hereinafter the day is referred to as the "Expiration Day", and in (2) below the period until that day is referred to as the "Expiration Period"), shall not be allowed after the Expiration Day.

(2) In the case that a Specified Embryo is stored frozen, such a storage period shall not be added to the Expiration Period.

(Export of a Specified Embryo)

Article 8

A Specified Embryo shall not be exported for the present.

(Prohibition of Transfer of a Specified Embryo into the Uterus)

Article 9

Specified Embryos, except for ones prescribed in Article 3 of 'the Law Concerning Regulation Relating Human Cloning Techniques and Other Similar Techniques (Law No. 146, 2000)' (hereinafter referred to as "the Law"), shall not be transferred into the uterus of a human or an animal for the present.

Section III. Procedure to Be Taken into Consideration on Handling of a Specified Embryo

(Institutional Review Board)

Article 10

(1) A person who is going to produce or be assigned a Specified Embryo and handle it after its production or assignment (hereinafter simply referred to as a "Handler") shall consult, on production or assignment of such a Specified Embryo and its handling after these acts (hereinafter referred to as "Handling"), the institutional review board (a review board (an organization which surveys and reviews the compliance of Handling with the Guidelines from points of view of ethical maintenance in scientific research) set by an institute to which Handler belongs (when Handler is a corporation, such a corporation, as same hereinafter), as same hereinafter) before a notification to the Minister of Education, Culture, Sports, Science and Technology prescribed in Article 6 of the Law.

(2) In the case of (1) above, a Handler shall be able to consult a review board set by any of the following institutes instead of consultation prescribed in (1) above, when a Handler does not belong to any institutes or when an institute to which a Handler belongs does not set an institutional review board:

1. A research institute of the Government or local public bodies;
2. A university (a university prescribed in Article 1 of 'the School Education Law (Law No. 26, 1947)') or an inter-university research institute (an inter-university research institute prescribed in Article 9.2(1) of 'the National School Establishment Law (Law No. 150, 1949)');

3. An independent administrative institute (an independent administrative institute prescribed in Article 2(1) of 'the General Law of Independent Administrative Institute (Law No. 103, 1999)');
4. A public corporation (a corporation established directly by a law or established by a special law through special act of establishment, to which the provision in Article 4-15 of 'the Ministry of Public Management, Home Affairs, Posts and Telecommunications Establishment Law (Law No. 91, 2000) is applied);
5. A quasi-governmental corporation (a corporation established by a special law, whose establishment require authorization by an administrative office); and
6. A corporation established by the provision in Article 34 of 'the Civil Law (Law No. 89, 1896)'.

(Public Disclosure of Information)

Article 11

A Handler shall make his/her best efforts to disclose to the public the contents of Handling and the outcomes from it.

Additional Rule

The Guidelines shall come into force from the date decided by a Cabinet order prescribed in Article 1-2 of the additional rules of the Law (December 5, 2001).