(Reference)

Review of Guidelines Pertaining to Human Embryonic Stem Cells

1. Background
    - Human embryonic stem cells have the ability to differentiate into various types of cells (pluripotency), and it is anticipated that they will be applied to medical care. However, since their creation (derivation) involves the destroying of human embryos, which are 'the emerging potential of human life', bioethical issues have also been identified. In 2001, the national guidelines were adopted (announced by the Ministry of Education, Culture, Sports, Science and Technology), which provided an appropriate promotion for basic research into human embryonic stem cells.
    - In November 2013, the 'Act on the Safety of Regenerative Medicine' was established, which provided a legal framework for clinical application of human embryonic stem cells. In response, in December of the same year, a study was initiated into a review of relevant guidelines at the Bioethics and Biosafety Commission of the Council for Science and Technology.
    - In October2014, new guidelines regarding points of compliance in the use of human embryonic stem cells ranging from basic research to their utilization in medical treatment, draft 'Guidelines for the Derivation of Human Embryonic Stem Cells', and 'Guidelines for Distribution and Utilization of Human Embryonic Stem Cells' were compiled and presented for consultation to the Council for Science, Technology and Innovation.
    - On 17 November, a response was received from the council indicating its support for the guidelines, and on 25 November 2014, the guidelines were adopted.

2. Summary of the new guidelines

    The main points in which the recently adopted guidelines differ from the previous ones ('The Guidelines on the Derivation and Distribution of Human Embryonic Stem Cells' (Min. of Education, Culture, Sports, Science and Technology Public Notice No. 156, 2009) and 'Guidelines on the Utilization of Human Embryonic Stem Cells' (Min. of Education, Culture, Sports, Science and Technology Public Notice No. 87, 2010)) are as follows:

- Guidelines on the Derivation of Human Embryonic Stem Cells (Min. of Education, Culture, Sports, Science and Technology / Min. of Health, Labour and Welfare Public Notice No. 2, 2014)
    - Add to basic research; add clinical utilization as an objective of derivation.
    - Where the purpose of derivation lead up to a clinical utilization, confirmation must be obtained from both the Minister of Education, Culture, Sports, Science and Technology and the Minister of Health, Labour and Welfare.
    - Enable anonymized of embryo donors' personal information in a linkable format.
    - Explain to the embryo donner that information on human ES cells derived from donated human fertilized embryos will not be disclosed to the donor.

- Guidelines on the Distribution and Utilization of Human Embryonic Stem Cells (Min. of Education, Culture, Sports, Science and Technology Public Notice No. 174, 2014)
    - Embryonic stem cells will be distributed from basic research institute (non-clinical tests etc.) to utilizing clinical institute under a written contract.
    - Germ cells derived from embryonic stem cells must not be distributed to utilizing clinical institute.

Overview of the reviews

1. Previous System

	Basic research	Clinical Research, Medical Care※
Procedures and ethics for derivation	Guidelines on the Derivation and Distribution of Human Embryonic Stem Cells	Guidelines on clinical research using human stem cells (Pharmaceutical Affairs Law in relation to clinical trials etc.)
Quality and safety		
Procedures and ethics for utilization	Guidelines on the utilization of Human Embryonic Stem Cells	

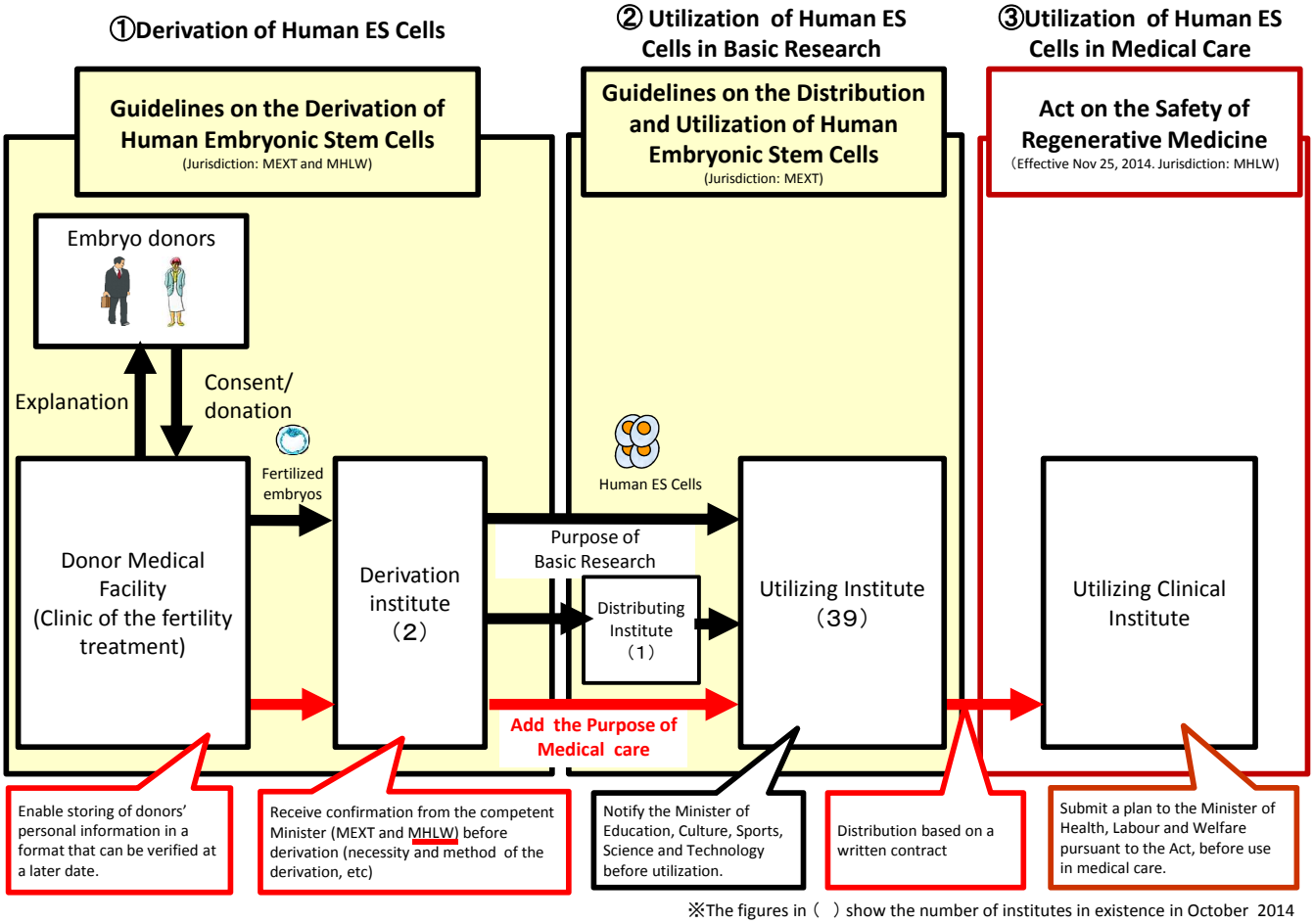
2. New System

	Basic Research	Clinical Research, Medical Care ※
Procedures and ethics for derivation	Guidelines on the Derivation of Human Embryonic Stem Cells	
Quality and safety		The Act on the Safety of Regenerative Medicine (Amended Pharmaceutical Affairs Law in relation to clinical trials etc.)
Procedures and ethics for utilization	Guidelines on the Distribution and Utilization of Human Embryonic Stem Cells	

Min. of Education, Culture, Sports, Science and Technology(MEXT)
Min. of Health, Labour and Welfare(MHLW)
both MEXT and MHLW

※Only for preventive, diagnostic and treatment purposes

Overview of the New System



※The figures in ( ) show the number of institutes in existence in October 2014