

Second Report on the revision of the “Basic Principles on the Handling of Human Embryos” (Summary)

June 19, 2019

Council for Science, Technology and Innovation

The Council for Science, Technology and Innovation (CSTI) has initiated an in-depth discussion on the use of genome modification techniques including genome editing on human embryos at its Expert Panel on Bioethics in July, 2015. Careful discussion took place in the light of advances in assisted reproductive medicine research achieved by the use of the rapidly progressing genome modification techniques including genome editing technique, possible development of definitive treatment for genetic and congenital diseases using the techniques, and the ethical and safety issues encountered during the course of research involving application of these techniques on human embryos.

Based on the “Basic Principles on Handling of Human Embryos (July 2004)”, the CSTI compiled the “Supplementary report of the Basic Principles on Handling of Human Embryos: regarding the use of genome modification techniques including genome editing in assisted reproductive medicine research” in March 2018.

Following the completion of Public Comment procedures, CSTI published the second report on the revision of the “Basic Principles on the Handling of Human Embryos” in June 2019, covering topics of the use of human embryos in the basic research of genetic and congenital diseases, the creation of human embryos for basic research purposes, the use of nuclear transfer technology on human embryos, and other issues decided to continue discussion in the previous report.

1) Basic research:

Provided that the individual research protocol is properly reviewed, the following research should be permitted. The ministries are expected to promptly consider establishment of the relevant guidelines and other documents.

- (1) Research of genetic and congenital diseases using genome modification techniques including genome editing on surplus embryos from assisted reproductive medicine
- (2) Research of assisted reproductive medicine on human embryos created for research purposes using genome modification techniques including genome editing
- (3) Research of mitochondrial diseases using nuclear transfer technology on surplus embryos from assisted reproductive medicine

2) Clinical application:

Reconfirmed the current position of should not allow the transfer of a human embryo on which genome editing or a similar technique has been applied, into either a human or an animal uterus. The relevant ministries are expected to begin discussion on a systematic framework design including legal regulations.

- 3) Coordination with public debate and international approaches is critical. CSTI shall be present and be the voice of the government on such occasions.

4) Way forward:

To facilitate the overall coordination and integration of items 1) and 2) above, the Bioethics Expert Panel shall continue necessary discussions including coordinated direction based on the expected reports from relevant ministries targeting to conclude in the autumn of 2019.