

Third Report on the Revision of the “Basic Principles on the Handling of Human Embryos” (Summary)

February 1, 2022

Council for Science, Technology and Innovation

There are growing expectations that, along with the rapid advances in genome modification techniques including genome editing, research in assisted reproductive medicine and in genetic and congenital diseases that makes use of such techniques on fertilized human embryos will lead to the development of new treatments. Meanwhile, their clinical applications face ethical and safety issues such as enhancement and off-target effects, etc. In July 2004, Expert Panel on Bioethics compiled the “Basic Principles on the Handling of Human Embryos” stating that in principle it does not allow handling that compromises fertilized human embryos—the “germ of human life”, however, exceptions are allowed only in cases where scientific rationality, safety, and social relevance are met.

Discussions related to the use of genome modification techniques including genome editing on human embryos initiated in July 2015. The following reports have since been compiled: “The First Report on the revision of the ‘Basic Principles on the Handling of Human Embryos’: regarding the use of genome modification techniques including genome editing in assisted reproductive medicine research” in March 2018; and “The Second Report on the revision of the ‘Basic Principles on the Handling of Human Embryos’: the use of genome modification techniques including genome editing on human embryos” in June 2019.

Among the issues referred for continued discussion in the Second Report related to basic research on genetic and congenital diseases using genome modification techniques including genome editing and basic research on mitochondrial diseases using nuclear transfer technology, the issue of whether or not to approve the use of human embryos created for research purposes was discussed, culminating in the preparation of the Third Report (Draft). Public comment procedures were also implemented. The Third Report was compiled as follows at Expert Panel on Bioethics on November 11, 2021, and the issuance of the report was decided at the Council for Science, Technology and Innovation (CSTI) on February 1, 2022.

1) Basic research:

Gamete donation must be obtained for research that requires the creation of research embryos, and it should be noted that there are some aspects of conducting such research that differ from those for surplus embryos from assisted reproductive

medicine, especially in matters such as obtaining informed consent from the egg donor. Based upon these considerations, research using newly created research embryos should be limited to such research that cannot be conducted in any other way. Sufficient care should also be ensured when eggs are donated, and proper use that complies with the provisions specified in the assisted reproductive technology (ART) guidelines should be followed.

Taking these issues into consideration and assuming that proper reviews are conducted for each research plan, the following research should be permitted:

- (1) Research of genetic and congenital disease using genome modification techniques including genome editing on human embryos created for research purposes.
- (2) Research of mitochondrial disease using nuclear transfer technology on human embryos created for research purposes.

2) Clinical applications

Considerations pertaining to clinical applications were excluded in this report. Based on the Second Report, the Ministry of Health, Labour and Welfare (MHLW) compiled the “Summary of discussions of the expert committee meeting studying the clinical application of genome editing technology and other techniques to track human fertilized embryo (Health Sciences Council Science and Technology Committee, MHLW)” on January 7, 2020, which stated that clinical use should be regulated by law.

3) Discussions conducted at the Bioethics Expert Panel should focus on issues concerning social norms such as ensuring the dignity of human embryos. The Panel should also continue efforts to ensure public discussion that addresses the concern that research on human embryos using genome editing or a similar technique may affect people’s opinions on diversity. The progress of discussions in other countries and international organizations should also be used as a reference.

4) This report will mark a point of closure for discussion related to research on human embryos that use genome editing or a similar technique.

When new technologies are introduced into society, it is always necessary to respond to ethical, legal, and social implications/issues (ELSI). When new technologies related to human embryos emerge in the future, and if bioethical issues related to science and technology arise, the Bioethics Expert Panel will examine the latest scientific findings and assess their social relevance.