

Update: Governmental Actions and Advisory Opinions
Regarding Human Genome Editing

Regulatory Actions for Researches Using Genome Editing Technology on Human Embryos in Japan



AKUTSU, Hidenori
Director, Department of Reproductive Medicine,
National Center for Child Health and Development
On behalf of the Science Council of Japan

Basic policy on using human embryos for research purpose

2004 “Basic Principles concerning the Handling of Human Embryos”

Basic policy on creating human embryos for research purposes

In Japan, creating human embryos for research purpose is not permitted in principle. It is permitted to use surplus embryos for biomedical research in exceptional cases, but all of the following conditions must be met:

- (1) scientific significance in life sciences and medicine, which cannot be obtained other than through the use of human embryos
- (2) the benefits or anticipated benefits are socially appropriate
- (3) assurance of safety for human being
- (4) safeguards must be put in place to avoid concerns of reducing human beings as a tool

Basic policy on using human embryos for research purpose

Related laws and regulations

Type of research	Status	Related guideline
Creation and use in assisted reproductive technology research.	Possible	<i>Ethical Guidelines for Research on Assisted Reproductive Technology Treatment Producing Human Fertilized Embryos</i>
Use for human embryonic stem cells.	Possible	<i>The Guideline on the Derivation of Human Embryonic Stem Cells</i>
Researches on producing germ cells from Human iPS Cells or Human Tissue Stem Cells, ES cells.	Possible *Prohibiting fertilizing induced germ cells	<i>The Guidelines on the Research on Producing Germ Cells from Human iPS Cells or Human Tissue Stem Cells, The Guidelines on the utilization of human embryonic stem cells</i>
Transfer of human SCNT embryos.	Impossible	<i>The Act on Regulation of Human Cloning Techniques</i>
Handling of human-animal chimeric embryos.	Possible	<i>The Guidelines for Handling of a Specified Embryo (human-animal chimera)</i>
Gene therapy to human embryos.	Impossible	<i>The Guideline for Gene Therapy Clinical Research</i>

● Expert Panel on Bioethics, Council for Science, Technology and Innovation (CSTI) of Japan

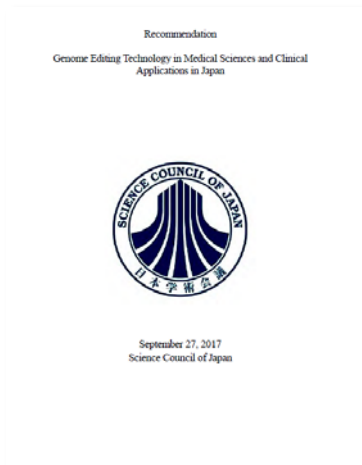
“The interim report for research using genome editing technology on human embryos” (Apr, 2016)



Implementing the public comments on the draft guidelines for research using genome editing on human embryos (Nov, 2018)



- Science Council of Japan in July 2016 started discussions by a committee of specialists on issues related to medical research and treatment that applies genome editing to fertilized human embryos.



“The Recommendation on Genome Editing Technology in Medical Sciences and Clinical Applications in Japan”
(Sep, 2017)



Public symposium on human germline editing (Apr, 2017)

**Summary of
the draft guideline/the Recommendation for
studies using genome editing technology on
human embryos in Japan**

1. Clinical Use (germline editing)

Transplantation of genome edited human embryos into human and animals should be prohibited.

2. Research purpose

Purpose of studies using human preimplantation embryos

a) Elucidate the function of genes in early development

b) To understand the mechanisms of hereditary diseases

c) Development of new treatments (preventive treatment) for diseases (cancer, etc.)

Basic studies may well contribute to the “understanding of genetic functions of embryo early development and growth (differentiation)”.

- **Surplus embryos (not intended for clinical use) must be used.**
- **The handling period of human embryos must be limited to the early embryo stage, prior to primitive streak formation (not over day 14).**
- **Human embryos used in research must also be disposed of in a secure manner.**

the draft guidelines for research using genome editing on human embryos

3. Other comments on the ethical guideline

- It cannot be approved that any clinics (germline genome editing) at the present time.
- The Panel has left the door open to acceptance of basic research, encouraging debate in the research community and the general public.
- The Panel will strive to continue finalization of the report incorporating with related government ministries and agencies.
- Ethical guidelines in Japan are similar to “soft law” but have some sanctions: for instance, researchers who violate them are required to repay research funds they received, or may be barred from qualifying for future grants (in a least 5 years).

Thank you so much for your attention!

