Second International Summit on Human Genome Editing Session: Social and Philosophical Reflections on Manipulating Genetic Variation

# Genome Editing in Japan: A Bioethical Perspective

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### Aim of the talk

• Explain Japan's regulatory framework concerning genome editing in human embryos

• Discuss the important considerations for future discussions in Japan and beyond

### Outline

- 1. The Draft Guidelines on Research involving the Use of Gene Editing Tools in Human Embryos
- 2. The Experts Panel on Bioethics and research using human embryos
- 3. Discussion

### Word of caution

Not representing Japan nor any organisation

1. The Draft Guidelines on Research involving the Use of GETs in Human Embryos

#### NEWS · 03 OCTOBER 2018

### Japan set to allow gene editing in human embryos

Nature, 03 Oct 2018

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Draft guidelines permit gene-editing tools for research into early human development.

#### David Cyranoski

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Researchers in Japan will be able to edit human embryos in the lab under proposed rules. Credit: Zephyr/SPL/Getty

Japan has issued draft guidelines that allow the use of gene-editing tools in human embryos. The proposal was released by an expert panel representing the country's health and science ministries on 28 September.

Although the country regulates the use of human embryos for research, there have been no specific guidelines on using tools such as CRISPR– Cas9 to make precise modifications in their DNA until now. The guidelines will <u>ALLOW</u>:

- BASIC research using GETs,
- using SPARE embryos,
- for improvement of ART

### It will <u>NOT ALLOW</u>:

- basic research for the treatment of genetic and other diseases

- CLINICAL application

2. The Expert Panel on Bioethics and research using human embryos

### The Expert Panel on Bioethics

Council for Science, Technology and Innovation

(1) Investigation and discussion on basic policy relating to science and technology

(2) Investigation and discussion on guidelines on Budgetary/Personnel Research Allocation

(3) Evaluation of research and development of national importance

#### Expert Panel on Basic Policy

Investigation and study of the basic plan related to science and technology promotion (the 5th Science and Technology Basic Plan) based on the situation in Japan and abroad so as to promote measures related to science and technology promotion comprehensively and systematically.

Expert Panel on STI Strategy

- Of all the matters listed in the 4th Science and Technology Basic Plan and the Comprehensive Strategy on Science, Technology and Innovation, expert study of the matters to be addressed in a crosscutting manner such as creation of an environment suitable for STI and strategic deployment of international activities. - Understanding of the implementation statuses of the policies listed in the 4th Science and Technology Basic Plan and the Comprehensive Strategy on Science, Technology and Innovation, and study of measures to further promote these policies (except for matters related to those to be studied by "Expert Panel on Important Issues.")

#### Expert Panel on Important Issues

- Of all the matters listed in the 4th Science and Technology Basic Plan and the Comprehensive Strategy on Science, Technology and Innovation, study of policies to promote the achievement of the issues listed as special focus issues.

 Understanding of the implementation statuses of the above policies, study of measures to further promote them, and study of issues to be addressed from now on based on social conditions and trends of technology.

- Study of other matters requiring expert study related to the above issues

<Strategy Consultative meeting under Expert Panel>

Energy\* Next generation infrastructure\* Regional resources \* The chairperson or vice chairperson of each council is also a member of an expert panel.



1. Basic Principles concerning the Handling of Human Embryos 2004



- human embryos = "sprouts of human life"

- need protection to maintain human dignity

- research use is <u>exceptional</u> but allowed on conditions of 1)scientific validity, 2)assurance of safety, and 3)social validity 2. 2016 Expert Panel's Interim Report on Using GETs in Human Embryos

- Basic Research using GETs: Conditionally OK
  - Applied the Basic Principles
  - <u>Approved</u> research of development and differentiation of embryos
  - But <u>not</u> other types of research
  - <u>No</u> new creation of human embryos for research

# 3. 2017 Task Force's First Report to Review the Basic Principles

- No revision of the principles
- Recommendation to create the guidelines on research involving the use of GETs in human embryos
- $\Rightarrow$  The 2018 draft guidelines

### 3. Discussion

### 1. The Basic Principles Approach

- Applying the principles to the types of research
  - Piecemeal
  - Consistent

### 1. The Basic Principles Approach (Cont.)

- Limitation of Scope
  - Silent on germline cells such as sperm and eggs
    - Not clear whether such research would undermine human dignity
  - Silent on the Clinical Application
    - The interim report is against the clinical application, but the reasons were not derived from the Basic Principles
  - ⇒Needs a major revamp

### 2. Need for more democracy in policymaking

- Tendency to avoid legislation
- Legislation is desirable for more public discussion
- Not doing bioethics *incognito*

### 3. Apparent absence of religion

- No mention of Buddhism or Confucianism
- Human dignity not associated with Christianity
- More democratic discussion may bring forth diverse perspectives including religion

## Thank you for listening

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