Global Perspective: from the Expert Panel on Bioethics at the Council for STI, Japan

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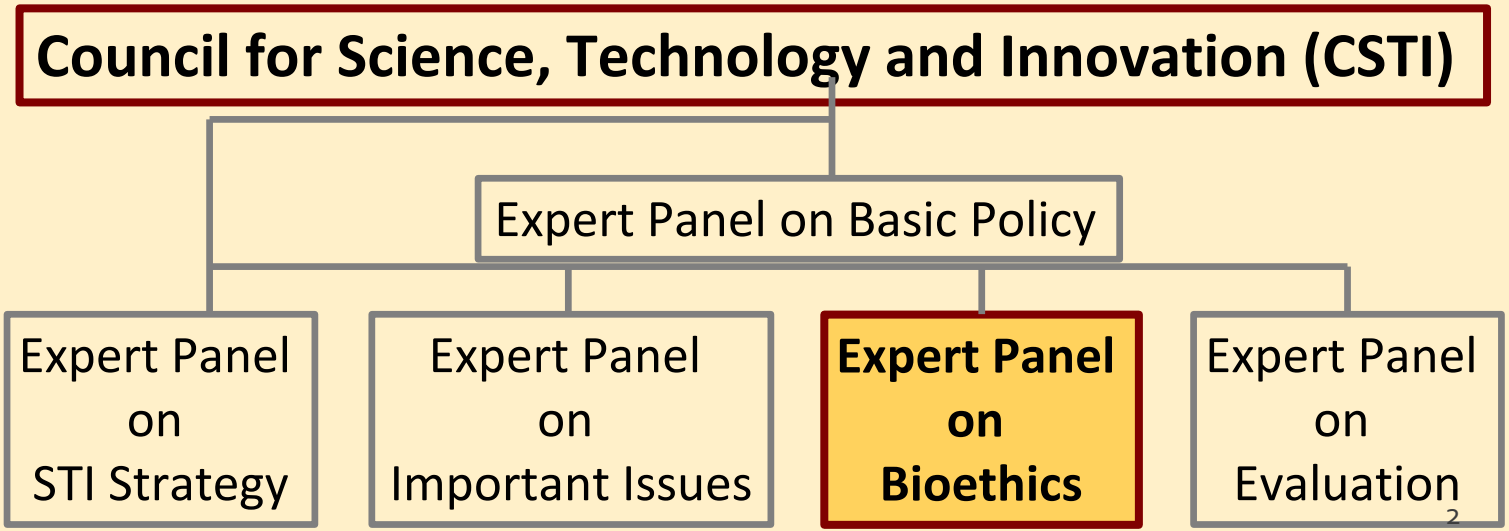
STI Policy in Japan

Cabinet Office

Roles:

- Support the Cabinet in **formulating important policies** and in **overall coordination** of Ministries
- Make total **planning and coordination from a higher standpoint of view than other Ministries**



Expert Panel on Bioethics

- Investigate and discuss bioethical issues of national concern
- Recommend policies and strategies for bioethical issues to the CSTI
- Harmonize regulation and guideline related to bioethics issues from ministries
  - Does not conduct the ethical review of individual scientific research
- Members' background
  - Ethics/philosophy, Law, Medicine, Physician, Journalist

Track record

- Report "Basic conception on reproduction of human being through cloning technology" (1999)

  → *Law* on regulation of cloning technology on human being (MEXT) (2000)
- Report "Basic conception on research on human embryo, including human ES cell" (2000)
- Report "Basic principles on human genome research"(2000)

  → Ethical *guidelines* on human genome/gene analysis research (MEXT, MHLW, METI) (2001)
- Report "Fundamental policy on handling of human embryo"(2004)

  → Ethical *guidelines* on research of assisted reproduction involving creation of human embryo (MHLW, MEXT) (2010)

Handling of human embryo (2004)(1)

- Basic principles
  - Human embryo should be handled as the "emerging of human life"
  - Damaging human embryos is not allowed
- Exceptions for research use if all conditions below are satisfied
  - Scientifically rational
  - Safe for human use
  - Social acceptance

Handling of human embryo (2004)(2)

Identified areas of research	Deliberation
Assisted reproductive technology	Preparation / use of human fertilized embryos acceptable
Hereditary diseases	To be discussed
Establishment of embryonic stem cells	Use of spare embryos tolerated
Others	To be discussed

Use of genome editing technology

- Report "Handling of study using genome editing technology to human embryos" (2016)
- Guiding principles
  - Basic research on gene function during embryonic development
    - Acceptable (use of spare embryos)
  - Clinical Application (embryo transfer to the uterus)
    - Not acceptable

Need for guidelines!

Revision of the report "Fundamental policy on handling of human embryo" (2004)

- Task Force (7/2017 -)
  - Members' background
    - Ethics/philosophy, Law, Biology, Medicine, Journalist, Patients association
  - Focus areas of research
    - Assisted reproductive research
    - Research on hereditary diseases
    - Research on cancer
- Public consultation
  - Collaboration with the Miraikan (National Museum of Emerging science & Innovation)
- Dialogue with patients association

→ Part 1: Use of genome editing technology for assisted reproductive research purpose"(2018)

Part 1. Assisted reproductive research

- Key points
  - Clinical Application
    - Not acceptable
  - Production of human embryo for research
    - Not acceptable (for the time being)
  - Review system
    - Two step process
      - 1st step: Institutional ethics review committee
      - 2nd step: National Ethics Review Committee
- Recommendation
  - Guidelines on "Basic research for assisted reproductive technology using spare embryos with genome editing technology" to be developed

What's next?

- Joint meetings
  - Expert panel on bioethics
  - Task force
- Discussion points
  - Research on hereditary diseases & Research on cancer
  - Creation of embryos for research purposes
    - Extending the scope to germline?
  - Review system: National Ethics Review Committee?