

The Analysis of Human Embryo Research Ethics in Japan

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Contents

I Introduction

- The need of human embryo research ethics in the age of iPS cell research
- Bioethics Committee of Japan: Its system and history
- Aim and method

I Human Embryo Research Ethics in Japan

- Ethical principles of human cloning, ESC and embryo research

I Discussion

- Subject of human dignity
- Restriction of Liberty
- Utilitarian or Communitarian Concept of Dignity

I Conclusion

Introduction

- The need of human embryo research ethics
in the age of iPSC research
- Bioethics Committee of Japan : Its system and
history

Introduction

The need of human embryo research ethics in the age of iPSC research

The ethical questions of human embryonic stem cells (h-ESCs)

in reference to human induced pluripotent stem cells (h-iPSCs)

- Human iPSC research has **NO** ethical problem of **destroying human embryos** that hESC research has (when it derives the cells).
- Human iPSCs will effectively **substitute** for hESCs for drug and poison tests.

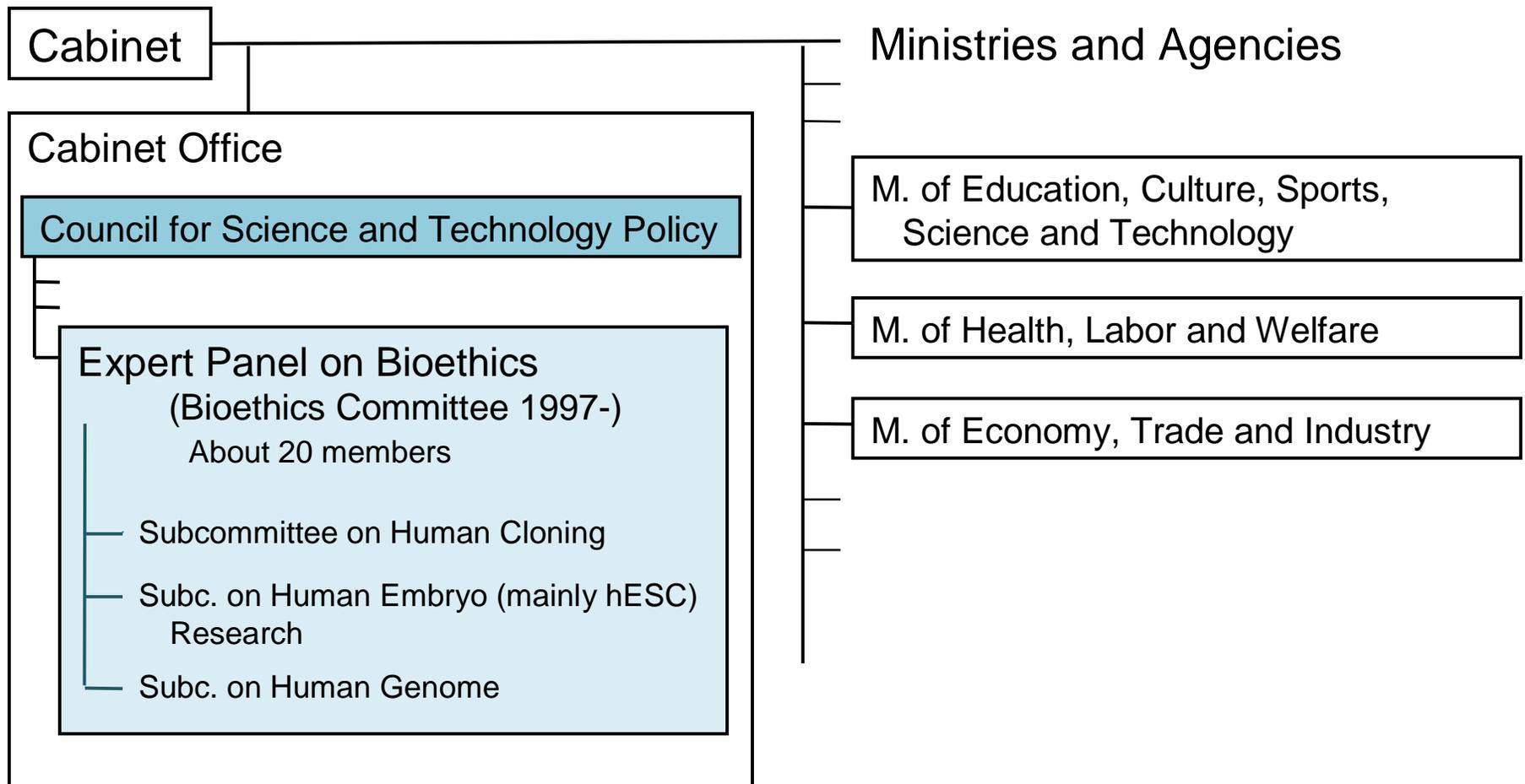
However,

- Research on h-iPSCs (that are artificial) **needs** (to create) (natural) **hESCs for comparison.**
- Will h-iPSCs be **equivalent** to hESCs in future? (We do not know.)

Now is a **trend to relax restrictions on hESC research** in Japan as well as U.S.A.

Introduction

Bioethics Committee of Japan : Its system



Introduction

Bioethics Committee of Japan : Its history

Feb 1997 A cloned sheep, Dolly

Sep 1997 The Bioethics
Committee

Nov 1998 Human ES and EG
cells

Dec 1999 *The **Basic Policy** on
**Human Reproductive
Cloning*** (HRC)
- Bans HRC.

Mar 2000 *The **Basic Policy** on
Human Embryo Research
focused on **hESC Research***

- Permits hESC research using
surplus embryos.

→ Dec 2000 The **Act** on Regulation of
Human Cloning Techniques

→ Sep 2001 The **Guidelines** for
Derivation and Utilization of
hESCs

Dec 2001 The **Guidelines** for
Handling of a Specified Embryo
(**chimeras and hybrids**)

Specific and limited



General and comprehensive

Introduction

Bioethics Committee of Japan : Its history

Jul 2004 *The **Basic Policy on the Handling of Human Embryos***

- Permits fertilization for reproductive research purpose
- Permits human somatic cell nuclear transfer (hSCNT) embryo research.

→ Amending the guidelines

Nov 2007 **Human iPSCs**

→ Amending the guidelines for utilizing hESCs

Introduction

Aim and Method

Aim: To explore the principles and their relations of human embryo research ethics in Japan

Method: To select, sort out and compare the principles in the three policies on human cloning (1999,) hESC research (2000) and human embryo research (2004.)

Human Embryo Research Ethics in Japan (1)

**Ethical principles of human
cloning, ESC and embryo
research**

Ethical principles of human **cloning**

in *Basic Policy on Human Reproductive Cloning* (1999)

A. Human Dignity

Respect for human individuals

HRC would be human breeding and instrumentalization, the violation of human rights, and disrespect for individuals.

It would also deviate from our basic understanding of human reproduction, and have harmful effects on society. (G. Social Consensus)

A1. Prohibition against the manipulation of human life

Human SCNT embryo research leads to the manipulation of human embryos as “the germ of human lives.”

(A2. Prohibition against human trade: irrelevant)

A3. Preservation of human specific identity

Human reproductive chimeras and hybrids obscure human specific identity, and is more harmful than HRC.

B. Safety

HRC has high risk of abnormality, therefore no utility (E).

(C. Egg Donors' Rights

Irrelevant)

Ethical principles of human **cloning**

in *Basic Policy on Human Reproductive Cloning* (1999)

D. Academic Freedom

Academic freedom is not limitless. It is socially responsible. Proper regulations within the limits of necessity fairly restrict the freedom.

E. Utility

Human SCNT embryo research could be useful for transplantation without

F. Information Disclosure

Research should be transparent and researchers should make efforts of explain their research to relieve people of their anxiety.

(G. Social Consensus

Not referred, because it exists concerning HRC.)

H. Regulation Method

H1. International Conformity

H2. Regulation Target

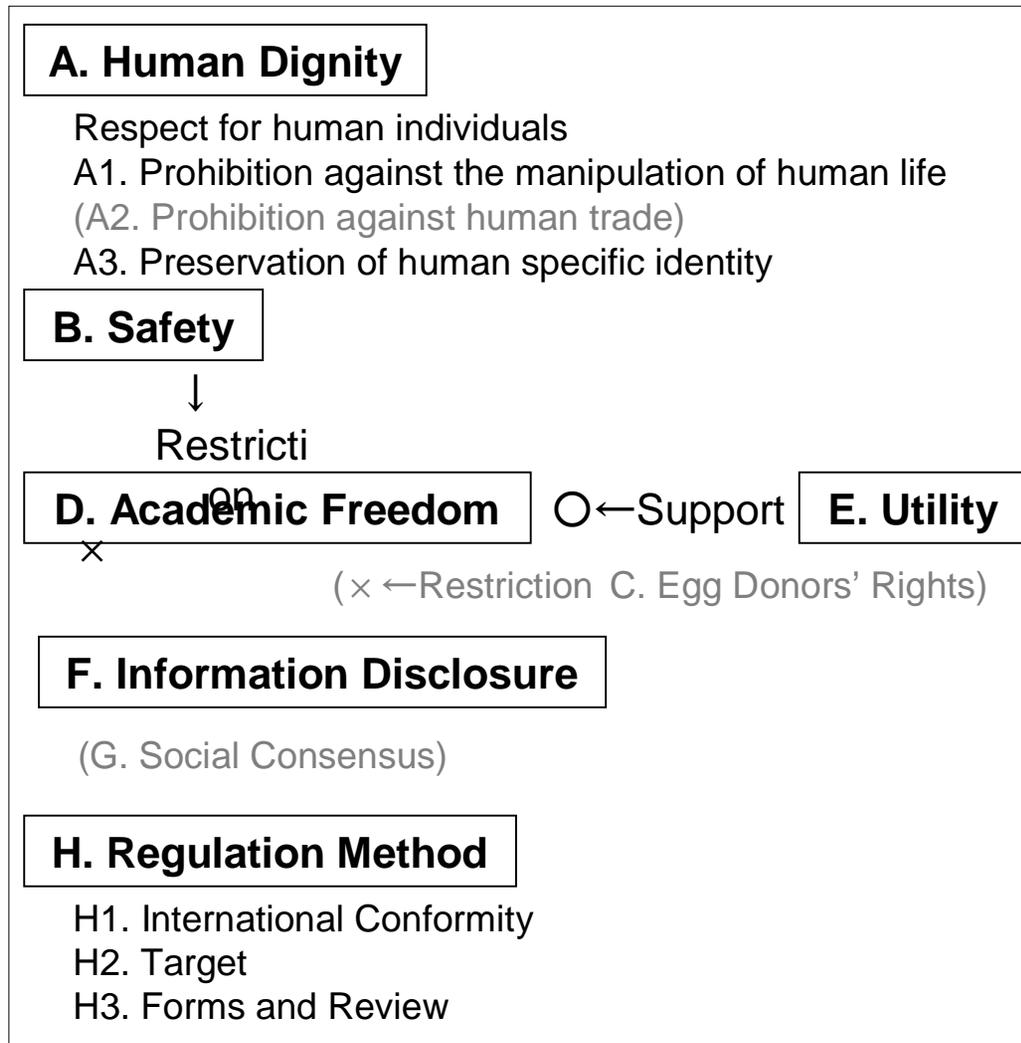
- Human SCNT embryo transfer into the womb should be prohibited.

H3. Regulation Forms and Revision

- HRC is prohibited by law.
- Regulations are reviewed in 3 to 5 years as the situation changes.

Ethical principles of human **cloning**

in *Basic Policy on Human Reproductive Cloning* (1999)



- A, B → Prohibition against HRC
- A, A3, B → Prohibition against human reproductive chimeras and hybrids
- A1, E → Continuous consideration for hSCNT embryos
- A3, E → Continuous consideration for chimerical and hybridized embryos
- (C → irrelevant)
- (G → exists concerning HRC, therefore is not referred)
- H2 → The Act on Regulation of Human Cloning Techniques (2000)

Human Embryo Research Ethics in Japan (2)

**Ethical principles of human
cloning, ESC and embryo
research**

Ethical principles of **hESC** research

in *The Basic Policy on Human Embryos focused on hESC research*
(2000)

(Modified Takahashi 2000)

A. Human Dignity

Respect for human (individuals and) embryos as “the germ of human lives”

They in vitro have no legal status, but could develop into humans if implanted.

People / Fetuses / Embryos / Somatic cells

A1. Prohibition against the manipulation of human life

- **Not to fertilize human embryos for research purpose.**
- **To utilize surplus embryos for research purpose is permissible** (←E. Utility.)
To derive hESCs from surplus embryos is permissible.
Human SCNT embryo research is individually examined.
- To receive (surplus) embryos as the need arises, and to utilize them soon.

A2. Prohibition against human trade

- To give and receive human (surplus) embryos should be gratis.

A3. Preservation of human specific identity

- Chimerical embryo research introducing animal cells into human embryos is prohibited. Hybridized embryo research is also prohibited in principle.
(▪ To produce a human-human chimera that has genomes is of no utility and prohibited

(A1).)

Ethical principles of **hESC** research

in *The Basic Policy on Human Embryos focused on hESC research*
(2000)

B. Medical Safety

- Human ESC research on human subjects is not permitted until a standard is settled.

C. Egg Donors' Rights

- C1. Informed consent by egg donors
- C2. Donor's right to privacy

D. Academic Freedom

- Human embryo research should have scientific necessity and appropriateness.
- It should also observe A and C.

E. Utility

- Human embryo and ESC research expects medical and techno-scientific development.
- The principles above restrict this principle.

F. Disclosure

- human embryo research should be open to the public

G. Social Consensus

- To find consensus is difficult on the research. Continuous examination adopting public opinions is necessary.

Ethical principles of **hESC** research

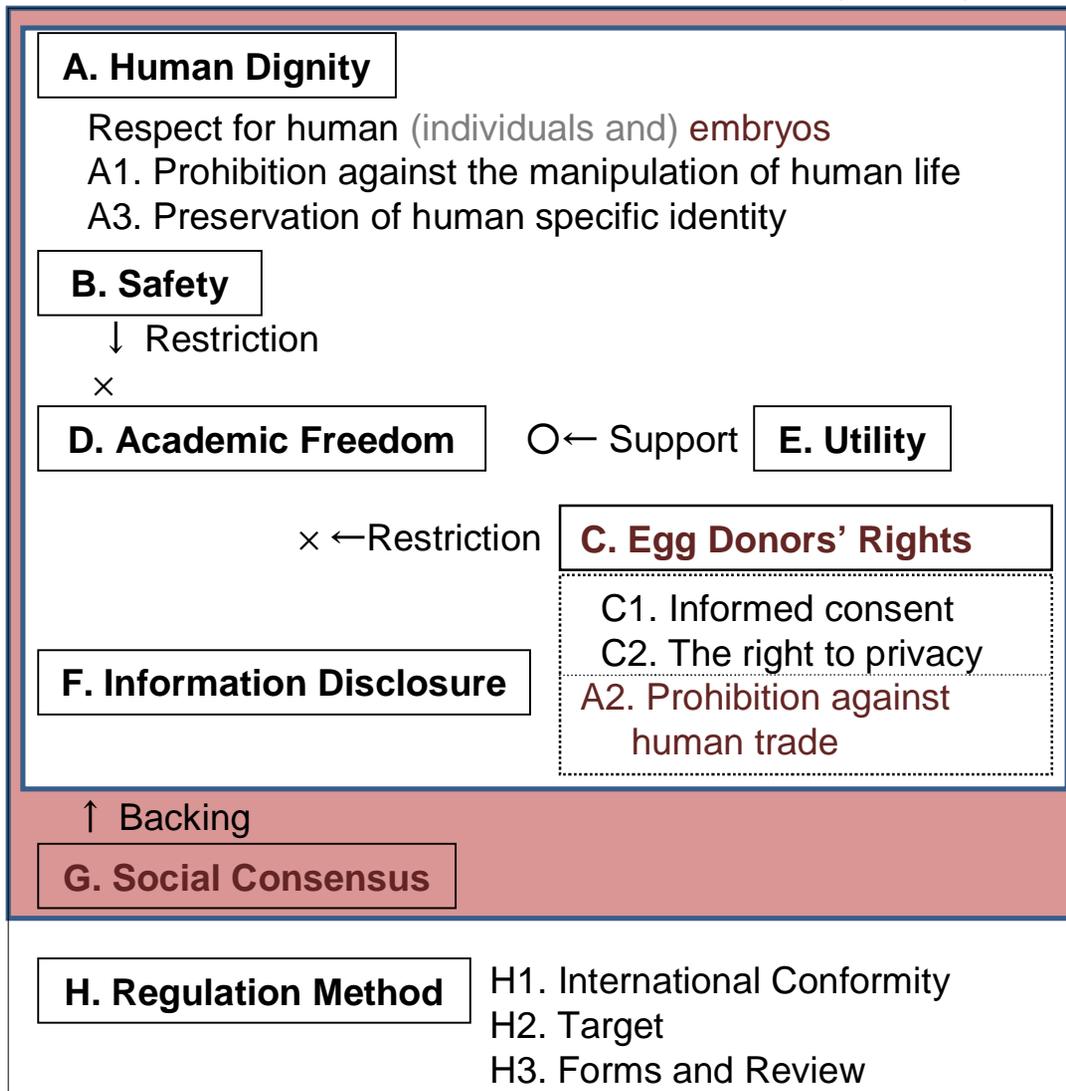
in *The Basic Policy on Human Embryos focused on hESC research*
(2000)

H. Regulation Method

- Scientific and ethical validity should be examined at IRBs and the government or an organization outside.
- Human ESC research should be regulated by guidelines and reviewed

Ethical principles of **hESC** research

in *The Basic Policy on Human Embryos focused on hESC research*
(2000)



- A1, E → Surplus embryos are utilized to derive hESCs
- A1, E → hSCNT embryo research is individually permissible.
- A1, A3, E → Chimera and hybrid embryo research is prohibited in principle, but examined individually.

The liberty of interested parties is limited.

Human Embryo Research Ethics in Japan (3)

Ethical principles of human cloning, ESC and embryo research

- The status and handling of human embryos in general
- Human fertilized embryos and SCNT embryos
- Some different principles

Ethical principles of human **embryo** research

in *The Basic Policy on the Handling of Human Embryos* (2004)

A. Human Dignity

A **basic social value** that respects human existence and life.

Ai. Respect for Human Embryos as “the germ of human lives,” (and

No legal status. Abortion and assisted reproductive technologies are permitted.

People/ Fetuses / Embryos / Somatic cells and tissues

They should be especially respected for as “the germ of human lives” **to maintain the value of human dignity.**

- Not to create them for research
- Not to destroy them for any purpose

Aii. The Right to Pursue Happiness

People's pursuit of happiness concerning health and welfare is “exceptionally” permitted when it meets scientific rationality, safety and social suitability.

Aiii. Prohibition against Human (Egg Donors’) Instrumentalization

To keep ovum acquisition to a minimum, and to **protect donors.**

- **Voluntary donation *in Gratis* of ova should be forbidden** not to put pressure on women concerned.
- Ova donation *in Gratis* (A2)
- Informed consent and privacy (C)
- To prevent unnecessary aggression

Ethical principles of human **embryo** research

in *The Basic Policy on the Handling of Human Embryos (2004)*

B. Medical Safety

- Genetic treatment on human fertilized embryos is not permissible.
- To derive and utilize hSCNT embryos for medical purpose is not permissible at this

(C. Egg Donors' Rights → Aiii. Prohibition against Egg Donors' Instrumentalization)

D. Scientific Rationality and Social Suitability

Di. Scientific Rationality

Dii. Social Validity (G. Social Consensus)

To be socially accepted. Not to disorder the social perception and common ideas.

(E. Utility → Aii. The Right to Pursue Happiness)

F. Information Disclosure

- Researchers should ask social to understand the necessity of research.
- Information disclosure is a basis to review human embryo regulations.

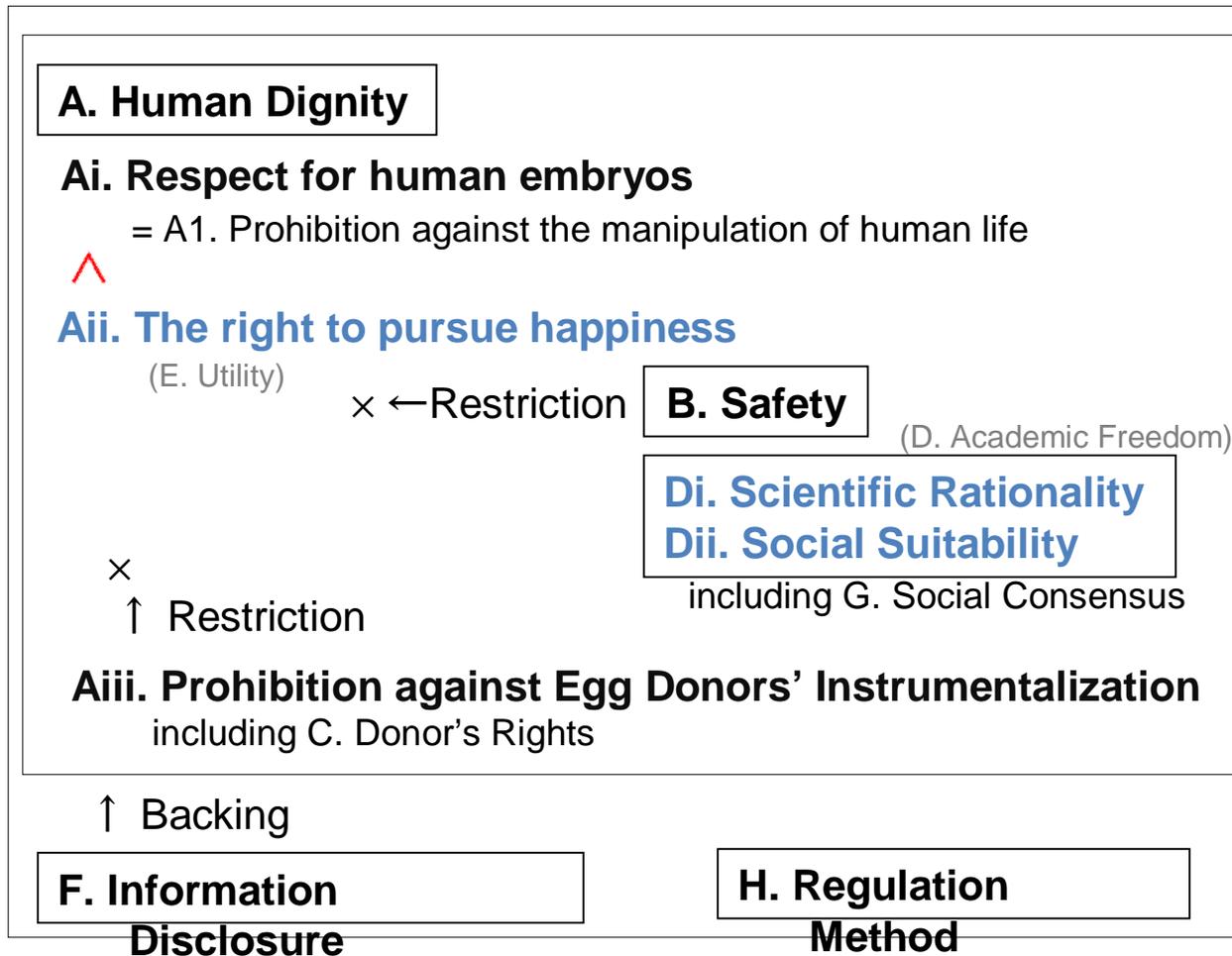
(G. Social Consensus → Dii. Social Suitability)

H. Regulation Method

- To set guidelines for ART research and continuous examination for a low
- To amend guidelines on hESCs, chimeras and hybrids for hSCNT research.

Ethical principles of human **embryo** research

in *The Basic Policy on the Handling of Human Embryos* (2004)



- D → Assisted reproduction and its research. To derive hESCs from surplus embryos.
- Di, Dii → Human SCNT embryo research meets D1 but is problematic in Dii. To introduce its regulations and proceed gradually for earlier relief to patients looking after social influence meets Dii.

Discussion

on human embryo research ethics in Japan

- The subject of human dignity
- The restriction of liberty
- The utilitarian or communitarian concept of dignity

Discussion

on human embryo research ethics in Japan

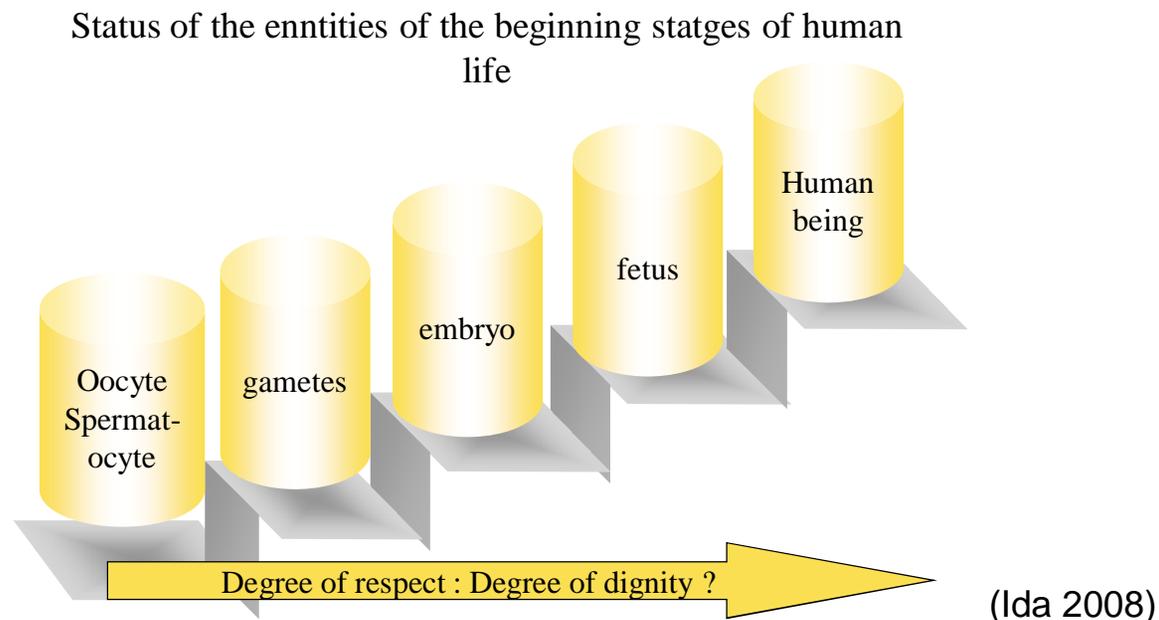
- *The Policy on Human Embryos* is not to answer human embryo ethics itself but to prepare social norms maintaining social basic values and responding to the request to pursue happiness.
- → Inference of presupposed ethical concepts



Discussion (1)

The subject of Human Dignity

- The main subject of human dignity is people after birth.
- The degree of human dignity gradually decreases from people to fetuses, embryos and other somatic cells.
- Human dignity concerns human species.
- The reason of the subject of human dignity is unclear.
- Human dignity as a basic social value may relate to social suitability.



Discussion (2)

The restriction of Liberties

- To exercise the right to pursue happiness is restricted by donors' rights.

(Constitution of Japan provides that the pursuit of happiness shall, to the extent that it does not interfere with the public welfare [or others' rights], be the supreme consideration.)

- It is also restricted by safety, scientific rationality and social suitability.
- Academic freedom on the human embryo is permissible only under the proper pursuit of happiness.
- Donors should be protected to be autonomous.

Discussion (3)

The Utilitarian or Communitarian Concept of Human Dignity

- *The Basic Policy on Human Embryo* is described by the words of human dignity and rights instead of a utilitarian concept of national economic interests, presenting the pursuit of happiness instead of utility and contrasting it with donors' rights.
- However, human dignity as a basic social value can include communitarian consideration of social suitability and consensus.
- Human dignity as a basic social value might be changeable according to the interests and perception of community.
- Is this flexibility good for the society of Japan and in international society?

Conclusion

Conclusion

Concepts below need to be more clarified for the ethics of human embryo research in Japan.

- Foundation for the subject of human dignity
- Foundation for liberties, their protection and restriction.
- Relationship between individuals and society
- Japanese concepts on them

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