

Beginning of Life in Bio-medical Research

Principles

- 1) Prohibition of creation of embryo for research
- 2) Permission of use of surplus embryo for research
- 3) Permission of differentiation of gametes from ES/iPS cell
- 4) Permission of therapeutic cloning only for ES cell derivation
- 5) Permission of research using chimeric animal-human embryo and induction of chimeric embryo to animal womb

2

Japanese Ethical Standard of the Beginning of Life in Bio-medical Research

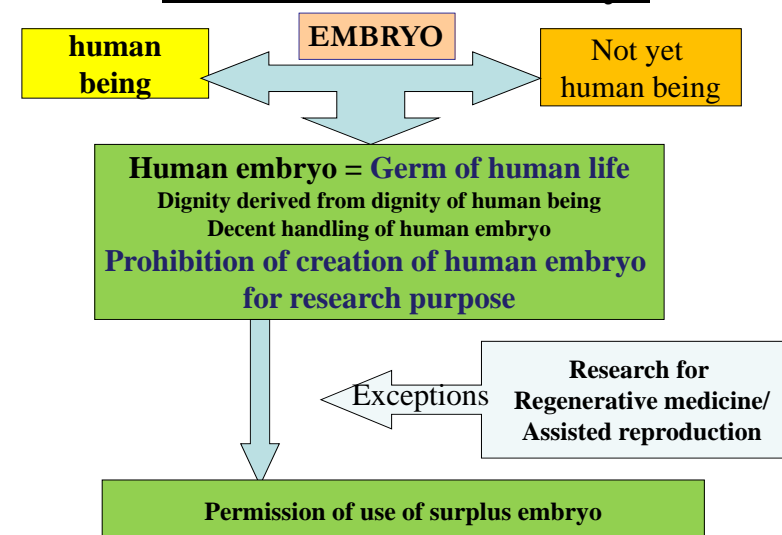
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 10th Global Summit of National Ethics/Bioethics Committees
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Historical development of regulations on embryo

- 1996 Birth of Dolly
- 1997 Establishment of National Bioethics Committee
- 1998 First derivation of human ES cell (Thomson, Wisconsin, US)
- 1999 [Report "Basic conception on reproduction of human being through cloning technology"](#)
- 2000 [Report "Basic Conception on research on human embryo, including human ES cell"](#)
[Law on regulation of cloning technology on human being](#)
- 2001 [Guidelines on derivation and use of human ES cell \(MEXT\)](#)
[Guidelines on the research on certain kinds of embryos \(MEXT\) \(therapeutic cloning ban\)](#)
- 2004 [Report "Basic conception on handling of human embryo"](#)
- 2006 Ethical guidelines on clinical trials using human stem cells (MHLW)
- 2009 [Revised Guidelines on research on certain kinds of embryos \(therapeutic cloning\)](#)
[Guidelines on derivation of human ES cell / Guidelines on use of human ES cell \(MEXT\)](#)
- 2010 [Guidelines on research of creation of gametes from human iPS cell an human stem cell \(MEXT\)](#)
[Revised Ethical guidelines on clinical trials using human stem cells \(iPS cell only\)](#)
- 2013 Approval of a protocol using iPS cell for a clinical research
[Act on Promotion of Regenerative Medicine](#)
[Act on Safety of Regenerative Medicine](#)
[Revised Act on Pharmaceutical Affairs](#)

3

Status of human embryo

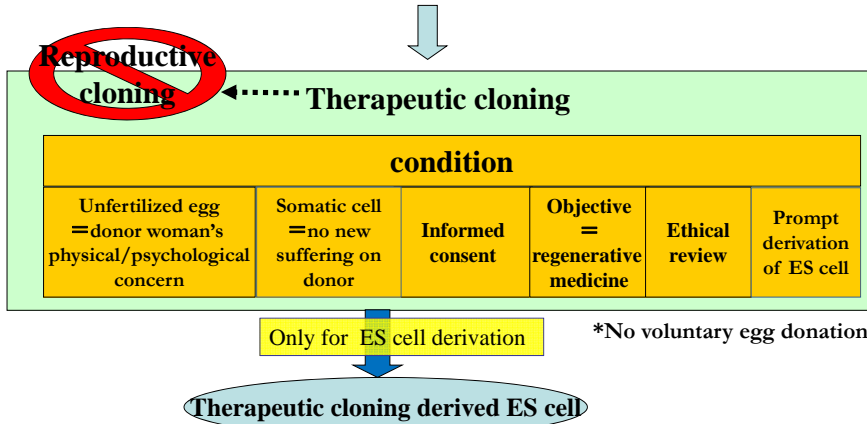


4

Ethical issues of therapeutic cloning

No creation of embryo other than for reproductive purpose

Exception = Research of regenerative medicine



5

Gametes and embryo from ES/iPS cell

Background

- **Expectation** for the **development of treatment** and diagnosis of incurable diseases in gametes and embryo
- **Scientific advancement** in creation of gametes from pluripotent stem cells in **small animals**
- Spread and establishment of **ethics awareness** on human embryo and human ES cells by ES guidelines since 2001

- **MEXT revised ES cell research Guidelines** for permission of creation of gametes from ES cells for the purpose of reproductive research (cause of infertility)
- **Ban of creation of an embryo from the artificial gametes**
⇒ Expert Panel on Bioethics is going to discuss this topic

Some ideas : Japan's current regulation on ART

- No Legislation on ART -

	Professional Associations (Ex. JSOG)		Government (Min. Health)							
	Guidelines		Law / Regulation					Guidelines		
	Married	Third Party	Married	Third party			Married	Third party		
	sperm	egg	sperm	sperm	egg	embryo		sperm	egg	embryo
AIH/AID	O	O	—	—	—	—	—	—	—	—
IVF	O	O	X	—	—	—	—	—	—	—
ICSI	O	O	X	—	—	—	—	—	—	—
Host	X		X	X			—	—		
PGD	limited		—							
Prenatal Diagnosis	—		not recommended							
Abortion	—		< 22 W Mother's health, economic condition			—	—	—	—	—

7

Topics for discussion in the Expert Panel on Bioethics

- 1) Creation of human embryo with gametes derived from ES cell or other stem cell
- 2) Creation of human embryo using new technologies of embryo creation :
e.g. induction of a nucleus to an unfertilized egg (not denuclearised)

Thank you!

8