

The Regulation of Research Involving Human Embryos in Australia:

a time of transition




The Key Decision:

**The Council of Australian Governments
(COAG), 5 April 2002**



The Goals:

- ⌘ That there be an approach taken to the regulation of research involving embryos that is nationally consistent**
 - ⌘ That embryo research may go ahead, but only under a strict regulatory regime**
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The Context:





GOOD GOD, MAN...
WHAT HAVE
WE DONE?!

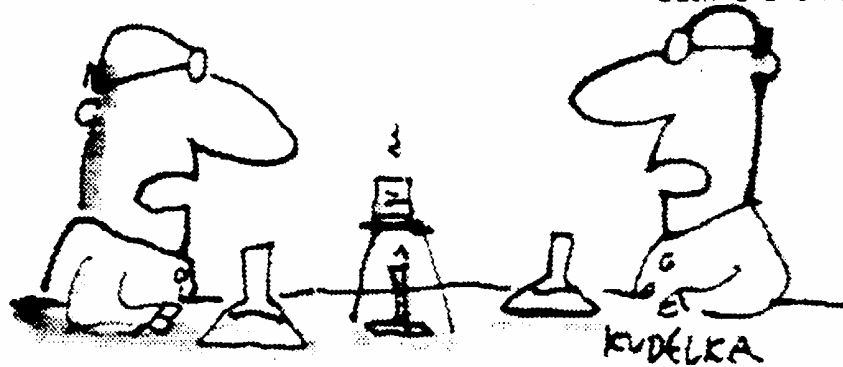
IVF
CLINIC
SPERM
DONOR
R&D
SECTION

TEST TUBES
ARE PEOPLE TOO


IVF
MUM

WHAT DO
POLITICIANS
KNOW ABOUT
STEM CELLS?


ABOUT THE
SAME AS THEY
KNOW ABOUT
ETHICS.




COAG agreed:

- ⌘ This is a difficult area of public policy**
 - ⌘ Community views vary widely**
 - ⌘ There are complex and sensitive ethical and scientific issues**
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COAG also agreed:

- ⌘ That permitting the research would enable Australia to remain at the forefront of medical research**
 - ⌘ That there were concerns that such research could lead to the creation of embryos specifically for research**
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To strike the balance between these concerns COAG also agreed:

- ⌘ To restrict destructive research to embryos created before 5 April 2002 for three years, but to review this restriction earlier, following a report on the adequacy of supply and distribution of embryos for research**
 - ⌘ To request a report on protocols to preclude the creation of embryos specifically for research**
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To strike the balance between these concerns COAG also agreed:

- ⌘ **That the regulatory regime should be reviewed within three years,**
 - ⌘ **including review of the ban on the development of embryos other than for assisted reproduction,**
 - ⌘ **taking into account the implications of therapeutic use of embryonic stem cells.**
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***Research Involving Human
Embryos Act 2002
(Commonwealth)***

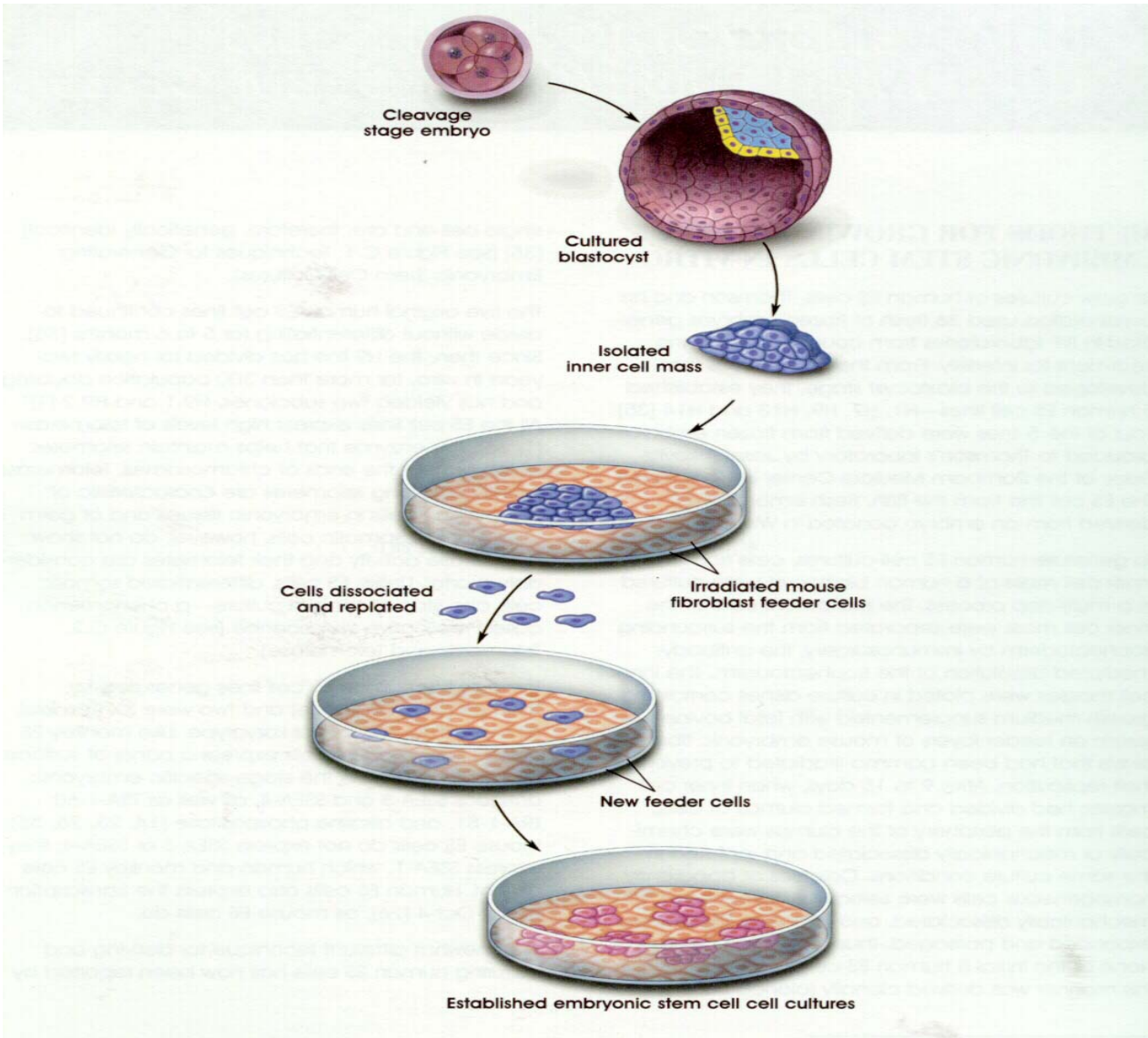


An excess ART embryo is defined as:

- ⌘ an embryo that was created by assisted reproductive technology for use in the treatment of a woman and is determined to be excess to the treatment needs of the woman,**
 - ⌘ according to the written authority of the woman and her spouse (if any).**
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NHMRC Licensing Committee

- **A member of AHEC**
 - **A research ethicist**
 - **A researcher**
 - **Expert in ART**
 - **Lawyer**
 - **Person with expertise in consumer issues relating to disability and disease**
 - **Person with expertise in consumer issues relating to ART**
 - **Person with expertise in the regulation of ART**
 - **Embryologist**
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Criteria for licence for research using excess ART embryos

- ◆ **Proper procedures in place to ensure consent to use of embryos**
 - ◆ **Embryos created before 5 April 2002**
 - ◆ **Project has been assessed and approved by a Human Research Ethics Committee**
 - ◆ **Number of embryos is limited to that required to achieve the goals of the project**
 - ◆ **Likelihood of significant advance in knowledge or improvement in technologies for treatment**
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