



Embryo Research

***changing regulation and what it means
for South Australia***

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Regulation across Australia

- Commonwealth laws prohibiting cloning and regulating embryo research
- corresponding laws in all states
- laws for assisted reproductive medicine in 3 states (SA, Vic, WA)
- national ethical guidelines apply

National legislation

- national legislative scheme – Commonwealth and every State
 - *Prohibition of Human Cloning Act*
 - *Research Involving Human Embryos Act*
- prohibit cloning and strictly regulate embryo research
 - regulates aspects of clinical practice, clinical reproductive medicine research and the development of embryonic stem cells
 - does not regulate the use of embryonic stem cells
- NHMRC Licensing Committee
 - issues licences for research and training using excess human embryos
 - established under the Cwth RHE Act in 2002
 - Under the SA Act - research requires a licence from the Cwth NHMRC Licensing Committee

Using embryos in research

⊗ Strict licensing criteria

- **limit embryo research**
 - valid research, HREC approved
 - justifiable use of human embryos
 - uses minimum number of embryos
 - likelihood of significant advance in knowledge or treatment technologies
- **requires informed consent from embryo donors**
- **'parents' decide whether embryos that are excess to treatment are discarded, donated to another couple or donated to research**

Regulation in South Australia

• South Australian

- Prohibition of Human Cloning Act 2003
- Research Involving Human Embryos Act 2003
- Reproductive Technology (Clinical Practices) Act 1998
- Code of Ethical Clinical Practice 1995
- Family Relationships Act 1975
- SA Council on Reproductive Technology
- clinical licence conditions

• National

- Prohibition of Human Cloning Act 2002
- Research Involving Human Embryos Act 2002
- Sex Discrimination Act 1984
- NHMRC guidelines 2007
- NHMRC National Statement 2007
- RTAC Code of Practice

The legislative journey 1996 - 2007

- what they wanted: national regulation of reproductive technology
- what was possible: a national ban on human cloning
- AHEC review of NHMRC ethical guidelines on assisted reproductive technology
- Commonwealth House of Reps Inquiry – Andrews Committee
- referral to COAG and Health Ministers
- COAG asked for national policy proposal, agreed by COAG 5 April 2002
- Commonwealth legislation drafted and passed December 2002 (conscience vote)
- Acts required a review in 3 years
- passage of State and Territory legislation 2003 to 2005 (conscience vote)
- review of Commonwealth legislation (Lockhart Review) 2005
- Commonwealth laws amended December 2006 (private member's bill)
- changes will become effective 12 June 2007
- amendments to State legislation required to re-establish the national scheme
- ***Coming to a Parliament near you!***

Why a national scheme?

⚙️ Constitutional coverage

- Commonwealth Acts cover Cwth govt agencies and trading corporations
- but not state govt agencies, non-trading corporations or individuals
- State Acts cover everyone
- Cwth Acts trump State Acts - but status of universities is unclear
- single national Licensing Committee

⚙️ Corresponding Act status

- Cwth Minister declares State Acts corresponding
- only researchers operating under the Cwth Act or a declared corresponding Act can be issued a research licence

⚙️ Intergovernmental Agreement

- signed by all premiers and the Prime Minister
- agreed to introduce an amendment bill (conscience vote)
- Victoria already amended; NSW Bill in Parliament

Human cloning prohibition

Original laws

- prohibited both reproductive and 'therapeutic' cloning
- could only create embryos by fertilisation and only to achieve pregnancy
- allowed ESCs only derived from embryos excess to ART treatment

Amended laws

- prohibit human reproductive cloning
- separate the regulation of excess ART embryos from those created by other means (SCNT, parthenogenesis)
- allow the use of excess ART embryos in research with a licence
 - but prohibit the creation of embryos for research by fertilisation
- allow the creation of embryos for research by SCNT with a licence
 - but prohibit the implantation of such embryos
- retain the 14 day limit on *in vitro* development of both types

Other prohibited practices

Original laws prohibit

- creating embryos with genes from more than 2 people
- developing embryos outside of a woman for >14 days
- using precursor cells from embryos or fetuses
- making heritable alterations to the genome
- collecting viable human embryos from a woman
- creating chimeric or hybrid embryos
- importing or exporting prohibited embryos
- placing prohibited embryos in a woman
- commercial trading in eggs, sperm or embryos

Amended laws

- retain these prohibitions, with exceptions
- prohibitions divided into
 - those completely prohibited and
 - those prohibited unless authorised by a licence
- all prohibitions still apply to embryos created by fertilisation
 - except allow a licence for hybrid fertilisation solely for testing sperm quality in a licensed ART facility
- allow a licence for some procedures for embryos created for research by other means such as
 - using precursor cells to create embryos
 - creating embryos with genetic material from more than 2 people

Defining an embryo

Original laws defined an embryo at the start of fertilisation

- *human embryo* means a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means
- *human embryo clone* means a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by human sperm

Amended laws define an embryo at the end of fertilisation

- *human embryo* means a discrete entity that has arisen from either:
 - the first mitotic division when fertilisation of a human oocyte by a human sperm is complete or
 - any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears
- and has not yet reached 8 weeks of development since the first mitotic division.

Amending the SA Acts

- ⊗ Acts are committed to the Minister for Health
- ⊗ Intergovernmental Agreement - by 12 June 2008
- ⊗ Expected to be a conscience vote
- ⊗ There is no SA Government position
- ⊗ Amendment Bill will reflect the changes made nationally
- ⊗ Parliament may amend the Amendment Bill
- ⊗ Aiming for Cwth and State legislation that will consistently cover all SA researchers