

2010 Legislation Review – The Use of Human Embryos in Research Further Reading and Background Information

Current Legislation

Since 2002, Australian scientists have been permitted to use donated excess assisted reproductive technology (ART) embryos in research. Under the Commonwealth legislation - *Research Involving Human Embryos Act 2002* – scientists can apply for a licence from the National Health and Medical Research Council (NHMRC) to use donated human ART embryos for stem cell research or research to improve infertility treatments and in vitro fertilisation (IVF), provided that the embryos are no longer required for infertility treatment. Additional legislation was also introduced in 2002, the *Prohibition of Human Cloning Act 2002* which made it illegal to create, or even attempt to create, a human using cloning technology. Australia was one of the first countries in the world to introduce laws to govern the use of human embryos in research.

In 2005 the Australian legislation was reviewed by an independent committee which became known as the *Lockhart Review* after the late Hon John Lockhart AO QC who chaired the committee. The committee's recommendations were incorporated into legislation in 2006 following a conscience vote in both houses of federal parliament. The amending legislation - *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* - specifically allowed Australian researchers to apply for a licence to use somatic cell nuclear transfer technology (SCNT: also known as therapeutic cloning) for stem cell research within a strict set of criteria. The amending legislation also increased the penalties associated with any attempts to abuse this technology to clone humans, with reproductive cloning remaining specifically prohibited.

2010 Legislation Review

The legislation that was enacted in 2006 included a mandatory requirement that the *Research Involving Human Embryos Act 2002* and *Prohibition of Human Cloning for Reproduction Act 2002* be reviewed within a certain timeframe and that there be a report back to the Council of Australian Governments (COAG) and the Australian Parliament.

The five member committee is chaired by the Hon Peter Heerey QC, who is joined by former Australian of the Year Professor Ian Frazer, Lockhart committee member and law ethics expert Professor Loane Skene, Doctor Faye Thompson an expert in midwifery ethics and the Reverend Kevin McGovern, Director of the Caroline Chisholm Centre for Health Ethics.

Full details on the current review including timelines and instructions on how to make a submission can be found at <https://legislationreview.nhmrc.gov.au/>. The deadline for public submissions is 15 March 2011.

Why Stem Cells?

Stem cells are of great interest to medical research as they have potential for benefit in many different areas of medical research and therapies. Whilst the uses and potential uses of stem cells tend to be thought of in terms of a using them to replace diseased and damaged tissues and cells, there are many other reasons these cells are important. Stem cells are used in the laboratory to study both normal human development and also the progression of disease through the use of stem cells that carry a particular disease. Stem cells are used to test new drugs and to screen toxins to see what adverse impacts they would have on humans.

The Australian legislative environment has provided Australian researchers with a stable environment in which to conduct research and the confidence to pursue research using human embryonic stem (ES) cells for many areas of discovery from looking at the basics of pluripotency to research into specific diseases such as diabetes, heart disease, Huntington's disease and many others. It has also allowed for Australians to collaborate with leading international researchers in order to exchange knowledge and progress the research.

Different Types of Stem Cells

Stem cells are often divided into two groups: tissue stem cells (also known as adult stem cells or multipotent stem cells) and pluripotent stem cells (including ES cells and induced pluripotent stem cells). They differ in their degree of differentiation and ability to self-renew. Currently Australian researchers are looking at all types of stem cells. Several groups in Australia have been granted licenses by the NHMRC to create human ES cells with one group having been granted a licence to investigate SCNT using human eggs that are not suitable for infertility treatment.

As yet no one in the world has been able to make human ES cells from SCNT embryos. Many groups continue to use stem cells derived from tissue including a new type of stem cell, induced pluripotent stem (iPS) cells.

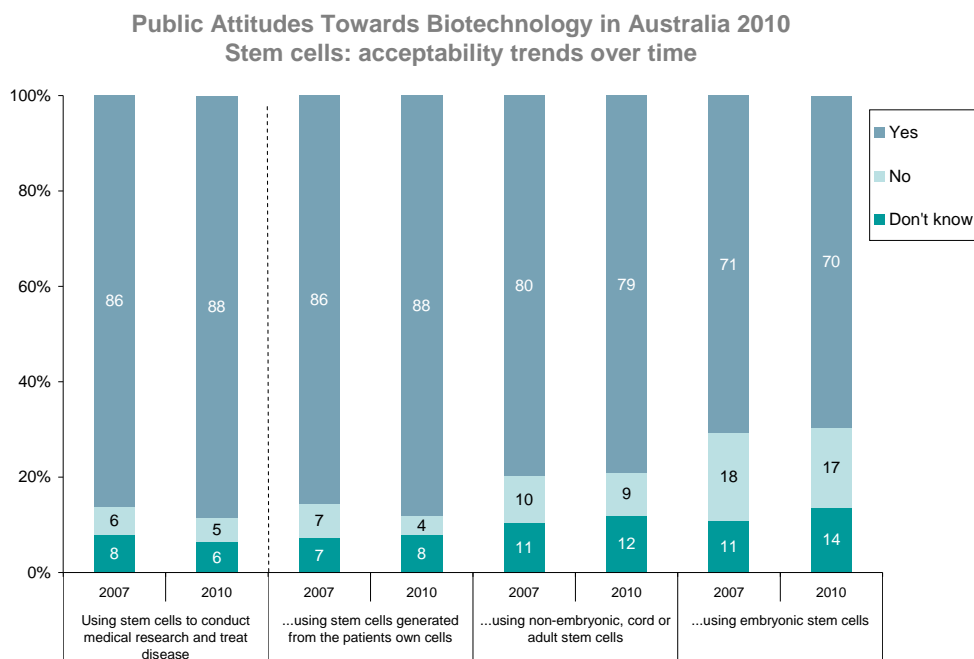
Since the discovery of iPS cells in 2007 there has been some debate as to the continued need to create new human ES cell lines from both excess IVF embryos and SCNT.

Scientifically, there is a strong need for the continuation of human ES cell research alongside all other types of stem cell research. Human ES cells were first discovered in 1998 and are now entering clinical trials, as such much is known about these cells including their stability over long periods of time. There is considerable scientific evidence for the continued development of all types of stem cells. Each stem cell type has considerable scientific validity and provides unique insights into human disease and development and potential for drug discovery and regenerative medicine solutions for disease and injury. The 2007 discovery of iPS cells are a valuable new research tool, complementing existing cell types. Of particular value is the ability to make iPS cells from a patient with a particular condition and then study that condition in the laboratory – so called ‘disease in a dish’. However, it remains unclear whether iPS cells can retain their stem cell characteristics over long periods of time and the extent to which they are identical to ES cells.

Each stem cell type (tissue specific, human ES cell, iPS) have unique properties and it is too soon to know which ones will be most effective for particular indications.

Public Attitudes

Public acceptance of stem cell research remains high in Australia. This was again highlighted in a biennial **Public Attitudes Towards Biotechnology in Australia Report**, released recently by the Department of Innovation, Science, Industry and Research. The project, which surveyed public attitudes across a range of biotechnologies between December 2009 and June 2010, found that ‘using stem cells to conduct medical research and treat disease’, was considered useful by around 88% of respondents, while only around 25% thought there were risks associated with



Note: Graph Taken from *Public Attitudes Towards Biotechnology In Australia - Results of a survey of public attitudes 2009-10*, from www.innovation.gov.au

the technology. There was also an overall positive attitude towards the more topical use of ES cells, which 70% thought of as acceptable, and only 17% thought of as unacceptable.

The Australian trends are reflected internationally. An American poll by **Interactive/HealthDay** surveyed 2113 adults and found that 72% of respondents felt researchers should be allowed to use embryos left over from IVF that had been donated with full consent. Only 12% of respondents felt that the donation of human embryos to research should not be allowed. This may seem a surprising result to some as news out of the United States (US) on funding restrictions and the seemingly endless legal challenges to funding stem cell science would have us believe that opposition to the research in the US is much stronger.

The other major survey recently released is the [European Commission's Europeans and Biotechnology 2010](#) report, a 176 page tome measuring all 27 European Union (EU) members reactions to various biotechnologies including stem cell science. The EU average for support of ES cell research is 67% with the United Kingdom registering the highest levels at 80%, followed closely by Spain at 78% and Austria the lowest level of 39% with a mixture of results in between.

Stem Cell Therapies and Clinical Trials

Currently, the range of diseases for which there are proven treatments using stem cells is quite small and the only established stem cell therapies are those of the blood system involving transplants of haematopoietic (blood forming) stem cells (usually from bone marrow but with cord blood as an alternative) to reconstitute the blood. Research on bone marrow began in the 1950s with the first successful bone marrow transplant performed in 1968 when doctors at the University of Minnesota transplanted bone marrow from one person into a child with a genetic blood disease. However, clinical trials using other types of tissue specific (adult or somatic) stem cells are becoming more common. For example, researchers at the University of New South Wales are using stem cells from the eye on contact lenses to treat blinding corneal disease and Australian company Mesoblast has conducted clinical trials using mesenchymal stem cells to treat non healing long bone fractures.

While human ES cells were only discovered in 1998 and there is still much to learn about the basic biology of these cells, the first clinical trial has recently begun and a second and third have been approved and will commence soon. US based biotechnology company Geron announced in October 2010 that it had begun its much awaited clinical trial using a human ES cell based therapy for the treatment of acute spinal cord injury. More recently, Massachusetts based Advanced Cell Technology have been granted FDA approval to commence two clinical trials of their human ES cell derived treatment for two rare types of blindness.

International Regulation and Legislation

Internationally, many countries have taken various approaches to regulating human embryo research and therapeutic cloning. Countries that are considered to have 'permissive' regulation that allows the derivation of human ES cells from excess IVF embryos and embryos created via SCNT include: United Kingdom, Spain, Israel, Sweden, China, India, South Korea and Singapore. Countries that allow the derivation of human ES cells but not SCNT include: Canada, France and Brazil. There are several countries with restrictive policies which includes Germany where scientists are allowed to research only imported existing human ES cell lines created before 2007 and Italy which only allows research only on imported human ES cell lines.

The US is a special case when it comes to human ES cell regulation. The US has no federal legislation or regulations governing embryo research including cloning research. The only federal rules exist around the funding stem cell research through the NIH which has been subject to change under the various presidents. In addition, the funding of human ES research by the US Government has been subjected to numerous legal challenges from individuals opposed to funding of such research. However, at time of writing, the funding of human ES research is ongoing. Significantly, some of the states with the most permissive legislation also have large stem cell research efforts such as California and Massachusetts.

A table of international stem cell regulations can be found [here](#) on the Australian Stem Cell Centre website.