



Australian  
Stem Cell  
Centre

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# **ASCC Submission to 2010 Legislation Review**

*Research Involving Human Embryos Act 2002*

and

*Prohibition of Human Cloning for Reproduction Act 2002*

15 March 2011

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## 1 Scope of Submission

The Board of Directors and Senior Managers of the Australian Stem Cell Centre (**ASCC**) welcome the opportunity to make a submission to the 2010 Review of the *Prohibition of Human Cloning for Reproduction Act 2002* (**PHCR Act**) and the *Research Involving Human Embryos Act 2002* (**RIHE Act**).

Human embryonic stem cells, along with other stem cell types, remain of great importance to medical research as they have the potential to benefit those afflicted by many different diseases and medical conditions. This submission makes five recommendations in support of the current regulatory framework and provides responses to the terms of reference relevant to stem cell science and related technologies in Australia. Specifically, the submission addresses developments that have occurred in these areas since the Review conducted in 2005 (**2005 Review**) and discusses the continuing requirement for the use of human embryos in Australia to derive human embryonic stem (**ES**) cells for research. This submission seeks to illustrate the importance of stem cells to Australian biomedical research and highlight Australia's achievement to date in this field. Australian scientists have worked in a stable regulatory environment that has allowed research to flourish and enabled collaborations with leading international researchers. The use of human embryos in assisted reproductive technology (**ART**) is outside our remit and expertise. We have therefore omitted from our submission any opinion of, or comment on, developments in this area.

The submission was prepared following consultation with ASCC-funded researchers, the Chairs of the Scientific Advisory Board of the ASCC, the ASCC Senior Scientific Faculty and ASCC employees. The ASCC has also engaged with its Stakeholders, key members of the broader Australian and international stem cell community, patient advocacy groups and biotechnology industry representatives during the preparation of this submission. We acknowledge that this submission may not be in complete alignment with the views of everyone who was consulted. However, the degree of consensus was very high and there are only a few areas where a consensus view was not held. These are indicated in the text of our submission.

Members of ASCC Board and Senior Management are available throughout March, April and May 2011 should the Review Committee require any clarification on the points raised in our submission, or should any additional information be needed to assist the work of the Review Committee. Given that some of the scientific literature cited in our submission is only available through subscription, we are also able to provide specific references upon request.

## 2 Declaration

This submission has the unanimous support of the Directors of the Board and Senior Management of the ASCC.

### **ASCC Board Members**

Emeritus Professor Graham Macdonald  
(Chair)  
Dr Graeme Blackman OAM  
Mr Stuart Gooley  
Dr Christopher Juttner  
Dr Peter Riddles  
Emeritus Professor Richard Smallwood AO

### **ASCC Senior Management**

Mr David Collins (Chief Executive Officer)  
Professor Joe Sambrook (Scientific Director)  
Mr Mark Cummings  
Mr Sean Meehan  
Mr Graeme Mehegan  
Dr Megan Munsie  
Ms Rebecca Skinner  
Mr Michael Vovos

### 3 ASCC Recommendations

#### 1. **The current national regulatory framework that oversees the responsible use of human embryos in Australian research should continue without significant change**

The RIHE Act and PHCR Act collectively provide an effective regulatory framework for the use of human embryos by Australian researchers. The current licensing requirements ensure that such research is restricted to the use of human embryos that are no longer required for infertility treatment or, in the case of somatic cell nuclear transfer (**SCNT**), have been created specifically for an ethically-approved research project. We support the continuing need for stringent licensing conditions where the researcher(s) must (i) demonstrate scientific merit of their proposed investigations and (ii) satisfy ethical consideration of the proposed patient-consent process associated with the donation of the human embryo(s) or eggs.

The current legislation has allowed researchers in the Australian stem cell community to generate over 50 human ES cell lines in five licensed research projects. Many of these ES cells have been used by researchers in ethically-approved research projects across Australia and around the world, and have contributed significantly to our understanding of the growth of human stem cells and their capacity to differentiate and develop into new types of cells such as blood cells, heart cells and nerves. Importantly, because of Australia's clear regulatory guidelines, researchers in this country have been able to collaborate widely with leading international stem cell scientists and hence to expedite the progress and broaden the scope of research in the field.

We believe that the current legislation offers an adequate balance between protecting the rights and interests of the donors of human embryos and eggs, and allowing ethically approved research. In addition, the stringent Australian laws provide reassurance for the broader community in an area of research that remains unacceptable to some, albeit a small minority of, Australians.

#### 2. **Access to human ES cells continues to be vital to stem cell research in Australia. We therefore support the continuation of the current licensing process to allow Australian scientists the opportunity to generate new stem cell lines for research**

Stem cells are the cornerstone of regenerative medicine research programs around the world. Whilst scientists have recently isolated induced pluripotent stem cells (**iPS cells**), a new type of stem cell that hold great promise for research and therapeutic application, there remain significant challenges that must be overcome before the potential of these cells can be fully realised. At this stage, pluripotent stem cells derived directly from human embryos (**human ES cells**) remain pivotal in the quest to understand, assist and control how the body repairs itself following injury or disease. Indeed, the first clinical trials using cells obtained from human ES cells to treat spinal cord injury and blindness have recently commenced. A relatively rapid development considering that human ES cells were only discovered in 1998.

It is still too early to know whether many of the proposed stem cell-based treatments, including those using cells created from human ES cells, will prove to be safe and effective. Indeed, it remains unclear which type of stem cells will prove to be the most useful for any given disease or condition. The only thing that is certain at this stage, is that further research is required to find out how stem cells can best be used to develop safe and effective regenerative therapies.

Many of the existing human ES cell lines available in Australia were created for research use and may not be suitable for clinical use. In the coming years, the development of new stem cell lines is likely to become a priority as the number and scope of clinical trials involving human ES cells increases. For the foreseeable future, there will continue to be a need for Australian researchers to access human embryos to create new ES lines. This is most appropriately subject to the licensing process currently overseen by the National Health and Medical Research Council (**NHMRC**). We believe that changes to the current regulatory framework are unnecessary and undesirable: the present framework has proven to be robust; it provides the necessary societal safeguards but does not unduly restrict progress.

**3. Research using human ES cell lines derived in NHMRC licensed projects, or derived in conditions consistent with Australian legislation, should be regulated by existing national guidelines on ethical use of animal and human material in research**

The use of human embryos in Australian research should continue to be regulated under the current legislation and restricted to projects issued with a licence from the NHMRC. In addition, the subsequent use of any material obtained in a licensed project should be regulated by the existing national guidelines.

This is particularly important for stem cell research, where ES cells created in a licensed project can be grown in large numbers in the laboratory and stored for future use. These cells can be shared with other scientists, a common practice that should be encouraged, provided it is consistent with the original consent given by the donors, and in accordance with current guidelines, namely the *National Statement on Ethical Conduct in Research In Human Research* (2007, NHMRC<sup>1</sup>) and the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2007, NHMRC). The ability to access a broad range of existing cell lines is a vital component of stem cell science. It fosters comparative research, enables validation of results and reduces the demand for each research group to create their own ES cell lines, thereby minimising the number of human embryos required for stem cell research.

Clinical research must continue to comply with regulations administered by the Therapeutic Goods Administration.

**4. Support should be provided to facilitate Australian researchers' access to human ES and other pluripotent stem cell lines created in conditions consistent with Australian regulations**

Support should be provided for a centralised and independent facility to assist the distribution of human ES cells, and other pluripotent stem cells such as iPS cells, for research use. Such a facility would enable Australian researchers access to high quality cell lines and products with expert advice and technical assistance as required, and has proven to be an effective model in Australia and overseas.

Over the last eight years, the ASCC has fulfilled this role through its StemCore laboratories. The ASCC has assisted the creation and distribution of accredited human ES cell lines to Australian and international researchers; and has facilitated the distribution to Australian researchers of cell lines generated overseas under ethically-approved guidelines consistent with Australian regulations. In addition, the ASCC has provided training on stem cell technology to increase the level of technical skill of the Australian biotechnology community, thereby facilitating the adoption of new technologies by the sector.

Without such a central distribution and training service, access to approved pluripotent stem cell lines for Australian scientists will be inefficient and much more expensive.

**5. Reproductive cloning should continue to be specifically banned in Australia**

It must continue to be an offence under Australian legislation to attempt to achieve a pregnancy through the transfer into the body of a human or an animal of a cloned embryo, that is a genetic copy of another living or dead human. There is no acceptable scientific or medical justification for such an endeavour.

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<sup>1</sup> The National Statement was jointly developed by NHMRC, Australian Research Council and the Australian Vice-Chancellors' Committee.

## 4 Responses to Relevant Review Terms of Reference for 2010 Review

Whilst we recognise that the responsible use of human embryos in research extends beyond the creation of human ES cells, we have restricted our response to the 2010 Review's Terms of Reference to issues directly relevant to stem cell research.

### 4.1 Developments in embryonic stem cell research, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research

Within Australia and internationally, major funding initiatives, both public and private, continue to support human ES cell research and its translation into clinically valuable treatments. Below are some of the current Australian and international stem cell funding initiatives.

- The California Institute of Regeneration Medicine (**CIRM**), established in 2004 to provide US\$3 billion for stem cell research in California<sup>2</sup>, has to date distributed over one third of its funding<sup>3</sup>. In October 2009 CIRM together with its international partners awarded more than US\$250 million to develop stem cell-based therapies for 11 diseases. This included collaborative research grants between researchers in California and the UK on leukaemia and macular degeneration (US\$8 million) and between Californian and Canadian researchers on cancer (US\$35 million)<sup>4</sup>. In a separate funding round also in 2009, over US\$67 million was awarded to research projects that aim to translate basic research using pluripotent stem cells into clinical therapies<sup>5</sup>. Four of the successful grants included collaborations with Australian researchers to develop safe stem cells based treatments for diabetes, Alzheimer's Disease and Parkinson's Disease. The Victorian State Government provided funding to support the Australian researchers (US\$3.869 million)<sup>6</sup>.
- In the UK, the Wellcome Trust has provided almost £3 million to fund a collaboration to turn human ES cells into red blood cells and ensure that the resulting cells are safe to use in patients<sup>7</sup>. They plan to produce type O-negative blood cells, which can be used for almost all patients in need of blood with the goal of satisfying the unmet demand for blood within the UK and around the world.
- Pharmaceutical companies are also investing in the area, with Pfizer, GlaxoSmithKline, AstraZeneca and Roche forming alliances with research institutes in the UK and US to accelerate stem cell science including the use of ES cells in drug toxicology screening<sup>8</sup>.
- In Australia, research involving human ES cells continues to be supported by the ASCC through funding provided by the Australian Research Council (**ARC**) and the Department of Innovation, Industry, Science and Research (**DIISR**) and by the NHMRC. Research projects are wide ranging but include understanding how to control the growth of human pluripotent stem cells, how to turn differentiation on and off, how to generate specific types of target cells (e.g. blood cells and cardiac muscle), how to grow the cells at large scale, how to detect and rank the genetic and epigenetic differences between human ES cells and other types of pluripotent stem cells<sup>9</sup>.

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2 CIRM established after the citizens of Californian passed Proposition 71, the California Stem Cell Research and Cures Initiative.

3 <http://www.cirm.ca.gov/GrantsSummary>

4 [http://www.cirm.ca.gov/PressRelease\\_102809](http://www.cirm.ca.gov/PressRelease_102809)

5 [http://www.cirm.ca.gov/PressRelease\\_042809](http://www.cirm.ca.gov/PressRelease_042809)

6 [http://www.business.vic.gov.au/BUSVIC/STANDARD/PC\\_63759.html](http://www.business.vic.gov.au/BUSVIC/STANDARD/PC_63759.html)

7 <http://www.wellcome.ac.uk/news/media-office/Press-releases/2009/WTX054309.htm>

8 <http://www.ft.com/cms/s/0/9f12390e-b1b7-11dd-b97a-0000779fd18c.html#axzz1Ew2fYx4F>

9 ASCC Collaborative Stream 3 – Pluripotent Stem Cell Differentiation

[http://www.stemcellcentre.edu.au/Research/Collaborative\\_Stream/Stream\\_3.aspx](http://www.stemcellcentre.edu.au/Research/Collaborative_Stream/Stream_3.aspx); <http://sydney.edu.au/medicine/people/academics/profile>

### Advances in human ES cell research

Many recent scientific publications demonstrate the value of human ES cells in improving our understanding of how stem cells grow and develop both in healthy individuals and following disease or injury. Human ES cells are also being used in the discovery of new drugs or therapeutic agents. For example:

- Australian scientists at Monash University have been able to genetically modify human ES cells to fluorescence when the stem cells develop into a number of clinically valuable cell types including red blood cells, precursors of blood and heart cells, insulin expressing cells and nerve cells<sup>10</sup>. These cell lines, plus others in still in development, are proving to be key reagents that are contributing to the generation of cells from human ES cells for future therapies.
- Researchers at the Salk Institute in the US have grown embryonic stem cells into the motor neurons and support cells that are involved in amyotrophic lateral sclerosis (**ALS**, Motor Neurone disease)<sup>11</sup>. ALS currently has no cure and no effective treatment. In addition to understanding the biology of ALS, the group plans to use this system to screen drugs that may be able to treat ALS.
- Significant progress has been made in making pancreatic cells from human ES cells, spurred on by the desire to generate insulin producing cells to treat patients with juvenile onset diabetes<sup>12</sup>.
- Researchers at the University of California have also recently shown that nerves derived from human ES cells are able to repair some neural damage in a mouse model of multiple sclerosis (**MS**)<sup>13</sup>. In people with MS, the immune system attacks the insulation – called myelin – that covers and protects neurons of the brain and spinal cord. The transplanted cells cause a response in the animals that allowed the myelin coating to be repaired on damaged cells. Whilst the researchers acknowledge that more work is needed to understand how the remyelination occurs and how the transplanted cells can be better retained, it is hoped that repairing the myelin sheath would also restore nerve function, bringing back feeling and motor control.
- Scientists from University of California have created early-stage retinas from human ES cells and are testing them in animals<sup>14</sup>. This work marks the first step towards the development of transplant-ready retinas to treat eye disorders such as retinitis pigmentosa and macular degeneration.
- Recently, four human ES cell lines were derived by scientists at Sydney IVF from embryos identified as affected by Huntington's disease (**HD**)<sup>15</sup>. These HD-affected human ES cell lines will be made available to biomedical research laboratories and will provide a valuable tool to investigate both mechanisms and potential treatments for HD.

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[s/kquinlan.php](http://www.stemcellcentre.edu.au/Research/Collaborative_Streams/Stream_1.aspx); and ASCC Collaborative Stream 1 – Bioreactors and Smart Surfaces for Stem Cell Propagation [http://www.stemcellcentre.edu.au/Research/Collaborative\\_Streams/Stream\\_1.aspx](http://www.stemcellcentre.edu.au/Research/Collaborative_Streams/Stream_1.aspx)

10 Hatzistavrou T *et al.* (2009) ErythRED, a hESC line enabling identification of erythroid cells. *Nat Methods* 6(9):659-62; Davis RP *et al.* (2008) Targeting a GFP reporter gene to the MIXL1 locus of human embryonic stem cells identifies human primitive streak-like cells and enables isolation of primitive hematopoietic precursors. *Blood* 111(4):1876-84; Nostro MC *et al.* (2011) Stage-specific signaling through TGF{beta} family members and WNT regulates patterning and pancreatic specification of human pluripotent stem cells. *Development* 138(5):861-71; Goulburn AL *et al.* (2011) A targeted NKX2.1 HESC reporter line enables identification of human basal forebrain derivations. *Stem Cells* Jan 7 [Epub ahead of print].

11 Hedlund E and Isacson O (2008) ALS model glia can mediate toxicity to motor neurons derived from human embryonic stem cells. *Cell Stem Cell* 3(6):575-6.

12 Kroon E *et al.* (2008) Pancreatic endoderm derived from human embryonic stem cells generates glucose-responsive insulin-secreting cells in vivo. *Nat Biotechnol* 26(4):443-52; Nostro MC *et al.* (2011) Stage-specific signaling through TGF{beta} family members and WNT regulates patterning and pancreatic specification of human pluripotent stem cells. *Development* 138(5):861-71.

13 Hatch MN *et al.* (2009) Endogenous remyelination is induced by transplant rejection in a viral model of multiple sclerosis. *J Neuroimmunol* 212(1-2):74-81.

14 Nistor G *et al.* (2010) Three dimensional early retinal progenitor 3D tissue constructs derived from human embryonic stem cells. *Journal of Neuroscience Methods* 190(1):63-70.

15 Bradley CK *et al.* (2011) Derivation of Huntington's Disease-affected human embryonic stem cell lines. *Stem Cells Dev* 20(3):495-502.

- In other developments, human ES cells continue to be used by researchers to develop methods to screen for drugs, and to develop model systems to study a wide range of heart diseases<sup>16</sup>.

Recently, human ES cell lines have been derived by researchers overseas from single cells, or blastomeres, taken from an early stage embryo<sup>17</sup>. The technique relies on the researcher taking a biopsy from the embryo – a standard procedure used in IVF to screen for genetic abnormalities prior to embryo transfer – and then culturing the single cell to form the stem cell line. Given that embryos were not destroyed in the process, such an approach may be seen as a desirable alternative to the use of donated excess ART embryos in research. However in the five years, since the first proof of principle experiment<sup>18</sup>, this approach has not been widely adopted due to the availability of excess embryos that would otherwise be discarded and the impracticality, and inherent risks, of performing such an intrusive procedure on an embryo that is to be used for infertility treatment.

Significantly, the last year has seen the commencement of the first clinical trial using cells derived from human ES cells.

- On 12 October 2010, US based biotechnology company Geron announced that they had commenced the world's first clinical trial for a treatment for spinal cord injury based on human ES cells<sup>19</sup>. The phase I clinical trial aims to treat up to 10 patients with acute spinal cord injury. The first patient was treated in October 2010<sup>20</sup>. The principal goal of this first-in-man study is to assess safety<sup>21</sup>. A larger trial is planned to follow to assess whether the treatment will restore function. Because the patients must be followed for a long time, it will be several years before the outcomes of the trial are fully known.
- Two additional early-phase clinical trials involving cells derived from human ES cells for blindness have also recently been approved by the US Food and Drug Administration. Massachusetts based Advanced Cell Technology (**ACT**) will be testing its ES cell based treatment on patients with Stargardt's macular dystrophy<sup>22</sup>, a rare form of juvenile blindness that can begin in children as young as six, and age related macular degeneration, the most common form of blindness in people older than 60<sup>23</sup>.

### **Advances in human ES cell research – Somatic Cell Nuclear Transfer**

In SCNT the nucleus of an adult cell (any cell of the body apart from egg and sperm) is used to replace the nucleus of an egg. The reconstituted egg can be stimulated to divide and to develop into a very early embryo, from which ES cells can be derived. These SCNT-derived ES cells would be genetically identical to the donor of adult cell. Theoretically, such cells could be used to generate patient-specific cells for therapy or disease-specific cells for research. Using this technique, ES cell lines have been created in mice<sup>24</sup> and other animals including monkey<sup>25</sup>. Indeed mice suffering from a genetic defect have been successfully treated with genetically modified cells created from SCNT-derived ES cells<sup>26</sup>.

In January 2008, a privately-held Californian company, Stemagen, reported it had successfully used SCNT to develop human embryos from human skin cells<sup>27</sup>. There was no attempt to create ES cell

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16 Dambrot C *et al.* (2011) Cardiomyocyte differentiation of pluripotent stem cells and their uses as cardiac disease models *Biochem J* 434(1):25-35.

17 Chung Y *et al.* (2008) Human embryonic stem cell lines generated without embryo destruction. *Cell Stem Cell* 2(2):113-117.

18 Klimanskaya I *et al.* (2006) Human embryonic stem cell lines derived from single blastomeres. *Nature* 444(7118):481-5.

19 <http://www.geron.com/patients/clinicaltrials/hESC.aspx>

20 [http://blogs.nature.com/news/thegreatbeyond/2010/10/geron\\_treats\\_first\\_patient\\_wit.html](http://blogs.nature.com/news/thegreatbeyond/2010/10/geron_treats_first_patient_wit.html)

21 Strauss S (2010) Geron trial resumes, but standards for stem cell trials remain elusive. *Nature Biotechnology* 28(10):989-90.

22 [http://blogs.nature.com/news/thegreatbeyond/2010/03/a\\_human\\_embryonic\\_stemcell\\_the.html](http://blogs.nature.com/news/thegreatbeyond/2010/03/a_human_embryonic_stemcell_the.html)

23 [http://blogs.nature.com/news/thegreatbeyond/2011/01/fda\\_approves\\_third\\_human\\_stem.html](http://blogs.nature.com/news/thegreatbeyond/2011/01/fda_approves_third_human_stem.html)

24 Munsie M *et al.* (2000) Isolation of pluripotent embryonic stem cells from reprogrammed adult mouse somatic cell nuclei. *Current Biology* 10(16):989-92.

25 Byrne JA *et al.* (2007) Producing primate embryonic stem cells by somatic cell nuclear transfer. *Nature* 450(7169):497-502.

26 Rideout WM *et al.* (2002) Correction of a genetic defect by nuclear transplantation and combined cell and gene therapy. *Cell* 109(1):17-27.

27 French A *et al.* (2008) Development of human cloned blastocyst following somatic cell nuclear transfer with adult fibroblasts *Stem Cells* 26(2):485-93.

lines in this study. Indeed the goal of generating lines of human ES cells from SCNT embryos has yet to be achieved. In 2004, South Korean scientists claimed to have derived patient-specific ES cells, but their publication was withdrawn following an investigation that found the researchers had engaged in research misconduct and that their publications contained fabricated data<sup>28</sup>.

Although research using SCNT to generate patient-specific ES cell lines continues, progress has been hampered by lack of access to human eggs<sup>29</sup>. In Australia, Sydney IVF has been granted licences for SCNT to create stem cells<sup>30</sup>. They have overcome the access to human eggs experienced by other researchers by using donated human eggs that were not required for infertility treatment as they were unsuitable for fertilisation (immature) or had fertilised abnormally. Whilst Sydney IVF has made progress in their research, they are yet to obtain human ES cells. An application for a licence from a second group is currently under consideration<sup>31</sup>.

Participants in a recent workshop on SCNT jointly hosted by CIRM and the UK Medical Research Council, highlighted the ongoing need for human SCNT to understand nuclear reprogramming and for therapeutic development, especially in providing insights into some of the molecular, epigenetic and functional characteristics of the earliest stages of human development under normal and disease conditions<sup>32</sup>.

Given that access to human eggs remains a rate-limiting step of SCNT, there was advocacy for the use of animal eggs to create SCNT embryos using human cells, so called animal-human hybrids or interspecies SCNT<sup>33</sup>. While this approach was supported in the 2005 Review, it was not introduced with the amending legislation in 2006. With little scientific progress since the first report of a rabbit/human SCNT-ES like cells in 2003<sup>34</sup>, at this stage the ASCC does not believe there is sufficient merit to call for a change to the legislation, but that developments in the field should continue to be monitored.

### **Reproductive Cloning**

In theory, if a human embryo generated by SCNT were implanted into the womb of a woman, an individual would be born whose nuclear genome would be identical to that of the donor's somatic cell. This scenario ('reproductive cloning') is laden with profound ethical, technical and biological problems<sup>35</sup>. ASCC, together with the overwhelming majority of the world's scientific and medical organisations, believes that human reproductive cloning should continue be banned with severe consequences for anyone breaching the prohibition (see **ASCC Recommendation 5**).

### **Advances in other areas of stem cell research**

The developments in human ES cell research have not occurred in isolation. Significant advances have also been made in using stem cells obtained from non-embryonic sources, often broadly referred to as 'adult stem cells' or 'tissue-specific stem cells'. Advances using these cells have been made in understanding a large number of cancers, including breast cancer<sup>36</sup>, lung development<sup>37</sup> and

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28 Kennedy D (2006) Editorial Retraction *Science* 311(5759):335.

29 Dizikes P (2007) Boston Globe Reluctance of egg donors stymies Harvard efforts;

[http://www.boston.com/yourlife/health/diseases/articles/2007/06/07/reliance\\_of\\_egg\\_donors\\_stymies\\_harvard\\_efforts/](http://www.boston.com/yourlife/health/diseases/articles/2007/06/07/reliance_of_egg_donors_stymies_harvard_efforts/)

30 <http://www.nhmrc.gov.au/research/embryos/monitor/database/index.htm>

31 [http://www.nhmrc.gov.au/research/embryos/monitor/license\\_application/index.htm](http://www.nhmrc.gov.au/research/embryos/monitor/license_application/index.htm)

32 [http://www.cirm.ca.gov/files/PDFs/Publications/Human\\_SCNT\\_Workshop\\_Report.pdf](http://www.cirm.ca.gov/files/PDFs/Publications/Human_SCNT_Workshop_Report.pdf)

33 Minger S (2007) Interspecies SCNT-derived human embryos – a new way forward for regenerative medicine. *Regen Med* 2(2):103-6.

34 Chen Y *et al.* (2003) Embryonic stem cells generated by nuclear transfer of human somatic nuclei into rabbit oocytes. *Cell Res* 13(4):251-263.

35 Palmieri C *et al.* (2008) Review paper: a review of the pathology of abnormal placentae of somatic cell nuclear transfer clone pregnancies in cattle, sheep, and mice. *Vet Pathol* 45(6):865-80; Sparrow R (2009) Therapeutic cloning and reproductive liberty. *J Med Philos* 34(2):102-18.

36 Lim E *et al.* (2009) Aberrant luminal progenitors as the candidate target population for basal tumor development in BRCA1 mutation carriers. *Nature Medicine* 15(8):842-4.

37 McQualter J *et al.* (2010) Evidence of an epithelial stem/progenitor cell hierarchy in adult mouse lung. *PNAS* 107(4):1414-9.

in the regulation of stem cell activity in bone marrow<sup>38</sup> to list a few examples. These studies help to understand stem cell function in healthy and diseased states.

Importantly, many clinical trials involving stem cells isolated from a variety of adult<sup>39</sup>, infant<sup>40</sup> and foetal<sup>41</sup> tissues for a variety of specific conditions are now underway. Findings from these trials will be valuable to progress the field of regenerative medicine.

### **Induced Pluripotent Stem Cells**

In recent years a new method has been discovered to create pluripotent stem cells, the iPS cells<sup>42</sup>. Currently, iPS cells are generated by inserting a combination of genes into adult somatic cells, turning fully differentiated mature cells such as skin cells back into primitive stem cells capable of developing into many different cell types, a characteristic referred to as pluripotency. Although the mechanism by which these genes cause adult cells to become pluripotent is not yet understood, the technique holds great promise for stem cell research and regenerative medicine. It presents a new opportunity to generate specific stem cell lines to study certain disease conditions and to screen promising new drugs. Whilst this application of iPS cells will most immediately yield new knowledge and discoveries, it is the possibility that reprogramming technology might offer a way to produce patient-specific stem cells that could be used in transplantation studies without concerns of immune rejection that has captured the public imagination<sup>43</sup>.

Many laboratories around the world are working on iPS cells. Scientists are using different types of donor cells to make iPS cells as well as trying to improve efficiencies of the reprogramming process<sup>44</sup>. For example, the first attempts to make iPS cells relied on the use of viruses to introduce key pluripotency genes into the adult somatic cells. New techniques have also been developed that reduce the reliance on the use of the viral infection, initially used to introduce the change in gene expression<sup>45</sup>. Indeed there are recent publications that demonstrate the ability to generate iPS cells using only one reprogramming gene in combination with chemicals or growth factors<sup>46</sup>.

Recent developments in the reprogramming field are now focusing upon the desire to change one type of adult cell directly into another without a pluripotent intermediate, a process termed direct reprogramming<sup>47</sup>. This process has already been reported for the generation of cardiac muscle, neural cells and blood cells<sup>48</sup>. It remains to be seen whether the direct reprogramming methodology is shown to be robust and potentially clinically useful. Nevertheless, these examples highlight the rapidly

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38 Grassinger J *et al.* (2010) Phenotypically identical hemopoietic stem cells isolated from different regions of bone marrow have different biologic potential. *Blood* 116(17):3185-96.

39 *Australian Life Scientist* (January 2011) Mesoblast sees positive interim results from heart stem cell trial; *Genetic Engineering & Biotechnology News* (July 2010) Prochymal new drug submission granted priority review by Health Canada; Di Girolamo N *et al.* (2009) A contact lens-based technique for expansion and transplantation of autologous epithelial progenitors for ocular surface reconstruction. *Transplantation* 87(10): 1571-8; *The Australian* (May 2009) Stem cells used to restore sight for corneal disease suffers.

40 Safety and Effectiveness of Cord Blood Stem Cell Infusion for the Treatment of Cerebral Palsy in Children <http://www.clinicaltrials.gov/ct2/show/NCT01072370?term=james+carroll&rank=2>

41 Mack G (2011) ReNeuron and stem cells get green light for neural stem cell trials. *Nature Biotechnology* 29(2):95-97.

42 Takahashi K and Yamanaka S (2006) Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors. *Cell* 126(4):663-76; Takahashi K *et al.* (2007) Induction of pluripotent stem cells from adult human fibroblasts by defined factors. *Cell* 131(5):861-72; Yu J *et al.* (2007) Induced pluripotent stem cell lines derived from human somatic cells. *Science* 318:1917-20.

43 Vogel G (2010) Cells rewrite their own destiny. *Science* 330(6011)1618.

44 Papp B and Plath K (2011) Reprogramming to pluripotency: stepwise resetting of the epigenetic landscape. *Cell Res* 21:486-501.

45 Gonzalez F *et al.* (2011) Methods for making induced pluripotent stem cells: reprogramming a la carte *Nature Reviews Genetics* [Published online 22 February 2011 | doi:10.1038/nrg2937]; Nakagawa M *et al.* (2008) Generation of induced pluripotent stem cells without Myc from mouse and human fibroblasts. *Nature Biotechnology* 26 (1):101-6; Li Z *et al.* (2011) Small RNA-mediated regulation of iPS cell generation *EMBO J* 30(5):823-34; Woltjen K *et al.* (2009) piggyBac transposition reprograms fibroblasts to induced pluripotent stem cells. *Nature* 458(7239):766-770 ; Kim KS *et al.* (2009) Generation of human induced pluripotent stem cells by direct delivery of reprogramming proteins. *Cell Stem Cell* 4(6):472-6; Stadtfeld M and Hochedlinger K (2010) Induced pluripotency: history, mechanisms, and applications. *Genes Dev* 24(20):2239-63.

46 Chen J *et al.* (2011) BMPs functionally replace Klf4 and support efficient reprogramming of mouse fibroblasts by Oct4 alone. *Cell Res* 21(1):205-12; Zhu S *et al.* (2010) Reprogramming of human primary somatic cells by OCT4 and chemical compounds. *Cell Stem Cell* 7(6):651-5; Stadtfeld M & Hochedlinger K (2010) Induced pluripotency: history, mechanisms, and applications. *Genes Dev* 24(20):2239-63.

47 Elefanty AG *et al.* (2010) On the streets of San Francisco: highlights from the ISSCR Annual Meeting 2010. *Cell Stem Cell* 7(4):443-50.

48 Ieda M *et al.* (2010) Direct reprogramming of fibroblasts into functional cardiomyocytes by defined factors. *Cell* 142(3): 375-386; Efe JA *et al.* (2011) Conversion of mouse fibroblasts into cardiomyocytes using a direct reprogramming strategy. *Nat Cell Biol* [Epub ahead of print]; Vierbuchen T *et al.* (2010) Direct conversion of fibroblasts to functional neurons by defined factors. *Nature* 463(7284):1035-41; Szabo E *et al.* (2010) Direct conversion of human fibroblasts to multilineage blood progenitors *Nature* 468(7323):521-6.

changing, dynamic and somewhat unpredictable nature of this field of cell reprogramming science.

However, whilst iPS technology has challenged how pluripotency is viewed by scientists, the development of iPS cells has not diminished the need for research involving human ES cells<sup>49</sup>. iPS cells and ES cells share many properties but they are not identical. At this early stage of their development, it remains unclear whether iPS cells, or even directly reprogrammed cells, can become bona fide therapeutic substitutes for human ES cells of proven pluripotency. Also, there are unresolved issues of safety, stability and reproducibility of differentiation outcomes that need to be addressed before it will be clear that reprogrammed cells will be of clinical benefit<sup>50</sup>. Recent publications highlight the areas that need to be further addressed:

- Many iPS cells carry a genetic memory of the type of adult cells from which they were derived demonstrating an incomplete resetting or reprogramming of their status with implications for future use<sup>51</sup>.
- The reprogramming process can cause abnormalities in the iPS cells with these cells displaying more genetic and epigenetic (changes in gene expression caused by mechanisms other than encoded in the DNA) abnormalities than ES cells and the adult cells from which they originated<sup>52</sup>. Indeed when 22 iPS cell lines, created by five different methods, were studied, the frequency of mutations in the iPS cells was ten times higher than expected<sup>53</sup>.
- The current methods used to generate iPS cells may inadvertently select cells with mutations in genes associated with cell-cycle regulation and cancer<sup>54</sup>.
- Research in mouse studies indicates that SCNT is more effective at establishing pluripotency than iPS cell technology which can leave a memory of the tissue origin that may restrict applications in disease modeling and ultimately, therapies<sup>55</sup>.

At present, iPS technology is exciting for scientists and hopeful for patients. But there are no guarantees of success, and more work remains to be done before the promise of the technology can be harnessed to generate populations of stem cells for safe and effective therapies. We argue that research using human iPS, ES and tissue (adult) stem cells needs to continue in parallel, a position widely supported by researchers in Australia and around the world<sup>56</sup>.

## Conclusions

The ASCC believes that:

- Investigations into the biology and therapeutic potential of ES cells will be the bedrock of stem cell research for many years to come.
- Research into all types of stem cells (ES, tissue and iPS) needs to continue in parallel.
- Australian scientists, for the foreseeable future, will have a continued need to access ART embryos and SCNT embryos for the generation of pluripotent stem cells.

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49 Hyun I *et al.* (2007) New advances in iPS cell research do not obviate the need for human embryonic stem cells. *Cell Stem Cell* 1(4):367-8.

50 Pera M *et al.* (2011) Stem cells: The dark side of induced pluripotency. *Nature* 471(7336):46-7.

51 Kim K *et al.* (2010) Epigenetic memory in induced pluripotent stem cells. *Nature* 467(7313):285-90; Polo JM *et al.* (2010) Cell type of origin influences the molecular and functional properties of mouse induced pluripotent stem cells. *Nature Biotechnology* 28(8):848-55.

52 Hussein SM *et al.* (2011) Copy number variation and selection during reprogramming to pluripotency. *Nature* 471:58-62; Gore A *et al.* (2011) Somatic coding mutations in human induced pluripotent stem cells. *Nature* 471 (7336):63-7; Lister R *et al.* (2011) Hotspots of aberrant epigenomic reprogramming in human induced pluripotent stem cells. *Nature* 471(7336):68-73.

53 Laurent LC *et al.* (2011) Dynamic changes in the copy number of pluripotency and cell proliferation genes in human ESCs and iPSCs during reprogramming and time in culture. *Cell Stem Cell* 8(1):106-18.

54 Gore A *et al.* (2011) Somatic coding mutations in human induced pluripotent stem cells. *Nature* 471 (7336):63-7; Mayshar Y *et al.* (2010) Identification and classification of chromosomal aberrations in human induced pluripotent stem cells. *Cell Stem Cell* 7(4):521-531; Laurent LC *et al.* (2011) Dynamic changes in the copy number of pluripotency and cell proliferation genes in human ESCs and iPSCs during reprogramming and time in culture. *Cell Stem Cell* 8(1):106-18.

55 Kim K *et al.* (2010) Epigenetic memory in induced pluripotent stem cells. *Nature* 467(7313):285-90; Zwaka TP (2010) Stem cells: troublesome memories. *Nature* 467(7313):280-1.

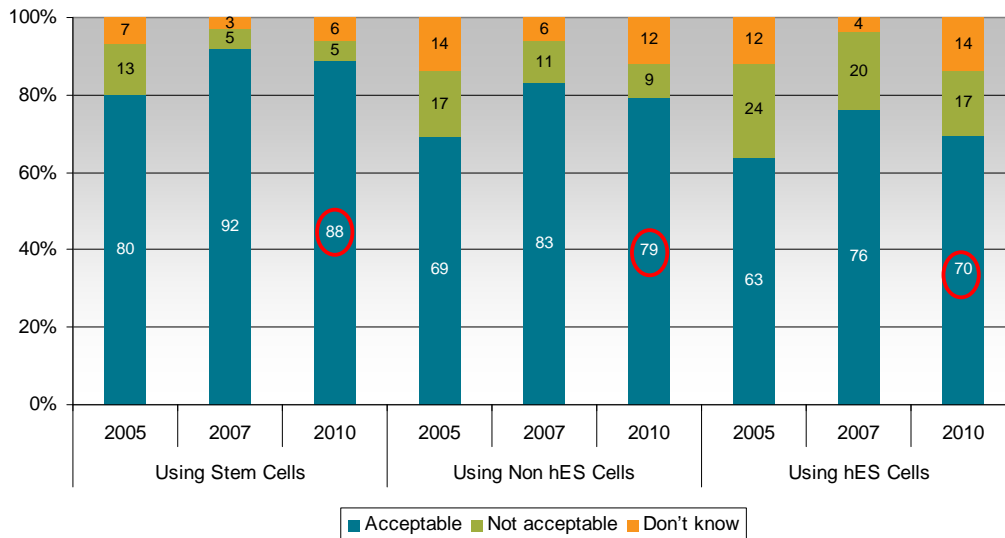
56 Löser P *et al.* (2010) Human embryonic stem cell lines and their use in international research *Stem Cells* 28(2):240-6; Hug and Hermerén (2010) Do we still need human embryonic stem cells and human embryonic stem cell research? Prepared for 3rd ESTOOLS Ethics Workshop, Lisbon, 26-28 May 2010; See ASCC response to TOR 4.8.

The ASCC recommends that the present NHMRC licencing system be continued, under which Australian scientists can apply for a licence to use donated excess ART embryos and SCNT embryos in ethically approved stem cell research (**ASCC Recommendation 2**).

## 4.2 Community standards

Stem cell science continues to capture the community's imagination with stories featuring stem cell research and possible clinical applications featuring regularly in mainstream media. This strong interest in stem cell research is reflected in the findings of a recent public attitudes survey commissioned by the DIISR<sup>57</sup>. This survey, conducted between December 2009 and June 2010, asked a series of questions to ascertain the Australian community's attitudes to a range of biotechnologies including stem cell research. Interestingly, 88% of participants believed that 'using stem cells to conduct medical research and treat disease' was acceptable, the highest of any of biotechnology applications asked. Only a quarter of those participating thought there were risks associated with stem cell research and its clinical application. When specifically asked about their attitudes to the use of ES cells in medical research, there was also an overall positive response, with 70% considering such use acceptable, while only 17% thought the use of ES cell was unacceptable (see Figure 1). Findings of a separate survey conducted in 2006, also indicated a high level of support within the community for the use of stem cells obtained from human embryos for medical research<sup>58</sup>.

**Figure 1: Public Acceptance of Stem Cell Research in Australia<sup>59</sup>**



Internationally, a similar high level of support for human ES cell research has also been demonstrated in recent surveys. In an extensive survey on European attitudes to biotechnology, 63% of participants across Europe supported human ES cell research provided that appropriate regulations were in place<sup>60</sup>. This was a similar finding to attitudes to gene therapy (see Figure 2). The level of support for the use of human embryos in stem cell research varied considerably in different countries with United Kingdom, Spain and Sweden registering the highest levels of support (between 70-80%) for the use

57 [www.innovation.gov.au/Industry/Nanotechnology/PublicAwarenessandEngagement](http://www.innovation.gov.au/Industry/Nanotechnology/PublicAwarenessandEngagement)

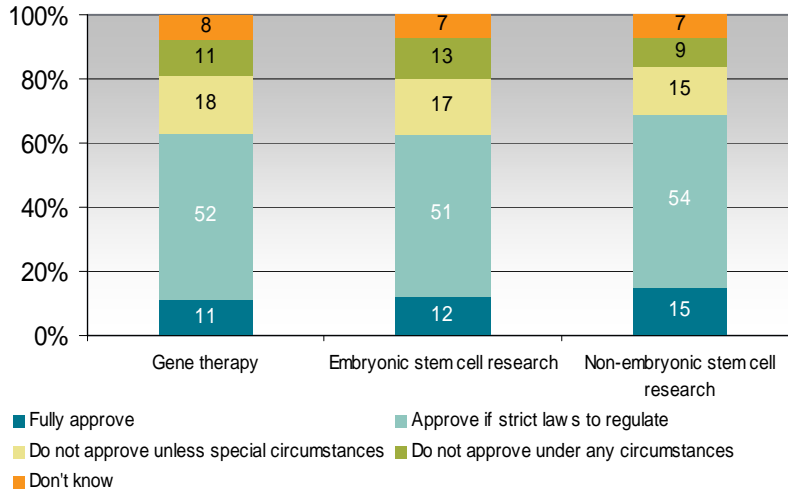
58 In the 2006 Roy Morgan Poll 82% of participants were supportive with 13% against and remainder undecided; <http://www.roymorgan.com/news/polls/2006/4036/>

59 Community Awareness Survey 2010 and Community Attitudes to Biotechnology 2007 [www.innovation.gov.au/Industry/Nanotechnology/PublicAwarenessandEngagement](http://www.innovation.gov.au/Industry/Nanotechnology/PublicAwarenessandEngagement)

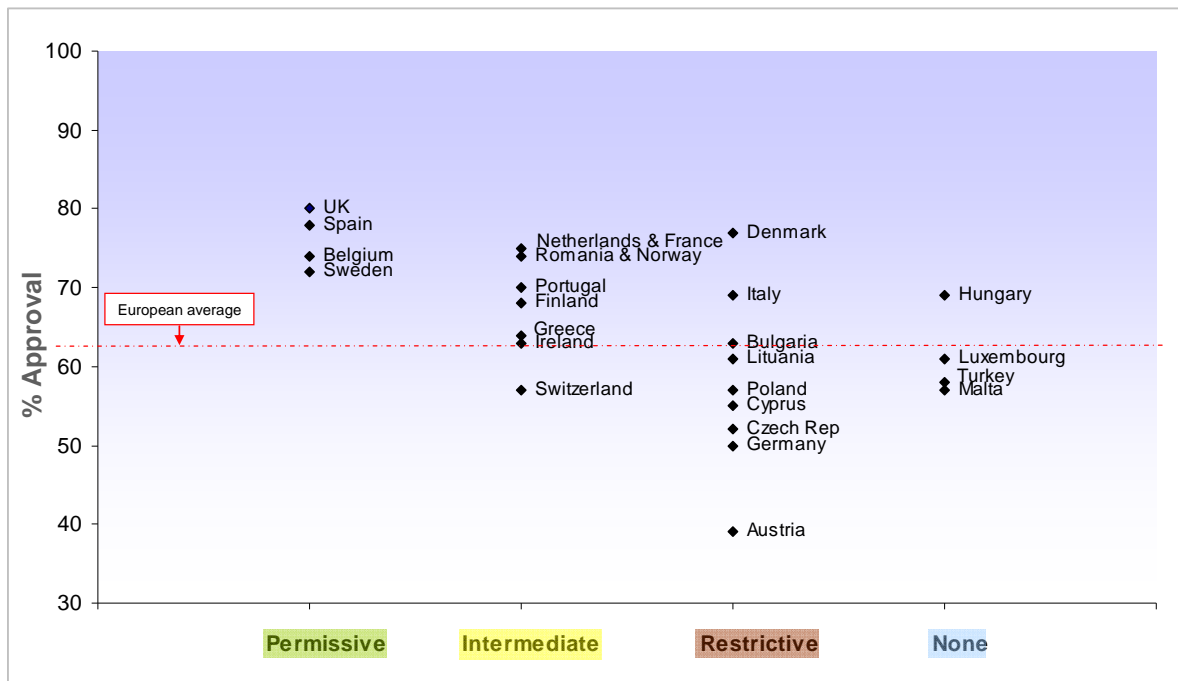
60 European Commission's Europeans and Biotechnology 2010 - [http://ec.europa.eu/research/science-society/document\\_library/pdf\\_06/europeans-biotechnology-in-2010\\_en.pdf](http://ec.europa.eu/research/science-society/document_library/pdf_06/europeans-biotechnology-in-2010_en.pdf)

of human embryos in stem cell research, while the attitude of participants from Austria, Poland, Germany and the Czech Republic registering the lowest level of support (between 39 and 52%; see Figure 3).

**Figure 2: European attitudes to biotechnology including stem cell research<sup>61</sup>**



**Figure 3: Level of approval for human ES cell research across Europe in relation to regulatory environment<sup>62</sup>**

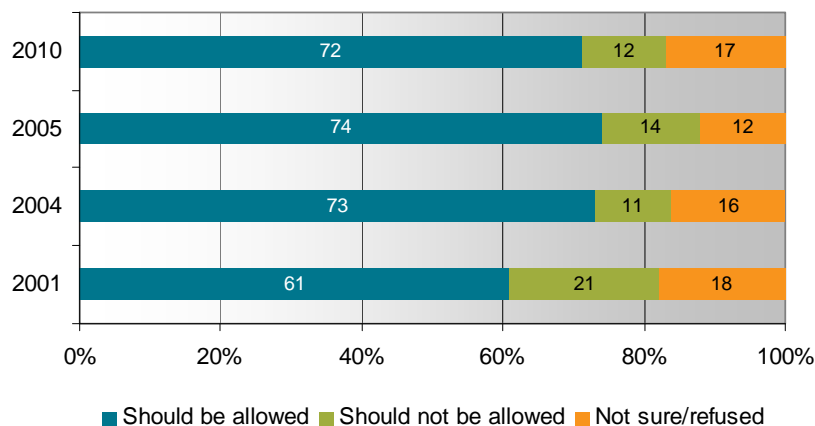


<sup>61</sup> [http://ec.europa.eu/research/science-society/document\\_library/pdf\\_06/europeans-biotechnology-in-2010\\_en.pdf](http://ec.europa.eu/research/science-society/document_library/pdf_06/europeans-biotechnology-in-2010_en.pdf)

<sup>62</sup> Prepared with data from European Commission's Europeans and Biotechnology 2010 Report and Stem Cell World Map published by StemGen, a module of the HumGen website ([www.humgen.org](http://www.humgen.org)).

When Americans were specifically asked if researchers should be allowed to use embryos left over from IVF that had been donated with full consent, 72% of participants were supportive with only 12% stating that this should not be allowed (see Figure 4). This high level of community support for the use of donated excess ART embryos, consistent with that observed in Australia, has been maintained since 2004 and continues despite strong opposition by the previous US federal government, under the Bush Administration, that restricted public funding for human ES cell research<sup>63</sup>.

**Figure 4: Public acceptance of human ES cell research in US<sup>64</sup>**



**Ongoing need for public education to enhance community understanding**

Whilst there remains a high level of support for stem cell research involving human embryos in Australia, keeping the public informed of developments in the field and their implications in a timely and responsible manner is essential if the level of community awareness and support is to be maintained.

In the last five years the discovery of iPS cells and a significant increase in the number overseas clinics and companies advertising stem cell-based treatments via the internet, demonstrates the need for public education in this area. Claims that iPS cells are an ‘ethical alternative’ to the ‘controversial’ use of human embryos for stem cell research<sup>65</sup>, ignores the situation that iPS cell research is not without significant ethical considerations and technical challenges. Questions regarding the reproducibility and stability of these cells and the feasibility of using this technology to create tailored cells to avoid rejection in therapy<sup>66</sup> and the potential to abuse this technology for reproductive cloning<sup>67</sup> are important aspects that must be considered in the evaluation of the impact of this new development.

Although clinical trials are now underway around the globe to evaluate new stem cell based therapies using human ES cells and other cell types, it remains unproven if such treatments are safe and effective. This, however, has not stopped a growing number of overseas clinics and companies advertising stem cell treatments for a myriad of conditions without scientific justification or even

63 Marwick C (2001) President Bush sidesteps critics in stem cell debate. *BMJ* 323(7309):357.

64 Data from Harris Interactive: Poll published 7 October 2010 -

<http://www.harrisinteractive.com/NewsRoom/HarrisPolls/tabid/447/mid/1508/articleId/579/ctl/ReadCustom%20Default/Default.aspx>

65 New stem cell technique shows ethical alternative to human embryonic cells (2010) [http://www.ewtnnews.com/catholic-](http://www.ewtnnews.com/catholic-news/US.php?id=1844)

[news/US.php?id=1844](http://www.ewtnnews.com/catholic-news/US.php?id=1844); Van Gend D (2010) An obituary for human cloning. *Viewpoint* 4:28-32.

66 Cyranoski D (2008) Stem cells: 5 things to know before jumping on the iPS bandwagon. *Nature* 452(7186):406-8.

67 Kou Z *et al.* (2010) Mice cloned from induced pluripotent stem cells (iPSCs) *Biol Reprod* 83(2):238-43; Zhou S *et al.* (2010) Successful

generation of cloned mice using nuclear transfer from induced pluripotent stem cells. *Cell Res* 20(7):850-3; Denker HW (2009) Ethical concerns over use of new cloning technique in humans. *Nature* 461(7262):341.

demonstration of safety<sup>68</sup>. Patients in Australia, desperate for anything to improve their plight, are turning to these overseas clinics and companies in the hope for an end to their suffering<sup>69</sup>.

Since its inception, the ASCC has made informing the public about developments in stem cell science and the ethical, legal and clinical implications a priority. The ASCC responds to hundreds of enquiries from the community and has developed targeted resources to provide detailed information<sup>70</sup>. With the cessation of our activities in June 2011, we are concerned that a balanced voice will be lost. While we welcome the recent announcement of the ARC Special Research Initiative, *Stem Cells Australia*<sup>71</sup>, which intends to have a public education component, concern remains whether the available funds will be sufficient to provide the same level of activity that the ASCC has been able to provide. As recommended in the Lockhart Review Report<sup>72</sup>, there should be ongoing public education and consultation programs in the areas of science that are relevant to the Acts.

#### 4.3 Brief analysis of international developments and legislation relating to the use of human embryos and related research

Internationally, a variety of approaches are taken to regulating human embryo research and therapeutic cloning (see Figure 5). Countries that are considered to exercise 'permissive' regulation that allows the derivation of human ES cells from excess ART embryos and embryos created via SCNT include: United Kingdom, Australia, 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 include Germany where scientists are only allowed to perform research on imported existing human ES cell lines created before 2007 and Italy, which only allows research on imported human ES cell lines. Interestingly, across Europe there is a correlation between public approval and a permissive legislative environment with countries with a permissive legislation environment also displaying some of the highest levels of public support (see Figure 3). A tabulated synopsis of the current status of international stem cell regulations can be found on our website<sup>73</sup>.

In the US, there is no federal legislation or regulations governing embryo research, including human cloning for research but specific States such as California, New York, and Connecticut have introduced permissive legislation (most recently Michigan in 2010)<sup>74</sup>. However, restrictions were previously imposed by the Bush Administration, limiting federal funding of human ES cell research to a select number of stem cell lines derived before 2001. In March 2009 President Obama issued an executive order<sup>75</sup> lifting this funding restriction. However, the use of US federal funds for stem cell research has subsequently been subject to a legal challenge which is ongoing<sup>76</sup>. Currently, US researchers can apply for National Institutes of Health (NIH) funds for research using approved human ES cell lines<sup>77</sup> but not for the creation of new human ES cell lines which must be undertaken with private or state funding due to a law known as the Dickey-Wicker amendment which forbids the use of federal funds for research that destroys an embryo. The lawsuit alleges that the federal funding of research using existing human ES cells is illegal as it also violates the Dickey-Wicker Amendment. A district judge presiding over the case originally put a stop to the NIH funding research, in August 2010, until the suit was finalised. However the NIH appealed the decision in the US Court of Appeals, which in September 2010 reversed the lower court judge's ruling, allowing funding to resume<sup>78</sup>. The

68 Ryan KA *et al.* (2010) Tracking the rise of stem cell tourism. *Regenerative Medicine* 5(1):27-33.

69 Seear K *et al.* (2010) *Hopeful Journeys: Experiences of Stem Cell Treatments Offered Outside Australia*. Prepared for National Enabling Technologies Program, DIISR. Monash University. ISBN: 978-0-9807530-4-2.

70 Editorial (2010) Regulators must step up stem cell oversight *Nature Medicine* 16(5):492; Sanderson A (2010) Hands on stem cells: how to make the elusive science of stem cells tangible for the classroom. *Teaching Science* 56(4):34-37.

71 [http://www.arc.gov.au/ncgp/sri/SRI\\_11\\_selrpt.htm#10](http://www.arc.gov.au/ncgp/sri/SRI_11_selrpt.htm#10)

72 [http://www.nhmrc.gov.au/files/nhmrc/file/research/embryos/review/legislation\\_review\\_reports\\_full\\_doc\\_19dec05.pdf](http://www.nhmrc.gov.au/files/nhmrc/file/research/embryos/review/legislation_review_reports_full_doc_19dec05.pdf)

73 <http://www.stemcellcentre.edu.au/site/DefaultSite/filesystem/documents/For%20the%20Public/Global%20Regulation%20of%20Human%20Embryonic%20Stem%20Cell%20Research%20Feb%202011.pdf>

74 <http://www.ncsl.org/default.aspx?tabid=14413>

75 Executive Order 13505 <http://edocket.access.gpo.gov/2009/pdf/E9-5441.pdf>

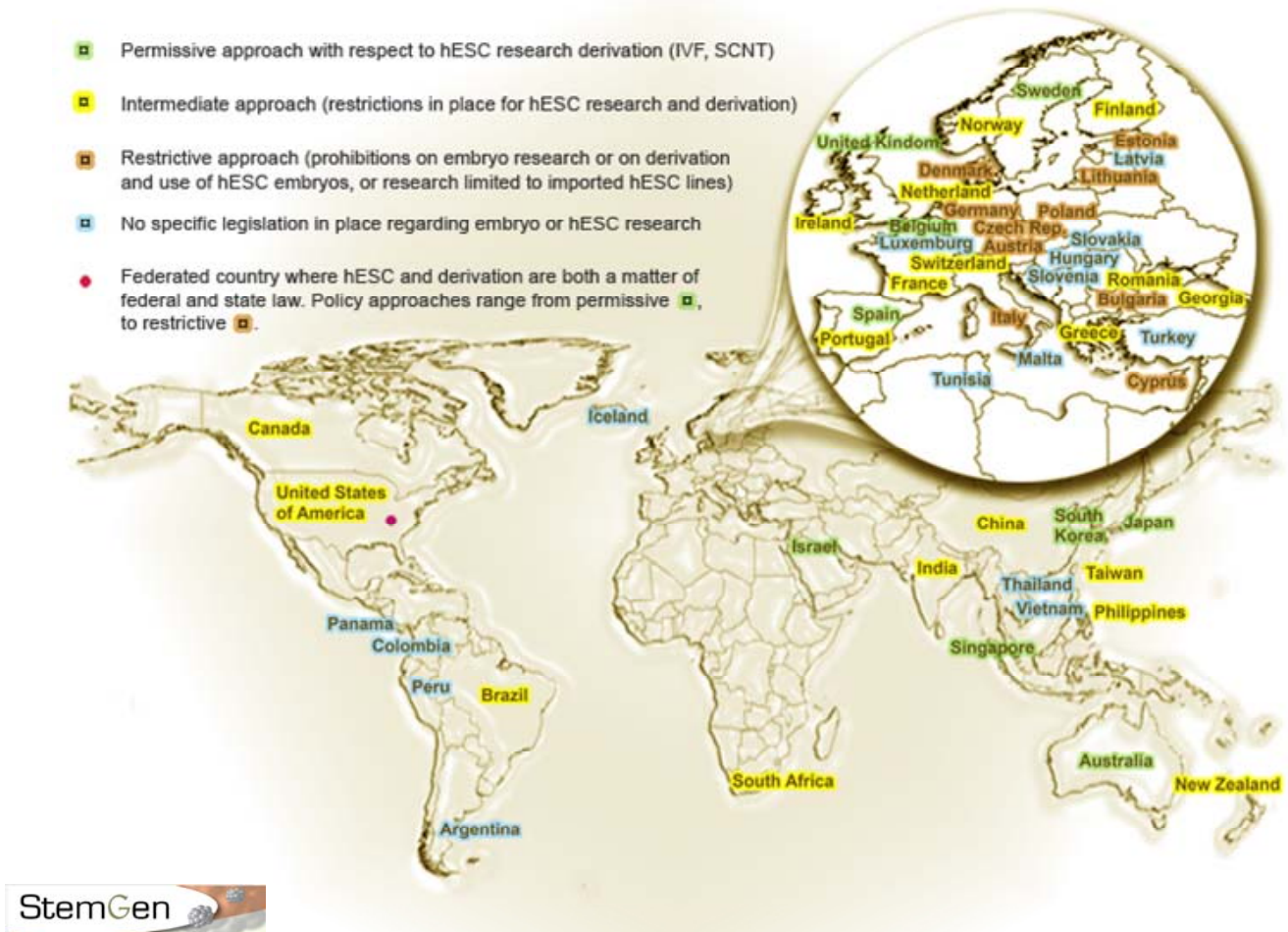
76 <http://www.economist.com/node/17672816>

77 [http://grants.nih.gov/stem\\_cells/registry/current.htm](http://grants.nih.gov/stem_cells/registry/current.htm)

78 [http://blogs.nature.com/news/thegreatbeyond/2010/09/appeals\\_court\\_temporarily\\_lift\\_1.html](http://blogs.nature.com/news/thegreatbeyond/2010/09/appeals_court_temporarily_lift_1.html)

court case is ongoing. A recent survey of US stem cell scientists shows that uncertainty following this ongoing legal action is likely to have negative scientific and economic impacts and affect the research of a range of stem cell scientists, not just those working with human ES cells<sup>79</sup>.

**Figure 5: Global regulatory environment for human ES cell research and derivation<sup>80</sup>**



#### 4.4 An analysis of research resulting from the licences granted

Since 2004, there have been 13 licences granted to Australian researchers to use human embryos in research. Five of these projects were granted for research related to improvements in ART technologies; five for human ES cell derivation from donated excess ART embryos; with three more licences recently granted to Sydney IVF for the derivation of human ES cells from SCNT embryos (see Figure 6).

Human ES cell lines derived in licensed research projects have been used extensively by Australian and international scientists in a wide range of research. MEL-1 and MEL-2, derived under Licence 309709, were characterised as part of the [International Stem Cell Initiative](#)<sup>81</sup> and have also been used

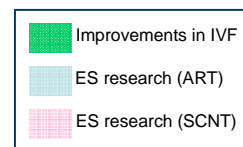
79 Levine AD (2011) Policy uncertainty and the conduct of stem cell research. *Cell Stem Cell* 8(2):132-135.

80 Stem Cell World Map published by StemGen, a module of the HumGen website ([www.humgen.org](http://www.humgen.org)).

81 Adewumi O *et al.* (2007) Characterization of human embryonic stem cell lines by the International Stem Cell Initiative. *Nat Biotechnol* 25(7):803-16.

in projects comparing characteristics of different human stem cell lines<sup>82</sup>, to develop new culture media, cell lines for research and improve understanding of differentiation<sup>83</sup>, as well as comparative studies with iPS cells<sup>84</sup>. Sydney IVF has derived 22 disease-specific cell lines (under Licence 309710) and 21 unaffected cell lines<sup>85</sup> (under Licence 309703). Recently four human ES cell lines were derived from embryos identified as affected by Huntington's disease (HD)<sup>86</sup>. These HD-affected human ES cell lines will be made available to biomedical research laboratories and will provide a valuable tool to investigate the mechanisms and potential treatments for HD.

**Figure 6: NHMRC Licences granted to Australian researchers**



Licence	Organisation	Licence Title
309700	Monash IVF Ltd	Use of Excess ART Embryos for Training in Embryo Biopsy
309701	Sydney IVF Ltd	Improvements in Laboratory Conditions for Embryo Culture
309702a	Sydney IVF Ltd	Effect of an Additive on Embryo Culture: Analysis of Growth and Epigenetic Programming
309702b	Sydney IVF Ltd	Development of Methods for Preimplantation Genetic and Metabolic Evaluation of Human Embryos
309703	Sydney IVF Ltd	Development of Human Embryonic Stem (ES) Cells
309704	Melbourne IVF Pty Ltd	Development of Testing Procedures for Unbalanced Chromosome Errors in Human Embryos
309707	Monash University	Derivation of Embryonic Stem Cell Lines from the Human Embryo
309708	IVF Australia Pty Ltd	A collaborative Project Between IVF Australia and the Diabetes Transplant Unit, Prince of Wales Hospital to Derive Human Embryonic Stem Cell Lines for the Treatment of Diabetes
309709	Melbourne IVF Pty Ltd	A Collaborative Project Between Melbourne IVF Pty Ltd and Stem Cell Sciences Ltd to Derive Human Embryonic Stem Cell Lines
309710	Sydney IVF Ltd	Derivation of human embryonic stem cells from embryos identified through preimplantation genetic diagnosis to be affected by know genetic conditions
309712	Sydney IVF Ltd	Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from adult human fibroblasts into clinically unusable human eggs.
309712	Sydney IVF Ltd	Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from adult human fibroblasts into clinically unusable human eggs.
309714	Sydney IVF Ltd	Reproducible production of human embryonic stem cell lines from somatic cell nuclear transfer (SCNT) of nuclei from adult human fibroblasts into clinically unusable human eggs.

82 Kolle G *et al.* (2009) Identification of human embryonic stem cell surface markers by combined membrane-polysome translation state array analysis and immunotranscriptional profiling. *Stem Cells* 27:2446–2456; Laurent L *et al.* (2010) Restricted ethnic diversity in human embryonic stem cells. *Nature Methods* 7(1):6-7.

83 Goulburn AL *et al.* (2011) A targeted NKX2.1 HESC reporter line enables identification of human basal forebrain derivations. *Stem Cells* Jan 7 [Epub ahead of print]; Davis *et al.* (2008) A protocol for removal of antibiotic resistance cassettes from human embryonic stem cells genetically modified by homologous recombination or transgenesis. *Nat Protoc* 3(10):1550-8; Ng E *et al.* (2008) A protocol describing the use of a recombinant protein-based, animal product-free medium (APEL) for human embryonic stem cell differentiation as spin embryoid bodies. *Nat Protoc* 3(5):768-76; Costa M *et al.* (2007) A method for genetic modification of human embryonic stem cells using electroporation. *Nat Protoc* 2(4):792-6.

84 Laurent L *et al.* (2011) Dynamic changes in the copy number of pluripotency and cell proliferation genes in human ES and iPS cells during reprogramming and time in culture. *Cell Stem Cell* 8(1):106-18.

85 Bradley CK *et al.* (2010) Derivation of three new human embryonic stem cell lines. *In Vitro Cell Dev Biol Anim.* 46(3-4):294-9; <http://www.sydneyivfstemcells.com/AboutUs/Ourstemcells/tabid/648/Default.aspx>

86 Bradley CK *et al.* (2011) Derivation of Huntington's Disease-Affected Human Embryonic Stem Cell Lines. *Stem Cells Dev* 20(3):495-502.

The MISCES-01 human ES cell line, derived under Licence 309707, has been used by researchers at Monash University and their collaborators. In a recently published paper, the method of derivation and growth of these cells was described. Importantly this line was developed under conditions that did not rely on animal support cells<sup>87</sup>. This is a critical step towards deriving cGMP (current Good Manufacturing Practice) ES cells which will be required for human clinical use.

Researchers at the University of New South Wales have also reported the derivation of human ES cell lines, Endeavour-1 and Endeavour-2<sup>88</sup> (derived under Licence 309708). Endeavour-2 is the first Australian human ES cell line, derived under NHMRC licensing system, to be registered on the NIH Human Embryonic Stem Cell Registry making them available to researchers with funding from the NIH<sup>89</sup>.

The ASCC currently provides the MEL and MISCES lines to Australian researchers through its StemCore facility<sup>90</sup>. International researchers can obtain the MEL-1 and MEL-2 lines through the UK Stem Cell Bank or through Millipore<sup>91</sup>. An application to have the MEL lines included in the NIH Human Embryonic Stem Cell Registry is pending. During the last four years, MEL-1 and MEL-2 have been distributed to 175 Millipore customers. Across Australia 26 research groups have been supplied with MEL stem cell lines or cells made from them.

#### 4.5 Any National Stem Cell Centre and any national register of donated excess ART embryos

The ASCC, as a dedicated funding body for stem cell research in Australia, welcomes the opportunity to make a written submission to the 2010 Review. Members of ASCC Board and Senior Management are available throughout March, April and May 2011 if the Review Committee requires any clarification in relation to our submission, or any additional information or assistance ahead of finalising their recommendations in May 2011.

In addition to our role in providing funding to support stem cell research in Australia, we have also assisted in the creation and distribution of human pluripotent stem cell lines, both ES and iPS. Specifically, we have provided financial assistance to two NHMRC licensed projects (Licence 309707 and Licence 309709) to derive the MEL and MISCES human stem cell lines and to specifically assist in their characterisation. Through our StemCore facility, we have distributed MEL lines to researchers across Australia and internationally in association with Millipore (see section 4.4). Furthermore, we have provided training programs to ensure Australian researchers wishing to use pluripotent stem cells in their research have the necessary skills to effectively conduct their experiments. Such an independent facility has proven to be an effective model both in Australia and internationally.

We are concerned that with the cessation of Commonwealth's funding of ASCC's operations from 30 June 2011 this valuable service will be lost and we recommend that consideration should be given to facilitating Australian researchers' access to human embryonic and other pluripotent stem cell lines, provided they have been created in conditions consistent with Australian regulations (**ASCC Recommendation 4**). Although we recognise that this recommendation falls outside the operations of the Acts, we have taken this opportunity to raise this issue as effective distribution and sharing of human ES cell lines has important implications for the numbers of embryos used in research.

One consideration could be a national registry of human pluripotent stem cell lines, derived in accordance with Australian regulations. Such a registry could be hosted by the NHMRC and include information on the provenance of the material and any restriction or special consideration in the use

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87 Tecirlioglu RT *et al.* (2010) Derivation and maintenance of human embryonic stem cell line on human adult skin fibroblast feeder cells in serum replacement medium. *In Vitro Cell Dev Biol Anim* 46(3-4):231-5.

88 Sidhu KS *et al.* (2008) Derivation of a new human embryonic stem cell line, Endeavour-1, and its clonal propagation. *Stem Cells Dev* 17(1):41-51; Sidhu KS *et al.* (2010) Derivation of a new human embryonic stem cell line, Endeavour-2, and its characterization. *In Vitro Cell Dev Biol Anim* 46(3-4):269-75.

89. [http://grants.nih.gov/stem\\_cells/registry/current.htm?sort=dtc](http://grants.nih.gov/stem_cells/registry/current.htm?sort=dtc)

90 [http://www.stemcellcentre.edu.au/Services\\_and\\_Infrastructure/StemCore/Accessstocelllines.aspx](http://www.stemcellcentre.edu.au/Services_and_Infrastructure/StemCore/Accessstocelllines.aspx)

91 <http://www.ukstemcellbank.org.uk/>; <http://www.millipore.com/catalogue/item/SCC020>

of specific cell lines. This would be an invaluable resource for Australian researchers and a point of reference for members of Australian human ethics committees. The site could be structured in a similar way to the US NIH Human Embryonic Stem Cell Registry.

In a recent survey of ASCC funded researchers<sup>92</sup>, 80% of participants agreed that there was a need for a central registry of stem cell lines available in Australia. Participants in the survey had a wide range of seniority and experience in stem cell science including just over a third who did not use human or mouse ES cells in their research instead utilising other stem cell types.

Findings from the survey also acknowledged that there is an ongoing requirement for a service to distribute human pluripotent stem cell lines throughout Australia, with 82% of all scientists surveyed in support:

*“The ASCC provides a vital service in establishing availability and maintenance of all the lines we currently use. If they no longer perform this function for Australian researchers then great inefficiencies will result as each lab replicates their work. Results will suffer and grants will be wasted on maintenance rather than original research.”*

At this time, the ASCC does not see the need for a national stem cell bank for human ES cells of the scope and scale exemplified by to the UK Stem Cell Bank and others<sup>93</sup>. Rather we would support the maintenance of a central facility such as StemCore to provide assistance in the characterisation and distribution of research materials with the additional capacity of training Australian scientists.

The ASCC is unaware of a need for a registry of donated excess ART embryos. Whilst not involved in the recruitment of embryo donors for licensed research projects, we understand licence holders and their partners have not had difficulty accessing excess embryos for their project.

#### **4.6 An analysis of any research or clinical practice which has been prevented as a result of legislative restrictions**

The ASCC does not see any evidence that research or clinical practice in Australian stem cell science has been hindered by the current regulatory framework. The ASCC recommends that the current national regulatory framework that oversees the responsible use of human embryos for research should continue without change (**ASCC Recommendation 1**).

Our opinion is supported by feedback from our funded researchers. When asked in a recent electronic questionnaire whether there are any restrictive aspects of the current legislation only 11% stated that they found the current legislation restrictive with 37% stating that there was no restriction and 53% unsure or did not know. However, those few concerned about restrictions to research in Australia were calling for a relaxation in the licensing process:

*“While I support regulation in this area the current regulations are quite restrictive and do not take into account the time and resource constraints of small or even medium sized research groups to deal with licensing from NHMRC, let alone providing the funding to actually establish new lines and develop the Australian expertise to do so”.*

The ASCC believes that a specific amendment to the legislation to allow the use of animal eggs for SCNT should not be pursued until such time as there is stronger scientific justification of merit (see Section 4.1).

Of the researchers who have collaborations overseas, less than 7% stated that the current legislation impeded or adversely impacted on their overseas collaboration.

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92 Survey was conducted as part of the ASCC's consultation in relation to the 2010 Review – see section 6.0.

93 Stacey G and Hunt CJ (2006) The UK Stem Cell Bank: a UK government-funded, international resource center for stem cell research. *Regen Med* 1(1):139-42; Hopkins TJ (2004) US government to open national bank of “approved” embryonic stem cells. *BMJ* 329(7459):190.

#### 4.7 An evaluation of the effectiveness of legislative provisions and NHMRC guidelines relating to proper consent

The ASCC fully supports the importance currently placed on obtaining proper consent as part of any licensed research involving human embryos in Australia. This is an essential aspect of the current regulatory framework that should continue into the future. It is testament to the stringency of the Australian regulatory framework that human ES cell lines derived in Australia under the current regulatory framework satisfy the rigorous standards of the US NIH in relation to proper consent<sup>94</sup> as seen by the recent listing of the Endeavour-2 cell line (derived under NHMRC Licence 309708) on the NIH Human Embryonic Stem Cell Registry. Registration of the MEL lines (derived under NHMRC Licence 309709) is pending but appears to be consistent with all key criteria required by NIH.

#### 4.8 An evaluation of the range of matters for which the NHMRC Licensing Committee may issue a licence and any recommendations to increase, decrease or alter these arising from the evaluation

The ASCC believes it is essential that the current national regulatory framework should continue without change and that Australian stem cell scientists retain the opportunity to apply for licences to use donated excess ART embryos and SCNT human embryos (**ASCC Recommendations 1 & 2**). Recent developments in iPS cell technology do not obviate this need, as they are not yet recognised as being equivalent to human ES cells by the scientific community (see section 4.1). Human ES cells are going to continue to be an invaluable aspect of stem cell research in Australia and around the world<sup>95</sup>. Any modification to the Australian legislation resulting in a decrease in the range of matters for which the NHMRC Licensing Committee may issue a licence would be a retrograde step and would compromise Australia's position as a leader of stem cell research.

The current regulatory framework works well. From a compliance perspective there is a system in place to monitor licence holder activities and to ensure prohibited practices are not being conducted in Australia. The NHMRC Licensing Committee oversees the regular monitoring activities and oversees the investigation of any potential irregularities that are brought to its attention. The Committee reports regularly (every six months) to the Parliament of Australia on its activities and to date there have been no instances of non-compliance reported<sup>96</sup>.

However, the ASCC does not support any extension to the remit of the current legislation to cover the use of derivatives of human ES cells in stem cell research. The use of research using human ES cell lines derived in NHMRC licensed projects, or derived in conditions consistent with Australian legislation, should be regulated by existing national guidelines on ethical use of animal and human material in research (**ASCC Recommendation 3**). These diploid cells, which are no longer capable of forming a new human being on their own, should be regulated by existing guidelines, such as the *National Statement on Ethical Conduct in Research In Human Research* (2007, NHMRC<sup>97</sup>) and the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2007, NHMRC) in the same manner as human cells obtained from tissue biopsies. Clinical research must continue to comply with regulations administered by the Therapeutic Goods Administration.

Our opinion is supported by feedback from our funded researchers. Although over 90% of our funded ES researchers stated in a recent survey that the currently available human ES cell lines met their research requirements, only 9% did not see the need for access to new human ES cell lines.

94 [http://hescregapp.od.nih.gov/NIH\\_Form\\_2890\\_Login.htm](http://hescregapp.od.nih.gov/NIH_Form_2890_Login.htm)

95 Hyun I *et al.* (2007) New advances in iPS cell research do not obviate the need for human embryonic stem cells. *Cell Stem Cell* 1(4):367-8; Laurent LC *et al.* (2010) Restricted ethnic diversity in human embryonic stem cell lines. *Nature Methods* 7(1):6-7.

96 A listing of NHMRC Licensing Committee reports to the Parliament of Australia can be found at <http://www.nhmrc.gov.au/research/embryos/information/reports/index.htm>

97 The National Statement was jointly developed by NHMRC, Australian Research Council and the Australian Vice-Chancellors' Committee.

When specifically asked if the discovery of human iPS cell technology replaced the need to use human ES cells in research, there were no researchers who agreed with the statement. The majority stated that either “No, and it is unlikely to ever displace the need for human ES cells” (49%) and “No, but it may in the future” (33%):

*“Human ES and iPS are simply two different cell types, and this is supported by an increasing body of genetic, epigenetic and other evidence. The differences between the different types of pluripotent cells are interesting scientific phenomena in themselves and warrant further investigation. Frankly, the idea that at this point iPS cells have replaced the need to use human ES cells betrays the ignorance its proponents.”*

*“There are still uncertainties surrounding iPS technology and there is inherent variability in the creation and propagation of human ES cells. It is essential that human ES cell research proceed in parallel so that technological advances can be made in both areas.”*

Furthermore, when asked whether Australian researchers should retain the ability to use human embryos to create new human ES cell lines in light of iPS developments, 92% were supportive, with some stating:

*“Essential, otherwise we lag behind.”*

*“Yes this is essential for our international competitiveness. New technological advances are being made all the time and we need to have freedom to be creative in this realm”*

There was also strong support for the licensing process with 80% agreeing that the creation of new human ES cell lines from donated, excess ART embryos should continue to require a licence:

*“I am happy for regulation and licences in principle however the overhead has to be streamlined so that especially smaller research groups can access the system and obtain any such licence”*

When specifically asked if the discovery of human iPS cell technology replaced the need for SCNT for human ES derivation, only 10% believed that iPS developments now replaced the need for SCNT. Strong support (87% of participants) was indicated for continued capacity to apply to NHMRC for a licence to create and use SCNT embryos in research:

*“.. Studies need to determine that iPS can replace SCNT before the option to generate SCNT is repealed.”*

*“There are still uncertainties surrounding iPS technology and SCNT is still the most efficacious way to reprogram human somatic cells to a pluripotent state”*

One researcher also stated that they would like to see the possible use of animal eggs for human SCNT research be allowed in Australia but as can be seen from the quote, this did not appear to be a strong position:

*“Perhaps freedom for creating animal - human hybrids but this is not essential”*

The ASCC believes that a specific amendment to the legislation to allow the use of animal eggs for SCNT should not be pursued until such time as there is stronger scientific justification of merit (see Section 4.1).

When asked to rank the impact on Australian stem cell research of any 2010 Review recommendation/s that may restrict the use of human embryos for the derivation of new human ES cell lines, the majority of those responding (74%) anticipated either a significant or moderate adverse impact on Australian stem cell science.

*“This would be a serious retrograde step and seriously restrict our ability to perform frontier and breakthrough science. Human ES cell technology is still evolving and we need every opportunity to stay abreast of the field internationally and innovate. Ethical issues have been worked through in this country and such a step would necessitate debating again these issues, retarding our progress by many years.”*

#### **4.9 The extent to which the NHMRC Licensing Committee has effectively used information and education tools to assist researchers working in the field, and any ongoing need for legally binding rulings**

The ASCC believes the NHMRC Licensing Committee provides invaluable guidance and useful information to assist Australian researchers working in stem cell science. However, when asked

whether they had read the information available from the NHMRC about how the current legislation regulates the use of human embryos in research, the majority (69%) of ASCC funded researchers had not read the information. Importantly, of those that had read the available information from the NHMRC, 83% commented that it was clear and easy to understand with one researcher commenting:

*“Comprehensive but complicated series of documents available from NHMRC website online”*

It should be noted that the participation of ASCC researchers in the study was not limited to those working on human ES cells, with just over a third of participants involved in research that did not involve human or mouse ES cells.

It has also been our observation that there is a gap in information about the breadth of the current legislation. There seems to be a perception both in the general community and in scientific circles that these Acts form the ‘stem cell legislation’. This has caused some difficulties for researchers who have requested approval from their institutional human ethics committees to use existing human ES cell lines but experienced delays as the ethics committees seek clarification. This could be addressed by:

- refining the National Statement on Ethical Conduct in Human Research (2007), a process the ASCC understands is underway;
- maintaining and publishing a list of human ES cell lines that have been derived in a manner consistent with Australian regulations, similar to the NIH Human Embryonic Stem Cell Registry (see section 4.5), and
- encouraging an ongoing education strategy to keep ethics committee members abreast of developments in the stem cell field.

#### **4.10 The extent of Commonwealth/State cooperation in the area of human embryo research and the requirement for further Commonwealth or State legislation on the matter**

The ASCC welcomes introduction of legislation in Victoria, New South Wales, Queensland, Tasmania, South Australia and the Australian Capital Territory supporting the use of human embryos for research and mirroring the Commonwealth legislation, in particular the changes introduced in the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006*. Whilst amending legislation to allow SCNT was defeated in 2008 in Western Australia, we are not aware of any stem cell research that has been compromised or prevented due to this inconsistency<sup>98</sup>. In a recent survey conducted by the ASCC, only 11% of our funded researchers stated that they found the current legislation restrictive. However, comments were restricted to calls to relax licensing regulations (see section 4.8).

The ASCC fully supports the current national regulatory framework that oversees the responsible use of human embryos in Australian research and believes this should continue without change (**ASCC Recommendation 1**).

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<sup>98</sup> The ASCC does not directly fund any research groups in Western Australia, but through our StemCore facility supplies cells created from human ES cells.

## 5 Glossary and Abbreviations

<b>2005 Review</b>	Independent review of the legislation pertaining to the use of human embryos in research, conducted in 2010 and chaired by the late Justice Lockhart
<b>2010 Review</b>	Independent review of the legislation pertaining to the use of human embryos in research, PHCR Act and RIHE Act
<b>Adult stem cells</b>	Undifferentiated cells found in the tissues and organs of the body. Often referred to as tissue stem cells. They are capable of self-renewal and their differentiation is mainly restricted to forming the cell types of that tissue or organ. The chief role of adult stem cells is to maintain and repair the tissue in which they are found.
<b>ACT</b>	Advanced Cell Technology
<b>ALS</b>	Amyotrophic Lateral Sclerosis or Motor Neurone disease
<b>ARC</b>	Australian Research Council
<b>ART</b>	Assisted Reproductive Technology
<b>ASCC</b>	Australian Stem Cell Centre
<b>Centre</b>	Australian Stem Cell Centre
<b>CIRM</b>	Californian Institute of Regenerative Medicine
<b>DIISR</b>	Department of Innovation, Industry, Science and Research
<b>Endeavour</b>	Series of human ES cell lines derived in NHMRC licensed research project
<b>ES cells</b>	Embryonic Stem Cells; created from a four to seven day old blastocyst (early embryo). They have the ability to form virtually any type of cell found in the human body, but are not capable of developing into a whole new organism on their own
<b>HD</b>	Huntington's disease
<b>iPS cells</b>	Induced Pluripotent Stem cells; created by reprogramming mature cells to become pluripotent stem cells similar in many ways to ES cells.
<b>IVF</b>	<i>In Vitro</i> Fertilisation
<b>MEL</b>	Series of human ES cell lines derived in NHMRC licensed research project
<b>MISCES</b>	Human ES cell lines derived in NHMRC licensed research project
<b>MS</b>	Multiple Sclerosis
<b>NIH</b>	US National Institutes of Health
<b>NHMRC</b>	National Health and Medical Research Council
<b>PHCR Act</b>	<i>Prohibition of Human Cloning for Reproduction Act 2002</i>
<b>Pluripotent</b>	Characteristic of certain stem cells where they have the ability to develop into all of the different types of cells in the body.
<b>RIHE Act</b>	<i>Research Involving Human Embryos Act 2002</i>
<b>SCNT</b>	Somatic Cell Nuclear Transfer
<b>Somatic cell</b>	Any cell of the body apart from egg and sperm
<b>UK</b>	United Kingdom
<b>US</b>	United States of America

## 6 Consultation Process for the Preparation of Position Paper

This submission represents the views of the Directors of the ASCC Board and ASCC Senior Management.

To assist in formulating these views, we consulted widely with our funded researchers and staff. Given the importance of the current legislation to the Australian stem cell community, in late 2010 we canvassed the opinion of over 160 scientists associated with ASCC funded research involving iPS, adult and embryonic stem cells. Researchers were asked to complete an anonymous electronic questionnaire designed to capture their experiences of, and opinion on, the current operations of the PHRC and RIHE Acts and developments in the stem cell field since the 2005 Review. They were also invited to participate in further discussions on this topic. Forty researchers with a wide range of experience in stem cell science participated in the electronic survey including postdoctoral students (15%), research assistants (26%), postdoctoral scientists (28%) and laboratory or departmental heads (31%). Although the majority of those responding were using human ES cells in some aspect of their research, participation in the study was not limited to researchers working on human ES cells. Just over a third of participants were engaged in research that did not specifically involve human or mouse ES cells.

ASCC staff were also invited to participate in the preparation of the ASCC submission. The ASCC also discussed the 2010 Review and its implication for the field with representatives from ASCC Stakeholders to identify key issues. Key representatives of the wider Australian stem cell community; IVF groups; the patient community; Australian and international stem cell networks; industry and government representatives, and key individuals interested in the area were also contacted.

We acknowledge that this submission may not be in complete alignment with the view of all individuals consulted. However, where possible we attempted to reflect where a consensus view was not held.

The final draft of this submission was provided to the Chair of the ASCC Scientific Advisory Board, Professor Patrick Tam, and the Chair of the ASCC Senior Scientific Faculty, Professor Andrew Elefanty, for review ahead of endorsement and approval by ASCC Board and Senior Management.

In addition to lodging our submission on the 2010 Legislation Review website, the ASCC submission was provided to:

- all stakeholders of the ASCC;
- all ASCC funded researchers, students and employees;
- key representatives in the Australian stem cell community, Australian biotechnology industry, and patient advocacy groups, and
- the general public via the ASCC website ([www.stemcellcentre.edu.au/For the Public/Legislation/Legislative Review 2011](http://www.stemcellcentre.edu.au/For_the_Public/Legislation/Legislative_Review_2011))

## 7 About ASCC

The ASCC was founded to capitalise on Australia's significant strengths in the field of stem cell research. The ASCC was selected in 2002, in a competitive bid process, as Australia's Biotechnology Centre of Excellence, an initiative of the then Australian Government. The Centre provides a unique national resource for stem cell researchers to deliver outcomes that benefit the wider Australian biotechnology industry and which will ultimately benefit human health.

The Centre was established with the financial and in-kind support of a number of institutions of which the current voting Members, who retain ultimate oversight of the Centre, are: Monash University, University of Queensland, Howard Florey Institute and University of Adelaide. The additional Stakeholder institutes are: University of Melbourne, Baker IDI, Murdoch Children's Research Institute, Victor Chang Cardiac Research Institute and Mater Medical Research Institute.

The ASCC is governed by a Board of Directors with independent scientific oversight and support from an eminent Scientific Advisory Board.

Total funding of \$100 million has been awarded to the ASCC by the Australian Government and is administered by the Australian Research Council and the Department of Innovation, Industry, Science and Research. The funding is provided in instalments from 2002 to 2011. To complement Australian Government funding, the State Government of Victoria's Science Technology and Innovation program awarded the ASCC a further \$11 million to support key infrastructure in Victoria.

Together the ASCC and partnering organisations support a critical mass of Australian stem cell research that is internationally competitive. The ASCC currently funds research at leading institutes and universities in Victoria, Queensland, South Australia and New South Wales with the major hubs of activity centred in Victoria and Queensland.

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