# LEGAL REGULATION OF HUMAN CLONING AND EMBRYO RESEARCH: THE FORTHCOMING REVIEW

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## LEGISLATION ON HUMAN CLONING AND EMBRYO RESEARCH

In 2002, two Acts were passed by the federal parliament to regulate human cloning and embryo research - the *Prohibition of Human Cloning Act 2002 (Cth)* ('the *Prohibition Act*') and the *Research Involving Human Embryos Act 2002 (Cth)* ('the *Research Act*').[1]

The *Prohibition Act* prohibited human cloning and a range of other research activities involving human bodily material and provided substantial penalties for breach of its provisions. It was designed to assuage community concerns about certain types of research by totally banning activities such as human cloning to breed identical people; combining human and animal gametes (sperm and eggs) to breed half-human and half-animal hybrids; allowing a human research embryo to develop longer than 14 days; and the sale of human eggs. All of these provisions are still in the current Act (the *Prohibition of Human Cloning for Reproduction Act 2002 (Cth)*[2]).

The *Research Act* allowed certain research on human embryos and human genetic material to be conducted, provided that the researcher obtained a licence from the Embryo Research Licensing Committee of the National Health and Medical Research Council (NHMRC) and complied with strict reporting requirements, subject to conditions set out in the Act. The research also had to be approved and monitored by an institutional ethics committee. To obtain a licence, scientists must justify the use of human embryos and use as few embryos as possible to achieve the aims of their research. Under this Act, the only human embryos that could be used in research were embryos that had been formed in fertility treatment programs but were no longer needed by the couples whose gametes (sperm and eggs) were used to create them and who wanted to donate them for research. Scientists were not permitted to create human embryos specifically for research.

The two Acts aimed for a compromise between scientists wanting to do research on early human embryos and the stem cells derived from them and people who opposed the use of human embryos in research. Scientists would know that they could lawfully undertake particular activities as long as they obeyed 'the rules'. The number of human embryos that could be used in research was limited by the licensing process and ethical review. And the only embryos that could be used in research were those donated from fertility programs that would otherwise have to be discarded by law after a certain period of storage.

The attempted compromise was not accepted by many opponents of human embryo research, who view human embryos as persons, or potential persons,[3] or at least of special moral significance, whether those embryos are 'excess' embryos formed for fertility treatment but no longer needed, or embryos created specifically for research. However, it enabled some human research to be done, both to improve fertility treatment procedures and to derive human embryos for stem cell research.

## THE LOCKHART COMMITTEE AND ITS PRINCIPAL RECOMMENDATIONS

The 2002 legislation stated that it had to be reviewed three years after it came into effect and in 2005 an extensive review was undertaken by a federal committee whose categories of members and terms of reference were stated in the 2002 legislation. This committee was known as the Lockhart Committee, named after its Chair, the late retired Federal Court judge, John Lockhart AO QC. The present author was Deputy Chair and official spokesperson for the Committee after the death of the Chair shortly after the Committee's report was tabled in Parliament.

The Committee produced a substantial report[4] after extensive and wide-ranging community consultation throughout the country. The federal legislation and the legislation in most states was amended to implement the Committee's recommendations.[5] That amending legislation requires that another review must be undertaken three years after it became effective, which means by the end of 2010. However, at the time of writing, the review process has not commenced and no one has been appointed to undertake the review.

The Lockhart Committee made 54 recommendations. The principal recommendations were as follows:

- The legislative framework and prohibited practices in the 2002

legislation should remain in place, including the ban on reproductive cloning and creating an embryo for research by fertilising a human sperm and egg; and the prohibition on selling human eggs.

- Therapeutic cloning, also known as somatic cell nuclear transfer (SCNT), should be permitted for research, subject to the same requirements of licensing, reporting and ethical review as those for other types of human embryo research. SCNT is the 'Dolly technique' in which an embryo is formed from a somatic or body cell, not by a sperm fertilising an egg. This type of embryo has genetic material (DNA) almost entirely from the person whose body cell was used to form the embryo, with only a small amount of mitochondrial DNA coming from the egg that was used to 'incubate' the DNA from that person. Stem cells derived from that embryo would be 'matched' to the person so that if they were used for treatment in future, they would not be rejected by the person's immuno-suppressive system, like material donated from another person.
- Research should be permitted on human embryos formed for fertility treatment that are not fit for implantation (formerly, these embryos were discarded, because only embryos that had been frozen for later implantation and then declared 'excess' were available for research, due to the waiting periods required in seeking consent for donation for embryos).
- Research should be allowed on an egg in the process of fertilisation, provided it stops at the point of syngamy when an embryo is formed. (This provision retains the ban on forming a human embryo for research by combining human sperm and eggs but allows important research on an egg being fertilised which may help understand more about foetal abnormalities).
- Provisions regarding consent, administrative procedures and oversight should be reviewed, with relevant guidelines and procedures being amended as necessary.
- It should be lawful to create human-animal hybrid or chimeric embryos using animal eggs, for research, so that research on embryonic stem cells can proceed despite the small number of human eggs donated for research. (These embryos formed using an enucleated animal egg would, like embryos formed by SCNT, contain almost entirely the DNA from the person whose DNA is used to create them.)
- It should be lawful to create embryos for research that contain DNA from more than two people (the people providing the sperm and egg). Adding DNA from a third person (an egg donor) might help avoid the transmission of mitochondrial disease to the next generation by replacing the cytoplasm of the woman with a family history of mitochondrial disease with cytoplasm from another woman's donated egg.
- Consideration should be given to a more flexible system of regulation, with the licensing committee being authorised to grant licences and make rulings within the tenor of the Acts and regulations, even if not expressly permitted by them, on condition that it reports immediately to the NHMRC and to Parliament.
- The legislation should be reviewed again three (or six) years after the amending legislation comes into effect.
- There should be ongoing community education and consultation.

## ACCEPTED RECOMMENDATIONS OF THE LOCKHART COMMITTEE

Nearly all of the recommendations of the Lockhart Committee have been implemented, either by the amending legislation in 2006 or by administrative changes made by the NHMRC and other bodies. The legislative structure and prohibited practices in the 2002 legislation are mostly unaltered, including the ban on reproductive cloning and creating a 'sperm-egg embryo' for research, and the prohibition on selling human eggs. However, creating an embryo by SCNT (therapeutic cloning) is permitted for research, subject to licensing, reporting and ethical review. Research is also permitted on embryos formed for fertility treatment that are not fit for implantation and on an egg in the process of fertilisation up to syngamy. The NHMRC has updated the consent provisions in the National Statement on Ethical Conduct in Human Research, together with other guidelines concerning consent for egg and tissue donation and deciding when embryos are unsuitable for implantation. The amending legislation is required to be reviewed again this year.

## REJECTED RECOMMENDATIONS OF THE LOCKHART COMMITTEE

On the other hand, there were some recommendations that the Parliament did not accept, such as using animal eggs to 'incubate' human DNA to derive stem cells for research (which was legalised in the UK in 2008 after extensive debates in both Houses of Parliament); and creating human embryos for research that contain DNA from more than two people (which has recently been achieved in research in Newcastle, UK). Parliament also rejected the Committee's proposal for a more flexible system of regulation.

## SOME RECENT DEVELOPMENTS

The statutory terms of reference for the forthcoming legislative review require the review committee to report on recent changes and there have been many significant developments in human stem cell technology since 2006.

In pure science, stem cell technology has revealed valuable information about the operation and function of cells in the body, the development of early human embryos and possible abnormalities that may cause or contribute to birth defects. Scientists can study the effectiveness of new drugs by extracting and multiplying cells from patients with particular diseases, creating a 'disease in a dish'. Research using adult and embryonic stem cell treatment with animals has had some encouraging results and new stem cell treatments have recently started in clinical trials involving adult stem cells

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in human patients, with the stem cells derived from the patient's own body cells. In other research, tissue-matched body parts have been developed (such as new tracheas and cheekbones) by transplanting a person's stem cells onto an artificial 'scaffold'. In future, this technique may be used to make body parts to replace diseased organs in the patient's body. Some reports of recent adult stem cell treatments for human patients and some proposed using human embryonic stem cells (one now being tested in animals) are noted in the Appendix.

The concept of treating patients by transplanting stem cells is not new. Indeed it has been an established treatment for more than 30 years in treating patients with leukemia. Bone marrow, a type of body tissue containing stem cells, is obtained from donors and transplanted into patients. But, if the transplanted cells can be obtained from the patient, rather than a donor, the cells are less likely to be rejected as foreign material by the patient's immune system and the patient may avoid a life-time of immuno-suppressive drugs which often have adverse effects on the patient's body and quality of life.[6]

## ISSUES FOR THE FORTHCOMING REVIEW: POSSIBLE CHANGES THAT MAY BE RECOMMENDED

The terms of reference for the forthcoming review are set out in the current legislation as amended after the last review. These include 'international developments and legislation relating to the use of human embryos and related research'. Matters that have attracted legislation in other countries, like payment for human eggs and creating human–animal hybrids for research, will therefore be included.

### Should human embryo research still be allowed?

Even people who initially accepted the need for embryo research have questioned whether it can still be justified. Induced pluripotent stem (iPS) cells have been obtained from human body cells, as well as animals, without creating embryos to derive them and at first they seem to have similar potential to embryonic cells for research and possible treatment. Also, the direct

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'reprogramming' of human body cells, to enable cells to be transplanted from one part of the body to another, or to be used to form new organs or tissue, has to date offered the best hope of success in human stem cell treatment. (The magazine *Science* judged the reprogramming of adult cells as the greatest scientific breakthrough of 2008, from any area of science, saying that '[I]t actually works. It is not all spin and vague promises'.[7])

However, one should not be too hasty in reinstating the early ban on human embryo research. Recent experiments in the US suggest that there are 'key genetic differences' between embryonic stem cells and iPS cells and that iPS cells may not have the potential of embryonic stem cells.[8] In the US, an increasing number of new stem cell lines of human embryonic stem cells has been approved for federally funded research[9] and human trials involving cells derived from human embryonic stem cells were just starting,[10] when federally funded research involving human embryos was suddenly halted by a preliminary injunction granted by a U.S. district judge in August 2010.[11] The U.S. Justice Department has appealed this decision and millions of dollars of funding await the result. However, the U.S. Court of Appeals in Washington has lifted the injunction on federal funding for embryo research pending the final determination of the legal issues.[12] However, it should be remembered that Australian law is different from American law and the Australian legislation clearly allows human embryo research to be undertaken under licence and ethical review.

There are many reasons to continue human embryo research despite the developments in iPS cells and cellular reprogramming. We do not know which type of stem cell research will ultimately be the most successful. As noted above, iPS cells may not be as effective as embryonic stem cells in their potential for continued multiplication and sustained stability. At present, the most promising developments seem to be in the area of cellular reprogramming, but many scientists still see benefits in research on embryonic cells. Already, knowledge gained from embryo research has assisted scientists doing research on iPS cells. If embryo research is ultimately not producing results, scientists will not want to do it. We don't need laws to stop them. If there is a promising breakthrough in embryo research, amending the law after it has been banned would be time-consuming and costly. Licensing, mandatory reporting and ethical review provide clear safeguards for the research.

Also, there are reasons to undertake research on embryos in addition to deriving stem cells from the embryos for use in research. The study of early human embryos is vital to understand the process and causes of abnormal foetal development and to improve techniques in fertility treatment. (Contrary to what many people believe, more licences for embryo research have been granted in Australia to improve fertility treatment than to derive stem cells). This type of research can only be done on embryos. Research on early embryos is also necessary to understand how pluripotent stem cells develop and differentiate into other kinds of cells, which will be important when iPS cells are developed for use in treatment. And, as noted below, it will be necessary to use SCNT if Australia follows the UK lead in the treatment of mitochondrial disease.

### Payment for donating eggs

If human embryo research continues, large numbers of human eggs may be needed and there is a shortage of

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human eggs for use in research. This raises the issue whether monetary payments or other inducements should be permitted for donating human eggs for use in research. In the UK, Canada, and Australia, the tradition in medical research has been that all tissue used in research should be given gratuitously, including human eggs and embryos, and payments are not permitted beyond reasonable expenses, such as reimbursement of the donors' medical expenses and compensation for loss of earnings due to the donation. Similarly, European countries disapprove of commercialisation or obtaining financial gains from the donation of human reproductive materials. However, in the UK, the policy of the Human Fertilisation and Embryology Authority (HFEA) on 'egg sharing' modifies the general approach of altruism to some extent, as women who are prepared to donate some of their eggs for research may gain accelerated access to fertility treatment programs and be charged lower fees. The US goes further. There is no federal legislation governing the sale of human eggs and they may be sold for a 'fair price' for use in fertility programs, and in research. The meaning of 'a fair price' is open to interpretation.[13] The state of New York has recently legislated to allow federally funded researchers to pay women for donating their eggs for research.[14]

Many people are concerned that paying women to donate eggs would create a bad precedent for other types of donation. It is 'commodifying' human tissue. However, one might say that the women are being paid for going through the process of donating eggs – taking drugs to stimulate their ovaries and undergoing surgery to collect the eggs. If no eggs are collected, they would still be paid for their participation.

### Human-animal hybrids

Even if the law permits women to be paid for donating their eggs for research, it is unlikely that there will be a large number available for research. Egg donation is invasive and may have risks that we do not yet know. However, there may be an alternative. It may be possible to 'incubate' the nucleus of a human cell in an enucleated animal egg in order to produce embryonic stem cells that are almost entirely human. This is currently prohibited in Australia, Canada, and in many European and other countries. It is not currently banned in the US (the Human-Animal Hybrid Prohibition Bill was introduced in 2008 but has not been passed), but federal funding is not permitted for this research in the US. In the UK, on the other hand, it is lawful. The first human-animal embryo was created in 2008 by scientists at Newcastle University under a licence from the Human Fertilisation and Embryology Authority and the validity of such a licence was confirmed in 2008 when the Human Fertilisation and Embryology Act 1990 was amended by Parliament. Since then, two more licences have been granted and the first human-animal embryo has been formed, though no stem cells have yet been derived from it. However, despite having licences to do this research, scientists have not been able to get research grants to do it.[15] Perhaps one reason is that the funding bodies and their reviewers do not believe that the proposed research will be successful, or they consider that other research will be more productive. In either event, this is perhaps an example of research finding its own 'level', in accordance with the argument above, without the need for it to be banned by legislation.

### Creating embryos with DNA from more than two people

Creating an embryo using the sperm and egg from prospective parents and another egg donated by a second woman offers the hope of avoiding mitochondrial disease being transmitted to children. Now that the procedure has been shown to work in Newcastle, UK, we should ensure that this research is lawful in Australia. (It may, in fact, be lawful at present, provided the embryo is formed by SCNT and not by fertilisation of an egg and sperm, but this should be clarified. This is another reason not to ban SCNT.)

### A more flexible regulatory approach

Regulating in an area of rapid change, like stem cell technology, inevitably leads to gaps and inconsistencies in policy. The statutory requirements are sometimes complex and difficult to interpret. Also, because of the speed and unpredictability of new scientific developments, the legislation needs to be constantly amended. This is time-consuming and costly. It also increases the risk of gaps and inconsistencies. Other regulatory options should be considered, as recommended by the Lockhart Committee in 2005.

## CONCLUSION

Since the legislation was last reviewed in 2005, there have been many developments in stem cell technology. Some of the recent research has enabled stem cells to be derived without the destruction of embryos (iPS cells) and also, ordinary body cells have been reprogrammed into stem cells which can be used in human health care. Some successful treatments have been reported, as noted in the Appendix. Some people question whether human embryo research can be justified and call for it to be banned again. However, for the reasons in this paper, human embryo research is still needed.

Indeed, there is much to be said for minimal legislative change at present. Australian scientists do not seem to be

***"Most seem to be happy to leave the current legislation as it is and many members of the community are apprehensive about changes that have occurred in other countries, such as payment for human eggs and the creation of human-animal embryos."***

clamouring to extend the research that they are currently undertaking. Groups of scientists at stem cell conferences, whom I have informally asked whether the current law is restricting their research activities, have said that it is not. They have all said that the law is generally operating well and they are not seeking changes. There seems to be little embryonic or stem cell research that they want to do that the legislation prevents them from undertaking. Most seem to be happy to leave the current legislation as it is and many members of the community are apprehensive about changes that have occurred in other countries, such as payment for human eggs and the creation of human-animal embryos.

## APPENDIX

### Some recent reports concerning adult stem cell treatments for human patients

In human patients, there have been reports of some treatments that have apparently been successful.

- In 2008, Spanish doctors used stem cells from bone marrow to create a whole new human organ - a trachea - for transplantation.[16]
- A British boy had stem cell treatment to grow new cheekbones.[17]
- Seventeen patients (of a test group of 21) suffering from early multiple sclerosis reportedly showed 'significant improvements in their condition' after being injected with stem cells from their own bone marrow by doctors in Chicago; and a 'control trial . . . has been approved with 110 patients and research teams in the United States, Canada and Brazil.'[18]
- A paralyzed man with a broken spinal cord was reported to be walking again after his stem cells (derived from his own bone marrow) were injected into the site of paralysis.[19]
- In Sweden, scientists at the Karolinska Institutet have shown how 'transplanted stem cells can connect with and rescue threatened neurons and brain tissue', which suggests that 'a possible strategy for treating neurodegenerative diseases is to transplant stem cells into the brain that prevent existing nerve cells from dying'.[20]
- In the UK, heart attack victims reportedly had 'positive changes' after stem cells from their own bone marrow were injected into their damaged hearts within six hours of the attacks.[21]
- In the UK, eight patients with seriously impaired vision in one eye had their vision improved and eye pain reduced after stem cells from their 'good eye' were transplanted into the impaired eye.[22] This provides hope for similar stem cell transplants for other patients with 'bilateral damage'.[23] Patients with hearing loss have also been treated by stem cell treatment 'to hair cells and neurons, deep inside the ear, that causes almost 90 per cent of hearing loss, by growing new cells and nerves'.[24]
- In Australia, three patients with 'very poor vision caused by corneal disease - the fourth most common form of blindness affecting around 10 million worldwide,' were treated with their own cells and had 'significant improvements in vision within a matter of weeks'.[25]

### Recent reports on proposed embryonic stem cell treatments for human patients

- Scientists from the University of California, Irvine have created early stage retinas from human embryonic stem cells and are testing them in animals [26]
- Patients with spinal injury will reportedly soon be enrolled in Geron Corporation's clinical trials involving embryonic cells.[27]
- If approved by the US Food and Drug Administration, patients with a genetic eye disease may be given embryonic stem cell treatment.[28]

*nature07864.html and by Ahmad at http://www.physorg.com/news175458227.html and by Zhou at http://www.eurekalert.org/pub_releases/2009-04/sri-amb042209.php*

*20. Yu J et al. (Thomson), Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells, Science published online 20 November 2007, doi: 10.1126/science.1151526*

*21. ES cells and iPS cells "indistinguishable" at http://bloodjournal.hematologylibrary.org/cgi/content/abstract/blood-2009-02-204800v1*

*22. "Memory" in iPS cells at http://www.nature.com/nature/journal/vnfv/ncurrent/full/nature09342.html and http://www.nature.com/nbt/journal/v28/n8/full/nbt.1667.html*

*23. ES cells and iPS "virtually identical" at http://www.physorg.com/news200224498.html Guenther MG et al., Chromatin Structure and Gene Expression Programs of Human Embryonic and Induced Pluripotent Stem Cells, Cell Stem Cell 7, 249-257, 6 August 2010*

*24. iPS cell lines achieved by mid-2009 http://ethicalstemcellresearch.blogspot.com/2009/05/for-scholars-ips-journal-references-up.html*

*25. ASC treatment references at http://www.sciencemag.org/cgi/data/315/5810/328b/DC1/1*

*26. ASC in heart attack at http://content.onlinejacc.org/cgi/content/abstract/54/24/2277*

*27. ISSCR 'Top 10 Things to Know about Stem Cell Treatments'*
*at point 2 http://www.closerlookatstemcells.org/Top_10_Stem_Cell_Treatment_Facts.htm*

*28. ES cell-derived trial (Geron Corp) at http://ethicalstemcellresearch.blogspot.com/2009/11/geron-and-on-and-on.html and http://www.washingtonpost.com/wp-dyn/content/article/2010/08/29/AR2010082901854.html?sid=ST2010082305519*

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**Legal regulation of human cloning and embryo research: the forthcoming review**

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*2. Note 1 above.*

*3. For example, in Jewish ethics, an embryo is apparently regarded as an embryo only when implanted in a woman's uterus; until implanted, it is regarded as a 'pre-embryo' which may be used in research: Steinberg, Professor Abraham 'Jewish medical ethics: May humans play God?', lecture, Oxford, 1 June 2010.*

*4. Legislation Review: Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002, viewed 27 August, 2010, http://www.nhmrc.gov.au/_files_nhmrc/file/research/embryos/review/legislation_review_reports_full_doc_19dec05.pdf*

*5. Prohibition of Human Cloning for Reproduction Act 2002; Research Involving Human Embryos Act 2002, note 1 above. WA did not amend its legislation.*

*6. Reed, Don, 'Overturn Dickey-Wicker Abomination, or Forget Stem Cell Cures for a Generation', Huffington Post, 26 Aug 2010, viewed 27 August, 2010, http://www.huffingtonpost.com/don-c-reed.*

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*9. See, press release of National Institutes of Health, 'First Human Embryonic Stem Cell Lines Approved for Use Under New NIH Guidelines', 2 Dec, 2009, viewed 27 August, 2010, http://www.nih.gov/news/health/dec2009/od-02.htm.*

*10. The U.S. based company Geron Corporation received federal approval in January 2009 from the US Food and Drug Administration (FDA), after extensive safety evaluation, to undertake clinical trials for human patients using neuronal precursor cells derived from human ES cells to treat spinal injury. The trials were deferred for further tests on animals but the FDA said in July 2010 they could proceed. In the trials, the cells will be inserted into 'the lesion site of the patient's injured spinal cord': News release of Geron Corporation, 'Geron to Proceed with First Human Clinical Trial of Embryonic Stem Cell-Based Therapy', 30 July 2010, viewed 28 September 2010, http://www.geron.com/media/pressview.aspx?id=1229. See also, note 28 below.*

*11. Katsnelson, Alla, 'US judge puts temporary block on human embryonic stem cell research', 23 August, 2010, viewed 27 August 2010, http://blogs.nature.com/news/thegreatbeyond/2010/08/us_judge_puts_temporarly_block.html.*

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**An R18+ Classification for Video Games Serves Everyone's Best Interest**

*Written by Dr Daniel King*

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**The R18+ Games Debate: A Critical Analysis of the Arguments**

*Written by Professor Elizabeth Handsley and Dr Wayne Warburton*

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