

Public Submission to the Prohibition of Human Cloning for Reproduction and Research Involving Human Embryos Act 2006 (the amending Acts) Review Committee

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Do you agree to make your submission available for public viewing?	Yes

Please provide comment against as many of the following statements that you wish. Note that these have been drawn directly from the Acts:

1. developments in assisted reproductive technology, including technological, medical and scientific developments, and the actual or potential clinical and therapeutic applications of such research.

Since the 2006 federal legislation, progress has been made with therapeutic cloning in humans both overseas and in Australia.

In California, human embryos have been created by somatic cell nuclear transfer [SCNT] (Stem Cells 2008; 26: 485-93), but human embryonic stem cell [hESC] lines have yet to be derived by this technique. Such lines have been produced by a number of groups using the technology of parthenogenesis in the USA, and, as is now known, in South Korea.

In Australia, two groups are actively pursuing the area with the support of the NSW and Victorian Governments . They are Sydney IVF and a research group located at Fertility East (Sydney) in conjunction with the Monash Institute of Medical Research.

The advantage of hESC lines produced by SCNT and parthenogenesis, as compared to those produced by assisted reproductive technology [ART] with sperm, is that the genes are the same as those of the recipient. Hence, the cells will be accepted as self when transplanted. Moreover, with SCNT, mitochondrial disorders, where the defective genes are in the cytoplasm rather than the nucleus of the cell, can potentially be overcome.

hESC produced by parthenogenesis (embryos produced by activation of eggs without use of sperm) are being banked by one company in California (International Stem Cell Corporation) for potential future clinical use. The stability and characteristics of such lines are still being examined, especially compared to the more traditional hESC lines produced by ART.

It can only be a matter of time before hESC lines are produced by SCNT. Such lines will be the gold standard against which lines produced without the need for eggs (induced pluripotent stem cells - see Section 2) will need to be compared. This was the conclusion reached at a workshop held on 13-14 June 2010 in San Francisco by the Californian Institute of Regenerative Medicine and the UK Medical Research Council.

It is requested that no change be made to the laws of Australia to permit further time to produce and characterise better the hESC made by the techniques of SCNT and parthenogenesis.

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

There have been at least two major developments in "embryonic" stem cell research since the 2006 legislation. These are:

1. the creation of induced pluripotent stem cells [iPSC] from non-gonadal tissues in the body, e.g., skin . Such cells created in the laboratory have some similarities to the hESC produced by ART with sperm, but are epigenetically different. This means that their ability to differentiate into the tissue of choice is limited to some extent by the site in the body the founder cells were taken from. Thus, cells derived from (say) the heart will be more likely to develop into and function as mature heart cells, than (say) insulin-producing cells.

iPSC are being created by many groups in Australia and overseas, especially for basic research. Cells obtained from a person with motor neuron disease have been converted into iPSC and now are being differentiated in the laboratory into nerve cell to better understand the pathology of the disease, and perhaps create a means of preventing/treating the disorder. A problem that will need to be addressed is the safety issue, in that iPSC are often made by gene technology, using a gene that is associated with cancer (cmyc).

2. human trials with cells derived from hESC began. The first trial started in Atlanta, Georgia, during October 2010 for paraplegia. The FDA also has approved a trial by Advanced Cell Technology for the juvenile form of macular degeneration, which results in blindness. There are plans to treat insulin-dependent diabetes with cells differentiated into pancreatic progenitors both in California (Viacyte) and Australia (CSIRO). Safety matters will be key issues in these initial trials.

Existing legislation is appropriate to allow further developments in these areas to occur, and we suggest that it remain as is.

3. community standards.

The majority of the community continues to support the use of hESC for medical research, with 70% of respondents to a survey carried out in 2010 by the Dept Innovation, Industry, Science & Research supporting this line of activities. This compares to 63% in a similar survey conducted in 2005.

4. a brief analysis of international developments and legislation relating to the use of human embryos and related research.

Some of the international developments were covered in sections 1 and 2 above..

5. an analysis of research resulting from the licenses granted.

This is partly addressed in Section 1 above. Further information might be sought from the NHMRC Licencing Committee and/or Sydney IVF, which is the only licensee at present in Australia.

6. any National Stem Cell Centre and any national register of donated excess ART embryos.

Nil comment

7. an evaluation of the effectiveness of legislative provisions and NHMRC guidelines relating to proper consent.

There are no instances of problems with consent/ethics as far as we are aware.

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.

These seem appropriate as they are.

9. an analysis of any research or clinical practice which has been prevented as a result of legislative restrictions.

This relates to:

(a) sources of eggs for SCNT and parthenogenesis. Animal sources of eggs and compensating women for their eggs are prohibited under current legislation, whereas this is possible in the UK and to some extent in New York. In Australia, eggs that are used for SCNT and parthenogenesis are those that are unsuitable for fertilization (IVF clinics) and from ovaries removed to prevent cancer (Hereditary Cancer Clinic). This significantly limits the ability to create hESC lines genetically matched to the donor. However, even if legislation was changed to include these items, the administrative disconnect between the NHMRC Licencing Committee and the HREC handling the research (see Section 10 below) would make it difficult to implement.

(b) research into mitochondrial disorders which requires the creation of embryos with DNA from 3 sources, two eggs and a sperm. This would require combining the nucleus from one egg, with the cytoplasm of the 2nd egg, and then fertilizing the cybrid with sperm. There are some who would wish to proceed with this research, and if new legislation was to be drafted, this should be allowed.

10. 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.

Whilst the NHMRC Licensing Committee has assisted researchers working in the field with available information, there is a need to direct it to work in a more connected manner with researchers and Human Research Ethics Committees (HREC).

At present, the Licensing Committee liaises with researchers, but not with the HREC, which also assesses the application from researchers, and may have differing requirements of the researchers. This leaves the researcher trying to satisfy the differing needs of two Committees. Much time is lost as the researcher tries to satisfy the requirements of one Committee, and then the 2nd, only to find a need to return to the 1st Committee to obtain approval for a matter the 2nd Committee requested.

Attempts to bring the 2 Committees and the researcher together at the same time is needed. Because of existing legislation, both the Licensing and the Ethics Committees advise this is not possible.

To overcome this communication disconnect, it is suggested that the rules be altered to allow the Licensing Committee and/or its Working Party to co-opt a member of the HREC involved in the particular licence application. It is hoped that this operational strategy, which should not require new legislation, will ensure there is one set of instructions given to researchers for them to obtain approval for their application.

11. 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.

There is a need for more directed communication between Commonwealth and State in the area of human embryo research, to facilitate the requirements researchers need to satisfy to obtain relevant licences (See comments to Section 10).