

Re:

Inquiry into legislative responses to recommendations of the Lockhart Review

Dear Mr Humphery

The South Australian Council on Reproductive Technology is a Ministerial advisory body established by the *Reproductive Technology (Clinical Practices) Act 1988* (SA)

[\[http://www.parliament.sa.gov.au/Catalog/legislation/Acts/R/1988.10.htm\]](http://www.parliament.sa.gov.au/Catalog/legislation/Acts/R/1988.10.htm).

The Council gave significant consideration to the recommendations of the Lockhart Review earlier this year, and developed a position on each of the recommendations for advice to the SA Minister for Health.

At the Council meeting of 9 October 2006, the Council asked me to forward that advice to the Community Affairs Committee inquiry. Unfortunately the short time frame did not allow the Council to give additional consideration to the specific questions posed in the Terms of Reference.

I hope you can accept the Council's submission although it is past the due date, and that it will assist the Committee in it's inquiry.

Please contact me if anything needs clarification, or if the Council can assist the inquiry in any other way.

Sincerely

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Executive Officer

SA Council on Reproductive Technology

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<p>SACRT POSITION ON THE RECOMMENDATIONS OF THE LOCKHART REVIEW</p>
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**Legislation Review: *Prohibition of Human Cloning Act 2002* and
Research Involving Human Embryos Act 2002, 19 December 2005**

Code	Description
S	Unanimously supported
IP	Unanimously supported in principle The Council has made additional comments.
M	Majority support [voting indicated]
U	Majority undecided [voting indicated]
O	Majority opposed [voting indicated]
Where members were undecided, this was based on a degree of ambivalence due to limited technical knowledge, which made it difficult to assess the ethics of the proposals.	

Recommendations	Code
<i>National legislation</i>	
1 Clinical practice and scientific research involving assisted reproductive technologies (ART) and the creation and use of human embryos for research purposes should continue to be subject to specific national legislation.	S
<i>Reproductive cloning</i>	
2 Reproductive cloning should continue to be prohibited.	S
<i>Prohibitions on developing and implanting embryos</i>	
3 Implantation into the reproductive tract of a woman of a human embryo created by any means other than fertilisation of an egg by a sperm should continue to be prohibited.	S
4 Development of a human embryo created by any means beyond 14 days gestation in any external culture or device should continue to be prohibited.	S
5 Implantation into the reproductive tract of a woman of a human–animal hybrid or chimeric embryo should continue to be prohibited.	S
6a Development of a human–animal hybrid or chimeric embryo should continue to be prohibited,	S
6b except as indicated in Recommendation 17.	M 5 for 1 opposed
7 Placing a human embryo into an animal or into the body of a human apart from into a woman's reproductive tract, or placing an animal embryo into the body of a human, for any period of gestation, should all remain prohibited.	S
8 Implantation into the reproductive tract of a woman of an embryo created with genetic material provided by more than two people should continue to be prohibited. <i>Comment: What is meant by 'genetic material' requires clarification.</i>	S
9 Implantation into the reproductive tract of a woman of an embryo created using precursor cells from a human embryo or a human fetus should continue to be prohibited.	S

10 Implantation into the reproductive tract of a woman of an embryo carrying heritable alterations to the genome should continue to be prohibited.	S
11 Collection of a viable human embryo from the body of a woman should continue to be prohibited.	S
<i>Creation of human embryos by fertilisation</i>	
12 Creation of human embryos by fertilisation of human eggs by human sperm should remain restricted to ART treatment for the purposes of reproduction.	IP
13a Creation of human embryos by fertilisation of human eggs by human sperm to create embryos for the purposes of research should continue to be prohibited, <i>Comment: These recommendations aim to prohibit the creation of embryos for research, and this is supported by the Council. However, when read together, they also have the effect of prohibiting the creation of embryos for therapeutic use. For example, a woman/couple may wish to have an embryo created and stored for future use in treating an existing child with an illness. Children are currently being created who are selected for therapy for siblings, and it seems anomalous to preclude the creation of embryos.</i>	IP
13b except in the situation described in Recommendation 15.	M 5 for 1 opposed
<i>Use of excess ART embryos in research</i>	
14 Use of excess ART embryos in research should continue to be permitted, under licence, as under current legislation.	S
<i>ART clinical practice and ART research</i>	
15 Research involving fertilisation of human eggs by human sperm up to, but not including, the first cell division should be permitted for research, training and improvements in clinical practice of ART.	M 5 for 1 opposed
16 Testing of human oocytes for maturity by fertilisation up to, but not including, the first cell division or by parthenogenetic activation should be permitted for research, training and improvements in clinical practice of ART.	M 5 for 1 opposed
17 Certain interspecies fertilisation and development up to, but not including, the first cell division should be permitted for testing gamete viability to assist ART training and practice.	M 5 for 1 opposed
18 The Licensing Committee should develop a simple proforma application for licences to undertake training and quality assurance activities for ART clinics.	S
19 Consideration should be given to the use of cytoplasmic transfer (including transfer of mitochondrial DNA), under licence, for research on mitochondrial disease and other uses to improve ART treatment.	M 5 for 1 opposed

<i>Use of fresh ART embryos</i>	
20 An expert body should formulate objective criteria to define those embryos that are unsuitable for implantation. <i>Comment: This represents good quality control and clinical practice.</i>	S
21 Fresh ART embryos that are unsuitable for implantation, as defined by the objective criteria, should be permitted to be used, under licence, for research, training and improvements in clinical practice. <i>Comment: Appropriate consent processes and counselling would be required.</i>	S
22 Fresh ART embryos that are diagnosed by preimplantation genetic diagnosis (according to the ART guidelines) as being unsuitable for implantation should be permitted to be used, under licence, for research, training and improvements in clinical practice. <i>Comment: Appropriate consent processes and counselling would be required.</i>	S
<i>Use of human embryos created by somatic cell nuclear transfer</i>	
23 Human somatic cell nuclear transfer should be permitted, under licence, to create and use human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.	O 4 opposed 2 undecided
24 In order to reduce the need for human oocytes, transfer of human somatic cell nuclei into animal oocytes should be allowed, under licence, for the creation and use of human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.	O 4 opposed 2 undecided
<i>Use of human embryos created by activation methods not involving fertilisation of a human egg by a human sperm or somatic cell nuclear transfer</i>	
25 Creation of human embryos and human embryo clones by means other than fertilisation of an egg by a sperm (such as nuclear or pronuclear transfer and parthenogenesis) should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.	U 4 undecided 3 opposed
26 Creation of human embryos using the genetic material from more than two people, or including heritable genetic alterations, should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.	O 4 opposed 3 undecided
27 Creation of embryos using precursor cells from a human embryo or a human fetus should be permitted, under licence, for research, training and clinical applications, including production of human embryonic stem cells, as long as the research satisfies all the criteria outlined in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.	U 4 undecided 3 opposed

<i>Definition of a human embryo</i>	
<p>28 The definition of a 'human embryo' in both Acts should be changed to: 'A human embryo is a discrete living entity that has a human genome or an altered human genome and that has arisen from either:</p> <p>(i) the first mitotic cell division when fertilisation of a human oocyte by a human sperm is complete; or</p> <p>(ii) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, 14 days and has not yet reached eight weeks of development.'</p>	<p>M 5 for 1 opposed 1 undecided</p>
<i>Consent arrangements for the donation of embryos</i>	
<p>29 The National Health and Medical Research Council (NHMRC) should review its guidelines in relation to consent to research on excess ART embryos, in order to clarify the consent process in relation to the following issues:</p> <ul style="list-style-type: none"> • the circumstances, if any, where those who choose to donate excess ART embryos to research may be able to choose not to be contacted at some later stage to give consent to a particular research proposal • the circumstances, if any, where a human research ethics committee can determine that the researcher need not ask for further consent to use embryos already declared 'excess' • the development of an appropriate form of consent that could be completed by the responsible persons for excess ART embryos shortly after the declaration that the embryos are excess • the manner in which those who donate embryos or gametes for the creation of ART embryos may express any preference for the type of research for which the tissue will be used, once the embryo is declared excess. 	<p>S</p>
<p>30 The NHMRC should develop ethical guidelines for the use of embryos that are unsuitable for implantation for research, training and improvements in clinical practice (see Recommendations 20–22).</p>	<p>S</p>
<i>Egg donation</i>	
<p>31 The current principles of consent for participation in medical research must apply to sperm, egg and embryo donors, so as to ensure that decisions are freely made.</p>	<p>S</p>
<p>32 The NHMRC should develop guidelines for egg donation.</p>	<p>S</p>
<p>33 The present prohibition of the sale of sperm, eggs and embryos should continue, but the reimbursement of reasonable expenses should continue to be permitted.</p>	<p>S</p>
<i>Licensing arrangements</i>	
<p>34 The Embryo Research Licensing Committee of the NHMRC (the Licensing Committee) should continue to be the regulatory body responsible for assessing licence applications, issuing licences and monitoring compliance, as under current arrangements.</p>	<p>S</p>
<p>35 The role of the Licensing Committee should be extended to include assessment of licensing applications and issuing licences for any additional activities permitted, under licence (see Recommendations 14–27).</p>	<p>S</p>
<p>36 The Australian Parliament and the Council of Australian Governments should give urgent attention to the problem of delays in the filling of vacancies on the Licensing Committee.</p>	<p>S</p>

37 There should be no attempt to recover the cost of administration, licensing, monitoring and inspection activities associated with the legislation from researchers at this point in time.	S
<i>Monitoring powers</i>	
38 The Licensing Committee should continue to perform its functions in relation to licences and databases for research permitted by licences under the Research Involving Human Embryos Act.	S
39 Licensing Committee inspectors should be given powers, under the Prohibition of Human Cloning Act and the Research Involving Human Embryos Act, of entry, inspection and enforcement in relation to non-licensed facilities in the same manner and by the observance of the same procedures as applicable to search warrants under Commonwealth legislation, if such powers do not clearly exist.	S
<i>Oversight of ART clinical practice and research</i>	
40 There should be a continuation of the role of the Reproductive Technology Accreditation Committee in the regulation of ART.	S
<i>Import and export of human reproductive materials for personal use</i>	
41 The import or export of a patient's reproductive material, including ART embryos, for the purpose of that person's ongoing ART treatment should not require any regulation other than that required under existing quarantine regulation.	S
<i>Trade and international exchange of human reproductive materials and stem cells</i>	
42 The import or export of ethically derived viable materials from human embryo clones should be permitted after approval by the appropriate authority.	U 6 undecided 1 opposed
43 The existing requirements for the import and export of human biological materials are satisfactory and, for ethically derived human embryonic stem cells, no further restrictions are necessary.	S
<i>Biotechnology and commercialisation</i>	
44 Trade in human gametes or embryos, or any commodification of these items, should continue to be prohibited.	S
45 Donors of tissue that is going to result in an immortal stem cell line should be informed by means of processes monitored by human research ethics committees about the potential use of that stem cell line, including the potential for commercial gain and the fact that they may not have any rights in potential stem cell developments.	S
46 The development of biotechnology and pharmaceutical products arising from stem cell research should be supported.	S
<i>National stem cell bank</i>	
47 A national stem cell bank should be established.	S
48 Consideration should be given to the feasibility of the Australian Stem Cell Centre operating the stem cell bank.	S
49 A national register of donated excess ART embryos should be established.	S

<i>Regulatory approach to legislation</i>	
50 The Licensing Committee should be authorised under the Prohibition of Human Cloning Act to give binding rulings on the interpretation of that Act, or the regulations made under that Act, on condition that it reports immediately and in detail to the NHMRC and to parliament on such rulings.	S
51 The Licensing Committee should be authorised by the Research Involving Human Embryos Act to give binding rulings and to grant licences on the basis of those rulings for research that is not within the literal wording of the Act, or the regulations made under the Act, but is within their tenor, on condition that the Committee reports immediately and in detail to the NHMRC and to parliament on any rulings it gives, or any licences it grants, in that way.	S
52 A researcher who conducts research on the basis of a ruling or a licence should be protected from liability under the legislation, provided that they act in accordance with the relevant ruling or licence.	S
53 In view of the fast-moving developments in the field, and the range of amendments proposed herein, the two Acts should be subject to a further review either six years after royal assent of the current Acts or three years after royal assent to any amended legislation.	S
<i>Public education</i>	
54 There should be ongoing public education and consultation programs in the areas of science that are relevant to the Acts.	S