

**Legislation Review:**  
***Prohibition of Human Cloning Act 2002 and  
Research Involving Human Embryos Act 2002***

**Reports**

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**Legislation Review Committee**

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# Letter of transmittal

**Legislation Review Committee**  
***Prohibition of Human Cloning Act 2002***  
**and the *Research Involving Human Embryos Act 2002***

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19 December 2005

The Hon Julie Bishop MP  
Minister for Ageing  
Parliament House  
CANBERRA ACT 2600

Dear Minister

In accordance with section 25(3) of the *Prohibition of Human Cloning Act 2002* and section 47(3) of the *Research Involving Human Embryos Act 2002*, I am pleased to present the reports of the reviews of both Acts.

The reports represent the consensus view of the Legislation Review Committee.

In order to complete the Terms of Reference for the Committee the reports are referred for tabling in both Houses of Parliament and presentation to the Council of Australian Governments.

Yours sincerely



John S Lockhart AO QC  
Chair  
Legislation Review Committee

cc The Hon John Howard MP  
Prime Minister



## Foreword

The task before the Legislation Review Committee has been challenging. The issues of human cloning and research involving human embryos raise important questions of morality, social values, ethics, alleviation of human distress and scientific research. To mention some of them:

- When does human life begin?
- How far should society allow research involving human embryos?
- What safeguards should surround the research?
- Should human embryos be accorded the same rights as human beings after birth?
- How should ‘human embryo’ be defined?
- What safeguards should be provided to protect the rights of women?
- Can common ground be found between the widely varying, indeed divergent, views of morality held by members of our society?
- Should society declare activities to be illegal, with all the attendant consequences of criminal conduct, when there is a wide range of ethical views on those activities?
- What are the limits of the use of in vitro fertilisation (IVF) and related methods (collectively known as assisted reproductive technology, or ART) and human embryo research?
- Should excess ART embryos continue to be available for research, with permission under licence?
- Should the creation of human embryos for research purposes be permitted?
- Should the creation of human embryo clones by somatic cell nuclear transfer be permitted, under licence, for research, training and clinical applications?
- Should an Australian stem cell bank be established?

These are large questions. There are others. Since the Committee was established earlier this year, it has grappled with all of them in forming its views and reaching its conclusions.

The Committee’s terms of reference required it to consider a large number of issues and to consult widely. The fact that all States and the Australian Capital Territory have enacted complementary legislation added to this necessity. Indeed, we visited all States and Territories (except Tasmania, where we conducted a video conference) gathering information, received over a thousand written submissions, and spoke directly to people holding widely divergent views.

In looking for common ground, the Committee found that there is strong community support for medical research to help people who suffer from debilitating or incurable disease or conditions, through better understanding of the processes of disease and the development of new treatments.

There is also considerable community support for medical research to help people to have children, including a general acceptance that this process involves the ‘wastage’ of some embryos.

For some people, the values attached to treating disease and overcoming infertility are more important than the value of an embryo. For others, the value of an embryo, as a potential human being, is predominant.

My colleagues on the Committee are Associate Professor Ian Kerridge, Associate Professor Pamela McCombe, Professor Barry Marshall, Professor Peter Schofield and Professor Loane Skene. They provided a wide range of skills and experience that proved invaluable in considering the issues in these reviews.

I thank my colleagues for their conspicuous dedication and tireless effort to the tasks before us. It has been a privilege for me to chair the Committee.

I also thank the people and groups that supported our reviews. Secretariat Australia provided overall secretariat support to the reviews. Biotext was responsible for assisting us in writing and producing these reports. McNiece Communications provided communication support and advice during the review. The Committee also received considerable administrative support from the National Health and Medical Research Council.

Finally, I wish to thank all individuals and groups who contributed to our reviews. The exchange of views by participants during our public hearings throughout Australia were sometimes lively, but generally conducted by all concerned with courtesy and concern or sympathy for the views of others who held different views.

We have considered all these views in arriving at our conclusions and have set out many of them in our two reports. It is now for the Australian Parliament and the Government to take this matter forward through the Council of Australian Governments (COAG) process. We will watch with interest. We offer our views and recommendations to the Australian Parliament and COAG.

John Lockhart  
Chair  
19 December 2005

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# Executive summary

## *Background to the reviews*

In the 1990s, developments in assisted reproductive technology (ART), including in vitro fertilisation (IVF) and other related methods, raised significant ethical issues about what forms of human reproduction may be possible or acceptable. At the same time, developments in other areas of biotechnology and medical research raised concerns about what uses of human embryos should be permitted for research purposes.

The *Prohibition of Human Cloning Act 2002* (PHC Act) and the *Research Involving Human Embryos Act 2002* (RIHE Act) were passed in 2002 to provide a national framework for regulation of these issues. The two Acts prohibit human cloning and several other reproductive practices; prohibit the creation of human embryos, by any means, other than to help a woman become pregnant; and allow the use for research, under strict regulation and licence, of human embryos created through ART but that are no longer needed by the couple for whom they were created.

Each Act required an independent review of its operation by 19 December 2005. In June 2005, the Hon Julie Bishop MP, Minister for Ageing (the minister with portfolio responsibility for human cloning and stem cell research), appointed the six-member Legislation Review Committee ('the Committee'). The Minister for Ageing and the Chief Executive Officer of the National Health and Medical Research Council (NHMRC) provided the Committee with terms of reference for the reviews of both Acts.

The Committee consulted the community extensively through a review website, written submissions, face-to-face meetings with key stakeholders, public hearings and some private meetings (at stakeholders' requests), facilitated stakeholder discussion forums, and selected site visits. In addition, the Committee reviewed the latest results of focus group and telephone survey research by the Public Awareness Program of Biotechnology Australia, and a literature review (commissioned by the NHMRC on behalf of the Minister for Ageing) of recent scientific and technological advances in human cloning, human embryo research and related matters, including stem cell technologies. Information from all these sources is summarised in this document, which forms the Committee's reports for the reviews of both Acts. This information contributed to the deliberations of the Committee and its considered view and led to 54 recommendations.

## *Rationale for the recommendations*

Australian society is made up of diverse 'communities' with different perspectives, interests and values. Furthermore, an individual may be the member of multiple communities, each with divergent perspectives, or 'standards', and these standards vary between and within communities and over time. Because of these divergent values and interests represented within Australian society, the Committee has accepted that some disagreement will remain, whether or not any changes are made to the two Acts.

However, certain moral values are held in common by all communities, such as commitment to social justice and equity and to the care of vulnerable people. This is reflected in broad community support for medical research aimed at understanding, preventing or treating disease, and for research and clinical practice aimed at assisting people to have children (including a general acceptance that this process may involve the 'wastage' of some embryos). Therefore, in considering whether certain activities should be made illegal, the social and moral value that some communities attach to the human embryo needs to be balanced against the social and moral value that other communities attach to the treatment of disease and to helping people to have a family.

In framing the recommendations for these reviews, the Committee considered that the higher the potential benefits of an activity, the greater the need for ethical objections to be of a high level and widely accepted in order to prevent that activity. Conversely, where benefits are not yet established, or where there is widespread and deeply held community objection, then total prohibition through the legal system may be justified. In addition, even though some people think that an activity is unethical, it does not necessarily follow that that activity should be made illegal. Furthermore, the wider the range of ethical views on a particular activity, the weaker becomes the case for declaring that activity to be illegal, with all the attendant consequences of criminal conduct.

However, despite the divergent views received by the Committee during the reviews, both proponents and opponents of embryo research agreed that the current system of legislation is valuable. Therefore, the Committee recommended a continuation of national legislation imposing prohibitions on human reproductive cloning and some other ART practices, as well as strict control and monitoring, under licence, of human embryo research.

### ***Prohibited practices***

Overall, the Committee heard strong agreement between all groups that human reproductive cloning should continue to be prohibited on ethical grounds. The serious health and safety issues associated with the birth of live cloned animals also preclude consideration of this procedure in humans. The Committee has therefore recommended maintaining the prohibition of human reproductive cloning.

In terms of the other prohibited embryos mentioned in the PHC Act (embryos created by nuclear transfer or other methods not involving fertilisation of eggs by sperm, human–animal hybrid or chimeric embryos, embryos with genetic material from more than two persons, embryos with genetic alterations and so on), the strongest community objection was to the implantation of such prohibited embryos in a woman’s body or to their development in any other way beyond 14 days. Therefore, the Committee has recommended that use of such embryos for reproductive purposes (that is, development beyond 14 days or implantation into a woman’s reproductive tract) should remain prohibited.

The Committee has also recommended continuing the prohibition of placing any human embryo into an animal or into the body of a human apart from in a woman’s reproductive tract, or placing an animal embryo into the body of a human for any period of gestation, because these practices are repugnant to the community. Similarly, the Committee did not hear any arguments for lifting the prohibition on the collection of viable embryos from a woman and therefore considers that this prohibition should continue.

### ***Creating a human embryo by fertilisation of an egg by sperm***

A range of views was expressed to the Committee on the status of human embryos, and their creation and use in research and to develop therapeutic products. Proponents of embryo research argued that the potential benefits of these activities meant that it would be unethical not to pursue the research and development made possible by such technologies. They also argued that current ART arrangements already sanction the possibility of the destruction of embryos, in the process of helping people to have a family, and hence not to allow embryo destruction to help people with other medical problems would be unfair. Opponents of embryo research argued that a human embryo, from the earliest stage of development, is an entity that deserves full protection and it is wrong to create such an entity for any purpose apart from ART treatment of a woman.

The Committee also learnt that different people and groups hold differing views about the meaning and use of the term ‘embryo’, both in medical science and as a more general term. The Committee considers that it is essential that the terminology used in the legislation is biologically accurate, clearly understandable by all stakeholders, and unambiguous to regulators, scientists and the public. However,

while it is critical to be clear about the terminology used, definitional clarity does not, in itself, resolve moral concerns and it is likely that, whatever language is used, different moral interpretations will be made regarding the status of such entities and the obligations owed to them.

Although a range of views was expressed about the precise moral status of preimplantation embryos in particular, there was an overall acceptance that human embryos created by the fertilisation of a human egg by a human sperm are entities of some social and ethical significance because of their association with the start of human life. Therefore, the Committee has recommended that the prohibition on the creation of an embryo by the fertilisation of a human egg by human sperm for any purpose apart from ART treatment of a woman should continue.

However, the Committee was concerned to hear that this provision, combined with the current definition of a human embryo as starting from the appearance of two pronuclei — a very early stage in fertilisation before the male and female genetic material combine — has had the apparently unintended consequence of impeding valuable research and clinical practice in ART clinics. In particular, the legislation has stopped research on culture and maturation of immature eggs (called ‘in vitro maturation of oocytes’, or IVM), storage of frozen eggs, various aspects of IVF, and gamete (egg and sperm) development. Research on maturation of eggs has been further prevented by the prohibition on oocyte activation (also called ‘parthenogenesis’). The ability to produce mature eggs in culture provides a way of reducing the treatment of woman with follicle stimulating hormone, which would benefit many women undergoing ART. It may also allow production of mature eggs from frozen ovarian tissue, thus allowing women who have undergone chemotherapy or other treatments that reduce ovarian function to have their own genetic children.

Adopting an independently developed definition of a human embryo<sup>1</sup> to a slightly later stage in the fertilisation process (the first cell division) would allow much of the research described above to occur without falling outside the scope of the RIHE Act. This change would also maintain a very broad definition of an embryo, in line with all the community views expressed during the reviews, including that a new and unique genetic entity is formed only after the genetic material from the male and female pronuclei combine. This stage is known as ‘syngamy’ and occurs about one to three hours before the first cell division (cleavage).

However, fertilisation would only be allowed to progress up to, but not including, the first cell division. To achieve this change, the Committee has recommended that the definition of a human embryo created by fertilisation of a human egg by a human sperm should include the fertilised egg from the first mitotic cell division (cleavage). In addition, the current prohibition of the creation of hybrid embryos has prevented the use of a standard test for sperm maturity by experimental fertilisation of animal eggs. The Committee has therefore also recommended that hybrid fertilisation should be permitted, under licence, up to, but not including, the first cell division.

### ***Use of excess ART embryos***

Excess ART embryos have been used for research and other activities to improve the clinical practice of ART or for the derivation of embryonic stem cells. Overall, there was support for the use of excess ART embryos in research under the provisions of the RIHE Act. This view was also heard from ART consumers, many of whom have donated their excess embryos for research. The Committee has recommended that the use of excess ART embryos continue to be permitted, under licence, for research, training and other uses to improve the practice of ART.

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1. NHMRC (2005). *Discussion Paper: Human Embryo — A Biological Definition*, NHMRC, Canberra. <http://www.nhmrc.gov.au/embryos/index.htm> (from January 2006)

Although some respondents suggested that ART clinics produce more ART embryos than required for treatment in order to ensure a supply of excess ART embryos, the Committee received no evidence that this is the case. Furthermore, ART clinics told the reviews that more excess ART embryos have been donated for research than there are research projects to use them. The Committee has therefore suggested that consideration should be given to a register of excess ART embryos available for research to facilitate the most efficient use of this resource.

The sunset clause in the RIHE Act (s46), which has now lapsed, was a response to similar concerns in 2002, and was an instrument of government to provide time for the development of an appropriate licensing and inspection system. The licensing system is now in place and the Reproductive Technology Accreditation Committee (RTAC) monitoring and annual reporting mechanisms for ART clinics are well established. Therefore, the Committee concluded that there is no further need to restrict the use of excess ART embryos to those produced before a specified date or for any further mechanism for monitoring of this process.

Information from the reviews showed that the status of embryos that are unsuitable for implantation is not clear in the current legislation. Such embryos are currently discarded, but researchers and ART practitioners indicated that these embryos would be useful for research, training and quality assurance activities. The Committee has therefore recommended that embryos that are not suitable for implantation should be permitted to be used for research, training and improvements in clinical practice and that the NHMRC should develop ethical guidelines for these uses. However, objective criteria should be developed by an expert body, against which decisions on declaring an embryo not suitable for implantation could be made. These criteria could include embryos that have not undergone mitotic divisions, carry additional pronuclei or show other major chromosomal defects, as well as those diagnosed by preimplantation genetic diagnosis (PGD) as having serious genetic defects.

In terms of using excess ART embryos to derive stem cells, research using excess ART embryos under licence since 2002 has yielded a number of new embryonic stem cell lines and researchers are working with these to further refine the methods of cell culture and differentiation that will be needed to develop cellular therapies. The Committee carefully considered all the submissions on embryonic stem cell research and equivalent research on adult stem cells and noted the following issues:

- many of the arguments made in favour of or against embryonic stem or adult stem cell research were speculative
- it is not possible, or helpful, to try to establish the relative experimental or potential therapeutic merits of embryonic stem and adult stem cells
- while embryonic stem cell research findings have not yet translated into any clinical trials or treatments, the use of excess ART embryos to derive embryonic stem cell lines has contributed to progress in the derivation and culture of the cells and in methods of promoting the growth of different cell types
- there have also been many preliminary findings in animal studies that indicate sufficient potential to warrant further investigation
- the range of diseases and conditions involved is substantial, and the number of people who may ultimately benefit from stem cell research is high.

These developments have continued to highlight moral and social questions about the use of human embryos in research. Indeed, it was clear to the Committee that much of the debate regarding the relative merits of embryonic and adult stem cell research was underpinned by differing attitudes towards the moral status of human embryos, and at times it was difficult to distinguish moral arguments from scientific or biological ones. This requires that all arguments be carefully examined not only in terms of the accuracy or lucidity of the argument itself, but also in terms of the values or

interests of the individual or group making the argument. Overall, the Committee therefore considered that further research on all aspects of stem cell biology, including those from embryonic and adult sources, is required to ensure that the potential of this field is fully realised.

### ***Creation of embryos other than by fertilisation***

The Committee also heard that further development of embryonic stem cell research requires creation of human embryo clones to generate embryonic stem cells that are either patient-matched for development of specific cellular therapies, or of known genotype for disease modelling and other research (so-called ‘therapeutic cloning’). The Committee has reached an opinion, based especially on the evidence of experts who work directly in one or both fields (adult or embryonic) of stem cell research, that further research is required to improve knowledge and develop effective disease treatments. However, during the reviews, the Committee heard a number of objections to methods of creating human embryos not involving fertilisation of an egg by a sperm (including somatic cell nuclear transfer (SCNT)) to generate embryonic stem cells.

One argument was that the technology is the same as that used for reproductive cloning and therefore allowing cloning to extract stem cells would inevitably lead to the use of cloning technology for reproduction. However, as discussed above, the Committee has recommended that development of human embryos created by any method not involving fertilisation of an egg with sperm beyond 14 days, or implantation of such an embryo into a woman’s reproductive tract, should continue to be prohibited to ensure that such embryos are not used for reproductive purposes.

A further argument was that it is wrong to create human embryos to destroy them and extract stem cells. Human embryo clones are human embryos and, given the right environment for development, could develop into a human being. Furthermore, if such an embryo were implanted in the uterus of woman to achieve a pregnancy, the individual so formed would certainly have the same status and rights as any other human being. However, a human embryo clone created to extract stem cells is not intended to be implanted, but is created as a cellular extension of the original subject. The Committee therefore agreed with the many respondents who thought that the moral significance of such a cloned embryo is linked more closely to its potential for research to develop treatments for serious medical conditions, than to its potential as a human life.

Furthermore, the production and destruction of such an embryo is not dissimilar to the production and destruction of excess ART embryos, which is permitted by the legislation and widely accepted by society. Thus, to permit one (production and destruction of ART embryos) but not the other (production and destruction of nuclear transfer and other bioengineered embryos) would be inconsistent and appear to attach more importance to the treatment of infertility than to the treatment of other diseases and conditions that could be helped as a result of this activity. In view of the wide range of diseases and conditions that stem cell research aims to help, and the burden of disease involved, the Committee has recommended that the creation of human embryo clones by SCNT should be permitted, under licence, for research, training and clinical applications.

In line with this recommendation, the Committee could also see potential benefits in other areas of research involving the creation of human embryos or human embryo clones by methods not involving fertilisation of a human egg by a human sperm. The Committee has therefore recommended that creation of such entities should also be permitted, under licence, for use in research, training and clinical applications. Similarly, creation of human embryos using the genetic material from more than two people, including heritable alterations to the genome or using precursor cells from a human embryo or fetus, should also all be permitted, under licence, for research to increase knowledge or treat diseases. The prohibition on developing a human embryo for more than 14 days and on implantation into the reproductive tract of a woman will prevent any of these embryos from being used for reproductive purposes.

### ***Egg donation***

A significant argument against the use of somatic cell nuclear transfer was that it requires the use of donated human eggs. The difficulties associated with attracting women to donate oocytes for research and with obtaining meaningful consent were seen as a major problem by many participants in the reviews. In this regard, the donation of eggs is riskier for the donor than the donation of other tissues, and the healthiest eggs would be those from young women. Therefore, the potential exists for coercion of young women to donate eggs (such as through social disadvantage, family or workplace pressures). Women in ART treatment programs may also be requested to donate eggs for research and, therefore, to avoid coercion of women in this situation, there needs to be clear separation between the obtaining of eggs for ART practice and research. While acknowledging that there is no completely satisfactory or generally agreed resolution to the issues raised by oocyte donation for research, the Committee has therefore recommended that egg donation should be managed by strict ethical guidelines (see below) and that payment to donors should not be permitted beyond reimbursement of reasonable expenses.

Furthermore, the Committee noted other sources of eggs, such as from frozen ovarian tissue or production of eggs from stem cells, may become available as research progresses and considered that use of these sources should be encouraged. In addition, the Committee has recommended that, to reduce the need for human eggs during the developmental stages of nuclear transfer research, use of animal oocytes should also be permitted, under licence (as long as all the requirements of the amended Acts in this regard are satisfied and that these embryos are not implanted into the body of a woman).

### ***Licensing arrangements and oversight of ART services***

Respondents to the reviews considered that the Licensing Committee fulfils a valuable role. The Committee has recommended that this role should be expanded to include licensing of the additional activities recommended in these reviews. However, the Committee supports the role of the institutional human research ethics committees (HRECs) and the dual system of approval, initially by the HREC, followed by application for a licence from the Licensing Committee. Therefore, although the Committee's recommendations allow a larger number of research proposals, institutional HRECs will be able to allow or decline specific research proposals for their institution.

During the reviews, the Committee heard that training and quality assurance activities at ART clinics have been impeded by the current licensing arrangements, which are not well suited to these activities. While all research involving human embryos should continue to require a licence, the Committee has recommended that the licensing process for training and quality assurance activities at ART clinics should be facilitated by the Licensing Committee developing a simplified proforma application for these activities.

Informed consent for embryo and egg donation was an important issue in the public consultation process. All stages of consent were seen as having an emotional component, with many people inclined to donate excess embryos to research rather than letting them succumb.

Donors of excess ART embryos expressed concerns that the current process for declaration of embryos as excess ART embryos, followed (at a later stage) by consent for a specific research project, is unnecessarily drawn out and stressful. However, the Committee noted that there are important distinctions between different purposes or intent of the research that are not known until the embryos are selected for a specific project. In addition, there are different issues to consider for research with human embryos for the purposes of improving ART services (where there is no ongoing live biological material produced from the embryos), compared with research with human embryos for the purpose of creating embryonic stem cell lines that are 'immortal' and will be used in various other ongoing research contexts. In this regard, the Committee considered that it is important for people to be fully informed about the commercial potential of their donation and, where possible, appropriate conditions should be put in place for personal use of any products of the research by the donors (such as for

treatment of children who are matched with any stem cell lines derived). Therefore, the Committee has recommended that the NHMRC Australian Health Ethics Committee should review its guidelines for consent in these circumstances.

The Committee heard that the processes that have been put in place for monitoring and facilitating compliance with the legislation are generally regarded as suitable, although suggestions for improvements to the system were also made. However, the limited powers of the inspectors appointed under the RIHE Act to monitor activities that are not covered by a licence means that suspected breaches by non-licence holders cannot be adequately investigated. The Committee has therefore recommended that the Acts should be amended to give inspectors adequate powers under both Acts to investigate suspected breaches of either Act.

Most respondents regarded the current arrangements for oversight of ART services by national and State or Territory bodies as appropriate and effective. The Committee noted that an important aspect of the accreditation arrangements is that the NHMRC ethical ART guidelines (ART Guidelines 2004<sup>2</sup>) are mandated in the Reproductive Technology Accreditation Committee Code,<sup>3</sup> a system that ensures compliance with these guidelines, including adherence to the arrangements for declaring ART embryos to be excess and for proper consent for donation of embryos for research. The latter arrangements are also included in the statutory arrangements under the RIHE Act. The Committee recommended that these arrangements are effective and should continue.

Finally, the Committee heard that the cost of the licensing arrangements are high relative to the number of licences issued and would be further increased by imposition of a cost-recovery system. Therefore, the Committee considered that it would be an unfair burden at this stage in the development of the technologies, to recover the costs of licensing from licence applicants.

### **Prescriptive versus regulatory legislation**

Although the reviews showed that both the proponents and opponents of human embryo research would prefer to have a legislative and regulatory environment as compared with no regulatory environment, the Committee heard a number of concerns about the ability of legislation to respond to research needs in a fast-moving area of technology, leading to inevitable ambiguities in the legislation and unfair exposure of researchers to prosecution.

The Committee has recommended that certain practices, including reproductive cloning, should remain prohibited. However, to provide further protection for researchers in a rapidly developing area of technology, the Committee has recommended that the Licensing Committee should be authorised to provide rulings on interpretation of the prohibited practices as long as it reports such rulings immediately and in detail to the NHMRC and parliament.

In terms of permitted practices under the RIHE Act, the Committee has also recommended a more flexible system, where the Licensing Committee would be able to grant licences for research that is not expressly permitted by the Acts or the regulations, but is within their tenor, on condition that it reports immediately to the NHMRC and parliament, as for the prohibited practices above. Importantly, the Committee has recommended that a researcher who conducts research on the basis of a Licensing Committee ruling will be protected from prosecution.

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2. NHMRC (2004). *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*, NHMRC, Canberra. <http://www.nhmrc.gov.au/publications/synopses/e56syn.htm>

3. RTAC (2005). *Code of Practice for Assisted Reproductive Technology Units*, Fertility Society of Australia. <http://www.fsa.au.com/rtac/>

Such flexible regulatory arrangements may ultimately reduce the need for ongoing reviews of the Acts. However, in view of the fast-moving developments in the field, and the range of amendments proposed in these reviews, the Committee has recommended that the two Acts should be subject to a further review either six years after royal assent of the PHC and RIHE Acts or three years after royal assent to any amended legislation.

### ***Trade and international exchange of human embryos, gametes and stem cells***

International controversy around trade and international exchange of gametes, embryos and embryonic stem cells is related to ethical concerns about the sources and uses of these materials, the commodification of human tissues, and commercialisation of any therapeutic products derived from them. However, the Committee heard from ART consumers that the current Australian export prohibitions and custom regulations regarding human embryos have made it difficult for couples to export their embryos overseas for their own reproductive use. The Committee has recommended that the current arrangements, which involve personal application to the Customs Minister to export embryos for personal reproductive use, should be streamlined as much as possible to make the process less stressful for ART consumers.

The Committee heard from some researchers that these arrangements had not affected their research, whereas others noted the importance of Australian researchers having access to further cell lines from overseas. There was general concern about whether such imported cell lines have been derived using practices consistent with Australian legislation. The Committee has recommended that, in light of potential scientific benefits, the import and export of ethically derived human embryo clones and human embryonic stem cells should be permitted after approval by the appropriate authority.

### ***Biotechnology and commercialisation***

There was strong support for the prohibition of trade in human gametes or embryos, or any commodification of these items, and the Committee has recommended these activities should continue to be prohibited. However, a number of submissions noted that there should be mechanisms to ensure that donors and other members of the public have access to the benefits of research and that social justice issues should be of concern at all stages of the stem cell research endeavour. While the majority of participants acknowledged such concerns, industry groups and researchers emphasised that commercialisation is an essential aspect of research and development in this area and that, without investment, new therapeutic products cannot be developed. The Committee noted that need for such commercialisation of a research was not well understood in the community.

Australia has a strong research base in human stem cell research and Australian scientists, backed by both public and private funding, have established several companies and organisations that are capable of commercial development of research outcomes. The Committee has recommended that commercialisation of research in this area should be supported in order to ensure that potentially beneficial products can be developed for therapeutic use. However, the donors of tissue that will result in an immortal cell line or the possibility of future commercialisation need to understand that they will have no rights to any commercial gain because these rights will reside with the investors (that is, the developers of the commercial products). The Committee has therefore recommended that donors are informed about these matters when they make their donation.

### ***Australian stem cell bank***

Stem cell banks offer a way of facilitating research by making the stem cell lines more widely available to the international research community. Although some scientific researchers argued that an Australian stem cell bank may not be necessary because overseas stem cell banks (eg the UK cell bank) were adequate, the Committee heard overall strong support for an Australian stem cell bank in order to improve access to stem cell lines for research and to provide a quality control mechanism for stem cell research.

Fair access and equal involvement were the two main concerns about community involvement in a national stem cell bank. Some respondents were also concerned that the driving forces behind a national stem cell bank were profit and commercial outcomes. However, the Committee considered that, although commercialisation of therapeutic products would be an outcome if research is successful, stem cell banks help to keep research resources in the public domain. The Committee concluded that an Australian national stem cell bank would make stem cells, including embryonic and adult stem cells, more widely available to researchers and also limit number of embryos required for further derivation of stem cell lines. The Committee has therefore recommended that a national stem cell bank be established and that consideration be given to the feasibility of such a bank being managed by the Australian Stem Cell Centre, although other models, such as a decentralised system, could also be considered.

Many respondents, both ART consumers and ART clinics, were concerned that, following the decision to make excess ART embryos available for research, there would be no opportunity for these embryos to be used in actual research projects. While an ‘embryo bank’ may not have broad community support, the Committee considered that there may be potential in a national register of donated embryos, which may facilitate embryo donation for research and provide a transparent account of the number of donated excess ART embryos held. Such a register may also facilitate embryo donation to another couple.

### ***Public education***

In addition to the divergent views expressed, the Committee noted that, within the community, there was often a lack of understanding of the processes involved in prohibited or licensed research. The Committee also found that the scientific community and the public (informed by the media) frequently underestimated the likely timeframes for translation of research activity into therapeutic outcomes and that this had led to disappointment and reduced public trust in science. The Committee therefore suggested that accurate presentation and reporting of research advances is critical for public engagement with this area of research. In particular, emphasis should be given to making realistic assessments of the short-term and long-term benefits of the research. The Committee has recommended that further public education and consultation programs are needed in the areas of research and development covered by the Acts.

## Recommendations

### *National legislation*

- 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.

### *Reproductive cloning*

- 2 Reproductive cloning should continue to be prohibited.

### *Prohibitions on developing and implanting embryos*

- 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.
- 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.
- 5 Implantation into the reproductive tract of a woman of a human–animal hybrid or chimeric embryo should continue to be prohibited.
- 6 Development of a human–animal hybrid or chimeric embryo should continue to be prohibited, except as indicated in Recommendation 17.
- 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.
- 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.
- 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.
- 10 Implantation into the reproductive tract of a woman of an embryo carrying heritable alterations to the genome should continue to be prohibited.
- 11 Collection of a viable human embryo from the body of a woman should continue to be prohibited.

### *Creation of human embryos by fertilisation*

- 12 Creation of human embryos by fertilisation of human eggs by human sperm should remain restricted to ART treatment for the purposes of reproduction.
- 13 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 except in the situation described in Recommendation 15.

### *Use of excess ART embryos in research*

- 14 Use of excess ART embryos in research should continue to be permitted, under licence, as under current legislation.

***ART clinical practice and ART research***

- 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.
- 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.
- 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.
- 18 The Licensing Committee should develop a simple proforma application for licences to undertake training and quality assurance activities for ART clinics.
- 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.

***Use of fresh ART embryos***

- 20 An expert body should formulate objective criteria to define those embryos that are unsuitable for implantation.
- 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.
- 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.

***Use of human embryos created by somatic cell nuclear transfer***

- 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.
- 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.

***Use of human embryos created by activation methods not involving fertilisation of a human egg by a human sperm or somatic cell nuclear transfer***

- 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.

- 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.
- 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.

### ***Definition of a human embryo***

- 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:

- (i) the first mitotic cell division when fertilisation of a human oocyte by a human sperm is complete; or
- (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.’

### ***Consent arrangements for the donation of embryos***

- 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:
- 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.
- 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).

***Egg donation***

- 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.
- 32 The NHMRC should develop guidelines for egg donation.
- 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.

***Licensing arrangements***

- 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.
- 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).
- 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.
- 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.

***Monitoring powers***

- 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.
- 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.

***Oversight of ART clinical practice and research***

- 40 There should be a continuation of the role of the Reproductive Technology Accreditation Committee in the regulation of ART.

***Import and export of human reproductive materials for personal use***

- 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.

***Trade and international exchange of human reproductive materials and stem cells***

- 42 The import or export of ethically derived viable materials from human embryo clones should be permitted after approval by the appropriate authority.

- 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.

### ***Biotechnology and commercialisation***

- 44 Trade in human gametes or embryos, or any commodification of these items, should continue to be prohibited.
- 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.
- 46 The development of biotechnology and pharmaceutical products arising from stem cell research should be supported.

### ***National stem cell bank***

- 47 A national stem cell bank should be established.
- 48 Consideration should be given to the feasibility of the Australian Stem Cell Centre operating the stem cell bank.
- 49 A national register of donated excess ART embryos should be established.

### ***Regulatory approach to legislation***

- 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.
- 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.
- 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.
- 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.

### ***Public education***

- 54 There should be ongoing public education and consultation programs in the areas of science that are relevant to the Acts.

## Abbreviations

ART	assisted reproductive technology
AS cell	adult stem cell
ASCC	Australian Stem Cell Centre
BA	Biotechnology Australia
BESST	birth emphasising successful singleton at term
BMS cell	bone marrow stromal cell
COAG	Council of Australian Governments
DNA	deoxyribonucleic acid
DTU	Diabetes Transplant Unit (Prince of Wales Hospital, Sydney)
EG cell	embryonic germ cell
ES cell	embryonic stem cell
FSH	follicle stimulating hormone
GIFT	gamete intrafallopian transfer
GMP	good manufacturing practice
hESC	human embryonic stem cell
HREC	human research ethics committee
ICSI	intracytoplasmic sperm injection
ITA	Infertility Treatment Authority
IVF	in vitro fertilisation
IVM	in vitro maturation
NHMRC	National Health and Medical Research Council
PGD	preimplantation genetic diagnosis
PHC Act	Prohibition of Human Cloning Act 2002
RCT	randomised controlled trial
RIHE Act	Research Involving Human Embryos Act 2002
RTAC	Reproductive Technology Advisory Committee
SACRT	South Australian Council on Reproductive Technology
s	section (of Acts)
SCNT	somatic cell nuclear transfer
WARTC	Western Australian Reproductive Technology Council

See the Glossary at the end of this document for definitions of terms used.