



AUSTRALIAN FEDERATION OF
RIGHT TO LIFE ASSOCIATIONS

Submission to the
Legislation Review Committee
on the
Prohibition of Human Cloning Act 2002
and
Research Involving Human Embryos Act 2002
by the
Australian Federation of Right to Life Associations
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EXECUTIVE SUMMARY

The Federation requests that the Review recommend that Federal Parliament:

- amend the *Research Involving Human Embryos Act* 2002 to exclude permission to engage in research involving the destruction of human embryos; and
- maintain the ban on those practices prohibited by the *Prohibition of Human Cloning Act* 2002.

The Federation represents a significant grouping of informed community organisations which advocate respect for human from its first beginnings to natural death. The Federation and its member organisations have for over three decades been active and influential participants in the community debates surrounding legislative and social issues relating to the treatment of human persons. The Federation contends that its submission to the current legislative review is founded on the rational ethical position that protection of, and respect for human life is a peremptory norm or *ius cogens* as reflected in international and domestic law and in the customary law of nations.

Terms of Reference [1-3]¹

The Federation is concerned that the Terms of Reference suggest that the ethical considerations which currently restrain and regulate the practice of research involving human embryos should no longer prevail and that the interests of those who wish to operate outside those constraints compel legislative change. Further, the Review's Issues Paper suggests among other things that: community standards might have changed in relation to research with human embryos; the current definition of 'human embryo' and 'human embryo clone' might not be in tune with 'community standards'; Australia might be suffering financial disadvantage by the present prohibitions on destructive research involving embryos.

***Prohibition of Human Cloning Act* 2002 [3-14]**

The Federation continues its unequivocal support of the prohibitions imposed by this Act. We assert that there is no essential difference between the procedure of cloning for reproduction or cloning for research. The result in each case is a cloned human being. Cloning for research means that a new embryonic human being is produced so that it can be destroyed for research – a repugnant practice.

***International standards* [4-6]**

The recent robust debate in the United Nations Assembly which resulted in a ban on human cloning should be noted and challenges claims that Australia is out of step with the international community. The outraged reaction of some Australian researchers demonstrates no respect for the relevant Australian laws and some have even denied that legislators should be the decision-makers in this field.

***Ethics and terminology* [6-8]**

The Review is in danger of being captured by the 'scientific imperative' (ie 'what can be

¹ [...] refers to pages of the body of the submission.

done must be done') unless it examines critically the claims of those who advocate the cloning of human embryos, resorting to inflated, enthusiastic promises of cure-alls and accusations of obstruction to 'progress'. Their assertion that science is self-validating in ethical terms is proof of extraordinary hubris of which history provides other disastrous examples. Their persistent efforts, reported recently in the print and electronic media, to change the definition of 'embryo' is evidence of intellectual legerdemain.

Disdain for Federal law and law-makers [9-12]

Some researchers, anxious to push their own agenda, are dismissive of community opinion and parliamentary rule; one has openly argued that Parliament must not be allowed "open slather" in these matters. It should be axiomatic that Parliament has the final say in deciding the boundaries of this research, particularly as it concerns the treatment of human lives.

The Research Involving Human Embryos Act 2002 [14-20]

Monitoring and compliance with this Act is effected through the National Health and Medical Research Council's *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*, 2004. While the Federation supports the ban on the practices which those Guidelines deem unacceptable, it has particular concerns about their effectiveness in relation to the following:

- the production of excess embryos (which are legally available for research) is common in ART programs and susceptible to manipulation;
- the difficulty of determining with any accuracy what are the "accepted standards" invoked by the Guidelines to inform ethical clinical practice;
- many practices are in conflict with stated principles of respect for human life in clinical practice including:
 - the use of pre-implantation genetic diagnosis (PGD) to select (and destroy) embryos; the Guidelines admit that there is no agreement on what constitutes serious disease or handicap;
 - sex selection of embryos where serious disease may be involved;
 - acknowledgment that some research **undertaken solely to develop new knowledge**, even on an embryo destined to be born, can carry a risk to the welfare of that embryo.

The difficulties in ensuring compliance with the NHMRC Ethical Guidelines include [20-25]:

- **information.** It is doubtful that ART participants are capable of weighing up the myriad issues affecting themselves and any embryos produced in the process.
- **counselling.** The Guidelines should require that participants be counseled by professionals who are entirely independent of the participating institution.
- **consent.** It is clear participants may fear that their place in the ART program might be compromised if they fail to consent to experimental procedure on their embryos.
- **storage of embryos.** There is a lack of clarity about the principles governing their control and decisions affecting their ultimate fate.
- **complaints about breaches.** An independent body should oversight complaints about clinical practices allegedly in breach of the legislation and/or conditions of a licence.
- **conscientious objectors.** There is no mechanism for hearing claims that staff have been pressured to participate in certain procedure to which they object.
- **disclosure of financial interest.** Disclosure is ineffective in harnessing the profit

motive in embryo research. Researchers should be precluded from profit taking.

Human Research Ethics Committees (HREC) [26]

The Federation wishes to point to the problems of:

- conflict of interest in the discharge of the responsibilities of a HREC when its members may include persons whose interests are directly or indirectly affected;
- difficulty in imposing restraints on professional colleagues.
- disinclination to attribute motives of self-promotion and/or commercial gain to medical and scientific staff colleagues of an institution;
- lack of adequate sanctions attendant on a breach of the guidelines.

Conclusion and Restatement of basic pro-life principles [27]

Consonant with the principles of the Nuremberg Code and of the Declaration of Helsinki, the Federation declares its opposition to research on a human subject where no benefit accrues to that subject. The Federation considers that all destructive, non-therapeutic research on embryos should be prohibited whether the embryos are produced by sexual reproduction, somatic cell nuclear transfer, cloning by splitting, or any other means that produce an individual organism with capacity to develop into an independent human being. This includes, of course, destructive harvesting of stem cells from human embryos. Such research is an abandonment of the most basic principle of good medical practice, that is, Do No Harm.

Introduction

This Submission wishes to address the Terms of Reference particularly in relation to:

- item (i) c) community standards and
- item (ii) the following additional matters in relation to the national legislative scheme
 - c) the effectiveness of monitoring and compliance under the *Research Involving Human Embryos Act 2002* (RIBE Act) in particular, but also in relation to the *Prohibition of Human Cloning Act 2002* (Cloning Prohibition Act) to the extent that issues may arise in relation to the latter Act;
 - d) the ongoing appropriateness and effectiveness of changes to the Customs regulations to regulate the export of human embryos derived through ART and the import of viable materials derived from human embryo clones;
 - e) options for regulating the import/ export of human embryonic stem cells;
 - f) the implications of cost recovery; and
 - g) implications for Australian science and economic activity.

The Federation comments that on numerous occasions the text of the Issues Paper is so phrased that it appears to be inviting dissatisfaction with any restraints currently imposed on research by the RIHE Act and Cloning Prohibition Act. For example:²

- querying whether the definitions of ‘human embryo and ‘human embryo clone’ are clear and unambiguous; whether they appropriately reflect community standards; and whether they cover all of the activities that should be regulated under the legislation? [*I2*]
- suggesting that the legislative restrictions have meant that researchers in Australia have not been allowed to use stem cells from human embryo clones for “research on cellular therapies” [*I5*]
- presenting the argument against the production and use of human embryo clones in prejudicial terms: the embryo is described as “capable of *becoming* a human being” (emphasis added). It is fact that the human embryo *is* a human being in the early stages of development. [*I5*]
- querying whether the prohibited embryos and practices described in the Act still relevant, and whether the current legislative prohibitions appropriately reflect community standards [*I5*]
- encouraging those involved in (a) ART programs and (b) stem cell research activities to advocate changes to the current import and export prohibitions such as may affect their operations [*22*]
- canvassing the advantages of a stem cell bank and the questioning of whether Australian researchers have “appropriate access” to overseas banks. No clarification is given as to the source of the stem cells, a critical point at issue [*23*]
- implying that, because other countries allow embryos to be created specifically for destructive research, Australia should do likewise. [*25*]

It is disappointing to observe this partial encouragement to those scientists who argue for ‘reform’ reflected in the Review’s Terms of Reference. In particular, **Terms (ii) (d) – (g)** invite consideration of lifting the import ban on material from cloned human embryos and ‘coat-trailing’ the possible economic effects of continuing the current ban on such activities.

² References in italics [] in the appended dot points are to pages of the Issues Paper.

Advocacy on these issues has been well aired in the print and electronic media and might have been best left to those who have openly urged the lifting of all restrictions on research involving human embryos, overturning the current prohibitions and the commercialization of the products of destructive research on human subjects for their own financial interests. They could have been relied upon to do so.

The Review lacks a Term of Reference which simply advocates retaining the current restrictions and prohibitions. Consequently it is dismaying to read that the Chairman of the Review, Justice John Lockhart, describes its task as "... to strike a balance between emotional reaction and rational progress".³ The words "emotional reaction" could easily be taken as a gratuitous and prejudicial reference to any view that supports the current legislative provisions.

Is "rational progress" code for the presumption that the 'scientific imperative' must lead to a pre-ordained outcome of the Review? There is no doubt that the Review will be regaled with appeals to the 'scientific imperative' which, simply put, amounts to "whatever can be done must be done" – and preferably before others do it! Nazi medical experiments should haunt us all; and Orwell's warning about deceptive language is still to be heeded.⁴

To dub "progress" as necessarily "rational" is to beg the question. Progress to those who push for the adoption of some policy or procedure is always rational in their terms; history is littered with havoc wrought by 'visionaries'.

"When one hears of progress one should ask for whom."⁵

The pejorative reference to "emotional reaction" implies that an emotional reaction to some proposal is unsupportable by reason: does horror at the Holocaust preclude reasoned moral objection to such a course of action?

Similarly the Federation finds puzzling that, while the Review states that it is not its purpose to revisit the underpinning community debate [preceding passage of the two items of legislation in 2002], the Issues Paper stresses throughout that it "must take account of 'community standards'".⁶ Does the Review Committee presume that the input of the community to the decision of the Federal Parliament some mere three years ago is now substantially altered or even obsolescent? Fundamental ethical positions are not likely to prove so ephemeral.

The Prohibition of Human Cloning Act 2002

The Federation continues its unequivocal support of the prohibition imposed by the Prohibition of Human Cloning Act on the following practices:

- creating a human embryo clone [s 9];
- placing a human embryo clone in the human body or the body of an animal [s 10];
- importing or exporting a human embryo clone [s 11];

³ *The Australian*, 2 September 2005 p 15.

⁴ George Orwell, *Nineteen Eighty-Four*. Newspeak, the language of the tyrannical State of Oceania, was designed to narrow the range of thought and to make impossible interpretations of reality not favourable to the ruling Party.

⁵ Robin Skelton. *A Devious Dictionary*. 1991.

⁶ For example, see Issues Paper p 12 and p 15.

- creating a human embryo other than by fertilisation, or developing such an embryo [s 13];
- creating a human embryo for a purpose other than achieving pregnancy in a woman [s 14];
- creating or developing a human embryo containing genetic material provided by more than two persons [s 15];
- developing a human embryo outside the body of a woman for more than 14 days (excluding any time in which its development has been suspended) [s 16];
- using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo [s 17];
- intentionally altering the genome of a human cell in such a way that the alteration is heritable by descendants of the human whose cell was altered [s 18];
- collecting a viable human embryo from the body of a woman [s 19];
- creating a chimeric or hybrid embryo [s 20];
- placing a human embryo into an animal [s 21(1)];
- placing a human embryo into the body of a human, other than in a woman's reproductive tract [s 21(2)];
- placing an animal embryo into the body of a human for any period of gestation [s 21(3)];
- importing or exporting a prohibited embryo [ss 22(1) and 22(2)];
- placing a prohibited embryo in the body of a woman [s 22(3)]; and
- commercial trading in human eggs, human sperm or human embryos [s 23].

Resolution of the United General Assembly of 8 March 2005

In relation to the prohibition on creating a human clone as provided by s.11 of the Prohibition of Human Cloning Act the Federation draws the attention of the Review to the recent United Nations ban on all forms of human cloning. On 8 March 2005 the United Nations General Assembly approved a declaration calling on UN Member States to ban all forms of human cloning, including cloning for medical treatment, as incompatible with human dignity and the protection of human life. The Assembly adopted the text to be known as the *United Nations Declaration on Human Cloning*.

The Declaration calls on member States to take a number of steps, including:

- adopting all measures necessary to adequately protect human life in the application of life sciences;
- prohibiting all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life;
- adopting the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity;
- taking measures to prevent the exploitation of women in the application of life sciences;
- adopting and implementing without delay national legislation to protect adequately human life and to prevent the exploitation of women.

It is to be noted that the Review commented that 35 countries did not support the UN resolution.⁷ It is surprising that the Review thus highlighted dissent rather than provide the full voting record: 84 in favour, 34 against, 37 abstaining, with 36 absent (it is a well-known tenet of international law that States who abstain from voting on a resolution are taken not to have vigorous objection to a resolution).

⁷ Issues Paper p 25.

Thus the United Nations has set out clear ethical standards that should guide scientific research calling on member states to ban all forms of human cloning, whether for reproduction or for research.

The resolution should not be interpreted as prohibiting all forms or types of research involving embryonic life. The United States, which voted for the Declaration, issued a position paper clarifying its support for the development of non-destructive cell and tissue-based therapies eg for producing DNA molecules, organs, plants, tissues, cells (other than human embryos), or animals (other than humans).⁸ Notably there is nothing in the Prohibition of Human Cloning Act that would affect these non-destructive procedures.

The Federation asserts that there is no essential difference between the procedure of cloning for reproduction or cloning for research. The result in each case is a cloned human being. Cloning for research means that a new embryonic human being is produced so that it can be destroyed for research – a repugnant practice. The Australian Government is to be commended for its support for the UN cloning ban.

When these matters were under discussion late last year and Australia had indicated its support for such a ban, some of the Australian media rather sensationally presented this position as a conservative push or “backflip”.⁹

The proposed UN cloning ban was predictably condemned by those elements of the Australian research and biotech community who wish to clone human embryos in Australia for international commerce and trade. These included David Newton, Australian head of international biotech firm Stem Cell Sciences, and Monash University stem cell scientist Alan Trounson who was reported as fearing the Government's "unfortunate" stance might hinder a "genuine and open discussion" on therapeutic cloning.¹⁰

This pronouncement by Professor Trounson appears to be a deliberate, self-serving propaganda exercise calculated to influence the Review. In like vein, Democrats science spokeswoman, Senator Natasha Stott Despoja, argued that Australia's support for the ban reflected a growing conservatism in Australian politics. Similar views were expressed by the then NSW Labor Premier Bob Carr, a strong proponent of embryo stem cell research, and by the federal Labor science spokeswoman Jenny Macklin.

Yet the content of the 2005 UN Declaration is no different from the prevailing Australian domestic legislation prohibiting human cloning. It is irrational to object to Australia's following of its own law in supporting the UN ban. It can only be concluded that those Australian researchers who have been urging a lifting of the Prohibition of Human Cloning Act's ban on cloning were confident that their view must prevail and do not readily countenance the ethical opposition, widespread in the Australian community, to the cloning of human beings for any purpose whatsoever.

Definitions and the abuse of language

The Review emphasises the importance of a common language for use in the debate on the current legislation:

⁸ UN News Centre 8/03/05 (<http://www.un.org/apps/news/story.asp?NewsID=13576&Cr=cloning&Cr1=>)

⁹ See Leigh Dayton, *The Australian* 22 November 2004, http://www.news.com.au/common/story_page/; Ray Welling, *The Scientist* 2 December 2004 <http://www.biomedcentral.com/news/20041202/02/>.

¹⁰ *The Australian* 22 November 2004.

“The Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002 include precise definitions of ‘human embryo’ and ‘human embryo clone’, around which the legislation and the national regulatory scheme are based. It is therefore important that everyone has the same understanding of these terms and the way that they are currently used in the legislation. Definitions of these terms from the legislation are provided below with an explanation in plain English and a brief discussion of the legal, scientific and public understanding of the terms.”¹¹

The Issues Paper then provides the accepted definitions of a human embryo and a human embryo clone respectively.

“Human embryo

A live embryo that has a human genome or an altered human genome and has been developing for less than eight weeks since the development of two pronuclei or the initiation of its development by any other means not including any period when its development was suspended for any reason. For an embryo to be defined as a ‘human embryo’, it must be viable (that is, able to grow and develop). This means that the embryo must have the usual component of human chromosomes containing the blueprint of human development in the form of DNA, organised as genes.

“Human embryo clone

Advances in cell biology have allowed embryonic development to be started by injecting a cell nucleus extracted from any cell in the body into an egg cell from which the nucleus has been removed (nuclear transfer). **This is the basis of cloning technologies** This part of the definition therefore means that **once a cell is created (by nuclear transfer or any other means) that has the same potential to continue development as a cell formed by fertilisation of a human egg and a human sperm, it is included in the definition of a human embryo.**¹² (emphasis added)

Despite the universal acceptance of these definitions, it has become increasingly the habit of some researchers to eschew the term “cloning” in favour of the phrase “somatic cell nuclear transfer”. Of course, the latter is simply the “basis of cloning technologies” that ultimately are capable of producing a clone; it is undeniably the very process that produced cloned sheep, calves, and, lately, a dog.¹³ The resort to this linguistic obfuscation can have no purpose other than to deliberately mislead and confuse the Australian community and distort evaluation of ‘community standards’.

¹¹ Issues Paper, page 5.

¹² Issues Paper pp 5-10.

¹³ The cloning of a male dog has recently been achieved in South Korea after some 1000 unsuccessful attempts.

An example of this is Professor Trounson's statement that "somatic cell nuclear transfer" is simply the process which allows scientists to obtain embryonic stem cells.¹⁴ What is not said in this disingenuous description of the process is that "somatic cell nuclear transfer" is followed by the creation of an embryo from which the stem cells are then taken, thus ensuring the destruction of the embryo. In like vein, Professor Bob Williamson, University of Melbourne, argues that, since the organisms created by nuclear transfer lack the social context of entities created by the usual process of fertilisation, **he** does not "regard this as an embryo in any sense".¹⁵ Later Williamson forecasts that in a few years time a diploid cell could be modified so that if implanted it could become an embryo.¹⁶

As proof that this was not some isolated instance of his reasoning in the sometimes hyperbolic style of academic debate, Professor Williamson recently put identical views in a bid for the hearts and minds of television viewers:

When it comes to therapeutic cloning, it's a pity that term has got out there because in my view what we're talking about is not cloning at all. Indeed, scientists want to have the permission from society to take a nucleus from a skin cell, a liver cell, any cell in the body of anyone in this room and put it into an egg, not in order to clone it, but in order to give it a little kick backwards so that it can turn in to a pancreatic cell for diabetes or a lung cell for cystic fibrosis. *My view is that that has nothing in common with an embryo.*¹⁷ [emphasis added]

Professor Williamson and like-minded colleagues have every right to push for amendment of the *Cloning Prohibition Act*.¹⁸ What should not be tolerated is their attempt to change the definition of cloning (as defined in the legislation), nor the omission of a critical stage in the description of the cloning process eg the same article reports as follows:

“Therapeutic cloning-nuclear transfer:

Used to create embryonic stem cells for research or therapeutic use. Genetic material from an adult, say skin or blood, is put into a donor egg emptied of its genetic material. After a few days ES cells are extracted and used to create a research stem cell line (colony), or re-injected into the donor to repair defective organs without rejection. Prohibited in Australia. Allowed in Britain, US, South Korea and Japan.”¹⁹

This article, published in a national newspaper with wide circulation, is typical of the misleading propaganda designed to influence the outcome of the review of the legislation. Firstly, it states as accomplished fact that ES cells will “repair defective organs without rejection”, whereas the claim is purely conjectural; secondly, it omits the critical step between nuclear transfer and the extraction of ES cells ie the creation of an embryo.

This ontological sleight-of-hand, whereby meaning is determined solely by the user's intention without reference to any agreed denotation, *precludes discussion based on a common terminology*. It is not a new approach to meaning, though not one of good repute and long the target of satire:

¹⁴ *The Australian*, 5 July 2005.

¹⁵ Bob Williamson, *Striving for an ethical way forward for stem cell research in Australia*. Australian Academy of Sciences Annual Symposium 6 May 2005.

¹⁶ See footnote 14.

¹⁷ Transcript of TV Channel SBS, *Insight*. 8 March 2005

¹⁸ *The Australian*, 2 September 2005, p19.

¹⁹ See footnote 17.

“When I use a word,” Humpty said in a rather scornful tone, “it means what I choose it to mean – neither more nor less.”²⁰

The Federation notes that Professor Williamson is co-author of the submission of the Australian Academy of Sciences to the Review.²¹

Cures for all ills

Predictably we are promised all sorts of cures for human conditions if only scientists are allowed to destroy the human embryos created in the laboratory for their ordained purposes. “The enormous distortion of hope that’s not tinged with reality” is how Professor Jack Martin describes the hyperbolic language used by those who promise sure cures, if only they are allowed to remove all boundaries on their research.²² So far there have been no cures for such ailments from embryonic stem-cell research; yet there have been numerous, impressive beneficial applications achieved from stem cells harvested from mature cells.

It is relevant to refer here to a press report of the First Consultation Meeting of the Committee held on Thursday 1 September 2005 in Adelaide. At that meeting Professor Peter Rathjen, head of the University of Adelaide's Department of Molecular Biosciences, is reported as saying that stem cell technology had vast applications; further, a stem-cell bank would aid in creating a new generation of Australians who had high quality lives until they died:

"If this sort of technology is adopted in its broadest sense, then my view is it will be an utter paradigm shift in the way we think about medicine".²³

Whether through omission either by Professor Rathjen or by the media reports, what is not made clear is the source(s) of the proposed stem-cell bank. If the stem-cells are derived other than from prohibited embryos (for example, embryos neither from excess ART embryos nor from cloned embryos), then there is no conflict between the proposal and the present legislative constraints. If the stem-cells referred to are derived exclusively from mature cells (for example, cord blood cells, other somatic cells), then there is no ethical issue to be resolved. The lack of information is typical of the reporting of promised cures; it does not promote community understanding of the issues.

ES cell researchers and the law

Professor Rathjen is reported to have said that Australia's laws must reflect the potential of the technology.²⁴ This attitude to law is unfortunately not uncommon among embryonic stem cell researchers. Professor Bob Williamson, clearly chafing under the current legislative restrictions, is dismissive of ethical restraints, states in this context:

“Research is inherently of value to society. It is inherently ethical”.²⁵

²⁰ Carroll, Lewis, *Through the Looking-Glass*. Chapter 6

²¹ See footnote 17.

²² See footnote 16.

²³ Professor Rathjen, *The Age* 1 September 2005.

²⁴ See footnote 22.

²⁵ See footnote 14.

From this novel standpoint he accuses many health research ethics committees of being “risk averse”. In pursuit of ethical hegemony for researchers, Williamson objects to even lawyers’ holding positions on Human Research Ethics Committees (HREC) and deplors the necessity of researchers’ having to wait upon access to embryos excess to ART programs. The clear conclusion is that Professor Williamson wishes to create embryos expressly for research; he should simply say so without overreaching ‘ethical’ claims.

Who will make the final decision?

The Issues Paper, in addressing the issue of who will make the final decision, is in no doubt: it is the Australian Government in consultation with State and Territory governments.²⁶ That of course is the way of a parliamentary democracy. It seems not to be the way of scientists such as Professor Williamson who sees the parliamentary process as no more than a road-block to his hubris born of scientific megalomania:

“... we must not allow parliament ‘open slather’ to regulate research that is carried out in laboratories. ... This research [cloning embryos for research purposes] is of great potential value, and is not embryo research.”²⁷

Of course not all scientists are so dismissive of ethical concerns nor so contemptuous of accepted scientific definitions. Others acknowledge the community’s right to decide the issue by democratic means:

“Professor Jack Martin – There is an ethical issue for our community.... it’s throughout our society. It’s not just one religion, it’s throughout the Christian religions and the non-Christian religions and people of no religion at all. So there is an ethical barrier and yet that barrier is being influenced by the enormous distortion of hope which is hope that’s not tinged by reality.”²⁸

We expect the Review to treat with great caution representations from researchers who do not concede that science is not a self-authenticating activity. Science like all areas of human endeavour has ethical obligations, particularly in this case respect for human life.

Customs regulations and economic arguments

A. Term of Reference (ii) d) - *the ongoing appropriateness and effectiveness of changes to the Customs regulations to regulate the export of human embryos derived through ART and the import of viable materials derived from human embryo clones;*

The Prohibition of Human Cloning Act 2002 makes it an offence to import, export or place in the body of woman a ‘prohibited embryo’. The Review acknowledges that the current legislation is designed to ensure that stem cell lines cannot be used in Australia if they were derived overseas using practices that are prohibited in Australia.²⁹

Comment

The Federation wishes to raise two matters of concern:

²⁶ Issues Paper, page 4.

²⁷ See footnote 14.

²⁸ See footnote 16.

²⁹ Issues Paper p 21.

- since March 2003 the Customs (Prohibited Exports) Regulations allows the Minister for Customs to consider an application for **export of a human embryo for the sole purpose of implantation** in the prospective mother or a relevant woman to achieve her pregnancy. If the prospective mother has died, an application can be made by her spouse at the time that the embryo was created or donated.
As required by subregulation 7(15) the Minister for Justice and Customs reported that during the period 1 January to 30 June 2005 he had approved five export permits for human embryos. Of these, three involved the use of the embryo(s) to achieve the applicant's own pregnancy and two involved the use of the embryo(s) to achieve the pregnancy of a surrogate. One of these surrogacy agreements was commercial and the other was non-commercial.

It must be asked: why was permission given for the export of an embryo for a commercial surrogacy when this practice is forbidden in Australia?

- The Australian Quarantine and Inspection Service administers quarantine arrangements for the import of human embryos, sperm and eggs. These items can be imported for human therapeutic use (including implantation), artificial insemination or IVF.

As the words “including implantation” imply that these imported embryos are used for purposes other than implantation in a woman, the Australian public and authorities need assurance that these embryos are not prohibited embryos in terms of Australian legislation eg created specifically for research purposes, cloned, or genetically modified by a banned process.

The Federation is opposed to any relaxation of Customs regulations which would render ineffective the provisions of s 9 and s 11 of the Cloning Prohibition Act with these predictable effects:

- to enable the “export of human embryos derived through ART”, presently prohibited by s 11, is indicative of promoting a commercialisation of human beings through their exploitation as merely products for research; and
- to enable the “import of viable materials derived from human embryo clones” is a blatant attempt to bypass the ban on human embryo cloning presently prohibited by s 9. To allow such a relaxation of Customs regulations would render the application of s 11 of the Cloning Prohibition Act ineffective and thus subvert the expressed intention of the Parliament to ban all forms of human cloning.

Those advocating the changes mooted in this Term of Reference are plainly seeking:

- a repeal of s 11; and further,
- to bypass the provisions of s 9, which prohibits cloning of human embryos, by obtaining the “materials” from human clones from overseas, in defiance of the substance of current Australian law and of any ban on human cloning within Australia which Parliament may choose to continue.

B. Terms of reference:

- (ii) e) options for regulation of the import and export of human embryonic stem cells;

- (ii) f) the implications of cost recovery; and
- (ii) g) implications for Australian science and economic activity;

To allow the import and export of human embryonic stem cells indicated in (ii) e) is no more than to advocate the repeal of s 23 of the *Cloning Prohibition Act* which prohibits the commercial trading in human eggs, human sperm or human embryos.

Comment

If such traffic were to be allowed by the Parliament it would encourage stem-cell traders to flout the provisions of s 22(1) and s 22 (2) which currently prohibit importing or exporting a prohibited embryo. In particular, it would lend impetus to those institutions and researchers which would flout, or seek to repeal current restrictions, such as the prohibitions on:

- creating a human embryo other than by fertilisation, or developing such an embryo [s 13];
- creating a human embryo for a purpose other than achieving pregnancy in a woman [s 14];

Allowing the export and import of ART embryos would encourage researchers:

- either to create human embryos other than through fertilisation eg through embryo splitting;
- or to produce more embryos through ART procedures than are necessary for the achievement of a pregnancy, or likely to be required by the woman in her reproductive years.³⁰

It would be naïve to ignore the track record of certain researchers in this field who first produce 'innovative' procedures and then purport to seek community approval for the product. Once a human embryonic 'product' is derived and proved profitable to those who 'own' the material, pressure will inevitably be brought on legislators not to forego the perceived economic benefits of the activity. This predictable pressure is in fact indicated in the Term of Reference (ii) g) - *implications for Australian science and economic activity*.

Professor Rathjen's testimony to the Committee in Adelaide supports the well-founded fear that a serious ethical debate will be subverted by appeals to trade and profit:

"The markets for this sort of thing are very difficult to estimate but certainly would seem to in excess of \$US100 billion (\$A132.75 billion) per year. If Australia can get even a slice of that kind of action, that also would have a spectacular impact."³¹

The Federation opposes any changes to the Cloning Prohibition Act for the reasons given above. It submits that there is a clear choice facing the Review: will it recommend that human subjects can become material for destructive research and/or commodities for economic gain; or will it uphold the current legislative bans provided by the legislation?

C. Terms of reference

³⁰ The substantial number of embryos stored by Australian IVF practitioners is clear indication that excess eggs are being gathered and fertilised. For a recent example see the *Canberra Times*, August 13, 2005, p B5 *High Price for Making Happy Babies* which reported that 15 embryos were created by Sydney IVF (Canberra) to (ostensibly) achieve a pregnancy.

³¹ See footnote 22.

(i) c) community standards;

The Federation contends that its submission to the current legislative review is founded on the rational ethical position that protection of, and respect for human life is a peremptory norm or *ius cogens* as reflected in international³² and domestic law and in the customary law of nations. In advocating its standpoint the Federation submits that its views reflect those of an informed community.

The Federation would urge the Review to be critical of the apparent defiance of professional ethical guidelines and of community opinion which is not infrequently displayed by those engaged in reproductive technologies and related research. Any informed reader of either the scientific or popular press is aware that often after undertaking new and contentious research in reproductive and related technologies researchers then promote self-serving publicity. The research is invariably heralded as holding great promise for the relief of major ills of humankind, albeit in a distant Utopia;³³ it is accompanied by the plea that those involved are looking for ethical guidance from the Australian community.

This type of *post hoc* appeal for such ethical ‘guidance’ is evidently quite insincere. It should be obvious that the public at large is neither well-informed on the issues involved nor able to grasp the technical detail of the innovation. Those community groups which are in a position to comment on moral and ethical implications of the new offering can find that it is difficult to have put on hold the innovation until its compliance with legislative restrictions or ethical constraints is thoroughly examined.

It is evident from the difficulties currently experienced in ensuring that the current National Health and Medical Research Council’s *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*, 2004 (NHMRC Ethical Guidelines) are observed in clinical practice and experimental protocols that there are inherent, and probably insuperable problems with regulation **under the current regulatory regimes** (see fuller discussion following)

D. Terms of reference

- (ii) c) *the effectiveness of monitoring and compliance under the Research Involving Human Embryos Act 2002 in particular, but also in relation to the Cloning Prohibition Act 2002 to the extent that issues may arise in relation to the latter Act;*

Legislative and Regulatory Framework

The Federation’s discussion of the effectiveness of monitoring and compliance with the RIHE Act and the Cloning Prohibition Act will address the NHMRC Ethical Guidelines

³² See the *International Covenant On Civil and Political Rights*, Articles 6 & 7. See also the *United Nations Convention on the Rights of the Child* 1989 which states that “the child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, before as well as after birth” (**Preamble**); Governments must recognise that “every child has the inherent right to life” and ensure the child’s “survival and development” to the maximum extent possible (**Article 6**).

³³ For a recent example in relation to motor neurone disease, see *The Australian* 2 September 2005, p 15. Everyone is aware of the substantial publicity given to the advocacy of ES cell research for spinal cord injuries in the case of the late Christopher Reeve.

which are the major instrument in fulfilling the NHMRC's obligation in carrying out its role in monitoring and regulating compliance with the provisions of the RIHE Act .

Those Guidelines were developed by the Australian Health Ethics Committee (AHEC) as a principal committee of the NHMRC. Clinical practice, research and all other activities referred to in these guidelines must comply with:

- relevant national legislation, including the Cloning Prohibition Act, the RIHE Act and the *Privacy Act 1988*; and
- relevant State and Territory legislation, including privacy legislation.

Under the NHMRC licensing arrangements, use of excess ART embryos for research and other activities that require a licence under the RIHE Act must comply with the conditions of the licence. Further, all proposals for research and activities requiring a licence for the use of excess Assisted Reproductive Technology embryos must be approved by a HREC.

AHEC considers that it is ethically unacceptable to create a human embryo *in vitro* for any reason other than to achieve a pregnancy in a woman; other practices prohibited by the RIHE and Cloning Acts are agreed by AHEC to be unacceptable.

Respect for human life

The Federation supports the ban on the practices which the NHMRC Ethical Guidelines, in accord with the RIHE Act, deemed unacceptable. However, it also the fact that those Guidelines pay much attention to consequential and lesser issues like privacy, choice between means of obtaining human research 'material', allocation of resources, and so on. While concern for the welfare of future children, of those adults who resort to ART practices, and for public interest are important matters, the primary principle of respect for human life should not be displaced by over-concentration on such considerations.

While acknowledging that the RIHE Act allows access to human embryos for the purposes of research not directed to the welfare of those particular subjects, the Federation is opposed to any expansion of the experimentation permitted by the legislation. For example, the Federation is concerned about the efficacy of monitoring and compliance regarding the particular prohibited practice of creating a human embryo for a purpose other than achieving a pregnancy in a woman (s.14 of the Cloning Prohibition Act).

There is an inherent difficulty in regulating compliance with this stricture. Production of 'excess' embryos in Assisted Reproductive Technology (ART) clinical practice is virtually assured, despite the principle set in **para 5.2**,³⁴ that is, clinicians must limit the number of embryos created to those likely to be needed by the participants in the course of their treatment. Conformity with this principle does not ensure that the permitted number of embryos created will necessarily be implanted in the woman, as she may subsequently decline to be implanted with the number of embryos which in theory she is capable of carrying in a multiple pregnancy or carrying in more than one pregnancy.

Ethical guidelines for clinical practice – general principles

The effectiveness of monitoring compliance with the RIHE Act relies essentially on the ethical positions which preface the NHMRC Ethical Guidelines. These are frequently so qualified in their application as to give no clear ethical foundation, and, on occasion, appear

³⁴ References [**para** ...] are to paragraphs of the NHMRC Ethical Guidelines.

contradictory. They state (**para 5.1** and **para 5.2**) that research involving gametes, embryos and/or participants in reproductive treatments must be conducted in a way that is respectful of all the human beings involved. Further, such research must be reviewed by a HREC attached to the research institution. Each HREC must be constituted and operating in accordance with the NHMRC's Ethical Guidelines and also with the NHMRC *National statement on ethical conduct in research involving humans 2003*. HRECs are required to be aware of, and heed, advice or guidelines on research provided from time to time by AHEC and/or the Licensing Committee.

Thus the fundamental mechanism for testing accord of research activities with principles set out in the Statement is the approval of the HREC attached to a relevant institution which is engaged in either the clinical practice and/or attendant research related to ART. In addition, any other activities involving embryos, such as for training, quality assurance, product development or development of therapies should also be reviewed by a HREC.

Clinical decision making

The statements in **section 5** of the NHMRC Ethical Guidelines are cause for concern. The Guidelines say that

“[w]hile there are different views held in our community about the moral status of a human embryo, one view that is very widely shared is that embryos are not to be treated as mere tissue. At all times, any embryos created must be dealt with according to these guidelines and accepted standards of clinical and laboratory practice”.

However the “accepted standards” are essentially those contained in the same Guidelines. The circularity of these statements concerning general principles and clinical decision making are not reassuring and do nothing to clarify the principles which should inform ethical clinical practice; they are inward-looking and claim for the Guidelines’ approach to research involving human subjects an overarching significance which dismisses other statements of good practice such as those contained in traditional and international manifestos of the ethical obligations of medical workers.³⁵ There is patently so much involved in the approved practices of ART that is not consonant with the stricture that ART should be conducted in ways that are “respectful of all involved” (**para 5.1**), that the statement is virtually without normative impact on the practice of licensees.

Respect all participants including embryos

The NHMRC Ethical Guidelines state that ART procedures must be conducted in a way that is respectful of all involved; and “clinical decisions must respect, primarily, the interests and welfare of the persons who may be born” (**para 5.1**). That statement does not sit well with the following stricture that “clinicians must limit the number of embryos created to those *likely to be needed* by the participants in the course of their treatment (**para 5.2**) (*italics added*). The consequent prospect of inevitable wastage or excess is apparently not seen as contradicting the principle of respect for all subjects involved.

³⁵ The Nuremberg Code (1949) which prescribes that experiments should not involve death or disabling injury to the subject; the Declaration of Helsinki (1964 & as amended up to 1983) which binds physicians and those involved in biomedical research involving human subjects to act only in the patient’s interests.

An approach consistent with the statement of principles in the NHMRC's *Ethical Guidelines* would require fertilisation *in vitro* to limit the number of embryos created to the number that the mother was able and willing to carry.³⁶

Practices in conflict with stated principles of clinical practice

The Council's statement of ethical principles for clinical practice that ART procedures requires respect for all involved; further, clinical decisions must respect, primarily, the interests and welfare of the persons who may be born (5.1). However the Guidelines undermine that statement in many respects. The stated respect for embryonic human life, which should be held to as a fundamental principle, is compromised by reference to what are essentially utilitarian considerations as set out in the Guidelines eg:

- **use of pre-implantation genetic diagnosis (PGD) to select (and destroy) embryos (para 12)**

Purported diagnosis of genetic disorders at the embryonic stage of development is one of the great benefits claimed to justify a practice which may involve the destruction of a human embryo or a decision not to implant a 'defective' embryo. The NHMRC Ethical Guidelines admits that the practice of selecting against some forms of abnormality may threaten the status and equality of opportunity of affected people and that the procedures involve the disposal of some healthy embryos (para 12.1). Yet the Statement goes on to permit the use of PGD to reduce the risk of a serious genetic condition, merely advising clinics to make "careful evaluation of these and other relevant issues before the use of PGD" (para 12.2).

The stricture that PGD should be used only to obtain information about a serious genetic condition or disease (para 12.1) is an exercise in medical, social and moral relativity, if not futility. It is admitted that opinions will differ on what constitutes a serious disease, and the estimate of the likely impact on families and individuals is capable of producing a multitude of outcomes in respect of the same condition. This practice should be the subject of community and professional discussion as it is clearly a case of a non-therapeutic procedure being performed on a human subject.

In addition, the claimed benefits of such procedures have not been objectively established. Many genetic disorders are not caused by one genetic mutation, but rather by more than one or several in interaction; and the realisation and severity of any such putative condition may be further influenced by internal and/or external environmental factors. The wanton destruction of human embryos on the dubious basis of potential defect smacks of eugenic ideology rather than sound principles of medical practice.

Further in section C2 of the NHMRC Ethical Guidelines, titled *Genetic Technology Associated with ART*, the arguments for and against PGD are canvassed. While this is an interesting venture into a critical area of community standards, it is a clear indication that the ethical standards imposed on licensees for embryonal research by the AHEC, and mediated by a particular institutional HREC, are at best 'debatable' standards. Detection of the sex of an embryo and its destruction for 'risk' factors is hardly research; it is essentially a 'search and destroy' mission. The factors put for support for selection by sex in 'risk' situations include:

³⁶ See footnote 29

- An interest in reducing the economic and social costs of caring for the incurable.
- Hope for progress in the overall health and fitness of human society.
- The belief that other people are not entitled to stop those who wish to use genetic technology.

This is a disturbing application of consequential ethics, combining economics and eugenics flavoured with an appeal to individual choice. Admittedly the arguments against these propositions are canvassed, but then only few involved in an ART program would resist the siren call of individual choice, no matter what the strength of arguments based on ethical principles. One must question the appropriateness of canvassing discussion of these issues by the NHMRC in the context of ethical guidelines for compliance with the existing legislation. If the NHMRC wishes to explore these issues then it should seek public opinion in a discussion specific to such matters.

- **sex selection of embryos, even though limited to medical grounds (para 11)**
The NHMRC Ethical Guidelines admit that sex selection is an ethically controversial issue and the AHEC believes that admission to life should not be conditional upon a child being a particular gender. Nonetheless, the clinical practice direction is then compromised by the statement that “selection by sex can serve medical goals” eg to reduce the risk of transmission of a serious genetic condition.

Again in section **C3**, the NHMRC Ethical Guidelines enter the field of community debate with arguments for and against the practice of embryo sex selection. Factors advanced for that practice include cultural practices, ‘family balancing’, and individual autonomy. Though each is countered by the opposing view, one must ask again why the NHMRC Ethical Guidelines broaches the subject; prediction of likely bias in sex preference by parents is unlikely to outweigh the fashionable mantras of ‘freedom of choice’ or ‘individual autonomy’. Such discussion in this context will inevitably be seized upon by those wishing to practice embryo sex selection, as with the application of PGD generally, to justify sex selection procedures.

- **admission that risks of research to the embryo should be balanced by the possibility of intended benefits from the research (para 15.4.1);**

Of course, the ‘benefits’ referred to in the NHMR Ethical Guidelines need not be for the benefit of the research subjects; in fact the research almost invariably involves the destruction of the human embryo(s) involved. While acknowledging that the RIHE Act allows such research dependent on licensees’ conforming to NHMRC Ethical Guidelines, one must ask whether, in light of the compromises embedded in them, there are any *effective* constraints currently imposed on licensees. Is it the case that research projects which might well surprise and dismay the broad Australian community can be readily justified by licensees’ referring to the “possibility of intended benefits”? Is the appropriateness of research, which admittedly involves the destruction of human subjects, to be judged by the ‘good intentions’ of the researchers?

In sum, it is difficult to discern objective standards in the NHMRC Ethical Guidelines as so much of the text is a balancing act of contradictions; indulging licensees to interpret them as widely as suits their purpose.

- **admission that where research undertaken solely to develop new knowledge, any risks (particularly any long-term risks to persons born) should be minimal (para 15.4.2).**

The same objection holds here as expressed above in relation to para 15.4.1. That is, who is to interpret the meaning and value of “new knowledge” or what constitutes “minimal” risks? Risks to whom?

Information giving, counselling and consent

The NHMRC Ethical Guidelines state that ART participants are entitled to detailed information about proposed procedures and any alternatives so that they can give informed consent, and to receive counselling about the consequences of those procedures. (para 5.4)

Information giving

The NHMRC Ethical Guidelines requires information be given to participants in the following situations:

- **research involving gametes.** Researchers must give gamete providers (and their spouses or partners, if any), and any persons for whom an embryo may be created, all relevant information about the research (para 16.5). The information provided should include a full explanation of any *consequences and risks involved for any embryo created and any person born after implantation of the embryo, and how they are balanced by potential benefits* (para 16.5.1) (italics added)
- **research on an embryo that will be used for achieving a pregnancy; and research involving excess ART embryos.** Researchers must provide the persons for whom an embryo is to be used to achieve a pregnancy with all relevant information about the research, including how it relates to clinical care, which includes the clinical care of the embryo, risks to the mother if implantation is intended and so on (para 17.7). *The information provided should include a full explanation of whether the research has intended benefit for the embryo or will not benefit the embryo or themselves but is intended to improve scientific knowledge or technical application* (para 17.7.1). (italics added)

If informed decision-making includes the absence of counteracting emotional and other pressures, the objectives are admirable but unrealistic. It is putting a considerable strain on the capacity of a man or woman to make a balanced assessment of the purportedly accurate and objective information about the ART procedure or ART-based research in this quite technical area. This information would presumably include: success and failure rates; treatment options; physical and psychosocial risks, risk of adverse outcome for the child to be born; the risks associated with multiple births, risk of ectopic pregnancy and so on. Since the participants are by definition willing to engage in ART in order to achieve a child, how likely is it that they will demur from agreeing to the procedure?

In respect of information about options for storage, and later use and disposal of cryostored gametes and embryos, it is reasonable to posit a not inconsiderable opportunity for researchers to advance the interests of their program whether connected directly or

indirectly with the ART clinical practice. This is particularly the case as embryo research subjects must be obtained from embryos excess to reproductive ‘need’.

It is obviously desirable that such information should be provided to participants at their level of comprehension about the purpose, methods, demands, risks, inconveniences, discomforts and possible consequences of the research (including the likelihood and form of publication of the research results). A note of caution should be sounded about experimentation on any person capable of understanding such matters to a very limited degree or not at all. And, of course, the embryo subject has no say in the matter.

Overall, a fault in the NHMRC Ethical Guidelines is that there is no explicit acknowledgement of the considerable difficulty of ensuring that participants in the clinical practice of ART are capable of weighing up the myriad complex issues which might affect themselves and any embryos produced by the process (both those who come to birth, those who are miscarried, those stored, those who become the subjects of research or those are simply destined to be destroyed).

Counselling

Nowhere in the NHMRC Ethical Guidelines relating to research involving donated gametes, embryos intended for implantation or embryos excess to ART procedures is there any stricture that participants in the research (embryos themselves being necessarily excluded!) should receive counselling that is independent of those intending to engage in the research. In the absence of counselling by professionals independent of the clinic or participating institution, it is reasonable to have strong reservations about the objectivity of advice and information provided. There are obvious risks to objectivity by considerations of self-interest.

Consent

The NHMRC Ethical Guidelines state that participants in ART have the right to decide for themselves whether or not to take part in the proposed procedures. Clinics are required, therefore, to obtain the consent of all participants in these programs (para **5.5**). The Guidelines are likely stating the obvious, viz. that it is unethical to coerce potential research participants in any way into taking part in the research and any concealment of the purposes of the proposed research would likewise be unethical and would exclude informed and voluntary consent. (para **15.5**). Consent must be freely given and be explicit for the proposed research. These principles are to apply to research involving gametes (para **16.6**) and to research involving excess ART embryos (para **17.8**).

The Federation supports the principle that informed consent should be obtained from all participants whose long-term health and psychosocial welfare might be affected by the research (para **5.1**). However, this statement fails to recognize that the human embryo is a participant in ART and attendant research programs. Particularly challenging for the participants in ART is the nature of the consent to be given, especially that consent related to specified research which can involve destruction of their embryos. The very warning expressed in the NHMRC Ethical Guidelines:

“Researchers must also ensure that the persons for whom the embryo is to be used to achieve a pregnancy are assured that their clinical care, or the clinical care of their embryo, will not be prejudiced in any way if they do not wish to be involved.” (para **17.8**)

confirms that there is an undeniable possibility of pressure being exerted upon participants to agree to this use of their 'excess' embryos in their anxiety to be welcomed into, or to continue to participate in an ART program. It is doubtful whether the participants are encouraged to, or are competent in many cases, to address such weighty issues when they are already caught up in a clinical context.

This concern is not effectively addressed by the requirement that:

“Researchers must not approach persons responsible for the embryos for consent to use their embryo in a specified research project until after a decision has been made, and confirmed in writing, by all persons responsible for the embryo that it is no longer needed for reproductive treatment and that it is therefore an excess ART embryo.” (para 17.12)

In many instances the lapse of time between undertaking an ART procedure and making a decision to no longer continue attempts at pregnancy would be considerable. Consequently when consent to research procedures on the 'excess' is sought it is very likely that the embryo has lost its personal significance to the participating adults, particularly if they no longer wish to continue in the ART program. Control of the disposition of human embryos after and beyond the immediate context of reproduction and implantation enshrines a particular view of the human being ie that the human embryo can be treated by arrangements appropriate to the disposal of property, rather than respected as an individual human being.

Record keeping and data reporting

The NHMRC Ethical Guidelines asserts that good record keeping is an essential component of clinical practice and vital for ART because of the long-term consequences of procedures involving ART on the health and psychosocial wellbeing of the persons who are born and on the participants in ART procedures themselves (and their spouses and partners, if any). Clinics must keep accurate records of all gametes and embryos in their care in accordance with s 10 of the RIHE Act (para 5.7). Further, clinics must collect and make public data on the outcomes of ART procedures in accordance with s 10 of the RIHE Act (para 5.8).

The Federation, acknowledging that the legislation allows procedures to which it objects, nonetheless is of the opinion that donor records should be maintained indefinitely and that these should be transferred to another practitioner when the participating practitioner ceases to be involved with ART programs. Such recording is an essential pre-requisite for assisting children born from the use of ART procedures to identify their parents and for tracing what has become of 'excess' embryos so that compliance with legislation can be monitored.

Storage of gametes and embryos

Since the production of excess embryos is permitted in ART programs, then appropriate provision has to be made for their storage and possible death. The Federation submits that the storage of gametes and embryos is tolerable only in that it is consequential on other practices which are unacceptable in its view. While storage of embryos in itself may not necessarily impinge on the preservation of life, there are, however, inherent problems with the process including:

- delaying reproduction beyond the normally accepted limits of the mother's biological capacity for carrying a child; complete control by the owners of gametes

must be set alongside legitimate social concern for children born as a consequence of these decisions;

- the need to be mindful of any restriction in law relating to the use of a deceased person's gametes for the purpose of reproduction;
- for the storage of the gonadal tissue of a young person, not yet competent in law to give consent, special ethical and legal considerations must be addressed.

Complaints and appeals

Mechanisms for complaints and appeals are provided in the NHMRC's *National Statement on Ethical Conduct in Research Involving Humans*. Similar mechanisms should be repeated in the NHMRC Ethical Guidelines relating to embryo research so that the same concerns can be addressed, namely:

- investigation and resolution complaints about clinical practice;
- methods for resolution of complaints about matters relating to the storage of, and research involving participants' embryos;
- mechanisms for complaining about matters relating to the conduct of research eg breach of consent;
- establishment of an independent, specialist body for the hearings of grievances and complaints. While participants might have resort to relevant external bodies such as the Human Rights and Equal Opportunity Commission, these are not necessarily the most appropriate forums for resolution of disputes/complaints falling within the scope of ART clinical and related research programs.

While these avenues might cover an individual who is the subject of damaging clinical procedures or has been treated in a discriminatory way, special provision is needed to enable objection by any person to any clinical practices or research protocols and/or practices which appear to breach legal requirements.

In sum, the widest possible forum should be facilitated for the discussion of new technologies concerning the treatment of human subjects. Professional scientists associated or not with ART programs, ethicists and various groups should be able to lodge objections to current or new ART applications when it would be in the public interest to examine critically the direction of proposed research which may not clearly be caught within the compass of legislative prohibition. Only an external, independent, specialist tribunal would possess the necessary competence ('specialist' in this context does not indicate confinement to those specialising in the practice of medicine or research).

Conscientious objection

The Federation welcomes the assurance that conscientious objectors are not obliged to be involved in the procedures or programs to which they object and that the clinic must allow him or her to withdraw from involvement in the procedure or program to which he or she objects. Clinics must also ensure that staff and students are not disadvantaged because of a conscientious objection (para 5.9 and para 15.12)

However, no mechanism is specified for conscientious objectors claiming that they have been discriminated against in their workplace or career opportunities. Without some independent forum to which complaints of this nature can be taken, the statement in this guideline is, at best, nothing more than wishful thinking.

Disclosure of financial interests

The NHMRC Ethical Guidelines requires that participants in research are entitled to know about any financial benefits that the researcher or clinic may gain from the research. For example, where researchers plan to request donation of embryos with the intention of undertaking research that may ultimately yield commercial profit, this must be made clear to the donors before consent is obtained (para **15.11**)

These restrictions should apply to researchers in both independent laboratories and educational institutions, where these persons are engaged in using materials derived from human embryos, especially products derived from human embryonic stem-cells.

The potential profitability of outcomes from embryonic stem-cell research provides motivation for research units to ignore, or defy either legislative restrictions or ethical principles. It should be noted that embryonic stem-cell lines available for research by the decision of the US Federal Government are ‘owned’ by commercial/academic research units and/or pharmaceutical companies; some half dozen are ‘owned’ by a prominent group of Victorian researchers.

Human Research Ethics Committees

While clinical practice, research and all other related activities referred to in the guidelines should conform to standards established by the relevant professional and accreditation bodies, it nevertheless remains the case that compliance with the legislation and attendant regulatory mechanisms is mediated to the actual practice of clinical medicine and scientific research through HRECs. It is of concern that innovative procedures require formal consideration only by a HREC and that a HREC can grant permission for such a procedure to be trialed on a person, couple, gamete, embryo or fetus even though the procedure is one which has not been fully assessed for safety and/or efficacy.

As HRECs are influential but largely self-regulating bodies located in numerous medical and research institutions, one must doubt whether, in all cases, the members of such bodies are sufficiently independent of colleagues/staff involved in the very clinical practice and research work they seek to regulate. In practice, the NHMRC Ethical Guidelines will be effective only to the degree that they can be imposed and monitored through the HRECs.

What measures of control, monitoring and sanctions are available to, and likely to be enforced by an HREC if the interests of the institution appear to depend on both avoiding open conflict and retaining those practitioners who get results and publicity by ignoring the restraints contained in the NHMRC Ethical Guidelines? What assurance is there that all research protocols approved by HRECs will be reported annually to the NHMRC?

Similarly, the composition of HRECs will reflect primarily the interests of the professional medical and research personnel who are to be regulated and in that sense are akin to an industry self-regulatory mechanism. The Federation wishes to point to:

- conflict in the discharge of the responsibilities of a HREC when its members may include persons whose interests are directly or indirectly affected;
- difficulty in imposing restraints on professional colleagues.
- disinclination to attribute motives of self-promotion and/or commercial gain to medical and scientific staff colleagues of an institution;
- lack of adequate sanctions attendant on a breach of the guidelines.

It is ironic that some researchers, far from being ready to defend the limited independence of HRECs afforded by inclusion of community members, are critical of such members.³⁷

Conclusion and restatement of basic pro-life principles

- The NHMRC Ethical Guidelines allow for both therapeutic and non-therapeutic research on embryos either during an ART program or subsequently when the embryo has been donated for research or other activities. The Federation declares its opposition to research on a human subject where no benefit accrues to that subject.
- It does not compensate for the surrender of principle here that destructive experimentation is to be allowed only where there is the prospect of significant advance in knowledge or improvement in technologies for treatment. These procedures, no matter how regulated, fail to accept a basic principle that non-therapeutic experimentation on a human subject is not to be permitted except in very limited circumstances.³⁸
- The frequent publicity given to the potential, hoped for rather than actual, value of stem cell research based on embryonic stem cell lines to bring great benefit to our species is noted. Whatever the promised benefits to others, it is still an abandonment of the most basic principle of good medical practice: **Do No Harm**.
- That access to embryos for research is conditional on the consent of the gamete providers does not answer the ethical objection, no more than it would for the case of a fully developed child. Consent to such treatment of human embryos and fetuses is contrary to the obligations of guardianship vested in parents (natural or adoptive) and any others who have a responsibility for the welfare of children.
- While the Federation concedes that legislative regime now in force allows destructive research involving human embryos, it contends that such procedures are in breach of Australia's international obligations.³⁹

The Federation considers that all destructive, non-therapeutic research on embryos should be prohibited whether the embryos are produced by sexual reproduction, somatic cell nuclear transfer, cloning by splitting, or any other means that produce an individual organism with capacity to develop into an independent human organism.

The Federation requests that the Review recommend to the Federal Parliament that it:

- amend the RIHE Act to exclude permission to engage in research involving the destruction of human embryos; and
- maintain the ban on those practices prohibited by the Prohibition of Human Cloning Act.

³⁷ See footnote 14.

³⁸ See footnote 34.

³⁹ See footnote 31.