

**ACT Right to Life Association Inc**

**COMMENT ON**

**OVERSIGHT OF ASSISTED REPRODUCTION TECHNOLOGY**

**CLINICAL PRACTICE IN THE ACT**

**ACT HEALTH  
POLICY DISCUSSION PAPER**

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## Executive Summary

The ACT Right to Life Association stands for the protection of human life from its first beginnings to natural death. The Association urges reform of ART practices in order to minimise the loss of embryonic life involved in ART procedures and to protect the rights of all participants.

The Association considers that the current system of accreditation of ART providers by the Reproductive Technology Accreditation Committee does not provide ART participants nor community interests in the ACT with sufficient transparency, and quality and safety in the services provided. It therefore recommends that ART practitioners in the ACT should comply not only with legislative restrictions contained in the *Human Cloning and Embryo Research Act (2004)* (ACT) but also with clinical practice guidelines such as the National Health and Medical Research Council's *Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2004* (NHMRC Ethical Guidelines).

Even so shortcomings experienced in monitoring compliance with the NHMRC Guidelines should be addressed in an ACT regime for ART clinical practice, including:

- Respect for all participants including embryos: is breached by the frequently unjustified production of 'excess embryos' which seems to be endemic in ART clinical practice;
- Information giving: no prescription of content nor check on understanding by those approached for embryo donation of the implications of long-term storage or of the implication of research protocols and/or likely outcomes (see particularly Attachment C);
- Counselling: no requirement that it be professional and independent of ART providers;
- Consent: when related to embryo donation, its integrity is dubious if the nature/value of research is poorly understood;
- Complaints and appeals: a lack of an independent, specialist body for hearing or resolution of complaints; nor is there protection for conscientious objectors;
- Disclosure of financial interests: neither the extent nor content of the information is mandated.

The ACT should establish a regime that addresses these deficiencies; also the exempt practices allowed under **Section 25(3)** of the *Human Cloning and Embryo Research Act (2004)*, for example storage and disposal, should be regulated by legislation, with breaches attracting appropriate sanctions. While being opposed in principle to pre-implantation genetic diagnosis (PGD) to discard/destroy embryos, the Association urges, that if it is permitted its application be strictly limited and that it not encourage the growth of a eugenics regime. Sex selection should be banned. Non-commercial surrogacy should be more tightly controlled under court supervision.

A central publicly-maintained register should best serve to provide information to donors and children involved in ART practice and should be maintained indefinitely.

## Introduction

The ACT Right to Life Association stands for the protection of human life from its first beginnings to natural death. The Association has frequently expressed its concern about the

loss of embryonic human life involved in most ART procedures and practice. However, given that ART services are offered in the ACT, it is essential that the rights and welfare of participants in these programs, especially children who may be conceived and/or born, be protected in so far as is possible. In this spirit the Association welcomes the Policy Discussion Paper by ACT Health which explores issues involved in providing a framework for development of legislation to regulate the clinical practices of assisted reproductive (ART) providers in the ACT.

## Comments

### Issue:

*Is there sufficient rationale for the development of legislation to regulate clinical practices of ART providers in the ACT? Are there any potential adverse effects on ART clinical practice arising from: a) regulation; b) the status quo (ie non-regulation)?*

**Yes.** It is essential that ART practitioners in the ACT should comply not only with legislative restrictions contained in the *Human Cloning and Embryo Research Act (2004)* (ACT) but also with clinical practice guidelines such as the National Health and Medical Research Council's *Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2004* (NHMRC Ethical Guidelines).

The NHMRC Ethical Guidelines cover critical matters of clinical practice eg practices prohibited by the *Research Involving Human Embryos Act 2002* (Cth) (RIHE Act) including: human cloning; import and export of prohibited embryos; use and storage of gametes and embryos; record keeping; information giving, counselling and consent relating to ART participants.

However, there are evident problems of monitoring compliance with the NHMRC Ethical Guidelines including consent, information giving, counselling, production of excess embryos, complaint and appeal mechanisms.

Detailed comment on these problems is at [Annexe A](#). In sum, there are deficiencies in respect of:

- **Respect for all participants including embryos.** It is prohibited to create a human embryo other than for the purpose of achieving a pregnancy in a woman. This principle is put at risk when there is no sanction for the deliberate and/or reckless production of 'excess' embryos. Production of 'excess' embryos in ART clinical practice is virtually entrenched by current practice.<sup>1</sup>
- **Appeal to standards.** It is acknowledged that there is general community acceptance that the embryo possesses a moral status distinct from that of mere tissue. However, there are no required standards of good clinical or research practice involving human subjects such as those contained in traditional and international manifestos of the ethical obligations of medical workers.<sup>2</sup>

<sup>1</sup> 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

<sup>2</sup> 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.

- **Information giving, counselling and consent.** The 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.
  - *Information.* These objectives are admirable but unrealistic. Since the participants are engaged in ART in order to achieve a child, how likely is it that they will demur from agreeing to any aspects of the procedure? There should be prescribed content for information provided to ART participants.
  - *Counselling.* There is no requirement that those involved in ART programs and/or attendant research be counselled by professionals independent of the clinic or participating institution.
  - *Consent.* Particularly challenging for the participants in ART programs is the nature of the consent to be given, especially that consent related to specified research which can involve destruction of their embryos.
  
- **Complaints and appeals.** There is a lack of an independent, specialist body charged with the investigation and resolution of complaints about clinical practice. This body should be able also to handle complaints from conscientious objectors in respect of involvement in particular procedures or programs
  
- **Disclosure of financial interests.** Where researchers plan to request donation of embryos with the intention of undertaking research that may ultimately yield commercial profit, the Guidelines state this must be made clear to the donors before consent is obtained. The extent of the information is not mandated and it is not difficult to provide incomplete/misleading information concerning financial interests in bio-tech companies. The requirements for disclosure should be legislated.

In view of the many difficulties and deficiencies attendant on monitoring compliance with the NHMRC Guidelines and particularly the inhibiting effect of a lack of effective sanctions, the Association urges that the ACT should enable a strict legislative regime to regulate ART practice. Though the Discussion Paper points to some effective restrictions on ART practice (for example, access to essential hormone products), any ACT regulatory regime should include sanctions for breaches of the NHMRC Ethical Guidelines and the RTAC Code of Practice and any other legislative provisions the ACT regime might encompass.

**Issue:** *Are the policy objectives (that is, those set out in para 4 of the Discussion paper) appropriate for the ACT?*

**Yes.** The Association considers that it essential that there be safeguards such as the Discussion Paper sets out: a standardised level of care for patients; ethically sound ART practices; certainty in the law concerning the use of genetic property; and access for children to their genetic information.

**Issue:** *Are there issues that either covered or not covered in the new 2004 [NHMRC Ethical] guidelines that warrant specific regulation?*

**Yes.** Appendix C of the NHMRC Ethical Guidelines raises the following critical issues for discussion:

- pre-implantation genetic diagnosis (PGD);
- sex selection; and
- non-commercial surrogacy

but fails to reach any resolution for the guidance of ART clinicians or researchers working with human embryos.

The Association's detailed views on the first two of these issues are at [Annexe B](#). In sum, objections are raised to practices in conflict with those stated principles of clinical practice requiring ART procedures to respect, primarily, the interests and welfare of the persons who may be born. The Association considers that the statement is undermined by:

- **use of pre-implantation genetic diagnosis (PGD)** to select (and destroy) embryos, purportedly justified by a diagnosis of genetic disorders at the embryonic stage of development. This practice may threaten the status and equality of opportunity of affected people and may involve the disposal of some healthy embryos. The wanton destruction of human embryos on the dubious basis of potential defect smacks of eugenic ideology and/or the commercial imperative rather than sound principles of medical practice.
- **sex selection of embryos.** Factors advanced for that practice include cultural practices, 'family balancing', and individual autonomy. None of these is compelling justification for the destruction of embryos solely on the basis of their gender.
- **admission that risks of research to the embryo should be balanced by the possibility of intended benefits from the research.** The appropriateness of research, which admittedly involves the destruction of human subjects, should not be judged by the 'good intentions' of the researchers.
- **admission that where research undertaken solely to develop new knowledge, any risks (particularly any long-term risks to persons born) should be minimal** Who is to interpret the meaning and value of "new knowledge" or what constitutes "minimal" risks? Risks to whom?

The Association therefore urges a ban on PGD, sex selection of embryos for implantation, and the donation of embryos excess to ART procedures to research programs which carry risks to embryos where useful outcomes are problematic or unlikely.

**Issue**

*Are there issues that either covered or not covered in the new 2005 Code of Practice that warrant specific regulation*

**Yes.** There is a failure to specifically proscribe the practices of PGD, selection of embryos for implantation on the basis of gender, appropriate controls of non-commercial surrogacy and prescribed delivery requirements for providing information and counselling to ART participants (see [Attachments A & B](#)).

**Issue**

*Should there be regulatory sanctions for breaches of the guidelines and/or Code of Practice?*

**Yes.** The ACT should promptly move to regulate clinical ART practice. The framers of a regulatory regime should address the difficulties and deficiencies in monitoring the current NHMRC Guidelines have been detailed above and in Attachments A & B. It is argued that the lack of sanctions for breaches of the matters covered there is a significant factor in the ineffectiveness of the Guidelines/Code of Practice.

**Issue**

*Is the current national and Territory legislation an adequate regulatory framework for ART clinical practice in the ACT?*

**No.** **Section 25(3)** of the *Human Cloning and Embryo Research Act (2004)* provides that certain practices in relation to excess ART embryos are exempt from sanctions. These include in relation to an excess ART embryo: storage, removal from storage, transport, observation, allowing to succumb, rejection for implantation, implanting in a woman other than the woman for whom the embryo was created.

The lack of sanctions in respect of these exempt practices is an undesirable omission in a control regime. For example:

- there are important issues related storage and disposal (see comment below);
- **s 25(3) (b)** allows the selection of embryos deemed not biologically fit for implantation and for their subjection to diagnostic investigation . The Association submits that such selection is a form of eugenics and should be constituted an offence: a full discussion is at Attachment B. At very least, the exemption should apply only where there are reasonable grounds to suspect serious genetic defect, a point covered in the NHRMC Ethical Guidelines (section 12 and C2).
- **s 25(3)(c)** allows the donation of an embryo for achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created. This exempt practice can impact on the appropriate control of non-commercial surrogacy.
- there are no prescribed requirements for delivering information and counselling to ART participants. The Association’s critique of these matters is at Attachment A.
- the fundamental mechanism for testing accord of research or clinical activities with principles set out in the NHMRC Ethical Guidelines is the approval of a Human Research Ethics Committee (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. ACT legislation should provide for an independent HREC to have oversight of each ART facility.

**Issue**

Having read Section C4 of the Guidelines are there issues relating to surrogacy that should be regulated?

**Yes.** Non-commercial surrogacy should be more strictly regulated primarily because it can

be not in the best interests of the child. In addition, there is always risk to the vulnerable birth woman who may be persuaded either for (clandestine) commercial gain or for reasons of psychological dysfunction to carry a child intended for surrender to others for raising. These are among a number of concerns raised in **C2** of the NHMRC Ethical Guidelines. The Association notes that **s 44** of the *Parentage Act 2004* (ACT) currently creates an offence where pregnancy is facilitated in connection with a commercial substitute parent agreement. The Association suggests that:

- court approval of a non-commercial surrogacy arrangement be required so that the court is satisfied –
  - the agreement is in the best interests of the child taking into account the character/circumstances of the putative parents and of the surrogate woman;
  - in respect of the psychological well-being of the intended surrogate mother;
  - of the absence of inappropriate pressure on her to acquiesce in the arrangements either through affection/familial feeling of obligation or any other cause; and
- where the surrogacy pregnancy is undertaken through ART procedures, the ART provider be required to:
  - ascertain that the procedure has been approved by a court; and
  - report the procedure (if it has eventuated) to a court-based record to avoid dispute about the undertakings given by the surrogate and the parent(s).
- that any failure by parties to receive approval for surrogacy arrangements or failure by an ART provider to report all surrogacy procedures be subject to penalties.

**Issue**

Having read Section C2 of the Guidelines are there issues in relation to the use of certain new and emerging technologies associated with ART that require regulation?

**Yes.** The Association is concerned that new technologies will lead to even more rigid selection techniques being applied to ART embryos. Unreal expectations of ‘perfection’ are not only lacking respect of human life in its many variations but will lead a child(ren) being evaluated as to how s/he meets adults’ goals/expectations rather than as a person(s) with rights. Further comment on Pre-implantation Genetic Diagnosis is at [Attachment B](#).

**Issue**

Having read Section 11, 12 and C3 of the Guidelines are there issues in relation to sex selection which require regulation?

**Yes.** The Association recognises the dangers cited in the NHMRC Ethical Guidelines; it also supports the concern expressed by the Australian Health Ethics Committee that sex selection could be interpreted as approving that admission to life would be conditional upon a child being a particular sex (para 11 of the Guidelines). The Association’s views on sex selection are set out in detail in [Attachment B](#).

The Association does not approve of the exception approving sex selection to reduce the risk of a serious genetic condition. This also is also a practice exempt from sanctions pursuant to the provisions of **s 25(3)(b)** of the *Human Cloning and Embryo Research Act 2004* (ACT). The exemption is too permissive in not defining what constitutes a reasonable expectation that an embryo of a particular sex will be handicapped or whether the handicap to be avoided is so serious as to severely diminish the worth of the life destroyed. The

exemption is also liable to abuse as the parameters are stretched either by parental ambition and/or provider acquiescence.

**Issue**

Should the ACT establish a central register to enable donors and children once they reach the age of 18 to access certain information on request?

**Yes.** 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 Association, 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.

As failure in compliance, whether deliberate or inadvertent, is not always to be guaranteed the Association supports the view of ACT Health that a publicly- maintained central register would provide the most reliable protection of the rights of ART participants.

**Issue**

What information other than that suggested above should be made available to people born as a result of ART and associated persons, and in what certain circumstances?

The Association has no particular experience of, or expertise in relation to the information that is likely to be requested by gametes donors or by the children born following ART procedures. The principles set out in the Discussion Paper appear reasonable and it is assumed that advice has been, will be taken from those organizations which have experience in re-union arrangements between children and their biological parents.

**Issue**

Does the current system of accreditation of ART providers by the Reproductive Technology Accreditation Committee (RTAC) provide ART recipients in the ACT with sufficient transparency, and quality and safety in the services that are provided?

**Not entirely.** The guarantees provided and the essential monitoring required are not met satisfactorily through the accreditation system. Critical aspects of ART clinical practice need legislative force and appropriate sanctions for breaches as indicated throughout this submission.

**Issue**

Which of the range of options for monitoring and enforcing compliance with the regulatory framework proposed is the most appropriate to the circumstances of the ACT?

As indicated in this *Comment* the Association recommends that in respect of those matters it indicated that the requirements for ART practice in the ACT be regulated by legislation with effective monitoring of compliance backed by appropriate sanctions.

#### **Other issues**

##### Appropriate 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.

## **Commentary on the NHMRC Ethical guidelines**

The NHMRC Ethical Guidelines 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 *Research Involving Human Embryos Act 2002* (Cth) (RIHE Act). They were developed by the Australian Health Ethics Committee (AHEC), a principal committee of the NHMRC. Clinical practice, research and all other activities referred to in these guidelines must comply with relevant national and State and Territory legislation.

There is an overlap between the licensing arrangements for research on human embryos and clinical practice as embryos for research are currently restricted to those embryos produced in excess of ART procedures. For example, 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 Act and the *Prohibition of Human Cloning Act 2002* (Cth) (Cloning Prohibition Act) are agreed by AHEC to be unacceptable.

### **Respect for 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.

The Association 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). While the Discussion Paper is concerned with ART clinical practice and not with licensing for conducting research on human embryos, it is imperative that ART clinical practice in the ACT be regulated to comply with this principle. There is an inherent difficulty in regulating compliance with this stricture.

Though it can be claimed that the number of embryos created is likely to be needed by the participants in the course of their treatment, there is no requirement that there be a realistic prospect that a particular woman make a reasonable undertaking to attempt implantation of those embryos. Currently there is no such undertaking required and the woman is free to 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. Production of 'excess' embryos in Assisted Reproductive Technology (ART) clinical practice is virtually entrenched by current practice.

An approach consistent with the statement of principles in the NHMRC's *Ethical Guidelines* would require that the fertilisation *in vitro* be limited to the creation of those embryos that the mother was able/willing to carry. ACT legislation should proscribe the production of embryos excess to ART procedures and the donation of any embryos produced lawfully to research institutes either in the Territory or in other Australian jurisdictions.

## Accepted standards in clinical decision making

Section 5 of the NHMRC Ethical Guidelines *state*:

“[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.<sup>3</sup> There is patently much involved in ‘approved’ ART practices that is not consonant with the stricture that ART should be conducted in ways that are “respectful of all involved” (**para 5.1**), that statements of this general nature are virtually without normative impact on the research or clinical practice.

## 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 participants receive the following information:

- **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) This is particularly relevant in light of knowledge about embryo research protocols/outcomes: that few embryos are used in research seeking new cures; where embryos have been used no useful results have yet been achieved. Further comment is provided at Attachment C.

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<sup>3</sup> See footnote 2.

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 (or providers of embryos to 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, with parental consent, become the subjects of destructive 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, or collaborate 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 or peer approval.

### *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 Association 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 allow 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.

### ***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 incorporated in the NHMRC Ethical Guidelines relating to **clinical practice** 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 Association welcomes the assurance in the NHMRC Ethical Guidelines 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 any such procedure or program. 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 state that participants in research are entitled to know about any financial benefits that the researcher or ART 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**)

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.

**Practices in conflict with stated principles of clinical practice**

The NHMRC'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:

- 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.

- **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);**  
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 and, by implication, those who provide them with embryos ‘excess to ART practice’, 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?



**Use of ‘excess’ embryos from ART procedures.**

The uses for which licenses have been issued is available on the public licensing database:

*[www.nhmrc.gov.au/embryos/monitor/database/index.htm](http://www.nhmrc.gov.au/embryos/monitor/database/index.htm)*

This database provides the following information:

- 840 human embryos may be used for research aimed at improving the culture of human embryos for IVF.
- 380 human embryos may be destroyed in an effort to refine the screening processes to identify human embryos with genetic or chromosomal problems so that human embryos that don't measure up can be discarded. This includes the use of 175 human embryos as mere training tools for technicians to practice embryo biopsy. The use of human embryos as training tools is contrary to Federal legislation and Guidelines as such a use leads neither to a significant advance in knowledge nor an improvement in technologies for treatment.
- 705 human embryos may be used to derive human embryonic stem cell lines. The justifications given for these licenses vary, including making stem cell lines to characterise and study growth and directed differentiation; for use in diagnosis and *eventually for treatment* of juvenile diabetes and Parkinson's disease; for treatment of diabetes; and to make stem cell lines “with improved properties”. In sum, none of this research has yet established that human embryonic stem cells will ever be able to be used safely and effectively for therapies.

Nearly the entire public debate about the use of human embryos for research was focussed on the potential of human embryonic stem cells for therapy. However, for only 150 out of the 1735 human embryos for which licenses have been issued is stem cell therapy mentioned as a justification. ART participants are entitled to this critical information when their consent is being sought for the donation of embryos for ‘research’.

In particular ART participants should be informed that, while there have been no significant advances towards the use of human embryonic stem cells for therapies since 2002, there have been great advances in the use of adult stem cells for therapy. There are now 65 disorders which are being treated by therapies utilising adult stem cells. For a full list of these disorders with references: *<http://www.stemcellresearch.org/facts/asc-refs.pdf>*.