



# **Australian Government**

---

**Government Response  
to the Senate Legal and Constitutional Affairs  
References Committee Report:**

*Donor Conception Practices in Australia*

**August 2012**



## Introduction

The Australian Government welcomes the Senate Legal and Constitutional Affairs References Committee's (Senate Committee) report *Donor Conception Practices in Australia* released on 9 February 2011. This report into the complex and often emotive issue of donor conception is an important document that will assist the Australian Government in extending its understanding of the changing experience of many Australian families. The number of donors, donor recipients and donor conceived children living in our community is growing and this report is an invaluable reflection on the issues they face, particularly in relation to knowing their biological history.

The report highlighted several areas of concern within the Australian community about the regulation of donor conception practices. Many of the recommendations in the report identified a desire for nationally consistent legislation regulating donor conception. The report also addressed concerns about consanguinity, importation of embryos and payments made to donors. The report also provided a comprehensive analysis of the record keeping practices of Assisted Reproductive Technology (ART) service providers. It recommended that there was a need for a nationally consistent method of maintaining and sharing information about donors, donor recipients and donor conceived individuals that will enable those concerned to access information, where appropriate, about their genetic history and relationships.

The Australian Government has reviewed the report in depth and has considered all of the recommendations in great detail. The Australian Government is grateful to those members of the Australian community that dedicated their time to assisting the Senate with their inquiry and acknowledges the valuable input of the Australian community through their submissions to the Senate Committee.

The Australian Government supports the need for the interests of donor conceived individuals to be protected but acknowledges that there is no constitutional power that would support a Commonwealth scheme to legislate comprehensively in this area. States and Territories are responsible for enacting legislation regulating donor conception practices in Australia.

For many years the Australian Government has recognised the need for improvements in the regulation of assisted reproductive technology, particularly as the number of affected individuals in Australian society increases. The Australian Government has shown leadership in this area by establishing and continuing to support the National Health and Medical Research Council (NHMRC) and the Australian Health Ethics Committee (AHEC), which in turn provides ethical guidelines on the use of ART in clinical practice and research. As early as 1996, the AHEC took a leading role, developing guidelines stating that ART service providers should obtain accreditation by a recognised body and that such accreditation should require compliance with those guidelines. The 1996 guidelines also strongly recommended that States and Territories that had not already done so should enact legislation to regulate ART. These guidelines have been consistently reviewed since that time and have resulted in the very comprehensive *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2007* (NHMRC ART Guidelines) that provide a high level of guidance to the ART industry today.

The NHMRC ART Guidelines represent a significant body of work and dedication of resources by the Australian Government to assist with the protection of the interests of donors, donor recipients and donor conceived children.

The NHMRC ART Guidelines are aligned with many of the recommendations contained in the Senate report. They provide a nationally consistent basis upon which other States and Territories may wish to develop regulation in this area. The Australian Government supports the use of the NHMRC ART Guidelines by States and Territories contemplating regulation of donor conception practices.

In addition, there has already been a national accreditation scheme developed in Australia that supports compliance with the NHMRC ART Guidelines. Although States and Territories may use an accreditation or licensing system unique to their jurisdiction to regulate the ART industry, a robust accreditation system that is independently reviewed and assessed has already been established by the Reproductive Technology Accreditation Committee (RTAC). RTAC was established in 1987 by the Fertility Society of Australia, the peak body representing doctors, scientists, nurses, researchers, consumers and counsellors involved in reproductive medicine. The RTAC accreditation scheme was developed by a combined technical committee comprising members from the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) and RTAC in accordance with international and domestic standards for bodies that operate product certification systems.

To obtain accreditation through RTAC, an ART service provider must obtain RTAC certification from an independent third party JAS-ANZ-accredited certification body, which measures the organisations compliance with the RTAC Code of Practice for Assisted Reproductive Technology Units (the RTAC Code of Practice). The certification body makes recommendations to RTAC about whether RTAC should grant a licence.

The RTAC Code of Practice requires as part of its compulsory criteria that an ART service provider must comply with the NHMRC ART Guidelines. In States and Territories that have not passed legislation requiring ART providers to obtain an RTAC licence, many ART service providers voluntarily participate in the accreditation scheme which requires them to comply with the NHMRC ART Guidelines and the RTAC Code of Practice. Where States and Territories have passed legislation, ART service providers may often also be compelled to comply with State based licensing schemes. To date, Victoria, New South Wales, South Australia and Western Australia have enacted legislation that specifically regulates donor conception practices.

States and Territories looking to regulate the ART industry have the opportunity to make use of two significant national resources. One supported by the Australian Government through the development of the NHMRC ART Guidelines and the other by the Fertility Society of Australia, through the RTAC Code of Practice and the development of a robust accreditation system. The Australian Government encourages States and Territories, who have not already done so, to implement a legislative framework that will mandate compliance with the established accreditation and regulatory scheme.

Using the RTAC accreditation process and the NHMRC ART Guidelines as the basis for legislative frameworks will ensure consistent approaches to donor conception across Australia. States and Territories also have the option of ensuring compliance with the regulatory framework through making provisions in their legislation for offences and penalties for ART service providers who do not comply with the national standards. In addition, individual Australians who are involved in ART procedures can assist in the protection of their interests and those of their donor conceived children by using the services of accredited facilities. In cases of non-compliance by accredited ART service providers, individuals are encouraged to avail themselves of the proper channels for making health related complaints, by contacting the Health Complaints Commissioner or equivalent in the relevant State or Territory.

The Australian Government notes the benefits to the continuing refinement and improvement of the NHMRC ART Guidelines, through NHMRC's policy of revising guidelines every five years. This will ensure that the national standard in Australia continues to provide a high level of protection for Australians who are conceived through the use of ART technologies. The Australian Government thanks the Senate Committee for the outstanding contribution their report provides to the development of policy on donor conception.

## **Government response to recommendations**

### **Recommendation 1**

**The committee recommends that jurisdictions which do not already have legislation in place, namely Queensland, Tasmania, the Northern Territory, and the Australian Capital Territory, should, as a matter of priority, establish legislation to regulate donor conception in those jurisdictions.**

The Australian Government supports this recommendation.

This recommendation is consistent with recommendations published by the NHMRC in the 2007 NHMRC ART Guidelines. States and Territories are responsible for the enactment of legislation in their respective jurisdictions. The Australian Government encourages those States and Territories that do not currently have legislation regulating donor conception practices to establish such legislation.

The Australian Government also supports consistency of State and Territory legislation. Consistent legislation will ensure that donors, donor recipients and donor conceived individuals will have the same access to information regardless of which jurisdiction they are in. It will also discourage the practice of forum shopping for persons who wish to donate or who wish to use ART services. The NHMRC ART Guidelines developed by the NHMRC and the RTAC accreditation system provide a sound basis for State and Territory legislation.

### **Recommendation 2**

**The committee recommends that the Australian Government pursue all available policy and political options, including through the Council of Australian Governments and the Standing Committee of Attorneys-General, to ensure that nationally consistent legislation relating to donor conception is developed as a matter of priority.**

The Australian Government supports this recommendation in principle.

The Australian Government does not have constitutional power to legislate comprehensively in this area to ensure that legislation is nationally consistent. The Australian Government supports consistency of regulation of donor conception practices across Australia and has been working to progress the issue with States and Territories. The issue of donor conception laws has been a stand-alone agenda item on the Standing Council of Law and Justice (formerly the Standing Committee of Attorneys-General) since April 2009.

As identified in the Senate report, in 2002 the Council of Australian Governments (COAG) agreed that RTAC-accreditation should provide the basis for a nationally consistent approach to the oversight of ART clinical practice and research in Australia. To be accredited an ART service provider must obtain an RTAC licence, which requires compliance with the RTAC Certification Scheme and the RTAC Code of Practice which were last revised in October 2010. The RTAC Code of Practice, in turn, requires compliance with the NHMRC ART Guidelines.

The NHMRC ART Guidelines and RTAC accreditation system provide a nationally consistent basis upon which States and Territories who have not done so, may wish to develop regulation in this area. The NHMRC ART Guidelines provide ethical guidance, in line with many of the issues raised by the recommendations in the Senate report, to clinical practitioners who provide ART services. The NHMRC ART Guidelines address issues such as the provision of counselling services to participants, collection and dissemination of information and consent. The RTAC Code of Practice ensures that the clinical delivery of ART services is as risk free and as of high quality as possible.

The Australian Government and the Fertility Society of Australia have demonstrated leadership and have encouraged States and Territories for many years, to give legislative force to the NHMRC ART Guidelines through the RTAC accreditation system to improve consistency of donor conception regulation across jurisdictions.

### **Recommendation 3**

**The committee recommends that any nationally consistent legislation should include, at a minimum:**

- **a prohibition on donor anonymity;**
- **a limit on the number of families a donor is able to assist;**
- **rights of access by donor conceived individuals to identifying and non identifying information about their donor and siblings; and**
- **protection for the welfare and interests of donor conceived children.**

The Australian Government supports this recommendation in principle.

The Australian Government encourages States and Territories to use the RTAC accreditation system and the NHMRC ART Guidelines as a basis for consistent donor conception regulation.

At paragraph 6.1, the NHMRC ART Guidelines require ART service providers to ensure that a 'donor has consented to the release of identifying information about himself or herself to the persons conceived using his or her gametes.'

At paragraph 6.3, the NHMRC ART Guidelines require ART service providers to consider a number of relevant factors to limit the number of families to which gametes from one donor can be provided.

Part 6 of the NHMRC ART Guidelines recognises entitlements to information for donors, donor recipients and donor conceived individuals. The NHMRC ART Guidelines provide guidance to ART service providers about balancing this entitlement with respecting the privacy of all persons involved in ART procedures.

The NHMRC ART Guidelines are designed to protect the welfare and interests of donor conceived children in a variety of situations and are a suitable basis for the development of nationally consistent legislation by States and Territories.

### **Recommendation 4**

**In the context of the development of nationally consistent legislation relating to donor conception, the committee recommends that the Australian Government and state and territory governments give consideration to how private donor conception arrangements can best be regulated to ensure the rights of donors, recipients, and donor conceived individuals are appropriately protected.**

The Australian Government supports this recommendation in principle.

The Australian Government does not have constitutional power to regulate private arrangements. The Australian Government encourages States and Territories to consider the regulation of private arrangements in the context of reviewing their legislative framework involving donor regulation. The Australian Government also encourages individuals considering becoming a donor or a donor recipient to protect their interests and the interests of their donor conceived children by engaging the services of an ART service provider who holds an RTAC licence.

## **Recommendation 5**

**The committee recommends that the Australian Government, through the Standing Committee of Attorneys General, do everything possible to ensure the establishment, as a matter of priority, of a national register of donors, and that such a national register should also include information about donor conceived individuals.**

The Australian Government does not support this recommendation.

The Australian Government does not have constitutional power to comprehensively legislate to create a national register, absent a referral of power from the States. Some States and Territories have already established donor registers in their jurisdictions and the Australian Government encourages States and Territories that have not yet done so to also establish registers.

The Australian Government has worked with States and Territories through the Standing Council of Law and Justice (formerly the Standing Committee of Attorneys-General) since 2009 to facilitate national consistency between States and Territories and provide certainty for donors and donor conceived individuals and their families, but ultimately this is a matter for the States and Territories.

## **Recommendation 6**

**The committee recommends that a national register established by the Australian Government and State and Territory governments should have a particular focus on:**

- **security arrangements;**
- **privacy protections; and**
- **a clear articulation of the role of the body administering the register.**

See Response to Recommendation 5.

The Australian Government supports the principle of the recommendation that registers established by State and Territory governments should have a focus on security arrangements, privacy protections and a clear articulation of the role of the body administering the register.

## **Recommendation 7**

**While the committee strongly recommends the establishment of a national donor conception register, if this is not achieved, the committee recommends that each state and territory should put in place their own centralised register.**

The Australian Government supports this recommendation in principle but notes that this is a matter for States and Territories.

## **Recommendation 8**

**The committee recommends that, in the establishment of state and territory central registers, consistency in approach to the granting of access to information held on those registers should be a matter of priority.**

The Australian Government supports this recommendation in principle but notes that this is a matter for States and Territories.

## **Recommendation 9**

**The committee recommends that a central register, either in the form of a single national register or a separate register in each state and territory, should operate according to the following principles regarding access to information:**

- **donor conceived individuals should be able to access identifying information about their donor, once the donor conceived person reaches 18 years of age, or such younger age as agreed by all states and territories;**
- **donors should be able to access identifying information about individuals conceived as a result of their donation only with the consent of the donor conceived person;**
- **donor conceived individuals should be able to access identifying information about their siblings only with the consent of those siblings; and**
- **donors, donor conceived individuals, and recipient parents, as well as close relatives of donors or donor conceived individuals, should be able to access non-identifying information about the donor or donor conceived person, as applicable (provided that where a donor conceived individual seeks information, the person is at least 16 years of age, or such younger age as agreed by all states and territories)**

The Australian Government supports this recommendation in principle but notes that this is a matter for States and Territories.

The NHMRC ART Guidelines are broadly consistent with this recommendation. The NHMRC ART Guidelines provide at:

- paragraph 6.10 that gamete recipients may access
  - details of past medical history, family history and any genetic test results that are relevant to the future health of the person born (or any subsequent offspring of that person) and the recipient of the donation;
  - details of the physical characteristics of the gamete donor; and
  - the number and sex of persons conceived using the gametes donated by the same gamete donor.
- paragraph 6.11 that ART service providers must supply identifying information on request to donor conceived individuals over the age of 18 years,
- paragraph 6.12 that donors can access only non-identifying information about their offspring, and
- paragraph 6.13 that identifying information about siblings can be provided only with the consent of those siblings.

The Australian Government encourages States and Territories to pass legislation mandating ART service providers to hold a valid RTAC licence, which will ensure that the principles regarding access to information contained in this recommendation and reflected in the NHMRC ART Guidelines are given legislative force.



### **Recommendation 10**

**The committee recommends that, if after further consideration by the states and territories of the issue of retrospectivity, registers will not be retrospective, a national voluntary register or separate register in each state and territory should be established to allow donors who previously donated anonymously to agree to have their information recorded and disclosed to any individuals conceived as a result of their donation.**

The Australian Government supports this recommendation in principle but notes that this is a matter for States and Territories.

### **Recommendation 11**

**The committee recommends that donors in private arrangements be encouraged to have their information recorded and disclosed to any individuals conceived as a result of their donation on a national voluntary register or separate register if such registers are established in each state and territory.**

The Australian Government supports this recommendation in principle but notes that this is a matter for States and Territories.

### **Recommendation 12**

**The committee recommends that any voluntary registers incorporate a DNA databank, to enable donors and donor conceived individuals to have their details placed on the register for possible matching, in circumstances where records relating to their identities have been destroyed.**

The Australian Government supports this recommendation in principle but notes that this is a matter for States and Territories.

### **Recommendation 13**

**The committee recommends that the states and territories jointly fund a campaign to widely publicise the establishment of either a national voluntary register or separate voluntary registers in each state and territory.**

The Australian Government supports this recommendation in principle but notes that this is a matter for States and Territories.

### **Recommendation 14**

**The committee recommends that the Australian Government review, within a period of two years after this report, the current regulatory framework for overseeing compliance by clinics and medical practitioners with the National Health and Medical Research Council Guidelines on the use of assisted reproductive technology in clinical practice and research, with a focus on:**

- **whether the regulatory framework is adequate to ensure compliance with the guidelines;**
- **whether sanctions applied to clinics for failure to comply with their obligations under the guidelines are sufficient; and**
- **whether a more comprehensive regulatory framework is required.**

The Australian Government does not support this recommendation.

The NHMRC has a legislated role to develop ethical guidance but it does not oversee compliance of the NHMRC ART Guidelines by ART clinics. Some States and Territories have used the NHMRC ART Guidelines in different ways in their own legislative regimes to provide best practice models and standards by which clinic accreditation can be assessed.

The RTAC accreditation scheme provides a basis for a nationally consistent approach to the oversight of ART clinical practice in Australia. To obtain an RTAC licence, an ART provider must comply with the RTAC Certification scheme and the RTAC Code of Practice which in turn requires compliance with the NHMRC ART Guidelines.

To obtain RTAC Certification, ART service providers must apply to a JAS-ANZ accredited independent certification body who will measure compliance with the RTAC Code of Practice. The independent certification body will make recommendations to RTAC about issuing an RTAC licence to the ART service provider.

ART service providers are audited annually by a JAS-ANZ independent certification body for their compliance with the RTAC Code of Practice. Criteria considered critical under the RTAC Code of Practice, which includes compliance with the NHMRC ART Guidelines, are reviewed during this annual visit. In addition every three years further criteria considered to be part of good practice for ART service providers is also audited.

If the independent certification body discovers non-compliance with the RTAC Code of Practice by an ART service provider they may withdraw or suspend RTAC certification. RTAC has responsibility for the issuing, suspending and withdrawal of RTAC licences and may order additional audits of an ART service provider if an exceptional circumstance has arisen.

The Australian Government encourages States and Territories to enact legislation that mandate participation by ART service providers in the RTAC accreditation system. The removal of an RTAC licence will have a significant impact on ART service providers who are unable to continue to provide ART services without such a licence. It is not the role of the NHMRC or the Australian Government to monitor compliance with the RTAC Code of Practice and the Australian Government does not have constitutional power to legislate for a comprehensive scheme to penalise non-compliance by ART service providers. The Australian Government encourages the Australian public to use ART service providers who participate in the RTAC accreditation; consistent with this, Medicare benefits are only paid to RTAC accredited providers. It is a matter for States and Territories whether additional penalties for non-compliance other than the withdrawal of an RTAC licence are warranted.

In 2007 the Australian Government reviewed the regulation of reproductive tissues in the ART sector as part of the proposed Class 1 Framework for regulating solid organs and reproductive tissues (now the Biologicals Regulatory Framework). This review recognised that the 'ART sector already has an effective, cross-jurisdictional system of regulatory oversight in place through the RTAC accreditation process'. At the Australian Health Ministers' Conference (AHMC) meeting on 22 July 2008, Health Ministers agreed that un-manipulated reproductive tissues should not be regulated by the Commonwealth through the Therapeutic Goods Administration under its proposed

Class 1 Framework for human cellular and tissue therapies 'because the Assisted Reproductive Technology Sector is already coherently and consistently managed'.

In view of the established compliance scheme and the review conducted in 2007, the Australian Government considers that a review of the current regulatory framework by the Australian Government is not warranted at this time. However, it is open to State and Territory Governments to provide a legislative framework that would ensure compliance with the NHMRC ART Guidelines, make provision for legal sanctions for ART service providers that failed to comply and offer greater certainty to individuals involved in ART procedures.

### **Recommendation 15**

**If, following the review as set out in Recommendation 14, it is considered that the current regulatory framework for clinics and medical practitioners undertaking assisted reproductive technology procedures is not sufficient, the committee recommends that the Australian Government, through the Council of Australian Governments and the Standing Committee of Attorneys General, work with the state and territory governments to develop a more comprehensive regulatory framework.**

See response to Recommendation 14.

### **Recommendation 16**

**Regardless of the outcome of the review described in Recommendations 14 and 15, the committee recommends that the Australian Government, in consultation with the Fertility Society of Australia, create a review mechanism (for example, an Ombudsman-type mechanism or health complaint commission), that can be accessed by donor conceived individuals and parties undergoing assisted reproductive technology procedures, to investigate and address complaints against clinics, including when they fail to comply with their obligations under the National Health and Medical Research Council Guidelines or relevant legislation and regulation.**

The Australian Government does not support this recommendation.

The Australian Government notes that States and Territories are responsible for regulating donor conception practices in their jurisdictions. They are therefore responsible for conferring complaint handling responsibilities on their own Ombudsman-type mechanisms to investigate complaints against clinics and their compliance with the NHMRC ART Guidelines and relevant legislation and regulation.

Every ART service provider that is accredited under the RTAC accreditation scheme must appoint a medical director who is responsible for the clinical management of the organisation. The medical director is required to be a recognised specialist gynaecologist or physician. The Medical Board of Australia, supported by Boards in each State and Territory, is responsible for investigating and handling complaints against medical practitioners, with other health practitioners similarly regulated by their respective boards.

Where individuals believe their personal information has been disclosed or handled in breach of the *Privacy Act 1988* (Cth) or the *National Privacy Principles 1988* contained in Schedule 3 to that Act, they may lodge a complaint with the Federal Privacy Commissioner.

### **Recommendation 17**

**The committee recommends that, except in circumstances where the parties have a particular ethnic background and it is difficult to obtain gametes or embryos from a person with the same ethnic background (or in any other similar circumstances), the importation of gametes and embryos from overseas donors should be banned in Australia.**

The Australian Government does not support this recommendation.

The NHMRC ART Guidelines do not currently support the proposed ban on the importation of gametes from overseas. See Recommendation 19.

In regards to the importation of an embryo from overseas, section 20 of the *Prohibition of Human Cloning for Reproduction Act 2002* makes it an offence to import, export or treat a woman with a prohibited embryo. Subsection 20(4)(b) defines a "prohibited embryo" as including "a human embryo created outside the body of a woman, unless the intention of the person who created the embryo was to attempt to achieve pregnancy in a particular woman".

Thus, if an embryo were to be created overseas without prior determination that a specific woman would receive the embryo, importation of, or treatment of a woman with such an embryo would be prohibited under this Act. However, the importation and subsequent treatment of a woman with an embryo created overseas for that particular woman would be permitted under this Act (provided the embryo was not otherwise a prohibited embryo).

### **Recommendation 18**

**If a ban on the importation of gametes and embryos from overseas is not possible, the committee recommends that any gametes and embryos imported into Australia from overseas donors undergo the same requirements and procedures for use in donor conception as gametes and embryos donated in Australia, including screening and counselling requirements.**

The Australian Government supports this recommendation.

Paragraph 6.2 of the NHMRC ART Guidelines are consistent with this recommendation and currently state that 'treatment in Australia using either gametes donated overseas or embryos created from gametes donated overseas must not take place unless all the relevant conditions of these guidelines and any relevant legislation have been fulfilled.'

### **Recommendation 19**

**The committee recommends that the Australian Government undertake a review of the National Health and Medical Research Council Guidelines to specifically address the rights of access to information of donor conceived individuals conceived with the use of gametes and embryos imported from overseas.**

The Australian Government supports this recommendation.

Paragraphs 6.1, 6.10, 6.11, 6.12 and 6.13 of the NHMRC ART Guidelines acknowledge the right to information of all those involved in ART procedures. The NHMRC ART Guidelines provide that clinics 'must not use donated gametes in reproductive procedures unless the donor has consented to the release of identifying information about himself or herself to the persons conceived using his or her gametes.' Paragraph 7.1 identifies a similar right for donor conceived persons to knowledge about genetic parents and the existence of any genetically related siblings.

Paragraph 6.2 of the NHMRC ART Guidelines states that 'treatment in Australia using either gametes donated overseas or embryos created from gametes donated overseas must not take place unless all the relevant conditions of these guidelines and any relevant legislation have been fulfilled.'

The timing of the review of the NHMRC ART Guidelines is somewhat contingent on the government response to the outcomes of the Heerey Review of the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) and the *Research Involving Human Embryos Act 2002* (Cth) which is required under legislation. The review was submitted to COAG and was tabled in both Houses of Parliament on 7 July 2011. The Government response is expected in due course.

### **Recommendation 20**

**The committee recommends that the Australian Government and state and territory governments work together, including through the Council of Australian Governments and other appropriate national forums, to agree to a nationally consistent and permanent long-term solution to the management of records relating to donor conception, to ensure that records which identify donors, donor recipients, and donor conceived offspring, are appropriately preserved.**

The Australian Government supports this recommendation in principle but notes that this is a matter for States and Territories.

The management of health records is governed by State and Territory legislation.

### **Recommendation 21**

**Until such time as Recommendation 20 is implemented, the committee recommends that a temporary moratorium be placed on the destruction of all records held by government agencies, doctors, clinics, and assisted reproductive technology providers that identify donor conception treatment procedures undertaken by donors and donor recipients.**

The Australian Government supports this recommendation in principle but notes that the regulation of health services and health records including data collection and mandatory record keeping requirements is a matter for States and Territories.

### **Recommendation 22**

**The committee recommends that the prohibition on payments for donations of sperm, oocytes or embryos in Australia should be maintained.**

The Australian Government supports this recommendation.

Under the NHMRC ART Guidelines, commercial trading in human gametes and/or the use of direct or indirect inducements must not be undertaken. Paragraph 6.5 of the NHMRC ART Guidelines states that 'gamete donation must be altruistic'.

Under subsections 21(1) and (2) of the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth):

(1) A person commits an offence if the person intentionally gives or offers valuable consideration to another person for the supply of a human egg, human sperm or a human embryo.

(2) A person commits an offence if the person intentionally receives, or offers to receive, valuable consideration from another person for the supply of a human egg, human sperm or a human embryo.

The Australian Government is serious in its efforts to prevent the commercial exploitation of human gametes and embryos. An offence against this provision of Commonwealth legislation is punishable by imprisonment up to 15 years.

### **Recommendation 23**

**The committee recommends that donors should continue to be able to be reimbursed for 'reasonable expenses' incurred in relation to their donation.**

The Australian Government supports this recommendation.

'Reasonable expenses' are specifically excluded from the definition of 'valuable consideration' under subsection 21(3) of the Prohibition of Human Cloning for Reproduction Act 2002 (Cth):

**reasonable expenses:**

(a) in relation to the supply of a human egg or human sperm— includes, but is not limited to, expenses relating to the collection, storage or transport of the egg or sperm; and

(b) in relation to the supply of a human embryo:

(i) does not include any expenses incurred by a person before the time when the embryo became an excess ART embryo; and

(ii) includes, but is not limited to, expenses relating to the storage or transport of the embryo.

**valuable consideration**, in relation to the supply of a human egg, human sperm or a human embryo by a person, includes any inducement, discount or priority in the provision of a service to the person, but does not include the payment of reasonable expenses incurred by the person in connection with the supply.

In addition, paragraph 17.21.2 of the NHMRC ART Guidelines addresses the issue of 'reimbursement of reasonable out-of-pocket expenses for the donation of gametes, gonadal tissue or cells for research purposes'.

Although paragraph 6.5 of the NHMRC ART Guidelines make reference to paragraph 17.21.2, it is not explicitly stated that reimbursement for reasonable out-of-pocket expenses in relation to the donation of gametes or embryos for ART procedures is ethically acceptable.

Paragraph 6.5 of the NHMRC ART Guidelines provides that 'commercial trading in human gametes and/or the use of direct or indirect inducements must not be undertaken'. The advice in the NHMRC ART Guidelines with respect to the reimbursement for reasonable out-of-pocket expenses in relation to the donation of gametes or embryos for ART procedures could be clarified in the next review of the NHMRC ART Guidelines. The Australian Government thanks the Senate for their input into the review of this recommendation. This is supported by recommendation 6 of the Report of the Independent Review of the Prohibition of Human Cloning for Reproduction Act 2002 and Research Involving Human Embryos Act 2002 (June 2011).

## **Recommendation 24**

**The committee recommends that the Australian Government, in consultation with state and territory governments and the Fertility Society of Australia, develop more detailed guidelines on what constitutes 'reasonable expenses' for which donors can be reimbursed.**

The Australian Government notes this recommendation.

The AHEC has issued general advice on the operation of the *National Statement on Ethical Conduct in Human Research 2007* and payments to participants in clinical drug trials (see [http://www.nhmrc.gov.au/files/nhmrc/file/health\\_ethics/hrecs/reference/using\\_the\\_national\\_statement.pdf](http://www.nhmrc.gov.au/files/nhmrc/file/health_ethics/hrecs/reference/using_the_national_statement.pdf)). This advice relates to research situations only and would have limited applicability to the range of activities discussed in the NHMRC ART Guidelines. This advice could be used as a base from which to develop further guidance for donors.

The *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) defines 'reasonable expenses' at subsection 21(3):

- (a) in relation to the supply of a human egg or human sperm - includes, but is not limited to, expenses relating to the collection, storage or transport of the egg or sperm; and
- (b) in relation to the supply of a human embryo:
  - (i) does not include any expenses incurred by a person before the time when the embryo became an excess ART embryo; and
  - (ii) includes, but is not limited to, expenses relating to the storage or transport of the embryo.

The NHMRC has provided some guidance to several ART clinics at their request about the level of reimbursement that would be appropriate as 'reasonable expenses' and what would be considered valuable consideration. It strongly recommends that clinics obtain their own legal advice. The NHMRC notes that 'reasonable expenses' for some parties may act as an inducement for other parties. The NHMRC considers that a 'one size fits all' approach may not be appropriate. The advice in the NHMRC ART Guidelines with respect to the reimbursement for reasonable out-of-pocket expenses in relation to the donation of gametes or embryos for ART procedures could be clarified in the next review of the NHMRC ART Guidelines (see Response to Recommendation 23).

## **Recommendation 25**

**In relation to counselling, the committee recommends that:**

- **counselling should be mandatory for donors and donor recipients prior to undergoing a donor conception procedure;**
- **donors and donor recipients should be able to elect to receive counselling on the donor conception process and its consequences from a counsellor independent of the fertility clinic in which they are undertaking treatment;**
- **parents of donor conceived individuals should have access to counselling following the birth of their child, to equip them to be able to tell their child about their conception and to support their child in dealing with any self-identity issues that may arise; and**
- **donor conceived individuals should have access to counselling as they mature and, in particular, when making contact for the first time with their**

**donor or half-siblings. Such counselling should be voluntary, except where the donor conceived person is aged under 18 and is making contact for the first time with their donor or half-siblings, in which case counselling should be mandatory.**

The Australian Government supports this recommendation in principle.

The NHMRC ART Guidelines define the nature of the counselling services which should be provided to participants in a donor conception program and the requirement for professionals with appropriate training skills and accreditation necessary for the counselling role.

The Australian Government encourages States and Territories to legislate to require ART service providers to maintain an RTAC licence which in turn will require ART service providers to comply with the NMHRC Guidelines on counselling of persons involved in ART procedures.

### **Recommendation 26**

**The committee recommends that State and Territory governments, in consultation with the Fertility Society of Australia, should give consideration to funding the provision of counselling for donors, donor recipients and donor conceived individuals following the birth of donor conceived individuals.**

The Australian Government notes this recommendation and considers that this is a matter for States and Territories and the Fertility Society of Australia.

### **Recommendation 27**

**The committee recommends that State and Territory governments, in consultation with the Fertility Society of Australia, should develop guidelines or requirements to ensure that counsellors providing counselling to donors, donor recipients or donor conceived individuals have an appropriate understanding of the issues involved with donor conception.**

The Australian Government notes this recommendation and considers that this is a matter for States and Territories and the Fertility Society of Australia.

### **Recommendation 28**

**The committee recommends that State and Territory governments should commission research to ascertain the numbers of individuals born through donor conception in their respective jurisdictions and that, once more accurate data is obtained, further research should be conducted in relation to the risk of consanguine relationships among those people.**

The Australian Government notes this recommendation and considers that this is a matter for States and Territories.



### **Recommendation 29**

**Noting the disparity in evidence received throughout the inquiry as to the appropriate limit for the number of families that donors should be able to assist, the committee recommends that each donor should only be able to assist up to a maximum of four families (in addition to their own) in Australia. Although the preference is that each donor only assists one family (in addition to their own), if more than one family is to be assisted, the committee recommends that the relevant clinic must consider the following factors:**

- **the number of genetic relatives that the persons conceived would have as a result of the treatment;**
- **the consent of the donor with respect to the number of families to be created;**
- **whether the donor has already donated gametes at another clinic; and**
- **the risk of a person conceived with donor gametes inadvertently having a sexual relationship with a close genetic relative (with particular reference to the population and ethnic group in which the donation will be used).**

The Australian Government notes this recommendation and considers that this is a matter for States and Territories.

This recommendation is consistent with the NHMRC ART Guidelines. Although no nominal upper limit is stated in the NHMRC ART Guidelines, the four factors listed in this recommendation are contained in paragraph 6.3 of the guidelines. Clinics must 'take all reasonable steps to reduce the numbers of genetic relatives created through donor gamete programs' and should consider the four factors listed here when deciding the number of families assisted by any one donor.

### **Recommendation 30**

**The committee recommends that the issue of limits on donations should be reviewed by the states and territories, in consultation with the Fertility Society of Australia, once further evidence becomes available about the importance of forming a strong sense of self-identity for donor conceived people and the risks of consanguine relationships.**

The Australian Government notes this recommendation and considers that this is a matter for States and Territories and the Fertility Society of Australia.

### **Recommendation 31**

**The committee recommends that clinics and medical services should amend the consent forms which are signed by donors, to ensure that consent is given to the sharing of information with other clinics and medical services in the same jurisdiction and in other jurisdictions in Australia.**

The Australian Government notes this recommendation and considers that this is a matter for States and Territories.

### **Recommendation 32**

**The committee recommends that, to the extent that the states and territories have not already done so, birth certificates of donor conceived children should be notated so that when they apply for a birth certificate over the age of 18 years, they can be provided with additional information about their donor conception circumstances if they choose.**

The Australian Government notes this recommendation and considers that this is a matter for States and Territories.