Information for ART Providers on the Assisted Reproductive Technology Act 2007

The Assisted Reproductive Technology Act 2007

In NSW a number of children are born every year as a result of ART treatment using donated gametes (sperm and ova). Until recently there was no process to support the disclosure of information about the people involved in this process and many gamete donors were anonymous. This has created a situation in which many individuals are unable to identify a biological parent and obtain information about their genetic heritage and background, which has been distressing for some and occasionally created medical and social dilemmas for both individuals and their parents.

The *Assisted Reproductive Technology Act 2007* (ART Act) and Assisted Reproductive Technology Regulation 2014 (ART Regulation) were developed to address this issue and a range of other matters in the area of ART.

This pamphlet has been prepared to give ART providers a general overview of the ART Act and ART Regulation. However, nothing in this pamphlet should be construed as legal advice and if you have any specific legal questions regarding the effects of the ART Act and Regulation on your practice, you should seek legal advice.

What are the main features of ART Act and Regulation?

The ART Act requires all ART providers to be registered in order to provide ART services in NSW.

The ART Act, which commenced on 1 January 2010 established a Central Donor Register (Central Register) to hold information about donors and children born as a result of ART treatment using donated gametes (sperm and ova).

Information held on the Central Register can be accessed by people who were conceived using donated gametes once they turn 18 years of age.

The ART Act also allows parents to access certain non-identifying information about their child's donor, and donors to access non-identifying information about their offspring.

In order to ensure that the Central Register holds information about donors and donor conceived individuals, the ART Act and Regulation require ART providers to collect and store information about donors and women undergoing ART treatment and to provide this information to the Central Register following the birth of each donor conceived child.

In addition, the ART Act and ART Regulation:

- set infection control standards that are to be observed by ART providers'
- require ART providers to ensure that counselling services are available at the place where the ART treatment is carried out,
- place certain restrictions on the use of gametes (such as only using gametes in a manner consistent with the donor's consent),
- place a time limit on the use of donated gametes (no more than 10 years after the gamete was obtained without the written approval of the Secretary, NSW Health),
- prevent ART providers from providing ART treatment using a gamete obtained from a donor more than five years before the ART treatment unless the ART provider has taken reasonable steps to determine whether the donor is alive,
- prohibit commercial surrogacy,
- prohibit the use of ART treatment using donated gametes if the treatment is likely to result in offspring of the donor being born, whether or not as a result of ART treatment, to more than five women (whether in NSW or elsewhere);
- provide for the appointment of inspectors who can enter and inspect premises where ART treatment is being carried out.

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Reasonable steps to determine if a donor is alive

Under section 24 of the ART Act an ART provider must not provide ART treatment using a gamete obtained from a donor more than five years before the provision of ART treatment, unless the ART provider takes reasonable steps to establish whether the donor is alive.

Reasonable steps include, (section 24(3) of the Act and clause 10 of the Regulation):

- obtaining a certificate from the NSW Register of Births, Deaths and Marriages as to whether the death of the donor has been recorded in the Births, Deaths and Marriages Register; and
- if the last address, of which the ART provider is aware, of the donor is in another State or Territory, obtaining a certificate as to whether the death of the donor has been recorded in the other State or Territory's register of Births, Deaths and Marriages.

Depending on the circumstances of the donor, an ART provider may have to undertake further reasonable steps to establish whether the donor is alive. Further reasonable steps may include:

- If the ART provider knows the donor lives overseas, it may be reasonable for the ART provider to undertake a search of the equivalent overseas' register of births, deaths and marriages.
- If an ART provider knows that a donor is a member of a registered profession it may be reasonable to undertake a search of the relevant public register to determine if the donor holds a current registration.

Maximum number of women who can receive ART treatment using donated gametes

Section 27 of the ART Act prohibits an ART provider from providing ART treatment using donated gametes if the treatment is likely to result in offspring of the donor being born, whether or not as a result of ART treatment, to more than five women (or such lesser number as specified in a donor's consent), including the donor and any current or former spouse of the donor. The number of women who have given birth to offspring of the donor includes all women regardless of whether they live in NSW or elsewhere, including overseas.

Although section 27 of the ART Act creates a five women limit, the ART Regulation includes a transitional provision in respect of women who had already conceived a child using a donated gamete and women who had embryos, created using donated gametes, in storage at the time of the commencement of the ART Act. As a result of the ART Regulation section 27 will not prevent ART treatment being given to a woman if the gamete used in the treatment is a donated gamete that was obtained before the 1 January 2010 and:

- the embryo was created using the donated gamete before 1 January 2010 and the embryo is used to provide the ART treatment to a woman; or
- the woman has, before 1 January 2010, already conceived an offspring as a result of ART treatment using a donated gamete from the donor and the gamete is used to provide ART treatment to the woman.

What information do I have to collect about a donor?

Before obtaining a gamete ART providers are required to collect the following information from the donor:

1. In respect of a gamete that is not donated, i.e. an ova that is to be used in providing ART treatment to the donor herself or sperm that is used in providing ART treatment to the partner or spouse of the donor:

   a) the donor's full name, date of birth and residential address.

2. In respect of a donated gamete, the following information must be obtained:

   a) the full name of the donor (includes each name by which the donor is or has been known),

   b) the residential address of the donor,

   c) the date and place of birth of the donor,

   d) the ethnicity and physical characteristics of the donor,

   e) any medical history or genetic tests of the donor or the donor's family that are relevant to the future health of:

      i) a person undergoing ART treatment involving the use of the donated gamete, or

ii) any offspring born as a result of that treatment, or

iii) any descendent of any such offspring,

f) the name of each ART provider who has previously obtained a donated gamete from the donor and the date on which the gamete was obtained,

g) the sex and year of birth of each offspring of the donor.

An ART provider must not use a gamete or an embryo for any purpose unless the ART provider has collected the above information in respect of each relevant gamete provider.

However, in order to allow women with embryos in storage and women who have already conceived a child using donated gametes to complete their families, the ART Regulation provides that an ART provider is taken to have obtained the above information in respect of a gamete donated before 1 January 2010 if:

- the embryo was created using the donated gamete before 1 January 2010 and the embryo is used to provide ART treatment to a woman; or
- the women has, before 1 January 2010, already conceived an offspring as a result of ART treatment using a donated gamete from the donor, and the gamete is used to provide ART treatment to the women.

Storage of information

ART providers are required to keep the following information in respect of all gametes, or embryos in the ART provider's possession, in an approved form. All records required to be kept under the ART Act must be retained by ART providers for 50 years after the record is made. A penalty applies if the records are not retained.

1) In respect of any gamete or embryo in the ART provider's possession:

A. in respect of a gamete that is not a donated gamete or an embryo created using a gamete that is not a donated gamete:

a) the donor's full name, date of birth and residential address

b) the provenance of such gamete or embryo (including the provenance of the gametes used to create the embryo),

c) the donor's consent,

d) the uses that have been made of the gamete or embryo,

e) the period during which any such gamete or embryo has been in storage.

B. In respect of a donated gamete or embryo created using a donated gamete, the following information must be kept

a) the full name of the donor (includes each name by which the donor is or has been known),

b) the residential address of the donor,

c) the date and place of birth of the donor,

d) the ethnicity and physical characteristics of the donor,

e) any medical history or genetic tests of the donor or the donor's family that are relevant to the future health of:

i) a person undergoing ART treatment involving the use of the donated gamete, or

ii) any offspring born as a result of that treatment, or

iii) any descendent of any such offspring,

f) the date the donor provided the above information,

g) the name of each ART provider who has previously obtained a donated gamete from the donor and the date on which the gamete was obtained,

h) the sex and year of birth of each offspring of the donor,

i) the provenance of such gamete or embryo (including the provenance of gametes used to create the embryo,

j) the donor's consent,

k) the uses that have been made of the gamete or embryo,

l) the period during which any such gamete or embryo has been in storage.

2) In respect of each woman undergoing ART treatment:

a) the identity of each woman.

3) In respect of offspring born as a result of ART treatment provided by the clinic:

a) the full name, sex and date of birth of each offspring born as a result of ART treatment, provided by the ART provider, and

b) the name of the woman who gave birth to the offspring, and

c) if the offspring was born as a result of ART treatment using a donated gamete, the full name and date and place of birth of the donor of the gamete.

4) Transitional Provisions

In order to allow women with embryos in storage and women who had already conceived a child using donated gametes prior to the commencement of the ART Act, to complete their families, the ART Regulation provides that ART providers are not required to keep the above records in respect of the following gametes and embryos:

a) embryos that were created using donated gametes before 1 January 2010 where the embryos are used to provide ART treatment; or

b) donated gametes obtained from donors before 1 January 2010 and used to provide ART treatment to women where the women have, before 1 January 2010, already conceived offspring as a result of ART treatment using a donated gamete from the donor.

Information to be provided to the Director-General

Within two months after the birth of a live offspring born as a result of ART treatment using donated gametes ART providers must provide the following information to the Secretary, NSW Health, for inclusion on the Central Register:

1) About the donor:

a) the full name of the donor (includes each name by which the donor is or has been known),

b) the residential address of the donor,

c) the date and place of birth of the donor,

d) the ethnicity and physical characteristics of the donor,

e) any medical history or genetic test results of the donor or the donor's family that are relevant to the future health of:

i) a person undergoing ART treatment involving the use of the donated gamete, or

ii) any offspring born as a result of that treatment, or

iii) any descendent of any such offspring,

f) the name of each ART provider who has previously obtained a donated gamete from the donor and the date on which the gamete was obtained,

g) the sex and year of birth of each offspring of the donor;

h) the donor's consent.

2) About the birth

a) the full name, sex and date of birth of a child born as a result of ART treatment using donated gametes, and

b) the name of the woman who gave birth to the offspring, and

c) the full name, date and place of birth of the donors of the gametes.

Who can access information on the Central Register?

Adult donor conceived individuals are entitled to have access to:

a) the full name of the donor,

b) the residential address of the donor,

c) the date and place of birth of the donor,

d) the ethnicity and physical characteristics of the donor,

e) any medical history or genetic test results of the donor or the donor's family that are relevant to the future health of:

i) a person undergoing ART treatment involving the use of the donated gamete, or

ii) any offspring born as a result of that treatment, or

iii) any descendent of any such offspring,

f) the name of the ART provider who provided the gamete and the date on which the gamete was obtained, and

g) the sex and year of birth of each other offspring of the donor.

Other adult offspring of the donor (not through donation) are entitled to have access to:

a) the sex and year of birth of each other offspring of the donor.

Parents of a child born as a result of ART treatment using a donated gamete are entitled to have access to:

a) the ethnicity and physical characteristics of the donor,

b) any medical history or genetic test results of the donor or the donor's family that are relevant to the future health of:

i) a person undergoing ART treatment involving the use of the donated gamete, or

ii) any offspring born as a result of that treatment, or

iii) any descendent of any such offspring,

c) sex and year of birth of each other offspring of the donor.

The Donor is entitled to have access to:

a) the sex and year of birth of each offspring of the donor.

The information on the Central Register reflects the circumstances of the donor, and any offspring of the donor, as at the time the donor donated his or her gametes, unless the donor or offspring provides updated information.

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