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| Movement of donated gametes and embryos formed from donated gametes into Victoria |
| Guidance document  |
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# Purpose

Under 36(3) of the *Assisted Reproductive Treatment Act 2008 (Vic)* (the Act), before a person brings donated gametes[[1]](#footnote-2) and/or embryos produced from donated gametes (donor material)[[2]](#footnote-3) into Victoria they must certify to the Secretary of the Department of Health (the department) that the certification criteria[[3]](#footnote-4) have been satisfied.

This document explains who can make a certification, the certification criteria to be attested to and how to submit a certification.

A certification does not need to be made if you intend to bring into Victoria your own eggs, sperm or embryo made without any donor material.

# Who can make a certification?

Any person responsible for moving donor material (either a body corporate or a natural person) must make a certification before bringing donor material Victoria. For example, an individual or a registered ART provider may make a certification.

# Certification Criteria – movement of donor material into Victoria

### Payment and valuable consideration

#### What must be certified?

The person must certify that any payment made or agreed to be made and any valuable consideration given or agreed to be given in connection with the donation does not contravene:

* *The Human Tissue Act 1982 (Vic)* ***or***
* *Prohibition of Human Cloning for Reproduction Act 2008 (Vic)* ***or***
* *Prohibition of Human Cloning for Reproduction Act 2002 (Cth)*

A donor can only be paid and/or reimbursed for ‘reasonable expenses’, in connection with their donation.

Reasonable expenses[[4]](#footnote-5) are those that the donor incurs **directly**, for example:

* medical and counselling expenses
* travel and accommodation expenses
* loss of earning or income
* cost of legal advice.

#### Note: The certifying person may be requested to provide evidence of all payments made; it is therefore recommended that a record of expenses be kept as part of official records.

### Consent

#### What must be certified?

The person must certify that they have a copy of the donor’s (or donors where relevant in the case of an embryo) consent.

A donor’s (or donors) consent must be written, be in the prescribed form[[5]](#footnote-6), and include consent to the following:

* to have their donor material brought into Victoria
* to the use of their donor material (including specifying the number of women who can have treatment[[6]](#footnote-7) using their donor material and the kinds of treatment procedures their donor material can be used for)
* to storage of the embryo for the purpose of later transfer (where relevant)

The person making the certification must ensure that at the time of certification, the donor/s consent is current and has not lapsed or been withdrawn.[[7]](#footnote-8) A withdrawal of consent must be in writing and be given to (or cause to be given to) the person making the certification as soon as practicable.

If an exemption has been granted in relation to:

* consent to storage of the embryo[[8]](#footnote-9)
* who consent must be given to (or cause to be given to)[[9]](#footnote-10)
* who withdrawal of consent must be given to (or cause to be given to)[[10]](#footnote-11)

the exemption/s and any conditions the exemption/s is/are subject to have been complied with.

#### Note: The certifying person may be asked to produce a copy of the prescribed form that shows the consent is current and applicable to the registered ART provider may be requested to support the certification.

### Counselling

#### What must be certified?

The person must certify that prior to donation each donor has received counselling[[11]](#footnote-12) about the below matters:

* requirements of the Act relating to disclosing the identity of the donor to the Donor Conception Registrar and disclosing information to a person born as a result of a donor treatment procedure following a request for the information from the person
* the ability of the donor to obtain identifying information about a person born as a result of a donor treatment procedure with the consent of the person and the right of the person to lodge a contact preference
* any issue or concern raised by the donor in relation to the donation, for example—
	+ the possible impact of donation on the donor's partner, if any
	+ the possible impact of donation on the donor's children, if any
* the implications for donors of—
	+ the withdrawal or lapsing of a donor's consent
	+ consent requirements for an extension of storage of an embryo
	+ consent requirements for the removal of an embryo from storage
	+ the effect of section 29 of the Act on using donor gametes
	+ when a person born as a result of a donor treatment procedure lives in
		- another State or a Territory, or
		- another country

#### Who can provide counselling?

* The certification must confirm counselling has been provided by a counsellor
	+ who provides services for a registered ART provider or
	+ who has full membership, or eligibility for full membership, of the Australian and New Zealand Infertility Counsellors Association (ANZICA).

#### Note: The certifying person may be asked to provide evidence that the donor received counselling in relation to all prescribed matters

### 10 Women Limit (section 29)

Section 29 bans a person from carrying out a treatment procedure using gametes, or an embryo formed from gametes, produced by a donor if the person knows the treatment procedure may result in more than 10 women having children who are genetic siblings.

It is important to note that the 10 women limit includes the **donor and any current or former partner** of the donor.

In Victoria, the 10-woman limit applies to **donor material coming from interstate and international donations**, a family audit is suggested if in doubt of the 10 women limit status of the donor.

If more than 10 women have children who are genetic siblings, the ban does not prevent a person from carrying out a treatment procedure on any of the women using the gametes, or an embryo formed from gametes produced by the donor to produce a child that will be a genetic sibling of the women's children.

This provision allows use of the same donor for:

* existing families to have genetic siblings to their existing child/ren
* a woman who has a female partner or whose female partner is deceased to produce a child who will be a genetic sibling of the child/ren of that woman and her partner or that woman and the deceased and
* existing families who use more than one surrogate mother to have child/ren who are genetic siblings.

Table 1 provides examples of how section 29 of the Act may apply to different family arrangements.

Table 1: Section 29 of the Act

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| **Examples of family arrangements** | **Application of section 29 of the Act** |
| **Same family arrangement:** Couple who remains together, or single person in same family arrangement seeks to have a genetic sibling for existing child using the same donor. | Couple (same-sex or heterosexual) or single person commissioning a surrogacy arrangement with a different surrogate | Allowed |
| **Different family arrangement:** Couple separates with a child and one or both seek to have a genetic sibling for their existing child using the same donor **on their own** | Man and woman separate and man or woman seeks to have a child, using a different surrogate from the surrogate who carried their existing child | Not allowed |
| Two men separate and one or both men seek to have a child using a different surrogate from the surrogate who carried their existing child | Not allowed |
| Two women separate and the woman who carried the first child seeks to carry another child | Allowed |
| **Different family arrangement:** Couple separate with a child and one or both re-partner and one or both seek to have a genetic sibling for existing child using the same donor **with the new partner**  | Man separates from partner (female or male). Re-partners with a woman and woman seeks to carry a child | Not allowed |
| Man separates from partner (female or male). Re-partners with a man or woman and needs a surrogate | Not allowed |
| Woman separates from partner (male or female). Re-partners with a man and needs a surrogate | Not allowed |
| Woman separates from partner (male or female). Re-partners with a woman and partner seeks to carry a child | Not allowed |
| Woman separates from partner (male or female). Re-partners with a man or woman and the woman who carried the first child seeks to carry another child | Allowed |
| **Posthumous use:** Couple have a child using donor eggs or sperm and one of the partners dies and surviving partner seeks to have a genetic sibling for existing child using the same donor | The surviving male partner seeks to have a genetic sibling for the couple’s existing child carried by his deceased female partner, **on his own** using a surrogate | Allowed, subject to consent to posthumous use |
| The surviving male partner seeks to have a genetic sibling for his and his deceased partner’s existing child carried by his deceased female partner, **with a new partner** using a surrogate | Not allowed |
| The surviving female partner who carried their child seeks to carry a genetic sibling for their existing child, on her own | Allowed, subject to consent to posthumous use |
| The surviving male partner seeks to have a genetic sibling for the couple’s existing child carried by his deceased female partner, **on his own** using a surrogate | Allowed, subject to consent to posthumous use |

#### Note: The certifying person may be asked to provide evidence showing the reasonable steps they have taken to ensure that any future use of the donor material will comply with Victoria’s 10 -woman worldwide limit (section 29 of the Act). An example of steps taken could be undertaking a family audit or agreements with international donor banks that also have a 10-women worldwide limit.

### Information donor/s must provide

#### What must be certified?

The person must certify that the donor or (where relevant) donors have given the following information:

* the donor's unique donor identifier (if any)
* the donor's full name
* any other name by which the donor is or has been known
* the donor's date of birth
* the donor's place of birth (suburb or town and country)
* the donor's sex
* the donor's residential address
* the date on which the donor produced the gametes
* the place at which the donor produced the gametes
* the ethnic background of the donor's parents and grandparents, if known
* the donor's height
* the donor's build
* the donor's blood group
* any known genetic abnormality of the donor and, if available, any results of tests undertaken in relation to that abnormality
* the number of women who have given birth to children conceived using the donor's gametes or an embryo produced from the donor's gametes, including any current or former partner of the donor
* whether the donor has donated, or intends to donate, gametes or an embryo to any other registered ART provider or to a doctor and, if so—
* the name and address of that registered ART provider; or
* the full name and business address of that doctor
* the date on which the donor received the required counselling[[12]](#footnote-13) and the name of the counsellor who provided the counselling.

#### Exemption

If an exemption has been granted in relation to the prescribed information required to be recorded in the register under section 49 or 50 of the Act[[13]](#footnote-14), that the exemption and any associated conditions have been complied with.

### Written advice to be provided to donor/s

#### What must be certified?

The person must certify that each donor (or donors), at the time of giving consent received written advice from either the registered ART provider or a doctor who carries out artificial insemination other than on behalf of a registered ART provider, receiving the donor material, about the following:

* the rights of any person born as a result of a donor treatment procedure, the parents of that person and any other persons to the disclosure of information on the Central Register (refer to Division 3 of Part 6 of the Act) and
* the nature of the information about the donor that that is recorded in the Central Register and
* the donor’s rights to obtain information under Part 6, Division 2 of the Act and Division 3 of the Act (information to be given by registered ART providers and doctors and disclosure of information on the Central Register) and
* the existence and function of the Voluntary Register.

#### Exemption

If an exemption has been granted in relation to written advice to be given[[14]](#footnote-15), that the exemption and any conditions the exemption is subject to has been complied with.

For information about the Central and Voluntary Register contact via email at <dcr@health.vic.gov.au>

#### Note: The certifying person may be asked to provide evidence they have provided the donor with the written advice and for best practice should include confirmation the donor has received it.

### Change to consent or donor information

#### What must be certified?

The person making the certification must certify that they have received a written undertaking from the person transferring the donor material (transferring party) or the donor that either the transferring party or donor (as relevant) will notify the person making the certification, as soon as practicable, of the following:

* any change or withdrawal of the donor’s consent and
* any change to the donor’s information[[15]](#footnote-16)

#### Note: The certifying person may be asked to provide evidence of the written undertaking from the transferring party or donor.

### Contact details - ART provider or doctor

#### What must be certified?

The person making the certification must certify that they have received a written undertaking:

* from the transferring party, committing to take all reasonable steps to give the donor with written notice, as soon as practicable, of either:
	+ the name and contact details of the receiving registered ART provider or
	+ the name and contact details of the doctor carrying out artificial insemination using the donor gametes

**Or**

* from the person receiving the donor material (receiving party) that they have provided written notice to the donor of:
	+ the name and contact details of the name and contact details of the receiving registered ART provider or
	+ the name and contact the doctor carrying out artificial insemination using the donor gametes clinic.

#### Note: The certifying person may be asked to provide evidence of the written undertaking from the transferring party or receiving party.

### Contact details and identification- donor

#### What must be certified?

The person making the certification must certify that they have sighted:

* the donor's passport, driver licence or any other identification document displaying the donor's photograph and signature; or
* a certified copy of the donor's passport, driver licence or any other identification document displaying the donor's photograph and signature.

The person making the certification must certify that they have received:

* the donor’s email address (if any) and
* the donor’s postal address
* information about whether the donor has donated, or intends to donate, gametes or an embryo to a person (other than a registered ART provider or a doctor) including an individual for the purposes of self-insemination.

If the person making the certification is a **registered ART provide or a doctor carrying out artificial insemination** using the donor material, they must certify that:

* they will use the unique donor identifier from the transferring party so far as is reasonably practicable.

#### Note: The certifying person may be asked to provide evidence that the above has occurred as required.

#### Prohibited locations

Where applicable, the person must certify that where an exemption has been granted in relation to bringing donor material into Victoria from a prohibited location[[16]](#footnote-17), as published in the Government Gazette, the exemption and any conditions the exemption is subject to have been complied with.

#### Note: The certifying person may be asked to provide evidence of the original location the donation.

# Class certification

A certification must be made for each donor (or where relevant donors in the case of an embryo) before bringing the donor material into Victoria. This means that it is not possible to submit a certification that covers movement of multiple different sets of gametes or embryos.

Prior to 1 January 2025, the process to import donor material on behalf of a class of individuals (class application) required the submission of a proposal for approval in principle to bring donor material into Victoria and, if approval in principle was obtained, a subsequent application each time the donor material was intended to be brought into Victoria. The certification process removes the requirement for approval in principle and pre-approval, streamlining the process to bring donor material into Victoria.

# How to fill out the certification

The certification is in protected Word format which allows you to fill out the required sections only. The form has instructions on the first page and includes:

* Read each certification criteria and tick the corresponding box to attest to the criteria
* As required, comment in ‘free text’ areas of certification.
* The certification will only apply to the donor material listed at the start of the certification, ensure you select the correct donor material type (donor gametes and/or embryos produced from donor gametes)
* A signature is required to certify the statements made are correct. To sign the document, insert a copy of your signature as an image or print and sign.

# How to submit a certification

The prescribed form to make a certification to bring donor material into Victoria is the ‘**Schedule 7-** **Certification to bring donor gametes or embryos produced from donor gametes into Victoria**.

The form is available from the [Assisted reproductive treatment regulation website](https://www.health.vic.gov.au/assisted-reproduction/assisted-reproductive-treatment-regulation) <https://www.health.vic.gov.au/assisted-reproduction/assisted-reproductive-treatment-regulation>

The form must be completed in full, attesting to all certification criteria (inclusive of any exemption, where relevant).

Email completed certifications to <artregulation@health.vic.gov.au> with the subject heading ‘Att: Schedule 7 certification’.

### How do I know my certification has been received?

Once the certification has been submitted, the donor material may be brought into Victoria. Approval from the Secretary (or delegate) is not required. The Secretary (or delegate) will acknowledge all certifications, confirming whether they are complete or incomplete. This acknowledgement does not assess the compliance of the certification. It is recommended a person making a certification waits for the Secretary (or delegate), to confirm, via return email that the certification is complete before bringing the donor material into Victoria.

# Record Keeping for certification

Under section 37B of the Act, a person making a certification must keep a written record of the matters certified.

Specifically, for 25 years after the date on which the certification is made, records of the following must be kept (and failure to do so is an offence):

For certifications made under section 36(3) of the Act (moving donor materials into Victoria)

* a copy of the certification
* a copy of the donor/s consent as prescribed, or if an exemption has been granted in relation to this provision evidence that any conditions to which the exemption is subject have been complied with
* evidence that the donor received counselling as prescribed, or if an exemption has been granted in relation to this provision evidence that any conditions to which the exemption is subject have been complied with
* the name and contact details of the person transferring the donor material including the country in which the person transferring the donor material is located
* the information to be provided by the donor, or if an exemption has been granted in relation to this provision, evidence that any conditions to which the exemption is subject have been complied with
* details of the donor material including:
	+ the number of straws, vials or containers of donor sperm
	+ the number of donor oocytes
	+ the number of embryos produced from donor gametes
* details of the intended transport or movement of the donor material into Victoria at the time of certification, including the date and method of transportation or movement.

For certifications made under section 36(4) of the Act (moving donor materials out of Victoria)

* a copy of the certification;
* a copy of the donor's consent under section 16 of the Act or evidence that the donor has provided the relevant consent;
* the name and contact details of the person receiving the donor gametes or embryo produced from donor gametes including the country in which the person receiving the donor gametes or embryo produced from the donor gametes is located;
* details of the donor gametes or embryo produced from donor gametes including: the number of straws, vials or containers of donor sperm; the number of donor oocytes; and the number of embryos produced from donor gametes;
* details of the intended transport or movement of the donor gametes or embryo produced from donor gametes from Victoria at the time of certification, including the date and method of transportation or movement.

#### Note: The certifying person may be asked to provide evidence that demonstrates their record keeping for the above.

# Offence to make false or misleading certification

Pursuant to section 37A of the Act, it is an offence for a person (body corporate or natural) to certify a matter specified in section 36(3) that the person believes to be false or misleading.

In addition under section 38 of the Act a person must not knowingly or recklessly give false or misleading information or omit to give material information in an application, consent or request under this Act; or with respect to the giving of information that is required—

* to be given under this Act; or
* to be included in a register, record or notice under this Act.

#### Note: When signing the certification and answering the question of the certification document, the certifying person is making a legal declaration that the information they have provided is true and correct.

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1. Sperm and/or oocyte [↑](#footnote-ref-2)
2. Reference to donor material in this document includes donor eggs, donor sperm, and embryos produced from donor eggs and/or sperm. [↑](#footnote-ref-3)
3. Certification criteria is s 36(3) of the Act for movement of donor material into Victoria and s 36(4) for movement of donor material out of Victoria [↑](#footnote-ref-4)
4. This is not an exhaustive list of reasonable expenses [↑](#footnote-ref-5)
5. The prescribed form for consent is Schedule 2AA of the Assisted Reproductive Treatment Regulations 2019. [↑](#footnote-ref-6)
6. Treatment has the same meaning as treatment procedure in the Act, meaning artificial insemination, other than self-insemination or assisted reproductive treatment. [↑](#footnote-ref-7)
7. Section 20 of the Act sets out the processes for withdrawal of consent, including subsection 1A which sets out when consent can be withdrawn in relation to use of donor gametes. [↑](#footnote-ref-8)
8. Exemption refers to the matters set out in 32(2)(c) and 32(3) of the Act [↑](#footnote-ref-9)
9. Exemption refers to the matters set out in 17(2) of the Act [↑](#footnote-ref-10)
10. Exemption refers to the matters set out in 20(3) of the Act [↑](#footnote-ref-11)
11. Regulation 9A sets out the prescribed matters donors must receive counselling about. [↑](#footnote-ref-12)
12. Refer to Counselling [↑](#footnote-ref-13)
13. Exemption refers to the matters set out in 19(a) of the Act [↑](#footnote-ref-14)
14. Exemption refers to the matters set out in 19(b) of the Act [↑](#footnote-ref-15)
15. See information to be provided by donor/s or regulation 9B of the Assisted Reproductive Treatment Regulations 2019. [↑](#footnote-ref-16)
16. See s 37E of the Act and 9H of the Assisted Reproductive Treatment Regulations 2019. [↑](#footnote-ref-17)