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

Under 36(4) of the *Assisted Reproductive Treatment Act 2008 (Vic)* (the Act), before a person takes donated gametes[[1]](#footnote-2) and/or embryos produced from donated gametes (donor material)[[2]](#footnote-3) out of Victoria, they must certify to the Secretary of the Department of Health (the Secretary) 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 take out of Victoria your own eggs, sperm or embryo made without any donor material.

# Who can make a certification?

Any person responsible for moving donated materials (either a body politic corporate or a natural person) should make a certification before taking donor material out of Victoria. For example, an individual or a registered ART provider may make a certification.

# Certification Criteria – movement of donor material out of Victoria

### The purpose for and way in which the donor material will be used

#### What must be certified?

The person making the certification must certify that the purpose for which donor material will be used and that the way in which the donated material will be used outside Victoria is consistent with a purpose for which it could be used in Victoria and the way in which it could be used in Victoria. This includes consistency with:

* the Act, including the guiding principles[[4]](#footnote-5) and
* the Assisted Reproductive Treatment Regulations 2019 (Vic) (the regulations) and
* any other prescribed or relevant guidelines which apply to the use of donated material in Victoria

#### Note: The certifying person may be requested to provide evidence that the donor material is being used for one of the permitted purposes within Victoria:

* assisted reproductive treatment and artificial insemination procedures (other than self-insemination), and
* promoting research into the incidence, causes and prevention of infertility, and
* to make provision with respect to surrogacy arrangements.

### Consent

**Note**: The certifyingperson may be requested to provide evidence that the donor material is being used consistently with a purpose and way it could be used in Victoria. Evidence should demonstrate compliance with the Act, including but not limited to:

* s.10 Persons who may undergo treatment procedures
* s.11 Requirements as to consent
* s.13 Counselling
* s.16 Donation of gametes or an embryo
* s.20 Withdrawal of consent
* s.20A Consent to treatment procedure taken to be withdrawn on separation
* s.21 Lapsing of consent
* s.25 Information and advice
* s.26 Procedures involving gametes produced by children
* s.27 Ban on certain procedures
* s.28 Ban on sex selection
* s.29 Ban on using donated gametes to produce more than 10 families
* s.30 Ban on destructive research on embryos created for treatment purposes
* s.31 Storing gametes
	+ This section is particularly important as different states and countries have different permitted storage timeframes. The movement of gametes from Victoria is not to be used to extend the storage time beyond that allowed in Victoria.
* s.31B Time for removal of gametes from storage
* s.32 Prohibition on storing embryos except in particular circumstances
* s.33 Storing embryos for later transfer
* s.34 Removal of embryos from storage
* s. 34A Time for removal of embryos from storage

#### What must be certified?

The person making the certification has provided the person receiving the donated material with a copy of the donor’s consent under section 16 of the Act or evidence that the donor has provided the relevant consent

**Note**: The certifyingperson may be requested to provide evidence of the above. For best practice, we suggest the person has acknowledgment from the receiving party that the information has been received.

### Identification

#### What must be certified?

The person making the certification has sighted the donors:

* passport
* driver licence
* any other identification document displaying the donor’s photograph and signature, or
* a certified copy of these identification methods

**Note**: The certifyingperson may be requested to provide evidence that they have sighted the above documents.

### Providing donor information to the person receiving the donor materials

#### What must be certified?

The person making the certification has provided the receiving party with the following information:

* the donor's unique donor identifier (if any)
* the donor’s full name
* the 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 donor’s phone number
* the date on which the donor produced the gametes
* 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 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

**Note**: The certifyingperson may be requested to provide evidence that they have provided the receiving party with the above information. For best practice the person making the certification should request an acknowledgment from the receiving party confirming the information has been received.

### Limits in relation to donated material

#### What must be certified?

The person making the certification has taken all reasonable steps to ensure that, at the time of certification, the limit imposed by section 29 of the Act in relation to the use of donated material has not been reached.

This section relates to a worldwide limit on carrying out a treatment procedure using gametes, or an embryo formed from gametes, produced by a donor in Victoria where the treatment procedure may result in more than 10 women having children who are genetic siblings.

#### 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.

### Contact information

#### What must be certified?

The person making the certification has:

* received the name and contact details of the receiving party
* provided written notice to the donor of the name and contact details of the receiving party

**Note**: The certifyingperson may be requested to provide evidence of the above. For best practice, the person making the certification should request an acknowledgment from the receiving party confirming the information has been received.

### If the person making the certification is a registered ART provider (only)

#### What must be certified?

In addition to the other matters which must be certified a registered ART provider must certify the following:

* If the donated material was not produced at the premises of the registered ART provider, the person making the certification has provided the receiving part with the date on which the donated material was received
* The date on which the person has sighted the donor’s passport, driver licence or any other identification document displaying the donor’s photograph and signature or a certified copy of these documents
* The number of children born as a result of a treatment procedure carried out by the person using the donor’s gametes or an embryo produced from the donor’s gametes

### If the person making the certification is a Doctor carrying out artificial insemination (only)

#### What must be certified?

If the person making the certification is a Doctor carrying out artificial insemination using the donated gametes the person has provided the receiving party with the following information about the donor:

* The date on which the donor gametes were received by the person
* The date on which the donor received counselling under section 18 of the Act and the name of the counsellor who provided the counselling
* The number of children born as a result of artificial insemination carried out by the person using the donor’s gametes

### Details

#### What must be certified?

### In the details section of the Schedule 8 certification, the person making the certification, must at the time of making the certification specify details about the \*donor gametes/\*embryo produced from donor gametes to be taken from Victoria are accurate.

# 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, please 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 take donor material from Victoria is the ‘**Schedule 8-** **Certification to take donor gametes or embryos produced from donor gametes out of Victoria.**

The form is available from the Assisted reproductive treatment regulation website [<https://www.health.vic.gov.au/assisted-reproduction/assisted-reproductive-treatment-regulation>.](%3Chttps%3A/www.health.vic.gov.au/assisted-reproduction/assisted-reproductive-treatment-regulation%3E.%20)

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 8 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 taking the donor material from 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 that specified in section36(4) 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. the welfare and interests of persons born or to be born as a result of treatment procedures are paramount; at no time should the use of treatment procedures be for the purpose of exploiting, in trade or otherwise: the reproductive capabilities of individuals; or children born as a result of treatment procedures; children born as the result of the use of donated gametes have a right to information about their donors; the health and wellbeing of persons undergoing treatment procedures must be protected at all times; persons seeking to undergo treatment procedures must not be discriminated against on the basis of their sexual orientation, marital or relationship status, gender identity, sex characteristics, race or religion. [↑](#footnote-ref-5)