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

Under 36(3) and 36(4) 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 or takes donor material out of 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 or 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 bringing donor material into or takes donor material out of 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 donated 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.

### 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)

At the time of certification, the donor/s consent must not have 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.

### Counselling

#### What must be certified?

The person must certify that each donor has received counselling 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
* information about how a person born as a result of a donor treatment procedure may lodge a contact preference
* information about how the donor may obtain identifying information about a person born as a result of a donor treatment procedure, if the person consents
* any issue or concern relating to the donation that is raised by the donor (for example, possible consequences of for the donor’s partner or children)
* the limit imposed by section 29 of the Act in relation to the use of the donor's gametes or embryo produced from the donor's gametes
* the operation of the Act in relation to:
* the withdrawal or lapsing of the donor's consent
* consent for extending the storage of an embryo
* consent for removing an embryo from storage
* the possible consequences for the donor if a person born as a result of a donor treatment procedure carried out using the donor's gametes or an embryo produced from the donor's gametes 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).

#### Exemption

If an exemption has been granted in relation to counselling[[11]](#footnote-12), that the exemption and any associated conditions have been complied with.

### Information to be provided by donor/s

#### 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 donor's phone number
* 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 dcr@health.vic.gov.au

### 10-woman worldwide limit

#### What must be certified?

That all reasonable steps have been 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).

The 2024 reforms have not made any amendments to section 29 of the Act.

In Victoria, there is a 10-woman worldwide limit on the number of women who can have children using donor material from one donor. The limit includes the donor and all of the donor’s current or former partners.

### 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)

### 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.

### 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.

#### 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.

# Certification Criteria – movement of donor material out of Victoria

### The purpose for 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 outside Victoria is consistent with a purpose for which it could be used in Victoria and that the way in which the donated material will be used outside Victoria is consistent with the way in which it could be used in Victoria.

This means the person making the certification to move donated material out of Victoria will need to make enquiries about the nature of use of the donated material prior to movement to be satisfied that the person receiving the donated material will use it for a purpose and in a way which is consistent with:

* the Act
* the Assisted Reproductive Treatment Regulations 2019 (Vic) (the regulations)
* Any other prescribed or relevant guidelines which apply to the use of donated material in Victoria

### Consent

#### 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

### 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

### 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

### 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.

### 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

### If the person making the certification is an ART provider

#### 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

#### 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

# 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 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 prescribed form to make a certification to take donor material into Victoria is the ‘**Schedule 8-** **Certification to take donor gametes or embryos produced from donor gametes out of Victoria.**

Both forms are 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 7/8 certification’.

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

The Health Regulator will acknowledge all certifications via return email. Once the certification has been submitted, the donor material can be brought into Victoria. Approval from the Health Regulator is not required.

# 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.

# 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 the person believes to be false or misleading.

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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. Exemption refers to the matters set out in 18 of the Act. [↑](#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)