

Schedule 7-Certification to bring donor gametes or embryos produced from donor gametes into Victoria

Regulation 9E(a) Assisted Reproductive Treatment Regulations 2019

Purpose

This is the certification form to bring donated gametes and/or embryos produced from donated gametes into Victoria.

A certification in this form must be provided to the Secretary to the Department of Health (the Secretary) attesting that the specified certification criteria have been met **before** a person (either an individual or a registered ART provider) brings donated gametes and/or embryos produced from donated gametes into Victoria.

Instructions

- 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)
- Additional information to assist a person to make a certification to bring donor gametes and/or embryos produced from donor gametes into Victoria is available in the [Guideline – Movement of donated gametes and embryos formed from donated gametes into Victoria](https://www.health.vic.gov.au/assisted-reproduction/assisted-reproductive-treatment-regulation) <<https://www.health.vic.gov.au/assisted-reproduction/assisted-reproductive-treatment-regulation>>
- To submit a certification to the Secretary, see Submission

Name of person making certification	
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Certification

For the purposes of section 36(3) of the *Assisted Reproductive Treatment Act 2008* (the Act),

I

of

propose to bring

into Victoria and certify that:

	Certification Criteria	
1	Any payment made, any valuable consideration that is given or agreed to be given in connection with the donation or any agreement entered into for payment to be made or valuable consideration to be given in connection with the donation does not contravene: - the Human Tissue Act 1982 or - the Prohibition of Human Cloning for Reproduction Act 2008 or - the Prohibition of Human Cloning for Reproduction Act 2002 of the Commonwealth	<input style="width: 40px; height: 25px;" type="checkbox"/>
2	The donor of the gametes, or each person who donated the gametes used to produce the embryo, has consented in writing to: - the donor's gametes being brought into Victoria; and - the use of the donor's gametes or the embryo produced from the donor's gametes in accordance with section 36(5) of the Act; and - the storage of the embryo produced from the donor's gametes for the purpose of later transfer, or <i>If an exemption has been granted in relation to section 32(2)(c) or (3) of the Act, any conditions to which the exemption is subject have been complied with</i>	<input style="width: 40px; height: 25px;" type="checkbox"/>
<i>If relevant, specify and conditions imposed by the Secretary on which the exemption is subject to in this box</i>		
3	I have been given a copy of: - the donor's consent; or - the consent of each person who donated the gametes used to produce the embryo	<input style="width: 40px; height: 25px;" type="checkbox"/>
4	The donor or each person who donated the gametes used to produce the embryo has received counselling in relation to prescribed matters from a counsellor who meets the prescribed requirements for counselling or <i>If an exemption has been granted in relation to section 18 of the Act, any conditions to which the exemption is subject have been complied with</i>	<input style="width: 40px; height: 25px;" type="checkbox"/>
<i>If relevant, specify and conditions imposed by the Secretary on which the exemption is subject to in this box</i>		
5	The donor or each person who donated the gametes used to produce the embryo has given information about the matters prescribed for the purposes of section 36(3) of the Act, or <i>If an exemption has been granted in relation to section 19(a) of the Act, any conditions to which the exemption is subject have been complied with</i>	<input style="width: 40px; height: 25px;" type="checkbox"/>
<i>If relevant, specify and conditions imposed by the Secretary on which the exemption is subject to in this box</i>		

Certification Criteria		
6	The donor or each person who donated the gametes used to produce the embryo has been given written advice on the matters set out in section 19(b)(i) to (iv) of the Act, or <i>If an exemption has been granted in relation to section 19(b) of the Act, any conditions to which the exemption is subject have been complied with</i>	☐
<i>If relevant, specify and conditions imposed by the Secretary on which the exemption is subject to in this box</i>		
7	I have taken all reasonable steps to ensure that any future use of the donor gametes or embryo produced from donor gametes in Victoria will comply with section 29 of the Act	☐
8	I have satisfied the following matters:	
	I have obtained a written undertaking from the person transferring the donor materials/(the transferring party) or the donor that the transferring party or the donor will notify me as soon as practicable of: - any change to or withdrawal of the donor's consent; and - any change to the donor's information provided under section 36(3)(e) of the Act	☐
	I 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	☐
	I have received: - the donor's email address (if any); and - the donor's postal address	☐
	I have received information from the donor 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) or an individual for the purposes of self-insemination.	☐
9	An exemption has been granted in relation to bringing donor material into Victoria from a prohibited location, as published in the Government Gazette. The exemption and any conditions the exemption is subject to have been complied with. <i>NB: If an exemption is not required mark 'NA'</i>	☐ NA ☐
<i>If relevant, specify and conditions imposed by the Secretary on which the exemption is subject to in this box</i>		
If the person making the certification is a registered ART provider or a doctor carrying out artificial insemination using donor gametes other than on behalf of a registered ART provider		
10	I will use the unique donor identifier from the transferring party so far as is reasonably practicable	☐
11	I have obtained a written undertaking from the transferring party that the transferring party will take all reasonable steps to give the donor written notice as soon as practicable of my name and contact details as a registered ART provider or doctor carrying out artificial insemination or I have given written notice to the donor of my name and contact details as a registered ART provider or doctor carrying out artificial insemination.	☐

Details

At the time of making this certification, the following details about the **donor material/s** to be brought into Victoria are accurate:

Specify the following details:			
Contact details of person making the certification:			
The unique donor identifier(s)			
Details about the donor material/s	Number of vials, straws or containers of donor sperm	Number of donor oocytes	Number of embryos produced from donor gametes
Details of the proposed transport or movement of the donor material/s	The name and contact details of the transferring party including the country in which the transferring party is located		
	The name and contact details of the person receiving the donor material/s		
	The date or proposed date of movement of the donor material/s into Victoria		
	The method of transportation		

Declaration

I acknowledge that providing information that I know or believe to be false or misleading is an offence.	
Person making certification	
Signed <i>(either print out and sign or add image of signature)</i>	
Name	
Date	
Witness details	
Witness signed <i>(either print out and sign or add image of signature)</i>	
Witness name	
Witness date	

Supporting information

Supporting information is sought to monitor compliance with the Act and must be true and correct.

Purpose of the import		Provide details here
Assisted reproductive treatment and/or artificial insemination procedures (other than self-insemination)	☐	
Surrogacy arrangement approved by the Patient Review Panel	☐	
Approved scientific purposes into the incidence, causes and prevention of infertility	☐	
Other purpose	☐	
Other		Provide details here
How many women 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?		
What geographic location (country and state or territory and town) do the donor material/s originate from?		
I have read and understood the Guidance document-Movement of donated gametes and embryos formed from donated gametes into Victoria (yes/no/unsure)		

Submission

- 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'.
- The Secretary (or delegate) will acknowledge all certifications via email. Once the certification has been submitted, the donor material/s can be brought into Victoria. Approval from the Secretary (or delegate) is not required.

Notes

Section 36(3) of the Act provides the matters that a person must certify before a person brings donor gametes or an embryo produced from donor gametes into Victoria.

Regulation 7A of the Assisted Reproductive Treatment Regulations 2019 prescribes the requirement for a counsellor for the purposes of section 36(3)(d) of the Act

Regulation 9A of the Assisted Reproductive Treatment Regulations 2019 prescribes the matters about which a donor or each person who donated the gametes used to produce the embryo has received counselling for the purposes of section 36(3)(d) of the Act.

Regulation 9B of the Assisted Reproductive Treatment Regulations 2019 prescribes the matters about which a donor or each person who donated the gametes used to produce the embryo has given information for the purposes of section 36(3)(e) of the Act.

Regulation 9C of the Assisted Reproductive Treatment Regulations 2019 prescribes the additional matters that a person making a certification must satisfy for the purposes of section 36(3)(h) of the Act.

To receive this document in another format, phone 1300 650 172 using the National Relay Service 13 36 77 if required, or [email the Health Regulator](mailto:artregulation@health.vic.gov.au) <artregulation@health.vic.gov.au>.

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Available at [Assisted Reproductive Treatment](https://www.health.vic.gov.au/assisted-reproduction/assisted-reproductive-treatment-regulation) <<https://www.health.vic.gov.au/assisted-reproduction/assisted-reproductive-treatment-regulation>>