VARTA
Victorian Assisted Reproductive Treatment Authority

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Guide for registered ART providers seeking to import donor material from an overseas provider on behalf of a class of individuals

This guide is for clinics in Victoria seeking to import donor sperm or eggs (donor material) from an overseas sperm or egg provider on behalf of a class of individuals.

Overview

Applying to import donor material from an overseas provider on behalf of a class of individuals is a two-step process:

1. Your clinic must submit a complete proposal that sets out the details of its proposed arrangement with the overseas provider (the proposal) for the Board's consideration and in principle approval.
   a. Please ensure that your clinic's **service level agreement** (or similar contract) with the overseas provider is included as an annexure to the proposal.
   b. Given the complexity of these arrangements, we strongly encourage your clinic to get legal advice to ensure that the proposal complies with all Commonwealth and Victorian law.
2. If the proposal receives in principle approval, your clinic must submit an arrangement-specific class application form each time that it wishes to import donor material under the arrangement. We will provide this application form to your clinic after it receives in principle approval under Step 1.

Step 1: Applying for in principle approval

1. Prepare a comprehensive written proposal setting out your clinic's proposed arrangement with the overseas provider. The proposal must attach:
   a. your clinic's service level agreement.
   b. information about how the proposal satisfies all relevant legal requirements under Victorian law (see **Attachment A**).
   c. if any documents are in a language other than English – a certified English translation.
2. Submit the proposal and supporting documents to importandexport@varta.org.au. If necessary, we may request further information about the proposal and/or supporting documents included in the submission.
3. The proposal and supporting documents will be presented to the Board for decision and:
   a. the Board will consider whether all relevant legal requirements are satisfied.
   b. if necessary, the Board may request further information or clarification.
4. We will notify your clinic of the Board's decision. If your clinic's proposal receives the Board's in principle approval, the approval may be subject to specific conditions.

What do we consider in a proposal?

We consider the following requirements set out in the *Assisted Reproductive Treatment Act 2008* (the Act):

Guiding principles of the Act

- The welfare and interests of people born as a result of fertility treatment are paramount.
- Fertility treatment should not be used to exploit the:
  - reproductive capabilities of men or women
  - children born as a result of fertility treatment
- Donor-conceived people have the right to access information about their genetic heritage.
- The health and wellbeing of people undergoing fertility treatment must be protected at all times.
- People seeking to undergo fertility treatment must not be discriminated against.

Consent, counselling, and information provision

We also consider whether the donor:

- was counselled by a counsellor who provides services for a registered Victorian clinic on the prescribed matters under the Act.
- consented to the use of their donor material in Victoria.
- has been given written notice of the clinic where their donor material will be sent.

- provided identifying/non-identifying information to be recorded in the Central Register.
- was given written information and advice about the Central Register, Voluntary Register, and the rights of individuals to apply to those registers.

The proposal must detail how the donor consent, counselling, and information provision requirements under Victorian law will be met **before** the import of donor material under the proposed arrangement.

As such, the service level agreement should outline:

- the donor recruitment and screening process.
- how donor consent will be obtained – which may include providing a copy of all relevant consent or withdrawal of consent forms.
- by whom and how a donor will be counselled on the prescribed matters under Victorian law.
- how any identifying and non-identifying donor information will be collected (and steps to be taken to keep such information up-to-date).

The registered ART provider in Victoria is responsible for ensuring that the proposed arrangement complies with these requirements and cannot outsource its obligations under the Act to the overseas provider or any other third-party.

For this reason, the service level agreement must also set out all governance mechanisms that your clinic (as distinct from or separate to the overseas provider) will implement to ensure the requirements are met.

Anonymous donors

Anonymous donation is not permitted in Australia. We **cannot** approve a proposal if a donor's identifying and non-identifying information is not available to record in the Central Register as required by law.

Therefore, the service level agreement should also address:

1. how the donor's identifying and non-identifying information will be collected.
2. how donor information will be kept up-to-date – which may include the proposed on-going steps that your clinic intends to undertake with the overseas provider to maintain donor information (e.g. periodically making contact with the donor to confirm key details and update records).
3. the notification mechanism between your clinic and the overseas provider about any necessary updates to donor information.

Worldwide limit for use of donor material

In Victoria, there is a 10-woman worldwide limit on the number of women who can have children using donor material from one donor.[1] The limit includes the donor and all of the donor's current or former partners.

As such, the service level agreement should further specify how worldwide family limits will be managed and monitored – including:

1. whether your clinic will have exclusive use of the donor material provided by a donor subject to the proposed arrangement.
2. how family limits will be monitored by your clinic and the overseas provider to ensure compliance with family limits in Victoria.
3. how the overseas provider will notify your clinic about any potential or suspected breaches to the family limits under Victorian law.

Fees payable to the overseas provider

In Victoria, it is prohibited to give or receive 'valuable consideration' for the supply of donor material.

Considering the above, the service level agreement should also set out:

1. the nature of all fees (including any service or supply fees) that may be payable to the overseas provider by your clinic under the proposal.
2. the costs associated with the donation process with the overseas provider.
3. whether any amounts paid to the overseas provider will be on-paid to the donor.

[1] Amendments to the 10-woman donor limit under the Act commenced on 21 December 2021 and enable both women in a same-sex relationship to carry children using the same donor, or existing families to have a genetic sibling through a surrogacy arrangement. The change applies to new donations under donor consents given after 21 December 2021. The change does not apply retrospectively to donations made under donor consents provided before 21 December 2021. However, donors may reconsent to the use of their donations for expanded family arrangements after 21 December 2021.

Paying and reimbursing donors

A donor can only be paid/reimbursed for 'reasonable expenses', which are expenses that the donor incurs directly in connection with their donation and can be verified with receipts or other supporting documents – such as (but not limited to):

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

Accordingly, the service level agreement should detail:

1. the overseas provider's donor reimbursement policy (if this includes a fixed amount component, your clinic must provide an itemised record for all expenses to be paid/reimbursed to the donor).
2. the nature and type of expenses that will be paid/reimbursed to the donor.
3. how donor payment/reimbursements paid to the donor are calculated or substantiated.

Final checklist before submitting the proposal

Our review of your clinic's proposed arrangement may be delayed if the proposal is incomplete or missing any supporting documents.

To minimise delays in processing, we encourage your clinic to prepare a written proposal and:

- ☐ review **Attachment A** (see pg. 4-6) and detail how each requirement will be satisfied. Ensure that all supporting documents have been annexed, clearly labelled, and accurately referenced.
- ☐ attach the service level agreement between your clinic and the overseas provider.
- ☐ provide a copy of the proposed fee structure of the arrangement – including a full break-down of how the fee has been calculated.
- ☐ provide a certified copy of the overseas provider's current accreditation or license. If the documents are in a language other than English, provide a certified English translation.
- ☐ provide a copy of all donor counselling forms.
- ☐ provide a copy of all donor consent forms.
- ☐ provide a copy of all forms to be used to collect the donor's identifying and non-identifying information.
- ☐ provide a copy of all donor expense payment and reimbursement forms – including a breakdown of what expenses will be paid/reimbursed to the donor for their donation.
- ☐ provide a copy of all policies and/or procedures relevant to the proposal (as detailed above).
- ☐ consider providing confirmation that your clinic received legal advice regarding the proposal. You may attach a copy of the legal advice (optional).
- ☐ attach any other relevant documents that support your clinic's submission.

A proposal that is front-loaded with the above allows us to process the application more quickly.

Step 2: Applications under an approved arrangement

If the proposal receives in principle approval, we will provide an arrangement-specific class application form for your clinic to submit each time that it wishes to import donor material under the arrangement.

1. Your clinic submits the details of the intended class of recipients or donors (depending on the nature of the arrangement).
2. The Board considers the application and decides.
3. We will notify your clinic of the Board's decision.

Privacy

The information provided in the proposal will only be used for the purpose of processing the proposal, and statistical, education, or reporting purposes in a de-identified form.

We will not share such information unless you have consented for us to do so, or we are required by law to disclose that information.

For more information

For more information, please visit our website or email us at importandexport@varta.org.au

Attachment A – Requirements for Class Import Arrangements

Your clinic is required to use this attachment to:

- set out the details of your proposed arrangement with the overseas provider (the proposal).
- include information about how the proposal will satisfy the legislative requirements – including the Act and:
  - the *Assisted Reproductive Treatment Regulations 2019* (the Regulations)
  - the *Prohibition of Human Cloning for Reproduction Act 2008* (the PHCR Act)
  - the *Human Tissue Act 1982*
  - the *NHMRC Ethical Guidelines on the use of ART in Clinical Practice and Research 2017* (NHMRC Guidelines)
- refer to relevant supporting documents provided as part of your submission to substantiate the above.

Please ensure that the proposal and all supporting documents are clearly labelled and appropriately referenced. Any incomplete references or unclear labels may delay the review process.

	Requirements	Legislative reference	Evidence of compliance under the proposed arrangement (please summarise and refer to source document e.g. relevant clause of the service level agreement)
Guiding Principles			
1.	The proposal is consistent with the guiding principles of the Act: • The welfare and interests of people born as a result of fertility treatment are paramount. • Fertility treatment should not be used to exploit the: – reproductive capabilities of men or women – children born as a result of fertility treatment • Donor-conceived people have the right to access information about their genetic heritage. • The health and wellbeing of people undergoing fertility treatment must be protected at all times. • People seeking to undergo fertility treatment must not be discriminated against.	Section 5 of the Act	
Donor Consent			
2.	The donor consents to use of gametes in the treatment procedure (as defined in section 3 of the Act).	Section 16 of the Act	
3.	Donor consent must: • be in the prescribed form.	Section 17(1) of the Act	

	• specify the number of women (up to 9) that may be treated with the donor material. • specify the kind of treatment procedures the donor material may be used in. • be able to be withdrawn in accordance with the Act.	Regulation 8 of the Regulations	
4.	Donor consent must be given to the designated officer of the registered ART provider (as defined in section 3 of the Act).	Section 17(2) of the Act	
5.	If the donor withdraws consent, the registered ART provider must ensure: • the withdrawal is in writing. • that the overseas provider communicates the donor's withdrawal of consent as soon as practicable.	Section 20 of the Act	
6.	Please provide a copy of all relevant donor consent documents proposed to be used by your clinic to ensure legislative compliance.		
Donor Counselling			
7.	**<u>Before</u>** the donor can consent under section 16 of the Act, the donor must receive counselling**:** • on the prescribed matters under the Act and regulations. • from a counsellor who provides counselling services for a registered ART provider.	Section 18 of the Act Regulation 9 of the Regulations	
8.	Please provide: • details of the donor counselling arrangements to be undertaken by your clinic and the overseas provider. • a copy of documents to be used in counselling, including your clinic's donor counselling checklist and/or report template. • information about the nature of the proposed counsellor's relationship with your clinic (i.e. is the counsellor an employee of your clinic or an independent		

	contractor who is contracted by your clinic to provide counselling services for your clinic?).		
Donor Information Provisions			
9.	At the time of consent, the donor must: • give and receive the prescribed information to be recorded in the Central Register. • be given written advice about their rights/obligations under the Act.	Section 19(a) of the Act	
10.	The registered ART provider must give the donor written advice about: • the rights of the donor conceived person and their parent/s (and any other related person) to the disclosure of their information. • the nature of information recorded in the Central Register. • the donor's rights to obtain information under the Act. • the Voluntary Register.	Section 19(b) of the Act	
11.	Please provide: • details about how your clinic intends to maintain donor details and ensure that the donor details remain up-to-date. • a copy of all forms, written advice, and/or other documents that your clinic and the overseas provider intends to give to the donor.		
Family Limits			
12.	Treatment must not be carried out if it will result in more than 10-women worldwide who have children who are genetic siblings (unless an exemption applies). The limit includes the donor and the donor's current and/or former partners. Provide details about how family limits will be maintained **by your clinic** under this proposal and whether an exclusive arrangement will apply to the use of donor material from a donor.	Section 29 of the Act	

Payments/Reimbursements			
13.	'Valuable consideration' cannot be paid for the supply of donor material. Provide a detailed breakdown of all proposed service and/or supply fees (or other similar fees) that may be payable to the overseas provider in the proposal.	Section 17 of the PHCR Act	
14.	A donor can only be paid and/or reimbursed for 'reasonable expenses', which are expenses that the donor incurs directly in connection with their donation and can be verified with receipts or other documentation. Provide details about: • the proposed donor payment/ reimbursement policy (e.g. will the donor be paid a fixed amount or based on actual expenses incurred? If fixed amount – how was this amount calculated? Will the donor be required to submit invoices to be paid/reimbursed?) • all proposed expenses to be paid/reimbursed to the donor in the proposal.	Section 5 of the Act Section 17 of the PHCR Act Guideline 5.4 of the NHMRC Guidelines	
Other			
15.	Evidence of the overseas provider's current accreditation or license.	VARTA requirement	