VARTA
Victorian Assisted Reproductive Treatment Authority

For more information visit the
Victorian Assisted Reproductive Treatment Authority
www.varta.org.au or **phone 03 8601 5250**

Guidelines for class applications to import donor gametes from an overseas sperm or egg bank

ART

When is VARTA's approval required?

The *Assisted Reproductive Treatment Act 2008* (Vic) (the Act) states that donor sperm, donor eggs or embryos produced using donor sperm and/or eggs (embryos) must not be taken into or out of Victoria without the written approval of the Victorian Assisted Reproductive Treatment Authority (VARTA). This means that ART providers in Victoria that wish to move donor sperm or eggs into or out of Victoria on behalf of a class of intended recipients must apply to VARTA for approval under section 36 of the Act.

Who are these guidelines intended for?

These guidelines relate to class applications by Victorian ART providers. Individuals seeking to import or export donor sperm, eggs or embryos should refer to our **Guidelines for individuals seeking to import or export donor sperm, donor eggs and embryos produced using donor sperm and/or eggs** for further information.

How to apply

Class import applications from overseas providers

The process for seeking approval for a class application to import donor sperm or eggs on behalf of intended recipients in Victoria involves a two-step process. An ART provider must first seek in-principle approval for a proposed arrangement with an overseas provider. Once the arrangement is approved, the ART provider needs to submit an application each time they wish to import donor sperm or eggs on behalf of a class of applicants under the approved arrangement. VARTA will make all efforts to process applications as quickly as possible.

In-principle approval of a class arrangement

1. An ART provider seeking to import donor sperm or eggs from an overseas provider under a class arrangement prepares a proposal setting out key details of the intended arrangement. The proposal should clearly address how the arrangement will meet the requirements of the Act, including the matters set out in the table at **Attachment A**. It may be appropriate for ART providers to obtain legal advice to confirm compliance.
2. The ART provider is encouraged to contact VARTA as soon as possible to discuss the proposed import arrangement and resolve any questions about the information which should be provided.
3. The ART provider submits a proposal and supporting documentation, including the intended service level agreement or similar, to VARTA at **regulation@varta.org.au**.
4. VARTA receives the proposal and may ask for additional supporting information if necessary.
5. VARTA's Board considers the proposal and the ART provider is notified of the Board's decision.

Request to import donor gametes under a class arrangement

1. Following confirmation of in-principle approval of a proposal to import donor sperm or eggs into Victoria, VARTA will provide the ART provider with a tailored application form to submit with a clinic declaration for each class application.
2. The ART provider submits details of the intended recipient/s and number of straws of sperm or eggs to be imported using the application form provided by VARTA by email to **regulation@varta.org.au**.
3. VARTA's Board considers the application and the ART provider is notified of the Board's decision, including any conditions imposed in respect of the application.

Requirements considered by VARTA

VARTA has regard to all the relevant facts and circumstances of a class application in exercising its discretion to grant approval to bring donor sperm or eggs into or out of Victoria under the Act, and may impose conditions on the approval of class applications.

Guiding principles of the Act

Section 5 of the Act sets out that the following guiding principles should be given effect by VARTA in carrying out its functions:

- 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 men and women or children born as a result of treatment procedures;
- children born as a result of the use of donated gametes have a right to information about their genetic parents;
- the health and wellbeing of persons undergoing treatment procedures must be protected at all times; and
- persons seeking to undergo treatment procedures must not be discriminated against.

In considering an application, VARTA needs to be satisfied that the approval of an in-principle arrangement will be consistent with these guiding principles. In particular, an application should provide sufficient information to demonstrate that the proposed arrangement does not involve financial transactions that could amount to exploiting in trade or otherwise the reproductive capabilities of a donor. The application should also demonstrate that there are appropriate processes in place to ensure that any child born as a result of the use of donated gametes sourced under the arrangement has access to information about their genetic parent/s.

Consent, counselling and information requirements

VARTA will consider whether, in accordance with the Act, the donor has:

- provided consent to the gametes being used in treatment by the registered ART provider (sections 16 and 17 of the Act);
- provided consent to the gametes being imported to Victoria and has been provided with information on how they can withdraw their consent should they choose to do so (section 20 of the Act);
- been given written notice of the registered ART provider where the gametes are to be sent (section 24 of the Act);
- received counselling on prescribed matters before consent, from a counsellor who provides services for a registered ART provider (section 18 of the Act)[1];
- provided identifying and non-identifying information for registration on the Victorian Central Register (section 19(a) of the Act); and
- been given written information and advice about the Central and Voluntary Registers and rights of individuals to apply to those registers (section 19(b) of the Act).

An application for in-principle approval of a class arrangement should provide information which addresses how each of these legislative requirements will be satisfied, including how consent, counselling and required information will be provided to donors. It should also include information about how the ART provider's proposed arrangement will work in practice, including donor recruitment and screening processes, consent processes, medical management, counselling, records maintenance, family limit monitoring and reporting. Copies of key forms to be used by overseas banks are useful to include in the proposal submitted to VARTA. Under the Act, registered ART providers are responsible for ensuring compliance with legislative requirements for donors, and these functions cannot be outsourced to third parties. As such, an application should demonstrate the governance arrangements which will be put in place by a registered ART provider, as distinct from the overseas bank, to ensure that all requirements relating to donors under the Act are satisfied.

The use of donations from anonymous donors is not permitted in Victoria. To ensure that a donor conceived person can obtain identifying and non-identifying information about their donor, appropriate processes need to be in place for overseas donors to ensure that donor information recorded on the Central Register is correct. In considering an import arrangement, VARTA will require information concerning proposed ongoing steps to be taken by the ART provider and overseas bank to maintain up-to-date donor information, including by way of periodically making contact with donors to confirm key details and update records.

[1] ART providers should clearly set out in the proposal and service level agreement (or equivalent) details of the counselling arrangements for overseas donors, including the relationship between the counsellor(s) undertaking the prescribed counselling and the registered ART provider, to demonstrate how they fall within the definition of a 'counsellor who provides services for a registered ART provider', as required under section 18 of the Act. Counselling undertaken by a counsellor who is not employed or contracted by a registered ART provider would not satisfy the legislative requirement for counselling (for example, where a third party overseas provider engages counsellor(s) to undertake counselling of donors).

Number of families created

Consistent with section 29 of the Act, ART providers in Victoria must not carry out treatment procedures using donor sperm, eggs or embryos if it is known that the treatment procedure may result in more than ten women having children who are genetic siblings, including the donor and any current or former partner of the donor. In the context of an import application, VARTA considers the number of women worldwide who have been treated using the sperm or eggs of a single donor. An application for in-principle approval of a class importation arrangement should set out the measures to be taken under the proposed arrangement to ensure compliance with this legislative requirement, including any exclusivity provision which would be put in place with the overseas bank to guarantee exclusive use of a donor's gametes by the Victorian ART provider.

Fees payable under an agreement with an overseas sperm or egg bank

The broad principle against the commercial exploitation of individuals' reproductive capacities set out in section 5 of the Act is also reflected in:

- s 39 of the *Human Tissue Act 1982* (Vic), which prohibits the unauthorised buying or selling of human tissue, unless it concerns the giving of reasonable expenses of a kind referred to in s 17 of the *Prohibition of Human Cloning for Reproduction Act 2008* (Vic) (PHRC Act); and
- s 17 of the PHRC Act, which prohibits any person from intentionally giving or receiving valuable consideration for the supply of eggs, sperm or embryos, and sets out the types of payments considered to be appropriate in relation to donations.

The *NHMRC Ethical Guidelines on the use of ART in Clinical Practice and Research 2017* (NHMRC Guidelines) relevantly provide that treatment in Australia using gametes donated by persons living in another country must not take place unless it can be established that the gametes were obtained in a manner consistent with any Commonwealth legislation and any relevant state or territory legislation, accreditation body guidelines and the Guidelines (at Guideline 5.5).

Section 5 of the Act states that it is the Parliament's intention that, in carrying out its functions under the Act VARTA give effect to the guiding principles. The fact that an arrangement may involve the exploitation of the reproductive capabilities of men and women is therefore a matter to which VARTA gives significant weight in exercising its discretion under section 36 of the Act. Accordingly, in considering approval of an in-principle class import arrangement, VARTA requires an application to set out information concerning the proposed financial arrangement between the Victorian ART provider and overseas bank. Information about the breakdown of fees payable for the supply of gametes, and any additional service fees which may be charged by an overseas bank, is particularly relevant to VARTA's consideration of the financial aspects of a proposed arrangement. ART providers may wish to obtain legal advice to ensure a proposed arrangement complies with these legislative requirements.

Reimbursing donors

In Australia, a sperm, egg or embryo donor cannot be given valuable consideration for their donation. Valuable consideration includes any payment or discount that could induce the donor to make a donation. Under section 17 of the PHCR Act, is a criminal offence to intentionally give or receive valuable consideration for supplying sperm, eggs or embryos. While commercial incentive or reward for donation is prohibited in Australia, reasonable expenses related to the supply of sperm, eggs or embryos are allowed. An expense is reasonable only if the expense is actually incurred by the donor directly in connection with the donation process and can be verified by receipts or other documentation. The NHMRC Guidelines provide that reasonable expenses may include medical and counselling expenses, travel and accommodation expenses; or loss of earnings, insurance, relevant childcare costs and legal advice (Guideline 5.4).

In considering an application, VARTA will require information about the payments made to donors by an overseas bank, in order to be satisfied that the donor has only been reimbursed for reasonable expenses incurred in connection with the supply of his or her donation. An application should set out information about donor reimbursement and whether proposed arrangements are consistent with the NHMRC Guidelines, as well as any legislative or regulatory requirements applicable in the jurisdiction where the overseas bank operates (if applicable).[2] Relevant information which should be provided as part of an application includes details about the types of reimbursable expenses that can be claimed by the donor; whether the ART provider will be provided with an individual itemised record of reimbursement; whether the donor is reimbursed a fixed or specific amount; details of the costs associated with sperm/egg donation process and donor reimbursement forms (if available).

[2] For example, VARTA can have regard to guidelines issued by overseas regulators such as the UK Human Fertilisation and Embryology Authority (HFEA) on donor reimbursement in determining whether a particular donor reimbursement arrangement is appropriate.

Final checklist

To ensure an application for in-principle approval of an arrangement can be considered as quickly as possible by VARTA, please check that the following documents are submitted as part of the proposal:

□ Victorian ART provider proposal outlining key features of the arrangement (Word or PDF format)
□ Copy of the overseas bank and ART provider service level agreement or similar
□ Completed copy of *Attachment A: Compliance with Victorian legislative requirements and evidence* setting out evidence of compliance with relevant attachments if appropriate
□ Copy of the overseas bank's current accreditation or licence
□ Copies of any other supporting documentation relevant to the application
□ Legal advice confirming that the proposed arrangement complies with Victorian legislative requirements (optional).

Attachment A: Compliance with Victorian legislative requirements

ART

	Requirements for import	Requirement	Evidence of compliance
1.	Proposed arrangement is consistent with the guiding principles of the ART Act: • 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 men and women or children born as a result of treatment procedures; • children born as a result of the use of donated gametes have a right to information about their genetic parents; • the health and wellbeing of persons undergoing treatment procedures must be protected at all times; and • persons seeking to undergo treatment procedures must not be discriminated against.	s5 of ART Act	ART provider to set out details of how each requirement will be satisfied under the proposed arrangement or refer to relevant documentation supplied in support of the application.
2.	Donor must have **consented** to use of gametes in treatment procedure	s16 of ART Act	
3.	Donor **consent must:** a) be in the prescribed form; and b) specify the number of women on whom treatment procedures using he donor oocyte, sperm or embryo may be carried out; and c) specify the kinds of treatment procedures for which the oocyte, sperm or embryo may be used; and d) not have been withdrawn or have lapsed when the treatment procedure takes place	s17(1) of the ART Act	
4.	Donor **consent** to use in treatment procedure must be given to a registered ART provider or a designated officer of the registered ART provider	s17(2) of ART Act	
5.	Donor must receive **counselling** on prescribed matters before consent, from a counsellor who provides services for a registered ART provider	s18 of ART Act	

6.	Donor must **give the prescribed information** for the Central Register (incl. identifying information) at the time of consent[3]	s19(a) of ART Act	
7.	Donor must **be given written advice** by the registered ART provider about: a) the rights of persons to disclosure of information b) the nature of information in the Central Register c) the donor's rights to obtain information d) the Voluntary Register[4]	s19(b) of ART Act	
8.	Overseas bank must ensure that any withdrawal of a consent is communicated to the registered ART provider	s20 of ART Act	
9.	A person must not carry out treatment procedures using donor sperm, eggs or embryos if it is known that the treatment procedure may result in more than ten women having children who are genetic siblings worldwide, including the donor and any current or former partner of the donor	s29 of ART Act	
10.	Proposed measures to ensure compliance with legislative requirements, including processes for maintaining up-to-date donor information	Part VI of ART Act	
11.	Proposed supply fee and other amounts payable to overseas bank under the arrangement	s17 of PHCR Act	
12.	Proposed reimbursement of donors under the arrangement	s17 of PHCR Act Guideline 5.4 NHMRC Ethical Guidelines	
13.	Evidence of the overseas bank's current accreditation or licence	VARTA requirement	

[3] Under Regulation 18 of the *Assisted Reproductive Treatment Regulations 2019* (Vic), the information listed in Schedule 6 is prescribed.
[4] For further information, see **VARTA Donor Conception Registers Services and Time to Tell Brochure.**