



Reproductive Technology Council

# Guidelines for importing donor gametes and embryos into Western Australia

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## 1.0 Background

In Western Australia (WA), regulation of the practice of in vitro fertilisation (IVF) and other assisted reproductive technology treatments (ART) is provided by the [Human Reproductive Technology Act 1991](#) (HRT Act), the [Human Reproductive Technology Regulations 1993](#) (HRT Regulations) and the HRT Act Directions 2021 (“Directions”). Compliance with provisions of the HRT Act, HRT Regulations and the Directions is mandatory for any person involved in IVF or ART in WA.

In addition, two national bodies, the Reproductive Technology Accreditation Committee of the Fertility Society of Australia (RTAC) and the National Health and Medical Research Council (NHMRC), have set out guidelines that underpin the provision of ART services in Australia: the [RTAC Code of Practice](#) (RTAC Code) and the [NHMRC Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research](#) (NHMRC Guidelines).

Under the HRT Act, it is a condition of holding a licence to provide ART services that the licensee must be accredited and, in order to gain and retain accreditation, the licensee must comply with the RTAC Code and the NHMRC Guidelines.<sup>1</sup> While the HRT Act and subsidiary legislation effectively incorporates the RTAC Code and the NHMRC Guidelines into regulation, the provisions of the HRT Act will always prevail over the terms of the RTAC Code and NHMRC Guidelines.

In this document, unless expressly stated to the contrary, references to legislative sections and directions are references to the HRT Act and the Directions made under the HRT Act.

## 2.0 Purpose

The intention of these Guidelines is to reflect, without wholly replicating, relevant legislative and regulatory requirements for importing donor gametes and donor embryos into WA. Nothing in this Guide is intended to be, or should be construed as being, inconsistent with the HRT Act, RTAC Code or NHMRC Guidelines. To the extent of any inconsistency, the terms and requirements of the legislation will always prevail.

## 3.0 Guidelines

It is the responsibility of the licensee to ensure compliance with all regulatory requirements before accepting imported donor gametes and embryos into WA and, in particular, sections 22-26 of the HRT Act (relating to consent, eligibility for treatment, storage of gametes/embryos and rights of control of gametes/embryos) and Parts 3, 4, 6 and 7 of the Directions (relating to consent, information, transfer and storage, and eligibility and assessment).

### 3.1 Specific Requirements

Direction 6.1 provides that a licensee may only accept gametes, embryos or eggs undergoing fertilisation from outside the state if:

- a) the gametes are to be used in an artificial fertilisation procedure;
- b) the embryo (or egg undergoing fertilisation) is to be used in an artificial fertilisation procedure;
- c) the material is to be used in a research project that has been approved by the

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<sup>1</sup> Compliance with these two instruments is required under the RTAC Code of Practice, and RTAC is currently the only accreditation body approved under the HRT Act.

Council; or

d) the embryo is an excess ART embryo that is to be used under an NHMRC licence.

In addition, the licensee must ensure:

- compliance with section 53Q of the HRT Act (and corresponding Commonwealth legislation), which prohibits commercial trade in human gametes and embryos.
- the donor has been provided with the information required under the Act, prior to the donor giving consent (see Directions 4.1; 4.2 and 4.3). The counselling provided to the donor must be of an equivalent standard to counselling provided to donors in WA.
- compliance with the consent provisions set out in section 22 of the HRT Act and Part 3 of the Directions.
- all information that would be required under the HRT Act for the Reproductive Technology (RT) Registers had the donated gametes or embryos been collected in WA, is available for submission to the RT Registers. The information required is set out in the [Reproductive Technology Registers Data Submission Specifications](#) as published by the Department of Health on its website. If all the required information is not available, an application to import the gametes/embryos may be made to the Reproductive Technology Council (Council) under Direction 6.3 (see paragraph 3.2 below).
- compliance with the limit of five recipient families (including families outside WA) for each donor. If the five-family limit would be exceeded, an application to import the gametes/embryos may be made to Council under Direction 8.2 (see paragraph 3.2 below).

If all requirements have been met, the licensee may accept the gametes or embryos. It is the responsibility of the licence supervisor to demonstrate due diligence that the import meets all legal requirements. To support this, the [RTAC Technical Bulletin 3](#) indicates that the proposed use of imported sperm should be supported by written independent legal opinion which specifically assess any issues associated with the origin of the donor sperm, with reference to Western Australian and Australian Federal requirements. Consideration should primarily be given to the country of origin of the gametes.

### 3.2 Applications to Council

Applications to Council to import donor gametes and embryos into WA (import applications) must be submitted by the licensee only when:

- there is a request to waive the five-family-limit (Direction 8.2)<sup>2</sup>; and/or
- there is a request to waive the requirement to have available the necessary information for the Reproductive Technology register (Direction 6.3)<sup>3</sup>.

In all other cases, the clinic may receive the imported material if they are satisfied it meets the import requirements outlined above.

If an import application is required, the licensee must submit documentary evidence that all other requirements for importing donor gametes and embryos have been met. Under the HRT Act and the Directions, applications that do not meet all the other requirements

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<sup>2</sup> Direction 8.2: Council may approve the use of donated gametes or embryos in an artificial fertilisation procedure that may result in more than five recipient families in exceptional circumstances.

<sup>3</sup> Direction 6.3: Council may, on compassionate grounds, approve the import of donated gametes or embryos where the information required for the RT Registers is not available.

for importation cannot be considered by Council.

### 3.3 Supporting documents

Required supporting documents for import applications under Direction 6.3 and/or 8.2 include:

- all fees incurred by the applicant in relation to obtaining the donated gametes or embryos, verified by receipts or other documentation (s53Q HRT Act).
- all payments made to the donor, verified by receipts or other documentation (s53Q HRT Act).
- the written information provided to the donor which is comparable to WA information requirements.
- a letter or certificate from the donor's counsellor to confirm counselling has been provided.
- confirmation that counselling to the donor was provided by a health professional who meets the criteria for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA).
- The written and signed consent of the donor/s and the donor's partner (if applicable) to donate.
- the consent to import gametes into WA signed by the donor/s and partner (if applicable).
- evidence regarding the current number of recipient families for the donor (including families outside WA) and the potential maximum number of recipient families worldwide.
- evidence that the licensee has obtained independent legal advice as per [RTAC Technical Bulletin 3](#) or an explanation of why it was not sought.

## 4.0 Compliance Monitoring and Evaluation

These guidelines are intended to assist licensees to ensure that the requirements of the HRT Act and Directions for approval of gamete and embryo import applications are met.

Donor and recipient records must be available for review by officers authorised under the HRT Act upon request. Evidence of due diligence relating to compliance with the Act and Directions must be present in these records.

## 5.0 Related Documents

- [Human Reproductive Technology Act 1991](#)
- [Directions](#) to the Human Reproductive Technology Act 1991
- Reproductive Technology Accreditation Committee (2011). [RTAC Technical Bulletin 3](#)
- National Health and Medical Research Council (2016). [Payment to gamete donors by Australia ART clinics](#) (NHMRC correspondence to clinics, 25 July)
- National Health and Medical Research Council (2017). [Ethical guidelines on the use of assisted reproductive technology in clinical practice and research](#). Canberra: National Health and Medical Research Council
- [Australian and New Zealand Infertility Counsellors Association Membership Criteria](#)

- [Application form to import donor gametes or donor embryos into WA.](#)

## Review

These guidelines are to be reviewed within three years of release.

<b>Version</b>	<b>Effective from</b>	<b>Effective to</b>	<b>Amendment(s)</b>
V 1.2	April 2022	Current	Clarify when applications must be made to Council
V 1.1	June 2021	April 2022	Alignment with HRT Directions 2021 and Surrogacy Regulations 2021
V 1.0	October 2018	June 2021	Original version

## Approval

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