

Explanatory Guide

Assisted Reproductive Treatment Regulations – Explanatory Guide

TERMS EXPLAINED

2010 ART Regulations means the *Assisted Reproductive Treatment Regulations 2010*.

ART means assisted reproductive treatment, which is any medical procedure directed at fertilisation of a human ovum by artificial means, including an in vitro fertilisation (IVF) procedure.

ART Amendment Act means the *Assisted Reproductive Treatment (Posthumous Use of Material and Donor Conception Register) Amendment Act 2024*.

ART Act means the *Assisted Reproductive Treatment Act 1988*.

ART Provider means a person (including a company) registered under Part 2 of the ART Act to provide ART.

DCR means the Donor Conception Register established under section 15 of the ART Act.

Minister means the Minister for Health and Wellbeing.

NHMRC Guidelines means the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2017) published by the National Health and Medical Research Council established under the *National Health and Medical Research Council Act 1992* of the Commonwealth.

RTAC means the Reproductive Technology Accreditation Committee of the Fertility Society of Australia and New Zealand.

WHY ARE THE REGULATIONS BEING MADE?

This Explanatory Guide provides details about drafted changes to the regulations which support the ART Act. The regulations explain how persons and companies registered under the ART Act are to provide ART in South Australia.

The 2010 ART Regulations are due to expire on 1 September 2024, with this expiry to be postponed to a final expiry date of 1 September 2025, to allow for public consultation and revisions.

The draft Assisted Reproductive Treatment Regulations will be a revision of the 2010 ART Regulations and include legal details needed to support changes to the ART Act made by the ART Amendment Act that expand the operation of South Australia's existing DCR to ensure that all people accessing information on the DCR can do so safely.



WHAT IS PROPOSED?

The 2010 ART Regulations will be updated to:

- > support regulation of the ART industry; and
- > include new regulatory details and requirements that support the expanded operation of the DCR (i.e. provide public access to the DCR).

Regulation of assisted reproductive treatment – updating existing regulatory details

ART services in South Australia are regulated under the ART Act, which is administered by the Minister. The Department for Health and Wellbeing (DHW) broadly oversees the authorisation of ART by registered ART Providers according to the ART Act and the supporting 2010 ART Regulations. ART Providers must be approved for registration and included on the South Australian ART register. There are currently four fertility specialist groups registered as ART Providers in South Australia.

ART Providers must comply with the NHMRC Guidelines, which set out clinical practice guidelines for ART, including clinical and ethical practices, as well as record keeping and data reporting requirements. ART Providers must also be licensed by RTAC and comply with the RTAC Code of Practice, which sets out practices for the structure and administration of an ART unit, patient management, patient treatment and ART outcomes.

There are no significant changes from the current 2010 ART Regulations proposed in the making of the new Assisted Reproductive Treatment Regulations.

South Australian Donor Conception Register – new regulatory details expanding the DCR

Since late 2021, the Minister has maintained a DCR to record information about births resulting from the use of donated human reproductive material. Currently, ART Providers upload details to the DCR; however under the ART Act, members of the public do not have rights to access DCR information.

The ART Amendment Act was passed by the South Australian Parliament in March 2024 and its amendments will become law once proclaimed by the Governor of South Australia. The Amendment Act will amend the ART Act to give the public (verified DCR users) access to the DCR for obtaining and sharing information about themselves (and others, where permitted). This includes sharing information about people who donated sperm, eggs or embryos before September 2004, who were previously assured anonymity of their donation via the ART Act.

DHW will operate the DCR as an online portal. Registered users can log in to view and update their own information and access information about other people they are connected to in the DCR. For example, a donor-conceived person connected to their parent's donor/s.

The Assisted Reproductive Treatment Regulations will prescribe information and details to support the operation of the DCR, such as rights of access and types of information to be included on the DCR.

DRAFT ASSISTED REPRODUCTIVE TREATMENT REGULATIONS

Part 1 – Preliminary (Regulations 1 to 3)

Regulation 1 identifies the name of the Regulations.

Regulation 2 identifies that the new Regulations would commence at the same time as the amendments for the expanded operation of the DCR commence. This is expected to be in early 2025 once the publicly accessible online DCR portal is ready to open and arrangements are in place to support the health and wellbeing of DCR users.

Regulation 3 defines terms used in the Regulations. The definition of **NHMRC Guidelines** has been updated to refer to its most recent publication and the definition of **RTAC** has been amended to refer to the Fertility Society of Australia and New Zealand.

Part 2 – Registration (Regulations 4 to 8)

Regulation 4 clarifies that nothing in the ART Act compels an ART Provider to provide ART to a particular person. This regulation is the same as is in the 2010 ART Regulations.

Regulation 5 states that a person (including companies such as a fertility specialist group) may provide ART only if the person holds a current RTAC licence. A maximum penalty of \$120,000 for a breach of this law applies under section 5(1) of the ART Act. This regulation is the same as is in the 2010 ART Regulations.

Regulation 6 states that a person will only be eligible for registration as an ART Provider if the person holds a current RTAC licence. This regulation is the same as is in the 2010 ART Regulations.

Regulation 7 provides the information that must be included in the Register of ART Providers by each ART Provider. The Regulations would now also require the ART Provider's principal business email address, in addition to the address of the premises at which ART is provided, the expiry date of the ART Provider's RTAC licence and the ART Provider's website. This will ensure members of the public can identify a point of contact for an ART Provider, which is generally already available on an ART Provider's website.

Regulation 8 outlines the circumstances in which ART may be provided as well as the conditions of registration the Minister must impose on an ART Provider. This includes the requirements to comply with the NHMRC Guidelines and to provide information to the Minister upon request. This regulation is the same as is in the 2010 ART Regulations, except for a minor proposed change from "confidential information" to "personal information", that matches terms in the amended ART Act.

Part 3 – Donor Conception Register (Regulations 9 to 18)

Regulation 9 defines the terms used in Part 3 of the Regulations and describes the types of information that is included within each term where it is used in Part 3.

Regulation 10 – Information to be included on the DCR

Section 15(2) of the ART Act outlines the types of information that must be included in the DCR. Identifying information about donors, the recipients of donated human reproductive material and donor-conceived persons is currently required to be included on the DCR.

With the ART Amendment Act creating a publicly accessible DCR to allow for the exchange of personal information between users (DCR connections) in certain circumstances, regulation 10 would set out the further types of information that are required to be included in the DCR, reflecting the types of information users will be able to add and upload to the DCR.

Personal biographical information about donors and adult donor-conceived persons would be included in the DCR. Some of this basic information will be available to the Minister through provision by ART Providers. DCR users may also choose to provide more personal information to the DCR (for example, what a donor-conceived person wishes to upload to their user profile in the DCR). This would include biographical statements, photographs, video recordings, information about personal physical characteristics, self-reported medical information about a person, and information about a person's family.

Importantly, regulation 10(2) clarifies that the Minister may determine that information is unsuitable for inclusion in the DCR. This would allow, for example, the withholding or the non-publication of offensive or abusive materials.

Regulation 11 – Access to the DCR

New section 15(4a) in the ART Act and outlines that a person may have access to information in the DCR in accordance with the regulations.

Regulation 11 sets out who may have access to information and under what circumstances. Where the ART was undertaken in South Australia, the following people may have access to information in the DCR:

- > donors
- > donor-conceived persons (upon reaching 18 years of age)
- > parents or guardians of donor-conceived children (those aged under 18 years old).

Regulations 12 to 15 state who can access what information in the DCR. You can find four DCR Access Matrices for the donor conception community, which explain the details of regulations 12-15 on the YourSAy website.

Regulation 12 is explained in DCR Access Matrix 1 – for donors.

Regulation 13 is explained in DCR Access Matrix 2 – for donor-conceived people.

Regulation 14 is explained in DCR Access Matrix 3 – for parents of a donor-conceived child.

Regulation 15 is explained in DCR Access Matrix 4 – for parents of a donor-conceived adult.

Regulation 16 – Information of a kind for inclusion on the DCR

New section 15(6) of the ART Act allows persons (who are not ART Providers) to submit information to the Minister for inclusion on the DCR.

If information relating to a historical (previously anonymous) ART is identified, regulation 16 would allow this information to be included in the DCR, to help fill in gaps and establish connections.

Information about births resulting from non-regulated ART, or under 'private donor arrangements', could also be included, to help ensure the DCR has as much information as possible about donor-conceived births, to better support the welfare of donor-conceived people.

Regulation 17 – Functions of authorised entities

New section 15A of the ART Act establishes a power for the Minister to authorise an entity to assist with the operation of the DCR. It is intended that an entity will be appointed to provide wellbeing support services.

Regulation 17 also explains the function of an authorised support service provider which is to provide information and support to DCR users.

Regulation 18 – Notice to Minister of certain records

Regulation 18 proposes that a person, other than a registered ART Provider who is in possession of donor conception records, must inform the Minister of the existence of those records and that a failure to do so is an offence punishable by a maximum penalty of \$2,500. This offence would apply whether the ART was provided in accordance with the ART Act (through a registered ART Provider) or not (through private arrangements). The intent of this provision is to help ensure that information from all available donor conception records can be included in the DCR to help establish connections and provide information to DCR users.

Part 4 – Miscellaneous (Regulation 19)

Regulation 19 – Record keeping

Regulation 19 sets out record keeping obligations for any person (including ART providers) who hold records relating to ART.

Regulation 19(1) would require ART Providers to make records and keep documents in accordance with Chapter 9 of the NHMRC Guidelines. ART Providers are already required to comply with the NHMRC Guidelines as a condition of their registration, however, this regulation will clarify that a failure to comply with those record keeping requirements is an offence.

Regulation 19(2) would establish that any person who is not a registered ART Provider who is in possession of donor conception records (for example, a lapsed ART Provider or a former medical professional) must ensure the secure storage and ongoing protection of those records.

Regulation 19(3) would establish that any person who is required to record or keep a document pertaining to ART must retain the record or document indefinitely unless a transfer has been authorised by the Minister in accordance with the new section 16(4) to (6) of the ART Act.

For more information

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