Queensland Health

Guidance for assisted reproductive technology providers on commencement

Assisted Reproductive Technology Act 2024

Queensland Government

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For more information contact
System Policy Branch, Strategy, Policy and Reform Division, Queensland Health, email: ART@health.qld.gov.au

Contents

Acknowledgement of Country

Queensland Health acknowledges the Traditional Owners and Custodians of the lands, waters and seas across Queensland.

We pay our respects to Elders past and present, while recognising the role of current and emerging leaders in shaping a better health system.

Queensland Health acknowledges the First Nations peoples in Queensland are both Aboriginal peoples and Torres Strait Islander peoples, and supports the cultural knowledge, determination and commitment of Aboriginal and Torres Strait Islander communities in caring for their health and wellbeing.

Introduction

On 10 September 2024, the *Assisted Reproductive Technology Act 2024* (ART Act) was passed by Queensland Parliament.

It is important that assisted reproductive technology (ART) providers understand their roles, responsibilities and obligations under the new ART Act.

The ART Act aims to improve confidence in Queensland's ART industry by providing greater oversight, transparency and safeguards. It aims to ensure the welfare and interests of people receiving treatment and people born as a result of ART are central to the delivery of ART services. The legislation positions Queensland Health to regulate ART providers and take action in the event of a breach.

Purpose

To support ART providers to meet their new obligations under the ART Act that commenced soon after the law was passed.

The information in this document should not be relied upon as a substitute for other professional or legal advice.

This guidance is designed to be read alongside, and is not a substitute for, the:

- *Assisted Reproductive Technology Act 2024*
- *Supporting explanatory notes*

Out of scope

Provisions that will commence later, following an implementation period, are not covered in this guidance. The implementation period following passage of the ART Act will provide time for ART providers, Queensland Health and the Registry of Births, Deaths and Marriages to establish the relevant infrastructure, policies and procedures for these provisions. The timeframe for implementation of the remaining provisions will be confirmed at a later time following passage of the Act.

Queensland Health and the Registry of Births, Deaths and Marriages plan to work closely with ART providers during implementation, to support them to implement the necessary changes to their practices, guidelines and processes to reflect the ART Act.

Intended audience

This guidance has been developed for ART providers' executives, managers and staff who are responsible for ensuring systems and processes are in place.

Additional resources

- Information collection and record keeping fact sheet
- Disclosure of health information fact sheet

- Antemortem and posthumous retrieval fact sheet

Key contacts

For more information, contact the Assisted Reproductive Technology Unit:
ART@health.qld.gov.au

Commencement timeframes

Table 1 provides a high-level overview of the commencement timeframes for provisions in the ART Act.

Table 1: Commencement of provisions

Part/Division	From 10 September 2024	Following implementation
Part 1 – Preliminary	✓	X
Part 2 – Regulation		
Div 1 – ART providers to be licensed	X	✓
Div 2 – Information and counselling	X	✓
Div 3 – Consent	X	✓
Div 4 – Use of gametes and embryos clause 22 – Use of gametes from close family members prohibited clause 23 – ART services for children prohibited clause 24 – Sex selection prohibited	✓	X
Div 4 – Use of gametes and embryos clause 25 – Limit on number of donor-related Australian families clause 26 – Use of gametes or embryos after death of gamete provider clause 27 – Time limit on use of donated gametes or embryos and their disposal	X	✓
Div 5 – Retrieval and use of gametes from deceased persons clause 28 – Interpretation for division clause 29 – Retrieval of gametes from deceased or unresponsive persons clause 30 – Persons authorised to request retrieval of gamete clause 32 – Application of Transplantation and Anatomy Act 1979 and related provisions	✓	X
Div 5 – Retrieval and use of gametes from deceased persons clause 31 – Use of retrieved gametes	X	✓
Div 6 – Information collection and record keeping	✓	X
Div 7 – Disclosure of health information	✓	X

Part/Division	From 10 September 2024	Following implementation
Part 3 – Donor conception information register	X	✓
Part 4 – Licensing of ART providers	X	✓
Part 5 – Investigation and enforcement	✓	X
Part 6 – Review of decisions and appeals		
Div 1 – Preliminary Div 2 – Internal review Div 3 – Stays of reviewable decisions Div 4 – External review	X	✓
Div 5 – Appeals against property decisions	✓	X
Part 7 – Legal proceedings	✓	X
Part 8 – Miscellaneous	✓	X
Part 9 – Transitional provisions		
clause 144 – application of Act to existing matters clause 150 – time within which information about pregnancies and births to be collected by ART providers	✓	X
clause 145 – licensing of existing ART providers clause 146 – donated gametes previously allocated to a person for ART procedures clause 147 – donated embryos previously allocated to a person for ART procedures clause 148 – embryos (that are created using donated gametes) not yet used for ART procedures clause 149 – time limit on use of existing donated gametes and embryos clause 151 – Information to be provided for donor conception information register for births using existing gametes or embryos	X	✓
Part 10 – Amendment of legislation		
Div 1 – Amendment of this Act Div 2 – Amendment of *Anti-Discrimination Act 1991*	✓	X

Part/Division	From 10 September 2024	Following implementation
Div 3 – Amendment of *Births, Deaths and Marriages Registration Act 2023*	X	✓
Sch 1 – Dictionary	✓	X

Provisions starting shortly after passage

Preliminary matters

The overarching objective of the ART Act is to protect the welfare and interests of people who are born as a result of ART, throughout their lives. The Act also aims to protect the welfare and interests of people who use ART, regulate the use of ART, and provide and regulate access to information relating to people born as a result of ART. This is captured by the Act's main objects.

To achieve the above objectives, the ART Act regulates ART providers, that is, Reproductive Technology Accreditation Committee (RTAC) accredited ART Units. It does not regulate individual medical practitioners.

The preliminary components of the Act include key definitions to support the operation of the Act:

- ART procedure
- ART service
- ART provider
- gamete and embryo
- donated gamete and embryo.

Penalties for non-compliance are detailed throughout the Act.

Use of gametes and embryos

The following prohibitions have commenced:

- using gametes from close family members;
- providing ART services to children; and
- sex selection.

These prohibitions are generally consistent with the NHMRC Guidelines and providers should already be operating in accordance with these requirements.

Provisions relating to the family limit on donated gametes and embryos, use of gametes or embryos after death and time limits on using donated gametes and embryos will commence later, following an implementation period.

Prohibition on use of gametes from close family members

The ART Act makes it an offence for an ART provider to use a gamete to create an embryo knowing the gamete provider is a close family member of the other person whose gamete is being used to create the embryo.

This is reflective of the position in the NHMRC Guidelines that state that clinics must not create embryos from gametes derived from close genetic relatives.

A close family member is defined to mean a parent, child, sibling (including a half-sibling), grandparent or grandchild of the person from birth.

This provision is not intended to prevent situations like a mother carrying her daughter's child using the daughter's gamete, or a woman's sister donating an egg to her to create an embryo with the woman's partner. It is about an embryo being created where both gamete providers are close family members.

Prohibition on ART services for children

The ART Act prohibits ART providers from carrying out an ART procedure on a child or obtaining a gamete from a child for use in an ART procedure.

Similar to the NHMRC Guidelines, an exception applies where a medical practitioner has certified that there is a reasonable risk that the child will become infertile before they become an adult and the gamete is obtained for the purpose of storing it for the child's future benefit.

Prohibition on sex selection

The ART Act prohibits ART providers from using a particular gamete or embryo, or performing an ART procedure, for the purpose of producing or attempting to produce a child of a particular sex.

The exception to this is if it is necessary for the child to be of a particular sex to reduce the risk of transmission of a genetic abnormality or genetic disease.

This generally aligns with the NHMRC Guidelines, which state that sex selection is prohibited in Australia for non-medical reasons such as 'family balancing'.

Retrieval of gametes from deceased or unresponsive people

Sometimes gametes are retrieved posthumously, which is authorised by the *Transplantation and Anatomy Act 1979* in the same way that retrieving organs for donation is. There is a streamlined process in the ART Act that is specific to the posthumous retrieval of gametes, along with retrieval of gametes from people who are unresponsive before their death. Table 2 outlines the requirements for retrieval.

Table 2: Requirements for retrieval of gametes from a deceased or unresponsive person

Retrieval of gametes from a deceased or unresponsive person	
Retrieval	Retrieval may only be performed by or under the supervision of a medical practitioner, for use in an ART procedure by the person's spouse. **Additional step for unresponsive people** In order to retrieve gametes from an unresponsive person, the person's respiration or blood circulation must be being maintained in a hospital by artificial means, and a designated officer of a hospital, who is also a medical practitioner, must certify in writing that the person would die if these means were withdrawn.
Consent	The retrieval can only occur if appropriate consent is in place. The person must have either: • consented to retrieval of their gametes for use in an ART procedure for their spouse; **or** • had not expressly objected to the posthumous use of their gametes and been likely to have supported the posthumous use of their gametes by their spouse. If the death is required to be reported to a coroner, or a coroner is investigating the death, the coroner must also consent to the retrieval or advise their consent is not required, for the retrieval to occur.
Request	The request to retrieve gametes can only be made by: • the spouse of the person; or • in exceptional circumstances, a family member of the person or spouse who is acting on behalf of the spouse. Exceptional circumstances where it would be appropriate for a family member to make such a request are that an urgent decision must be made for the gamete to be successfully used in the future and the spouse: • is incapacitated and can't reasonably make an informed decision; or • can't be contacted despite reasonable attempts to do so.
Record keeping	In line with the existing requirement under the *Transplantation and Anatomy Act 1979*, a designated officer for a hospital, who is also a medical practitioner, must record the following in the person's hospital record as soon as practicable after the retrieval: • the retrieval of the gamete; • the name of the person who requested the retrieval; and • if the person who requested the retrieval was not the spouse, the exceptional circumstances that applied.
Donation	Gametes retrieved posthumously cannot be treated as donated gametes.

Subsequent use of gametes from deceased or unresponsive people

Provisions relating to the use of gametes from a deceased person will not commence until later. This will allow time to develop a regulation for the ART Act, which is proposed to include more information about this process, particularly regarding the qualifications of an independent review body that will need to authorise use of the gametes. Note that this will not be a single body, but rather any body that meets the requirements in the legislation.

In the interim, ART providers should continue with current practices for determining use of gametes from deceased people under the NHMRC Guidelines, including ensuring sufficient time has passed so that:

- grief and related emotions do not interfere with decision-making;
- the prospective parent has undergone counselling; and
- an independent body has reviewed the circumstances and supports the proposed use.

Information collection and record keeping

ART providers are a crucial source of information about gametes and embryos used in ART procedures (including donated gametes and embryos), patients who have used ART services, and treatment outcomes. It is important that information about ART patients and procedures is collected and retained in line with good record keeping practices. Good record keeping and data reporting are an integral part of ART best practice.

It is particularly important for information about donor conception procedures to be collected and retained, because it has significant implications for the person born as a result.

Information to be collected

The ART Act requires ART providers to collect information about:

- gamete providers, including donors, before obtaining gametes for ART procedures or storage; and
- people who undergo ART procedures.

Information that ART providers must collect is outlined in Table 3.

In relation to information about gamete providers:

- the information must be collected regardless of whether a gamete is obtained directly from an individual, or indirectly, for example through a sperm bank, clinic or another ART provider, in Australia or overseas; and
- ART providers must not use a gamete or embryo unless the relevant information has been collected.

ART providers must collect all the information outlined in Table 3, this should be reflected in internal policies, processes and forms to enable compliance. Additionally, providers should request any information that they do not have for gametes or embryos already in storage from and before using them in an ART procedure.

An ART provider must not use a gamete or an embryo unless they have collected the information in Table 3.

The information collected about donors and donated gametes is important to support the establishment and operation of the donor conception information register, which will be established later.

Table 3: Information to be collected

Information	All gamete providers^	Donated gametes providers^	All people undergoing ART procedures	People undergoing ART procedures using donated gametes or embryos
Full name	✓	✓	✓	✓
Residential address	✓	✓	✓	✓
Phone number	✓	✓	✓	✓
Email address	✓	✓	✓	✓
Date of birth	✓	✓	✓	✓
Place of birth	✓	✓	✓	✓
Full name and date of birth of any spouse at the time of the procedure	X	X	✓	✓
Ethnicity	X	✓	X	X
Physical characteristics	X	✓	X	X
Relevant medical history *Any medical history or genetic test result of the donor or the donor's family that is relevant to the person undergoing an ART procedure, the donor-conceived person or a descendant of the donor-conceived person.*	X	✓	X	X
Sex and year of birth of each offspring of the donor *Donor-conceived offspring* *Non-donor conceived offspring*[*]	X	✓	X	X
Any other information prescribed by regulation	✓	✓	X	X
If a person became pregnant as a result of the procedure, within four months after the procedure*#	X	X	X	✓

Information	All gamete providers^	Donated gametes providers^	All people undergoing ART procedures	People undergoing ART procedures using donated gametes or embryos
If a child was born as a result of the procedure, within 15 months after the procedure*#	X	X	X	✓
If a child is born was born as a result of the procedure, the child's full name, sex, date of birth and place of birth*#	X	X	X	✓

^ Regardless of whether the ART provider obtained the gametes directly from the gamete provider or indirectly, for example through a sperm bank, clinic or another ART provider, in Australia or overseas.

* An ART provider must take reasonable steps to collect this information. At a minimum this should include attempting to contact the person by more than one method of communication, such as via email and phone and following up with a phone call and email if the first attempt at communication is not successful.

Providers are to take reasonable steps to collect information about procedures that occurred before commencement of the ART Act on 19 September 2024, that resulted in pregnancies and births after commencement:

- **In the case of pregnancy** – the procedure was carried out within four months before commencement of the Act. The information must be collected within six months after the procedure was carried out.
- **In the case of the birth of a child** – the procedure was carried out within 15 months before commencement of the Act. The information must be collected about the birth within 18 months after the procedure is carried out.

Transferring information between ART providers about gametes or embryos

The ART Act requires that when ART providers supply to or receive gametes or embryos from another provider, they must exchange relevant information, including a copy of the consents and other information about the gametes or embryos. This transfer of information must occur regardless of the other provider's location.

ART providers must make sure gamete and embryo transfer procedures include an information exchange process that meets the above requirements.

Information given to one ART provider by another is considered to have been collected in accordance with the collection requirements in the ART Act. This means that the ART provider does not need to reconfirm the information with the gamete provider, if all the required details are already provided.

Information to be retained

ART providers must keep required records for at least 99 years. ART providers must retain all the information outlined in Table 3 **and** all information outlined in Table 4. Additional information requirements may be prescribed later in regulation.

Table 4: Information to be retained

	Information
Gamete or embryo that is or has been in provider's possession	• Name of any other ART provider who previously possessed the gamete or embryo (whether in or outside of Queensland). • Each relevant consent: – Including copies of any consent received by the ART provider or any other ART provider who previously possessed the gamete or embryo. • Uses of a gamete or embryo by the ART provider including supply to another ART provider or person (whether in or outside of Queensland). • Period during which the gamete or embryo has been in storage.
ART procedures carried out by an ART provider	• For procedures using a donated gamete or embryo, the place where a procedure was carried out.
Each child an ART provider knows was born as a result of its ART procedures	• The child's full name, sex, date of birth and place of birth. • The full name, residential address, phone number and email address of the person who gave birth to the child. • If a donated gamete or embryo was used in the ART procedure, the donor's full name and date and place of birth.

Prohibition on destruction of records

The ART Act outlines it is an offence to destroy:

- any records outlined in Tables 3 and 4; and
- historical records created before commencement relating to the birth of a donor-conceived person. These records will be required for the donor conception information register.

ART providers can apply to Queensland Health to seek approval to destroy records. Queensland Health would only approve destruction in limited circumstances where it is reasonably satisfied the destruction would not adversely affect anyone. As part of applying for this approval, an ART provider would be expected to provide evidence demonstrating all actions taken to ensure that destruction would not adversely affect anyone.

Disclosure of health information

ART providers have an important role in ensuring the appropriate disclosure of health information to people involved in donor conception. This includes health information that may become known many years after the original gamete donation or ART procedure occurred, while a person is pregnant, or while gametes or embryos are in storage.

The ART Act gives ART providers clear authority and confidence to disclose health information about a donor-conceived person, or their relative with impacted people.

ART providers are a crucial source of information about gametes and embryos, patients using gametes and embryos, and outcomes of treatments. Providers are therefore best placed to make this disclosure to potentially impacted parties.

The ability to disclose health information to certain people is separate to the donor conception information register.

For disclosure to occur, a medical practitioner must certify that the disclosure of health information is necessary to:

- prevent or reduce a serious risk to a person's life or health; or
- warn a person about the existence of a health condition that may be harmful to the person or their descendants.

Clinical understanding of genetic origins of conditions may evolve over time, which is why a list of conditions that meet this test have not been provided. This should be a clinical decision made by an appropriately qualified medical practitioner on a case-by-case basis.

ART providers may disclose information to any of the impacted people, as outlined in Table 5.

Table 5: Who health information can be disclosed to

Who information can be disclosed to	Information about a donor or about a relative of a donor	Information about a donor conceived person, or a relative of a donor-conceived person
Donor-conceived person and/or any donor-conceived siblings born as a result of an ART procedure using a gamete donated by the donor	✓	✓
Descendant of a donor-conceived person born as a result of an ART procedure using a gamete donated by the donor	✓	N/A
Parent, or other person with parental responsibility for, a donor-conceived person born as a result of an ART procedure using a gamete donated by the donor	✓	✓
A person who is pregnant as a result of an ART procedure using a gamete donated by the donor	✓	✓
A spouse of a person who is pregnant as a result of an ART procedure using a gamete donated by the donor	✓	✓
A person who has a gamete donated by the donor in storage with an ART provider	✓	✓
The donor	N/A	✓
Medical practitioner treating the person to whom the disclosure may be made	✓	✓
Any other person prescribed by regulation	✓	✓

ART providers should determine who could be affected by the health condition based on its clinical records. ART providers may also reach out to other providers who have either supplied or received potentially impacted gametes and embryos previously.

The medical practitioner disclosing the information must take reasonable steps to ensure a donor-conceived person does not become aware they are donor-conceived as a result of the disclosure.

The purpose of this requirement is to ensure that disclosures are managed sensitively on a case-by-case basis to prevent unnecessary trauma being experienced by donor-conceived people as a result of health information disclosures. This does not mean that the important health information should be withheld from the donor-conceived person, but rather that they are appropriately informed and supported regarding their donor-conceived status.

ART providers should consider timeliness throughout the disclosure process to facilitate early screening, interventions and improved health outcomes.

Queensland Health disclosure process

There is a safeguard in the ART Act that allows Queensland Health to disclose the health information if providers don't disclose it. ART providers are expected to make health disclosures in the first instance. Queensland Health will only consider the disclosure of health information in limited instances where an ART provider has not done so and the person seeking the information has exhausted all available avenues with the ART provider.

If Queensland Health needs to become involved in the disclosure of health information, there will be an expectation for ART providers to assist with this, through the provision of requested information.

Investigation and enforcement

The investigation and enforcement powers give Queensland Health robust oversight of ART providers, including the ability to audit providers and investigate suspected non-compliance and adverse events.

Queensland Health can appoint inspectors to investigate and enforce commenced provisions. This includes matters relating to:

- use of gametes from close family members;
- provision of ART services to children;
- sex selection;
- retrieval of gametes from deceased people; and
- information collection and record keeping requirements.

Inspectors

Inspectors are appointed by the Director-General of Queensland Health, or their delegate, to investigate, monitor and enforce compliance with the Act. They are appropriately trained and have experience in regulatory and compliance activities in the health sector.

Inspectors have a range of general powers, including to:

- enter places;
- conduct searches;
- inspect, examine and seize things;
- require production of documents or information; and
- request reasonable help.

In exercising their powers, inspectors will act to ensure quality, safety, respect, integrity and dignity for patients, staff and community is paramount.

Inspectors cannot examine, take for examination, or seize a gamete or an embryo.

Review of decisions and appeals

Most of the review and appeal provisions in the ART Act apply to licensing decisions, which will not become relevant until after the implementation period.

Decisions relating to seizure or forfeiture of property are reviewable. Decisions dealing with property, namely decisions to refuse to return seized property or to forfeit seized property are appealable to the Magistrates Court.

Additional requirements

The ART Act has a range of legal and technical provisions, including:

- **Offence for giving false or misleading information** – It is be an offence for a person to give an official (Queensland Health Director-General, Registrar of Births Deaths and Marriages, a member of either of their staff, a contractor engaged by them) performing a function under the Act information that they know to be false or misleading.
- **Transitional provisions** – The majority of the transitional provisions in the ART Act will commence following an implementation period. They will only be relevant to a small number of people that would be using donated gametes or embryos that would otherwise contravene the Act. Only transitional provisions relating to collection of information about pregnancies and births (see information to be collected) and application of the Act to existing matters have commenced. ART providers cannot be prosecuted for actions that happen prior to the commencement of the Act.
- ***Anti-Discrimination Act 1991*** – The ART Act removes section 45A of the *Anti-Discrimination Act 1991*. This means that ART providers can no longer discriminate on the basis of sexuality or relationship status in the provision of ART. This has been omitted given it is redundant and no longer meets clinical, ethical or community standards.