VARTA
Victorian Assisted Reproductive Treatment Authority

Version 10/2022

Conditions for Registration

Effective: 13 October 2022

For Assisted Reproductive Treatment (ART) Providers under the *Assisted Reproductive Treatment Act 2008.*

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VARTA is an independent statutory authority funded by the Victorian Department of Health

www.varta.org.au

Section 1 – Background

The Victorian Assisted Reproductive Treatment Authority (the Authority) is a statutory authority established by the *Assisted Reproductive Treatment Act 2008* (Vic) (the Act).

Under the Act, the Authority is responsible for several services – including (but not limited to):

- registering ART providers in Victoria
- promoting research and public education
- managing the donor conception registers
- monitoring various programs and activities carried out under the Act

The Authority also advises the Minister for Health on:

- breaches under the Act, the *Assisted Reproductive Treatment Regulations 2019* (the Regulations), or the Conditions for Registration; and
- any developments (in Victoria or elsewhere) that it considers important or concerning about infertility and infertility treatment.

For more information about the Authority's regulatory role and approach, please see our Strategic Plan.

The Act includes several requirements that must be satisfied for a 'treatment procedure' (as defined in Section 3 of the Act) to be carried out in Victoria:

1. **For ART** – the person carrying out ART must be a doctor carrying out the treatment on behalf of a registered ART provider (or someone under the supervision and direction of such a doctor).
2. **For artificial insemination (AI)** – the person carrying out AI must be a doctor or a person acting under the supervision and direction of a doctor who is carrying out AI on behalf of a registered ART provider.

In providing ART or AI, the person providing treatment must further be satisfied that all requirements under Divisions 2, 3, and 4 of the Act have been met.

If an ART provider intends to become a 'registered ART provider' as defined in the Act, it must:

3. hold a Reproductive Technology Accreditation Committee (RTAC) accreditation; and
4. apply to the Authority using the prescribed form – available here: Application for registration of a Victorian ART clinic.

The Authority may impose conditions on an ART provider's registration that it considers necessary in the public interest. Where this occurs, the Authority's conditions would not be inconsistent with conditions imposed on the ART provider's RTAC accreditation.

The Authority may suspend (either in whole or in part) an ART provider's registration by written notice to the registered ART provider if the Authority:

1. believes that the ART provider has breached a Condition for Registration; or
2. is satisfied that there are reasonable grounds for suspension.

The Authority publishes the conditions that it has imposed on each registered ART provider's registration on its website at www.varta.org.au.

Please contact the Authority if clarification is required about the conditions contained in this document.

Section 2 – Conditions for Registration

All registered ART providers must comply with these Conditions for Registration (as amended by the Authority from time to time), along with any additional specific conditions imposed by the Authority on a registered ART provider's registration under the Act. Where the Conditions for Registration refer to a 'treatment procedure', the definition of 'treatment procedure' in section 3 of the Act applies.

2.1 Compliance with the Law

(a) An ART provider must comply with the Act, all regulations issued under the Act, and all other applicable Victorian and Commonwealth laws and regulations.

(b) An ART provider must co-operate with the Authority in good faith to facilitate the performance of and compliance with the Conditions for Registration. Acting in good faith includes, but is not limited to:

i) acting consistently with the expectations set out in the Conditions for Registration, the Act, and other applicable Commonwealth laws and regulations;

ii) not omitting information or documentation that the Authority may consider necessary to demonstrate compliance with the Conditions for Registration, the Act, and any other applicable Commonwealth laws and regulations; and

iii) not knowingly providing false or misleading information upon which the Authority may rely.

(c) An ART provider must have appropriate governance, processes and systems in place to ensure compliance with the Act, these Conditions for Registration, its accreditation, and all other applicable laws, regulations and conditions on approvals granted by the Authority, and the *National Health and Medical Research Council (NHMRC) Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research, 2017*. The ART provider must provide evidence of the same when requested by the Authority.

(d) Designated Officers must attest to Clause 2.1 in the prescribed form by **1 August** annually.

2.2 RTAC Accreditation

(a) An ART provider must be accredited by RTAC in order to be a registered ART provider in Victoria. Evidence of accreditation must be provided with the application for registration, together with a copy of the accreditation report from the RTAC Certification Body.

(b) An ART provider must notify the Authority within **three (3) business days** if its RTAC accreditation ceases or if RTAC imposes conditions on its accreditation.

(c) An ART provider must provide the Authority written notice of any scheduled or upcoming RTAC audits no less than **15 business days** prior to the audit date. The Authority reserves a right to attend the RTAC audit in order to fulfill its function of administering the registration system under the Act.

(d) Within **three (3) business days** of receipt, an ART provider must provide the Authority with a copy of its RTAC accreditation, audit and surveillance reports and conditions, and any corrective action plans and related documentation issued to the ART provider in response to any non-conformity with the RTAC Code of Practice.

(e) An ART provider must notify the Authority within **three (3) business days** of any individual clinicians and/or any entity (which may include any entity that is either wholly or partially independent of the ART provider

and/or a subsidiary of the ART provider) that operates under its RTAC accreditation. This notification must include the following:

i) the clinician/entity's name and address

ii) the period for which the clinician/entity will be operating under the ART provider's RTAC accreditation;

iii) the types of services that are being provided by the clinician/entity;

iv) names of all clinicians providing services at the entity – including information about how they are engaged by the entity and ART provider; and

v) any other information or documentation that the Authority may consider relevant.

(f) An ART provider must notify the Authority within **ten (10) business days** of any individual clinicians and/or entities (which may include any entity that is either wholly or partially independent of the ART provider and/or a subsidiary of the ART provider) that ceases operating under its RTAC accreditation. This notification must include:

i) the clinician/entity's name and address; and

ii) the date that the clinician/entity ceased operating under the ART provider's RTAC accreditation.

(g) Designated Officers must attest to Clause 2.2 in the prescribed form by **1 August** annually.

2.3 Provision of Information to the Authority

An ART provider must provide the Authority with any information and documents that the Authority considers relevant to the carrying out of its functions under the Act, including (without limitation):

2.3.1 Information required under section 81(2) of the Act

(a) the ART provider's name;

(b) the address of each premises at which the ART provider carries out treatment procedures;

(c) the period for which the ART provider holds RTAC accreditation;

(d) details of the ART provider's internet site, if any; and

(e) any changes to that information as they arise.

2.3.2 Information for annual reporting to Minister

(a) An ART provider must provide the information that the Authority requires to report annually to the Minister for Health under section 114 of the Act, including information about treatment programs, participants in treatment procedures conducted, embryos formed, and embryos and gametes stored by **the last Friday in July** or such other date as is notified by the Authority.

(b) Designated Officers must provide an attestation in the prescribed form by **1 August** annually when supplying data and/or other information for the annual report.

2.3.3 Donor conception

(a) An ART provider must provide any documents, records or information the Authority requires to exercise its powers under Part 6 (Registers and access to information) and Part 7 (Voluntary Register and donor-linking) of the Act, including:

i) birth notifications, which must be provided to the Authority on a fortnightly basis in the prescribed form as provided to the ART provider.

(b) If the ART provider becomes aware that one of its clinic-recruited donors has donated their donor material through private donation, the ART provider must:

i) notify the Authority in accordance with Clause 2.6; and

ii) immediately suspend any further use of donor material from that donor due to the high risk of the family limits being exceeded.

(c) If the ART provider becomes aware that a donor was recruited through a donor recruitment agency, the ART provider must, if intending to proceed with the donor arrangement:

i) notify the Authority prior to collection of the donor material; and

ii) provide any relevant documents, records or information to the Authority demonstrating that the use of the donor material in treatment is consistent with Victorian legal requirements, including the Guiding Principles under the Act which prohibit the exploitation of a person's reproductive capabilities.

(d) An ART provider must monitor family limits to ensure compliance with the 10-women limit under Victorian law. The Authority considers the 10-women limit a maximum rather than a starting point for allocations. As such, an ART provider should be conservative in its allocation to ensure that compliance with the family limit can be managed. In doing this, an ART clinic must:

i) automatically set aside one family allocation for the donor, regardless of whether the donor has:

1) an existing family with their current and/or former partner; or

2) advised that they do not intend to have their own family.

ii) ensure that their patients understand in counselling that an allocation by an ART provider of certain donor material is not a guarantee that the patient will be able to use that donor material, even if embryos have been formed, if it were to lead to a breach of the 10-women limit.

(e) If the ART provider becomes aware of an actual or potential contravention of the Act (including, but not limited to, in the above sub-clauses (b) – (d)), the ART provider must:

i) immediately suspend the use of the gametes in treatment or otherwise; and

ii) notify the Authority in accordance with Clause 2.6.

The Authority reserves a right to impose a condition suspending the use of such gametes notwithstanding any approvals previously granted and/or the fact that they may already be in Victoria.

2.3.4 Developments in treatment and research

(a) An ART provider must provide the Authority with a list of all adjuvant therapies offered by that ART provider or doctors who carry out treatment procedures on the ART provider's behalf by 1 August annually. It is also expected that they will provide patients access to this list as recommended in the *RTAC Technical Bulletin 11 Use of Adjuvants in ART (November 2019)*

i) The Authority considers adjuvant therapies to be interventions offered in addition to recognised standard ART or AI which are claimed to improve fertility and/or reproductive outcomes. For example, use of prednisolone should be reported as an adjuvant, but vitamins or acupuncture is not considered by the Authority to be reportable.

(b) An ART provider must notify the Authority of a new treatment procedure, treatment for infertility or research which:

i) is proposed to be used in the course of a program of treatment by the ART provider or by a doctor carrying out treatment procedures on the ART provider's behalf; and

ii) could have a significant impact on the practice of ART or AI and/or is not in routine clinical use.

(c) With reference to 2.3.4(b), the notification must:

i) be made at least **25 business days** prior to the commencement of the new treatment, development or research to enable the Authority to report to the Minister in accordance with section 100(2)(c) of the Act and perform its monitoring and public education functions under section 100(1)(b) and (d) of the Act; and

ii) for a new treatment procedure, include the following:

1) the proposed and/or actual commencement date of the new treatment procedure

2) any information fact sheets or other written material to be provided to prospective patients regarding the new treatment procedure

3) proposed consent forms

4) the cost arrangement for the new treatment procedure, including eligibility for any Medicare rebates

5) the screening process to determine patient suitability/eligibility for the new treatment procedure

6) the frequency, number of treatment cycles, and care arrangements that will be recommended and/or available to eligible patients

7) how the effectiveness and safety of the new treatment procedure will be tracked, recorded, and reported to the Authority

8) information about how the treatment procedure will be performed and where (e.g. if the procedure requires general anaesthetic, is an in-patient procedure, etc)

9) proposed information to be published by the clinic regarding the new treatment procedure accessible to the public on its website or elsewhere

10) any other information or documentation that the Authority may request

(d) By **1 August** of each year, an ART provider must report to the Authority of other developments which, in its opinion, will significantly impact the practice of ART or AI and/or are not in routine clinical use.

2.3.5 Audits

(a) Where the Authority considers that an ART provider's processes, policies, procedures and/or systems may pose a serious risk to patient welfare and/or result in a contravention of the Act, Regulations or these conditions, an ART provider must at the Authority's request engage an external auditor at its own expense to conduct an audit of such processes, policies, procedures and/or systems.

(b) Prior to the audit, an ART provider must consult with the Authority regarding its choice of auditor. The Authority must approve the auditor prior to the audit being carried out.

(c) An ART provider must provide the audit report and any supporting documents to the Authority within **three (3) business days** of the report being completed.

2.4 Advertising and other published information

(a) Published claims, comparisons and advertising by an ART provider must comply with section 133 the *Health Practitioner Regulation National Law (Victoria) Act 2009* (Vic) and have due regard to the Australian Health Practitioner Regulation Agency (AHPRA) *Guidelines for Advertising Regulated Health Services* and any other guidelines on social media.

(b) All advertising, claims and other information published or provided to the public, patients, practitioners or any other third parties must be verifiable and not likely to be misleading or deceptive, either directly, or by implication, by use of emphasis, comparison, contrast or omission in whole or in part or in any other manner.

(c) An ART provider must, on request, provide the Authority with evidence verifying published claims, comparisons or information. If the Authority considers that any published claims, comparisons or information may not have been adequately verified, or may be likely to be misleading or deceptive, the Authority may refer the matter to another Australian regulatory authority such as AHPRA and/or the Australian Competition and Consumer Commission.

(d) Designated Officers must attest to Clause 2.4 in the prescribed form by **1 August** annually.

2.4.1 Social media

(a) When using social media, an ART provider should monitor and remind itself and/or any doctor who carries out treatment procedures on behalf of the ART provider that the *Health Practitioner Regulation National Law*, as in force in each state and territory, their National Board's *Code of Ethics and Professional Conduct*, and the *Guidelines for Advertising Regulated Health Services* apply.

(b) An ART provider should ensure that it and/or any doctor who carries out treatment procedures on behalf of the ART provider only post information that:

i) complies with all relevant legal, ethical, and professional obligations

ii) is presented in an unbiased, evidenced-based context

iii) is not an unsubstantiated claim

iv) is supported by acceptable evidence – as defined by the Australian Health Practitioner Regulation Agency.

2.5 Provision of treatment and information to patients

An ART provider must have regard to the accessibility of the information and quality of treatment that it provides to its patients, donors, surrogates, and their partners (if any).

2.5.1 Provision of treatment

(a) An ART provider must provide safe, person-centred services and foster continuous improvement in the safety and quality of the treatment procedures that they provide.

(b) In providing treatment, an ART provider must ensure that the health and well-being, including emotional and mental health, of the individual undergoing treatment (including patients, donors, and surrogates and their partners, if any) are protected at all times.

(c) Designated Officers must attest to Clause 2.5.1 in the prescribed form **1 August** annually.

2.5.2 Provision of information

(a) An ART provider must provide its patients and the public with accessible and easily understood information about the risks and benefits of treatment procedures, including adjuvant therapies and new treatment procedures that are offered as part of a program of treatment by the doctors who carry out treatment procedures on behalf of the ART provider. The information must include evidence that accurately demonstrates the risks and benefits of such treatments.

(b) An ART provider must inform its patients about the role and complaint handling services of the Health Complaints Commissioner (HCC) – including the legal protections available to those who lodge a complaint with the HCC.

(c) Designated Officers must attest to Clause 2.5.2 in the prescribed form by **1 August** annually.

2.6 Notification of Incidents

(a) An ART provider must give the Authority written notice of:

i) any actual or potential contravention of the Act or Regulations;

ii) any actual or potential breach of its Conditions for Registration or conditions attached to any approval granted by the Authority;

iii) any incident that is reported to RTAC as part of accreditation requirements; and

iv) any contravention of the guiding principles of the Act in carrying out activities regulated by the Act, including any incident which is or is likely to be harmful to the health or wellbeing of patients, gametes or embryos (including, for example but without limitation, if incorrect gametes are used to form an embryo, an incorrect embryo is transferred to a women in a treatment procedure, or where a number of gametes or embryos are lost through freezing unit or dry shipper failure).

(b) For the avoidance of doubt, this includes any actual or potential contravention that the provider becomes aware of by patients, donors or other third parties. A notification must be made using the Authority's 'Adverse Incident Report Form'. For guidance in relation to how to complete this form and examples of the types of incidents that should be reported, please refer to the 'Guidance Note – Reporting Adverse Incidents'. The Authority welcomes attachments pertaining to the notification such as RiskMan reports.

(c) Generally, a notification must be given as soon as practicable and no later than **six (6) calendar weeks** after the ART provider becomes aware of the incident. However, where the incident is:

i) a sentinel event, involves an error in identification/traceability of genetic material, poses an immediate risk to patient safety or could otherwise result in severe consequences, notification must be made within **48 hours** of the ART provider becoming aware of the incident.

ii) involves an actual or potential legislative breach, notification must be made within **ten (10) business days** of the ART provider becoming aware of the incident.

(d) The notification must include the following information:

i) the date of the incident;

ii) a description of the incident (including the type of incident, how it occurred and cause);

iii) whether there was any damage to or loss of embryos;

iv) action taken (including immediate action and corrective action to avoid the incident occurring again);

v) steps taken or to be taken in relation to disclosure with patients affected by the incident; and

vi) the name of the treating clinician.

(e) A copy of any records, documents or information relevant to the incident must be provided to the Authority on request.

(f) An ART provider must disclose an incident to the patient and/or persons that the incident may affect within **five (5) business days** of the clinic becoming aware of the incident. This communication must be guided by the *Australian Open Disclosure Framework* and the *Australian Charter of Healthcare Rights*.

2.7 Notification of Change in Clinic Ownership or Clinic Closure

(a) If an ART provider changes ownership, the ART provider must notify the Authority in writing within **ten (10) business days** of the ownership changing. This notification must include any changes to the medical director, the designated officer, and all relevant contact details.

(b) If an ART provider closes, the ART provider must notify the Authority in writing within **ten (10) business days** of closure. This notification must include the clinic location and confirm that patients have been notified of the closure.

2.8 Continuing Professional Development

(a) An ART provider must ensure that all staff undertake continuing professional development in ART, including (but not limited to) familiarity with the regulatory framework and changes to the Act.

(b) An ART provider must ensure that all staff involved in patient contact be required to undertake training in LGBTIQ+ inclusivity and cultural competency practices.

(c) An ART provider must have appropriate record-keeping mechanisms in place to ensure compliance with this condition and must provide evidence of the same when requested by the Authority.

(d) Designated Officers must attest to Clause 2.8 in the prescribed form by **1 August** annually.

Section 3 – Term, Suspension and Further Conditions

(a) Once granted, registration of an ART provider shall continue until terminated or suspended in accordance with the Act or the Conditions for Registration.

(b) The Authority may impose further conditions on the registration of the ART provider if the Authority considers it necessary in the public interest.

(c) These Conditions for Registration are reviewed by the Authority on a regular basis and updated where appropriate.

Version history

Date effective	13 October 2022
Superseded version	23 November 2021

Appendix A – ART Provider Attestation Form

Registered Assisted Reproductive Treatment (ART) Provider Attestation

In accordance with the *Conditions for Registration (effective 13 October 2022)*, a Designated Officer of a registered ART provider must submit an attestation to the Victorian Assisted Reproductive Treatment Authority (the Authority) each year by **1 August.** Please submit a signed copy to **regulation@varta.org.au.**

I, _____ (*name of Designated Officer*), certify that _____ (*name of ART provider*) complies with all conditions set out in the Conditions for Registration and submit the following (including all relevant supporting documents) to demonstrate compliance:

Compliance with the Law

Date(s) of Review	Process / System Reviewed
Example: *28 October 20XX; 28 February 20XX; 28 April 20XX*	Example: *Review of donor consent counselling forms*

PLEASE ATTACH ANY FORMS AND USE SEPARATE DOCUMENT IF MORE SPACE IS REQUIRED

Comments (optional):

RTAC Accreditation

Report Type	Date of Receipt	Date of VARTA Notification

For RTAC Audits – please specify (required):

	Response
Audit report date	
Recommended date for next audit	
Summary of previous non-conformities closed/open and actions taken	
Summary of non-conformities following this year's audit	
Summary of opportunities for improvement	

PLEASE USE SEPARATE DOCUMENT IF MORE SPACE IS REQUIRED

Comments (optional):

Provision of Information to the Authority

Information Required	
ART Provider Name	
Address of each premises at which the ART provider carries out treatment procedures	
Period for which the ART provider holds RTAC accreditation	
Details of the ART provider's internet site	

PLEASE ATTACH A SEPARATE DOCUMENT IF MORE SPACE IS REQUIRED

Clause	Date to Submit Information	Date of Submission	Reviewed By
2.3.2(a)	Last Friday in July or such other date as notified by the Authority		

Comments (optional):

Developments in treatment and research

Adjuvants Therapies Offered	Comment

PLEASE ATTACH ANY HANDOUTS AND USE SEPARATE DOCUMENT IF MORE SPACE IS REQUIRED

New Research / Treatment Procedures / Adjuvant Therapies Introduced or Offered Since 1 August of Last Year	Date of Introduction / Commencement	Date of VARTA Notification

PLEASE ATTACH ANY FORMS AND USE SEPARATE DOCUMENT IF MORE SPACE IS REQUIRED

Comments (optional):

Audits

Purpose of Audit	Auditor	Date of Audit Completion	Date of VARTA Submission

Comments (optional):

Advertising and other published information

Advertising / Claim / Information / Comparison Published	Verifying / Supporting Documents	Reviewed By

PLEASE ATTACH ANY VERIFICATIONS AND USE A SEPARATE DOCUMENT IF MORE SPACE IS REQUIRED

Comments (optional):

Provision of treatment and information to patients

Information / Forms Provided to Patients	Most Recent Date of Review

PLEASE ATTACH ANY HANDOUTS AND USE A SEPARATE DOCUMENT IF MORE SPACE IS REQUIRED

Comments (optional):

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Conditions for Registration

Notification of Incidents

Incident Number	Date of Incident	Date of VARTA Notification

PLEASE ATTACH A SEPARATE DOCUMENT IF MORE SPACE IS REQUIRED

Comments (optional):

Notification of Change in Clinic Ownership or Clinic Closure

Change Type	Date of Event	Date of VARTA Notification

Comments (optional):

Continuing Professional Development

Date	Topic

PLEASE ATTACH ANY HANDOUTS AND USE A SEPARATE DOCUMENT IF MORE SPACE IS REQUIRED

Treating clinicians

Name of Clinician	Location

PLEASE ATTACH A SEPARATE DOCUMENT IF MORE SPACE IS REQUIRED

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Conditions for Registration

Designated Officer	
Name	
Title	
Signature	
Date	