VARTA
Victorian Assisted Reproductive Treatment Authority

Version 11/2021

Conditions for Registration

Effective: 23 November 2021

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

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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 Regulator 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.[1]

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:

1. hold a Reproductive Technology Accreditation Committee (RTAC) accreditation; and
2. 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.

[1] This requirement is anticipated to change by approximately 20 April 2022 in accordance with the *Assisted Reproductive Treatment Amendment Bill 2021* (Vic), which received Royal Assent on 19 October 2021.

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 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 must provide evidence of the same when requested by the Authority.

(c) Designated Officers must attest to the following by 1 August annually:

> *I, [name of designated officer], certify that [name of ART provider] has processes and systems in place which comply with the Assisted Reproductive Treatment Act 2008 (Vic), its Conditions for Registration 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 [name of ART provider] reviews these processes and systems annually to ensure that these requirements are met. Written notice has been given to the Authority as required under the Conditions for Registration of any non-compliance or other notifiable incidents which occurred during the past year.*

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 immediately if its RTAC accreditation ceases or if RTAC imposes conditions on its accreditation.

(c) Upon 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.

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 end of the third week in August** or such other date as is notified by the Authority.

(b) Designated Officers must provide the following attestation when supplying such information:

> *I, [name of designated officer], certify that [name of ART provider] has to the best of my knowledge after due and proper verification provided accurate data for the Authority's annual report. The [name of ART provider] critically reviews patient information management processes and systems annually to ensure that annual report data can be provided in a timely and reliable way.*

2.3.3 Donor Registers

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.

2.3.4 Developments in treatment and research

(a) As recommended in the 'RTAC Technical Bulletin 11 Use of Adjuvants in ART' (November 2019) to provide patient access to a list of all adjuvant therapies offered by the ART provider, 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.

(b) 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

(c) 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.

This notification must be made at least 30 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.

(d) By 1 August 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 two weeks 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'.

(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 the following by **1 August** annually:

> *I, [name of designated officer], certify that [name of ART provider] has processes and systems in place to ensure that it complies with section 133 the Health Practitioner Regulation National Law Act 2009 (Victoria). The [name of ART provider] critically reviews advertising, claims and information for the general public, patients and others annually, verifying the accuracy of information provided with appropriate senior scientific/medical staff to ensure that the Conditions of Registration are met.*

2.5 Provision of information to patients

(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) The Designated Officer of an ART provider must attest to the following by **1 August** each year:

> *I, [name of designated officer], certify that [name of ART provider] provides its patients and the public with accessible and easily-understood information about the risks and benefits of treatment procedures including new or adjuvant therapies, including accurate information about the evidence which demonstrates those risks and benefits.*

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 woman in a treatment procedure, or where a number of gametes or embryos are lost through freezing unit or dry shipper failure) –

by the ART provider or by a doctor carrying out treatment procedures on its behalf.

(b) 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 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 two weeks 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) Disclosure in relation to all incidents and the way that the ART provider communicates with its patients and persons affected by ART generally should be guided by the Australian Open Disclosure Framework and the Australian Charter of Healthcare Rights.

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	23 November 2021
Superseded version	1 February 2020