VARTA
Victorian Assisted Reproductive Treatment Authority

For more information visit the
Victorian Assisted Reproductive Treatment Authority
www.varta.org.au or phone 03 8601 5250

Conditions for Registration

For Assisted Reproductive Treatment Providers under the *Assisted Reproductive Treatment Act 2008*

Effective: 1 February 2020

The Victorian Assisted Reproductive Treatment Authority (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).

The Authority has responsibility under the Act for administration of the registration system for assisted reproductive treatment (ART) providers in Victoria, monitoring programs and activities carried out under the Act, public education, promotion of research, management of the donor conception registers and a number of other matters outlined in the Act.

The Authority is also required to advise the Minister regarding any contravention of the Act, the Assisted Reproductive Treatment Regulations 2009 (the Regulations) or a registered ART provider's registration, as well as any developments, whether in Victoria or elsewhere, that the Authority considers of major importance or concern with regard to research relating to infertility and treatment for infertility.

For more information about the Authority's regulatory role and approach, please see the Authority's *Regulator Plan*, which is available at **www.varta.org.au**. Under the Act, a person may only carry out ART if that person is (or is under the supervision and direction of) a doctor who is carrying out the treatment on behalf of an ART provider registered under the Act, and is satisfied that the requirements of Divisions 2, 3 and 4 of Part 2 of the Act have been met. Similarly, a person may only carry out artificial insemination (AI) of a woman if that person is a doctor, and is satisfied that the requirements of Divisions 2, 3 and 4 of the Act have been met. Where these conditions make reference to a 'treatment procedure', the definition of 'treatment procedure' in section 3 of the Act applies.

An application for registration as an ART provider may be made to the Authority by any provider who holds an Reproductive Technology Accreditation Committee (RTAC) accreditation.

The Authority may impose conditions on registration only if it considers it necessary in the public interest. Conditions imposed on an ART provider's registration must not be inconsistent with a condition imposed on the ART provider's RTAC accreditation.

The Authority may also, by written notice given to a registered ART provider, suspend the provider's registration, either in whole or in part, if it believes the ART provider has contravened a condition of registration or if it is satisfied that there are reasonable grounds for the suspension.

Conditions imposed on registration include the condition that a registered ART provider must ensure that its advertising and patient information is not misleading for patients, for instance, the publication of misleading comparative success rates.

The Authority will publish on its website the conditions that have been imposed upon each registered ART provider's registration.

Further clarification about the conditions contained in this document can be sought directly from the Victorian Assisted Reproductive Treatment Authority:

Postal address: Level 30, 570 Bourke Street, Melbourne VIC 3000
Phone: (03) 8601 5250
Email: varta@varta.org.au
Web: www.varta.org.au

SECTION 2: Conditions for Registration

An application for registration as a registered ART provider in Victoria must be in the Authority's prescribed form.

All registered ART providers must comply with these Conditions for Registration, as amended by the Authority from time to time, along with any other specific conditions imposed by the Authority on a registered ART provider's registration under the Act.

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.

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.

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.

(c) 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* 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 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, including accurate information about the evidence which demonstrates those risks and benefits.

(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); and

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

(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	1 February 2020
Superceded version	1 June 2018
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