Attachment A – Summary guidance

Outline of requirements under the Assisted Reproductive Treatment Act 2008 and Assisted Reproductive Treatment Regulations 2019, for registered medical practitioners who perform artificial insemination in Victoria

Background

The *Assisted Reproductive Treatment Act 2008* (Vic) (the Act) and Assisted Reproductive Treatment Regulations 2019 (Regulations), regulate aspects of assisted reproductive treatment in Victoria. The Act, among other things:

- provides for certain requirements relating to the use of assisted reproductive treatment (which excludes artificial insemination), and artificial insemination procedures (other than self-insemination), including the use of donated gametes and embryos (donor treatment procedures). These matters include threshold criteria for treatment, consent and counselling requirements and the provision and collection of information,
- regulates access to certain information relating to these procedures, such as information about the identity of donors and people conceived through donor treatment procedures, and
- regulates surrogacy arrangements.

Under the Act medical practitioners registered to practise in the medical profession under the *Health Practitioner Regulation National Law* may carry out the following treatment procedures in Victoria in accordance with the Act:

- artificial insemination whether or not they do so on behalf of a registered ART provider, and
- assisted reproductive treatment only if they do so on behalf of a registered ART provider.

The threshold treatment criteria, and consent, counselling and information requirements are contained in Divisions 1 (General), 2 (General requirements for treatment procedures), 3 (Requirements for donors), 4 (Provisions about consent), and 5 (Requirements for donor treatment procedures) of Part 2 of the Act relating to treatment procedures. Other relevant provisions include division 1 of Part 3 (Prohibited procedures) and Part 6 (Registers and access to information) relating to the keeping of registers and provision of information to the Victorian Assisted Reproductive Treatment Authority (Authority).

The requirements in the Act supplement any other clinical and regulatory requirements outside the Act that may apply to the practice of this medical procedure, including the collection and use of sperm. Requirements other than those under the Act are not identified in this information sheet.

A registered ART provider is a person who is registered by the Authority under the Act as a registered ART provider. It is a prerequisite for registration as a registered ART provider to hold accreditation of the Reproductive Technology Accreditation Committee of the Fertility Society of Australia. Further information regarding the requirements of the Fertility Society of Australia can located at: https://www.fertilitysociety.com.au.

The Act defines and refers to medical practitioners registered to practise in the medical profession under the *Health Practitioner Regulation National Law* as ‘doctors’. In this Summary Guidance, they are referred to as ‘medical practitioners’.

The table below summarises some of the key obligations under the Act and Regulations on medical practitioners who perform artificial insemination in Victoria, both where they are not aligned with a registered ART provider and where they perform the procedure on behalf of a registered ART provider. The table also identifies changes to the Act relating to artificial insemination that were made by the Assisted Reproductive Treatment Amendment Act 2021 (Amendment Act). The table is not intended to be a complete summary of all requirements and obligations under the Act and Regulations.

Table 1 – Summary of treatment and information obligations
Definitions

Term	Section of Act	Definition
Artificial insemination	Section 3 Definitions	means a procedure of transferring sperm without also transferring an oocyte into the vagina, cervical canal or uterus of a woman
Assisted reproductive treatment	Section 3 Definitions	means medical treatment or a procedure that procures, or attempts to procure, pregnancy in a woman by means other than sexual intercourse or artificial insemination, and includes— (a) in-vitro fertilisation; and (b) gamete intrafallopian transfer; and (c) any related treatment or procedure prescribed by the regulations
Authority	Section 3 Definitions	means the Victorian Assisted Reproductive Treatment Authority established under Part 10
Central Register	Section 3 Definitions	Central Register means the register kept by the Authority under section 53. (This register contains information that medical practitioners and registered ART providers are required to provide to the Authority in relation to treatment procedures including donor treatment procedures).
Doctor	Section 3 Definitions	means a person registered under the Health Practitioner Regulation National Law to practise in the medical profession (other than as a student)
Donor treatment procedure	Section 3 Definitions	means a treatment procedure in which donor gametes or a donor embryo is used
Self-insemination	Section 3 Definitions	means artificial insemination not carried out by a doctor
Treatment procedure	Section 3 Definitions	means— (a) artificial insemination, other than self-insemination; or (b) assisted reproductive treatment
Voluntary register	Section 3 Definitions	Voluntary Register means the register kept by the Authority under section 70. (This register contains information that donors, people conceived through donor treatment procedures and others may request the Authority to include on this register).

Treatment obligations **(refer to note below)**

The following obligations apply with respect to artificial insemination procedures

Summary of obligations (not a replication of the provisions in the Act).	**Medical practitioners performing artificial insemination treatment on behalf of a registered ART provider**		**Medical practitioners performing artificial insemination treatment not on behalf of a registered ART provider**	
	Before amendments	After amendments	Before amendments	After amendments
Section 8 of the Act permits medical practitioners to carry out artificial insemination only if the requirements of Divisions 2, 3 and 4 of Part 2 of the Act have been met. Penalty: 480 penalty units or 4 years imprisonment or both	Permitted	Permitted (Please note that amendments made by the Amendment Act to enable persons such as nurses and other health professionals to carry our artificial insemination under the supervision and direction of a medical practitioner in a registered ART provider (only), will commence on 24 June 2022).	Permitted	Permitted
Section 10(1) provides that a woman may only undergo a treatment procedure (including artificial insemination), if the women and her partner have consented to that procedure in the prescribed form. The prescribed form is contained in schedule 1 of the Regulations. In addition:	Medical practitioner must be satisfied that the requirements of section 10 have been met	Requirements remain unchanged	Medical practitioner must be satisfied that the requirements of section 10 have been met	Requirements remain unchanged

(1) the criteria in section 10(2) must be satisfied; or (2) The Patient Review Panel must have decided that there is no barrier to the woman undergoing a treatment procedure of that kind. Section 10(2) – Under this section, medical practitioners proposing to undertake artificial insemination must be satisfied on reasonable grounds that eligibility criteria for persons wishing to undergo treatment procedures, are satisfied, namely that: (1) in the woman's circumstances, the woman is unlikely to become pregnant other than by a treatment procedure; or (2) the woman is unlikely to be able to carry a pregnancy or give birth to a child without a treatment procedure; or (3) the woman is at risk of transmitting a genetic abnormality or genetic disease to a child born as a result of a pregnancy conceived other than by a treatment procedure, including a genetic abnormality or genetic disease for which the woman's partner is the carrier, based on advice obtained in accordance with section 10(3).				
Section 11 – consent by the woman and her partner (if any) must be given to: (1) the medical practitioner in charge of the woman's treatment if it is carried out other than by a registered ART provider; or (2) a designated officer of the registered ART provider carrying out the treatment. The consent must not have been withdrawn or lapsed when the treatment procedure takes place. Section 20 provides that withdrawals of consent must be provided to the medical practitioner or registered ART provider to whom the consent was given or where the gametes are stored or in accordance with the Regulations. Please note that the Amendment Act clarifies that consent to treatment using a partner's gametes is taken to be withdrawn on separation and introduces	Medical practitioner must be satisfied that the requirements of section 11 have been met	Subject to inclusion of new provisions relating to separation and notices of separation, the requirements remain unchanged. The new provisions relating to separation and notices of separation are proposed to come into effect mid August 2022 and further information will be provided in a	Medical practitioner must be satisfied that the requirements of section 11 have been met	Subject to inclusion of new provisions relating to separation and notices of separation, requirements remain unchanged. The new provisions relating to separation and notices of separation are proposed to come into effect mid August 2022 and further information will be provided in a separate Information Sheet.

requirements in relation to notices of separation. These changes to the Act are proposed to come into effect mid August 2022 and further information will be provided in a separate information sheet.		separate Information Sheet.		
Section 13 – the woman and her partner (if any) must have received counselling before consenting to undergo the treatment procedure. The counselling must include the matters prescribed in regulation 7 of the Regulations.	Medical practitioner must be satisfied that the requirements of section 13 have been met	The Amendment Act inserts a new section 13(2) of the Act which allows patients to seek pre-treatment counselling from a counsellor outside of a registered ART provider where the counsellor meets prescribed requirements (in addition to a counsellor within a registered ART provider). This change is proposed to come into effect mid August 2022 and further information will be provided in a separate Information Sheet.	Medical practitioner must be satisfied that the requirements of section 13 have been met	The Amendment Act inserts a new section 13(2) of the Act which allows patients to seek pre-treatment counselling from a counsellor outside of a registered ART provider where the counsellor meets prescribed requirements (in addition to a counsellor within a registered ART provider). This change is proposed to come into effect mid August 2022 and further information will be provided in a separate Information Sheet.
Section 22 – provides the requirements on medical practitioners and designated officers of registered ART providers with respect to obtaining, keeping and recording consents, withdrawals of consent and provision of certified copies to the person who provided them.	Designated officer of a registered ART provider must comply with requirements under sections 22	Subject to inclusion of new requirements relating to notices of separation, requirements remain unchanged.		The Amendment Act inserts a new section 22(2) to clarify that a medical practitioner must comply with requirements under section 22.

Please note that the Amendment Act introduces requirements in relation to notices of separation. This change is proposed to come into effect mid August 2022 and further information will be provided in a separate information Sheet.		The new provisions relating to separation and notices of separation are proposed to come into effect mid August 2022 and further information will be provided in a separate Information Sheet.		This change is proposed to come into effect mid August 2022.
Section 25 requires written advice about the following to be provided to a woman and her partner (if any) before the woman undergoes a treatment procedure: (1) The rights of a person born of a donor treatment procedure and others to the disclosure of information under the Act (2) The nature of the information that is recorded about the donor on the Central Register (3) The rights of the woman and her partner to obtain information (4) The existence and function of the Voluntary Register	Registered ART provider must comply with requirements under sections 22	Requirement remains unchanged		The Amendment Act inserts a new section 25(2) to clarify that medical practitioners performing artificial insemination outside registered ART providers are subject to the same information requirements as those who perform the procedure on behalf of a registered ART provider. This change is proposed to come into effect mid August 2022

Prohibited procedures **(refer to note below)**

The Act contains a range of offences relating to treatment procedures, including artificial insemination. These offences include the following:

Section of Act	Person required to comply	Obligation
Section 26 - Procedures involving gametes produced by children	A person carrying out a treatment procedure. This includes a medical practitioner carrying out artificial insemination whether or not on behalf of a registered ART provider	This section prohibits use in a treatment procedure of among other things, gametes produced by a child. Penalty: 240 penalty units or 2 years imprisonment or both The section provides for an exception subject to conditions, where gametes are obtained from a child for storing for the child's future benefit where there is a risk the child will become infertile before becoming an adult.
Section 27 - Ban on certain procedures	A person carrying out a treatment procedure. This includes a medical practitioner carrying out artificial insemination whether or not on behalf of a registered ART provider	A person must not carry out a procedure using, among other things, sperm produced by more than one person. Penalty: 240 penalty units or 2 years imprisonment or both
Section 29 - Ban on using donated gametes to produce more than 10 families	A person carrying out a treatment procedure. This includes a medical practitioner carrying out artificial insemination whether or not on behalf of a registered ART provider	The section prohibits a person carrying out a treatment procedure (including artificial insemination) using gametes of a donor if the person knows the treatment procedure may result in more than 10 women having children who are genetic siblings, including the donor and any current or former partner of the donor. Penalty: 240 penalty units or 2 years imprisonment or both There are certain exceptions to the provision and amendments came into effect on 21 December 2021 to expand the range of families who may have genetic siblings for an existing child using the same donor where the limit has been reached. Further information is contained in the Fact Sheet of the Authority "Expansion of the exceptions to the '10 women limit', Assisted Reproductive Treatment Amendment Act". To obtain a copy, please contact the Authority by phoning 8622 0500 or emailing varta@varta.org.au'. A donor may consent to less than 10 women using their gametes, as expressed on their 'consent to donation' form which is a prescribed form in schedule 2 of the Regulations.

		A medical practitioner should have appropriate process and procedures in place to ensure compliance with the ’10 family limit’.

Surrogacy arrangements

Description	Person required to comply	Obligation
Artificial insemination in a traditional surrogacy arrangement (where the surrogate uses her own egg)	A medical practitioner carrying out artificial insemination other than on behalf of a registered ART provider.	In addition to relevant obligations under the Act with respect to the treatment procedure on the surrogate, the medical practitioner must comply with the requirements under the Act relating to donor treatment procedures with respect to the use of donor sperm. Refer to the section regarding ‘donor treatment procedures’ below. Note that in making a substitute parentage order under the Status of Children Act 1974 for surrogacy arrangements where a surrogate uses her own egg, the Court must be satisfied of certain matters including that the surrogate mother is at least 25 years of age and the parties to the surrogacy arrangement have received counselling and legal information (refer to section 23 of the Status of Children Act 1974).

Donor Treatment Procedures **(refer to note below)**

The following obligations apply where donor sperm is used in artificial insemination

Summary of obligations (not a replication of the provisions in the Act).	Medical practitioners performing artificial insemination treatment on behalf of a registered ART provider		Medical practitioners performing artificial insemination treatment not on behalf of a registered ART provider	
	Before amendments	After amendments	Before amendments	After amendments
Section 16– Donated gametes may only be used in a treatment procedure (for example sperm to be used in artificial insemination) if the donor has consented to the use of their gametes in that procedure. The Amendment Act includes an amendment to insert a new section 16(3) to clarify that a person does not donate gametes where they are to be used by that person or their partner or a surrogate where the person who produced the gametes is an intending parent. This change is	Medical practitioner must be satisfied that the requirements of section 16 have been met	Subject to insertion of section 16(3), requirements remain unchanged. The insertion of section 16(3) is proposed to come	Medical practitioner must be satisfied that the requirements of section 16 have been met	Subject to insertion of section 16(3), requirements remain unchanged. The insertion of section 16(3) is proposed to come

proposed to come into effect mid August 2022 and further information will be provided in a separate information Sheet		into effect mid August 2022.		into effect mid August 2022.
Section 17- The prescribed form of the consent referred to in section 16 is contained in schedule 2 of the Regulations. The consent must specify: (1) the number of women on whom treatment procedures may be carried out using the donor's gametes. (refer to the section above on the '10 women limit') (2) the kinds of treatment procedures where the gametes may be used (3) must not have been withdrawn or lapsed when artificial insemination takes place. The consent must be given to (1) the medical practitioner if the donation is made other than to a registered ART provider; or (2) a designated officer of the registered ART provider if the donation is made to the registered ART provider. Section 21 provides that in the case of donor gametes, consents lapse 10 years after they have been provided or at the end of any lesser period specified in the consent.	Medical practitioner must be satisfied that the requirements of section 17 have been met	Requirements relating to artificial insemination remain unchanged	Medical practitioner must be satisfied that the requirements of section 17 have been met	Requirements relating to artificial insemination remain unchanged
Section 18 – the donor must have received counselling before consenting to donate their gametes. The counselling must include the matters prescribed in regulation 9 of the Regulations.	Medical practitioner must be satisfied that the requirements of section 18 have been met	Requirements remain unchanged	Medical practitioner must be satisfied that the requirements of section 18 have been met	Requirements remain unchanged
Section 19 – At the time the donor gives consent: (a) donor must give information prescribed in the Regulations to be included in the register maintained by the medical practitioner or registered ART provider. This includes information relating to: (1) each artificial insemination procedure using the donor's sperm (2) the donor (3) the woman who is artificially inseminated and any partner	Medical practitioner must be satisfied that the requirements of sections 19 (a) and (b) have been satisfied	Requirements remain unchanged	Medical practitioner must be satisfied that the requirements of sections 19 (a) have been satisfied	The Amendment Act clarifies that a medical practitioner must be satisfied that the requirements of section 19 (a) have been satisfied **and** must give the written

(4) the child born as a result of artificial insemination using donor sperm (b) The donor must be given written advice by the person to whom the donation is made about: (1) the rights of a person born of a donor treatment procedure and others to the disclosure of information under the Act (2) the nature of the information that is recorded about the donor on the Central Register (3) the donor's rights to obtain information (4) the existence and function of the Voluntary Register				advice in section 19 (b). The amendment regarding section 19 (b) is proposed to come into effect mid August 2022.
Section 55 – Information recorded by registered ART providers that is to be given to donors Where a registered ART provider proposes to carry out among other things, artificial insemination using donor gametes, the donor may ask the designated officer of the provider to provide information required to be recorded by the provider about the woman to be treated and any partner. The section imposes requirements on the designated officer regarding provision of information. A penalty of 50 penalty units applies to non-compliance. Section 55A – Information recorded by medical practitioners other than on behalf of registered ART providers that is to be given to donors Where a medical practitioner proposes to carry out artificial insemination using donor gametes other than on behalf of a registered ART provider, the donor may ask the medical practitioner to provide information required to be recorded by the medical practitioner about the woman to be treated and any partner. The section imposes requirements on the medical practitioner regarding provision of information. A penalty of 50 penalty units applies to non-compliance.	Designated officer must comply with section 55	Requirements remain unchanged		The Amendment Act inserts a new section 55A to align the requirements to provide information to donors on request with those on designated officers of registered ART providers under section 55. The amendment is proposed to come into effect mid August 2022.

Registers and information to be kept under Part 6 of the Act

The table below contains information about certain registers and information that are required to be kept under Part 6 of the Act by registered ART providers and medical practitioners other than on behalf of a registered ART provider carrying out artificial insemination.

Table 2 – Part 6 register and information requirements

Section of Act	Person required to comply	Obligation
Section 49 – register to be kept by registered ART providers	Registered ART provider	A registered ART provider must keep a register that includes prescribed information relating to a range of matters including: • the donors of gametes or embryos kept or stored by the provider • the woman on whom the provider carries out a treatment procedure including the woman's partner (if any) • information about the use, collection, storage and disposal of gametes and embryos • information about treatment procedures and treatment outcomes, including particulars of the birth of any child born • information about import to and export from Victoria of donor gametes and embryos • information about consent and withdrawal and lapsing of consent to treatment
Section 49A – register of pre-1988 donor treatment procedures to be kept by registered ART providers	Registered ART provider	A registered ART provider must keep a register that includes prescribed information about pre-1988 donor treatment procedures.
Section 50 – register to be kept by medical practitioners carrying out artificial insemination	A medical practitioner carrying out artificial insemination other than on behalf of a registered ART provider	A medical practitioner carrying out artificial insemination other than on behalf of a registered ART provider must keep a register that includes prescribed information relating to a range of matters including: • each procedure carried out • the donor, if donor sperm is used • the woman who is inseminated and her partner, (if any) • a person born as a result of the artificial insemination, including particulars of the birth, if known to the medical practitioner; • information about consent and withdrawal and lapsing of consent.

Section 51 – information to be given to the Authority by registered ART providers	Registered ART provider	By 1 July each year, each registered ART provider must provide information to the Authority, including • information about births and pregnancies as a result of a treatment procedure; and • information about donor treatment procedures and the outcome.
Section 52 – information to be given to Authority by medical practitioners	A medical practitioner carrying out artificial insemination other than on behalf of a registered ART provider	By 1 August each year, each medical practitioner must provide information to the Authority, including • information about births and pregnancies as a result of a treatment procedure; and • information about artificial insemination procedures carried out by the medical practitioner.
Section 52A – information to be given to Authority by registered ART provider – register of pre-1988 donor treatment procedures	Registered ART provider	By 1 July each year, each registered ART provider must provide new information to the Authority, relating to pre-1988 donor treatment procedures
Section 52B – information may be given to Authority by persons other than registered ART providers – pre-1988 donor treatment procedures	A person other than a registered ART provider who is in possession of or has control of records relating to pre-1988 donor treatment procedures	A person other than a registered ART provider who is in possession or has control of pre-1988 donor treatment procedures may give the records to the Authority.

Note: The Act also contains offences and requirements relating to specific aspects of the ongoing management of gametes, including relating to storage (division 2 of Part 3), import into and export from Victoria of donated gametes (division 3 of Part 3), and posthumous use of gametes (Part 5). These offences and requirements are not outlined in the table and further reference should be made to the Act and the Regulations.

Summary

This information has been provided as a summary of certain provisions of the Assisted Reproductive Treatment Act 2008 (Vic) and recent amendments to this legislation relating to artificial insemination procedures.

The Information Sheet including this attachment, is provided as general guidance only and does not constitute legal advice. The Act and Regulations can be accessed at legislation.vic.gov.au. The Amendment Act can be accessed at https://www.legislation.vic.gov.au/as-made/acts/assisted-reproductive-treatment-amendment-act-2021.