|  |
| --- |
| Assisted Reproductive Treatment reforms – amendments to the Act and Regulations |
| Guide – December 2024 |
|  |

Contents

[Overview 1](#_Toc185198054)

[Changes to the Assisted Reproductive Treatment Act 1](#_Toc185198055)

[Changes to the Assisted Reproductive Treatment Regulations 3](#_Toc185198056)

[Assisted Reproductive Treatment Regulation 3](#_Toc185198057)

[Donor Conception Registers 5](#_Toc185198058)

[Further information and questions 6](#_Toc185198059)

[Appendix 1 7](#_Toc185198060)

# Overview

The Assisted Reproductive Treatment Amendment Regulations 2024 (2024 Amendment Regulations) will commence on 1 January 2025 and amend the Assisted Reproductive Treatment Regulations 2019 (ART Regulations).

The 2024 Amendment Regulations support changes to the Assisted Reproductive Treatment Act 2008 (ART Act) made by Part 2 of the Health Legislation Amendment (Regulatory Reform) Act 2024 Regulatory Reform) Act which will also come into effect on 1 January 2025.

The substantive changes in the 2024 Amendment Regulations are summarised below and detailed in [Appendix 1](https://auc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en-US&rs=en-AU&wopisrc=https%3A%2F%2Fdhhsvicgovau.sharepoint.com%2Fsites%2FRegulationPolicyandReformTeam%2F_vti_bin%2Fwopi.ashx%2Ffiles%2Fe959b4b7c5c9402b9a71b46cef31cbc7&wdenableroaming=1&mscc=1&hid=A5A06CA1-B098-4000-27CE-48D35B47607B.0&uih=sharepointcom&wdlcid=en-US&jsapi=1&jsapiver=v2&corrid=a3926a58-a6db-99df-0b37-5e2ec7003f86&usid=a3926a58-a6db-99df-0b37-5e2ec7003f86&newsession=1&sftc=1&uihit=docaspx&muv=1&cac=1&sams=1&mtf=1&sfp=1&sdp=1&hch=1&hwfh=1&dchat=1&sc=%7B%22pmo%22%3A%22https%3A%2F%2Fdhhsvicgovau.sharepoint.com%22%2C%22pmshare%22%3Atrue%7D&ctp=LeastProtected&rct=Normal&wdorigin=ItemsView&wdhostclicktime=1733956566604&csc=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush#_Appendix_1).

The updated Regulations will be available on the [Victorian Legislation website](https://www.legislation.vic.gov.au/in-force/statutory-rules/assisted-reproductive-treatment-regulations-2019/003) <https://www.legislation.vic.gov.au/in-force/statutory-rules>

# Changes to the Assisted Reproductive Treatment Act

The Regulatory Reform Act received Royal Assent on 29 October 2024. In developing the Regulatory Reform Act the department consulted, by publishing a consultation paper. A summary of feedback received, and responses, was subsequently published. Both documents are still available on [the Reforms to health regulation page](https://www.health.vic.gov.au/legislation/reforms-to-health-regulation-in-victoria) on the department’s website < https://www.health.vic.gov.au/legislation/reforms-to-health-regulation-in-victoria>

The Regulatory Reform Act amends the ART Act to transfer functions currently undertaken by the Victorian Assisted Reproductive Treatment Authority (VARTA) to the Secretary to the Department of Health (Secretary) and a new Donor Conception Registrar employed within the Department of Health (department). This will occur from 1 January 2025.

## Donor Conception Registers

The Regulatory Reform Act removes mandatory counselling requirements relating to accessing information on the donor conception registers (the Central Register and the Voluntary Register) and includes a new requirement for the registrar to provide prescribed explanatory material. Details of the material to be provided are set out in the amended ART Regulations – see further detail below.

The Regulatory Reform Act also introduces a process for people applying to the registers to provide a ‘statement of reasons’ that outlines their reasons for seeking the relevant information, which can be provided to the person to whom the information relates, where they are asked to consent to release of the information, to assist them in making a decision in relation to their consent. The amended ART Regulations will include some detail about information to be included in that statement of reasons – see further detail below.

The provisions in the ART Act relating to the management of the donor conception registers, and how information on the registers can be accessed, are otherwise not amended.

## Compliance and enforcement

In line with recommendations of the *Final Report of the Review of Assisted Reproductive Treatment* undertaken by Michael Gorton AM (the Gorton Review), the Regulatory Reform Act also makes changes to strengthen ART regulation by providing the regulator with a range of mid-range compliance and enforcement tools. These include powers to:

* Issue improvement and prohibition notices. These may require a specified action to remedy non-compliance, or prohibit a specified activity from being undertaken. Non-compliance is an offence.
* Accept enforceable undertakings. This enables regulated persons to offer to undertake certain actions as part of a binding agreement to remedy a contravention or prevent future contraventions. Where the undertaking is contravened it can be enforced through the courts.
* Issue a notice to provide information or documents. These notices can require provision of specified information or documents, to monitor compliance. Non-compliance is an offence.
* Issue infringement notices – that is, issue a fine where particular offences have been committed. This power will apply to particular offences that are listed in the ART Regulations. It is anticipated that the ART Regulations will be amended in 2025 to prescribe the offences for which infringement notices can be issued. These will be offences that already exist in the ART Act or Regulations as at 1 January 2025. The maximum amount of any fines will be a less (no more than 25%) of the maximum financial penalty that would apply if the offence were prosecuted through the courts.

## Regulation of movement of donor material into or out of Victoria

The Regulatory Reform Act replaces the pre-approval process for the movement of donor gametes and embryos produced from them into and out of Victoria with a certification process, from 1 January 2025. The certification process requires the person who is moving the donor material to provide a certification to the Secretary before the donor material is moved, attesting that certain requirements have been met. There will no longer be a requirement to wait for approval from the regulator before the donor material is moved.

The matters to be certified will be set out in section 36 of the amended ART Act and in the amended ART Regulations.

The matters set out in the amended ART are as follows:

* For bringing donor gametes or an embryo produced from donor gametes into Victoria
  + facts relating to compliance with relevant legislation regarding altruistic donation;
  + facts about the donor having given written consent in the prescribed form to the movement, use and storage of the gametes/embryos, and the person certifying having a copy of that consent;
  + the donor having received counselling on prescribed matters by a counsellor who meets prescribed requirements, prior to consenting;
  + the donor having provided specified information (required for the registers under the ART Act);
  + the donor having been provided with information as set out in section 19(b)(i)-(iv) of the ART Act; and
  + that the person making the certification has taken all reasonable steps to ensure that any future use of the donor gametes or embryo produced from donor gametes in Victoria will comply with section 29; and
  + any additional matters set out in the ART Regulations (see below).
* For taking donor gametes or an embryo produced from donor gametes out of Victoria
  + that the purpose for which the gametes or embryo will be used outside Victoria is consistent with a purpose for which it could be used in Victoria;
  + that the way in which the gametes or embryo will be used outside Victoria is consistent with the way in which it could be used in Victoria; and
  + Any additional matters set out in the ART Regulations (see below regarding)

Further information about the relevant provisions of the amended ART Regulations is below, and information about certification requirements is also available on the Department’s Health Regulator webpage <[https://www.health.vic.gov.au/assisted-reproduction/assisted-reproductive-treatment-regulation>](https://www.health.vic.gov.au/assisted-reproduction/assisted-reproductive-treatment-regulation%3e).

It will be an offence to make a false or misleading certification, and the person certifying will be required to keep records relating to the matters certified. Failure to keep the particular records specified in the amended ART Regulations for the specified period will be an offence. The strengthened compliance and enforcement powers will be used to monitor compliance with all the certification and related requirements.

# Changes to the Assisted Reproductive Treatment Regulations

As a result of the changes to the ART Act, amendments to the ART Regulations are needed to support the transfer of functions from VARTA to the Secretary and Donor Conception Registrar, to prescribe matters relating to requirements for certification to bring into or take from Victoria donor gametes or embryos produced from them, to outline the subject matters to be included in explanatory material that must be provided to persons to whom the Donor Conception Registrar is required to provide that material under the amended ART Act, and to prescribe new forms, including in relation to certification, donor consent (when a donation is made outside Victoria) and a statement of reasons form for applicants to the Central Register.

In developing the 2024 Amendment Regulations, the Department undertook targeted consultations with key stakeholders including those with lived experience in relation to donor conception, and registered ART providers. The Department is grateful to stakeholders for their ongoing engagement and contributions.

## Assisted Reproductive Treatment Regulation

### Consent forms and to whom they must be given

Several changes will be made to ensure the certification process can operate as intended in relation to donor consents. A new consent form for donors where the donation is made outside Victoria will be included as a new Schedule 2AA in the amended ART Regulations. The current Schedule 2 form will also be amended slightly to reflect the introduction of Schedule 2AA. New regulations will also be added to provide for the person to whom a donor must give or cause their consent or withdrawal of consent to be given in circumstances where donor gametes/embryos produced from them are brought into Victoria.

### Certification criteria – details and additional matters for certification

Under section 36(3) and (4) of the amended ART Act, a person must certify that specified criteria have been satisfied prior to moving any donor gametes or embryos formed from them into or taking them out of Victoria.

The 2024 Amendment Regulations include details relating to criteria in the amended ART Act to be met for the purpose of a certification, including prescribed matters about which a donor must receive counselling, prescribed requirements for a counsellor who can deliver that counselling, and information the donor must have given.

The 2024 Amendment Regulations also prescribe additional matters (over and above those in the amended ART Act) that a person must certify prior to moving donor gametes or embryos produced from them.

Prescribed forms for a certification to bring donor gametes or embryos produced from them into Victoria or take them out of Victoria are also prescribed in the new regulations. These will be Schedules 7 and 8 in the amended ART Regulations.

### Exemption under section 37

The 2024 Amendment Regulations include a prescribed form to apply to the Secretary for an exemption from compliance to specified provisions of the ART Act in relation to donor gametes or embryos produced from them that are brought into or taken from Victoria. A new exemption has been added to the regulations in relation to the new offence in section 37E of the amended ART Act for moving donor gametes or embryos produced from them into or out of Victoria in contravention of a prescribed prohibition or requirement (see below). A prescribed form for an application for an exemption is also included in the 2024 Amendment Regulations and will be Schedule 10 to the ART Regulations, once the amendments come into effect.

### Record-keeping

The 2024 Amendment Regulations set out the records that must be kept relating to a certification and for how long. It is an offence under section 37B(2) of the amended ART Act if a person does not keep written records of these matters for the prescribed period from the date they made the certification.

### Prohibition

The 2024 Amendment Regulations provide that a person is prohibited from bringing into Victoria donor gametes or an embryo formed from donor gametes from a country or geographical location declared in a notice published in the Government Gazette where, in the Secretary’s opinion, because of ongoing armed conflict or political unrest, it is unlikely consent and record-keeping requirements can be complied with.

### References to VARTA

There will also be technical amendments to replace references to VARTA in the ART Regulations. Because the regulation of ART and oversight of the donor conception registers will sit in different areas of the department, the 2024 Amendment Regulations replace references to the VARTA in the ART Regulations with either the Secretary or the Donor Conception Registrar, as relevant. For example, information about donor treatment procedures or artificial insemination using donor sperm must now be provided to the Donor Conception Registrar.

## Donor Conception Registers

### Part 6 counsellor

The amended ART Act will no longer require counselling to be provided or offered before disclosure of information from the registers or lodgement of a contact preference. However, current requirements for a counsellor to confirm the maturity of a child involved in accessing information on the registers will be retained. Under the amended ART Act, this counselling must be provided by a ‘Part 6 counsellor’. This is defined by section 67A of the amended ART Act as a person who provides counselling to a child under section 59(b)(ii) or 63H(2)(a) of the Act for the purposes of determining the maturity of the child and who meets the prescribed requirements for counselling. The 2024 Amendment Regulations prescribe the same requirements as those currently in Regulation 7A of the ART Regulations, that is, full membership or eligibility for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA).

### Statement of reasons

The 2024 Amendment Regulations will add a new prescribed form to the ART Regulations which applicants to the Central Register must submit when applying for information. This provides the reasons for their application and when a person’s consent is required under the ART Act for that information to be disclosed, will assist with decision making. This form will be Schedule 9 in the ART Regulations once the amendments come into effect. A person will be able to provide additional information in/along with their statement of reasons, should they wish to.

### Explanatory material and removal of mandatory counselling

The ART Act amendments commencing on 1 January 2025 include the removal of requirements to offer or ensure counselling has been undertaken prior to disclosure of information from the donor conception registers. There is a new requirement for the Donor Conception Registrar to provide individuals with prescribed explanatory material for them to consider. The 2024 Amendment Regulations set out the essential subject matter that must be addressed in that explanatory material in each circumstance where it is required to be provided under the amended ART Act. The explanatory material will contain more detail and will be developed by relevant experts. The Donor Conception Registrar, who will be employed by the Secretary will have discretion to include additional detail, and/or detail about matters not prescribed in the regulations, as needed/as becomes available over time.

# Further information and questions

Further information about the operation of the amendments will be available from the teams within the Department who will be overseeing ART regulation and the donor conception registers.

Questions can be directed as follows:

**Contacts**

For **queries relating to reforms to the ART Act or ART Regulations** please contact Department of Health Legislative and Regulatory Reform Team. Email: [legandregreform@health.vic.gov.au](mailto:legandregreform@health.vic.gov.au)

For **operational queries relating to ART regulation including ART provider registration, reporting and certification relating to movement of donor gametes into or out of Victoria** please contact the Department of Health Regulated Services – Assisted Reproductive Treatment Team. Email: [artregulation@health.vic.gov.au](mailto:artregulation@health.vic.gov.au)

For **operational queries relating to the donor conception registers including access, applications and support** please contact the Department of Health’s Donor Conception Register team. Email: [dcr@health.vic.gov.au](mailto:dcr@health.vic.gov.au)

# Appendix 1

**Table 1: Snapshot - Assisted Reproductive Treatment Amendment Regulations 2024**

|  |  |
| --- | --- |
| **Relevant Regulation** | **Amendment** |
| **Regulation 6 amended**  **Requirements for persons providing counselling other than on behalf of a registered ART provide** | As amended this regulation prescribes consistent requirements for counsellors delivering counselling for the purposes of sections 13(2)(b), 18(2)(b), 36(3)(d), 48(b)(ii) and 67A(b) of the amended ART Act.  The requirements are *full membership or eligibility for full membership[[1]](#footnote-2) of the Australian and New Zealand Infertility Counsellors Association.*  This means that is the consistent requirement for counsellors whenever counselling is not delivered by a counsellor who provides counselling on behalf of a registered ART provider (that is, counselling of a donor where the donation is not made in Victoria, counselling where artificial insemination is undertaken, and counselling of a child to assess maturity in relation to disclosure of information to the register). |
| **Regulation 8 substituted**  **Prescribed forms for donor consent** | The new regulation 8 distinguishes between the prescribed form of consent required if a donation is made in Victoria (Schedule 2) or outside Victoria (new Schedule 2AA of the amended ART Regulations). |
| **New regulations 8AA and 8AB inserted – withdrawal of donor consent** | Inserts new regulations that provide avenues for giving/withdrawing consent where a donation is made outside Victoria. In addition to the avenues under 17(2) and 20(3) of the Act, they allow consent to be withdrawn by providing the withdrawal or causing it to be provided to the person making the certification. |
| **New Regulation 9A inserted**  **Counselling of donors - details to be certified under section 36(3)(d) of the amended ART Act before bringing donated gametes or embryo produced from donor gametes into Victoria** | Prescribes detail of the matters that must have been addressed in counselling of donors, for the purposes of certification when brining donor gametes or an embryo produced from donor gametes into Victoria.  Under section 36(3)(d) of the amended ART Act a person bringing donor gametes or an embryo produced from donor gametes into Victoria must certify that “the donor or each person who donated the gametes used to produce the embryo has received counselling in relation to prescribed matters from a counsellor who meets the prescribed requirements for counselling or, if an exemption has been granted in relation to section 18, any conditions to which the exemption is subject have been complied with.”  The prescribed matters specified in the Amended ART Regulations as follows:   1. the requirements of the Act relating to 2. disclosing the identity of the donor to the Donor Conception Registrar; and 3. disclosing information to a person born as a result of a donor treatment procedure following a request for the information from the person; 4. information about how a person born as a result of a donor treatment procedure may lodge a contact preference; 5. information about how the donor may obtain identifying information about a person born as a result of a donor treatment procedure, if the person consents; 6. any issue or concern relating to the donation that is raised by the donor; 7. the limit imposed by section 29 of the Act in relation to the use of the donor's gametes or embryo produced from the donor's gametes; 8. the operation of the Act in relation to— 9. the withdrawal or lapsing of the donor's consent; and 10. consent for extending the storage of an embryo; and 11. consent for removing an embryo from storage; 12. the possible consequences for the donor if a person born as a result of a donor treatment procedure carried out using the donor's gametes or an embryo produced from the donor's gametes lives in— 13. another State or a Territory; or 14. another country. |
| **New regulations 9B inserted**  **Information provided by donors – details to be certified under section 36(3)(e) of the amended ART Act before bringing donated gametes or embryo produced from donor gametes into Victoria** | Prescribes detail of the information that must have been provided to a donor for the purposes of certification when brining donor gametes or an embryo produced from donor gametes into Victoria.  Under section 36(3)(e) of the amended ART Act a person bringing donor gametes or an embryo produced from donor gametes into Victoria must certify that the donor or each person who donated the gametes used to produce the embryo has given information about the matters prescribed for the purposes of this section or, if an exemption has been granted in relation to section 19(a) of the ART Act, any conditions to which the exemption is subject have been complied with.  The prescribed information specified in the amended ART Regulations as follows:   1. the donor's unique donor identifier (if any); 2. the donor's full name; 3. any other name by which the donor is or has been known; 4. the donor's date of birth; 5. the donor's place of birth (suburb or town and country); 6. the donor's sex; 7. the donor's residential address; 8. the donor's phone number; 9. the date on which the donor produced the gametes; 10. the place at which the donor produced the gametes; 11. the ethnic background of the donor's parents and grandparents, if known; 12. the donor's height; 13. the donor's build; 14. the donor's blood group; 15. any known genetic abnormality of the donor and, if available, any results of tests undertaken in relation to that abnormality; 16. the number of women who have given birth to children conceived using the donor's gametes or an embryo produced from the donor's gametes, including any current or former partner of the donor; 17. whether the donor has donated, or intends to donate, gametes or an embryo to any other registered ART provider or to a doctor and, if so— 18. the name and address of that registered ART provider; or 19. the full name and business address of that doctor; 20. the date on which the donor received the counselling referred to in section 36(3)(d) of the amended ART Act and the name of the counsellor who provided the counselling. |
| **New Regulation 9C inserted**  **Additional matters to be certified before bringing donated gametes or embryo produced from donor gametes into Victoria**  **(additional to those in section 36(3) of the Amended ART Act)** | Prescribes matters that must be certified under section 36(3)(h) of the amended ART Act, where a person is bringing donor gametes or an embryo produced from donor gametes into Victoria. These are in addition to those matters in section 36(3) of the amended ART Act.  These additional matters are also included in the certification form (Schedule 7 of the amended ART Regulations) are as follows (note that ‘the person’ refers to the person making the certification)   1. the person has obtained a written undertaking from the person transferring the donor gametes or embryo produced from donor gametes (the transferring party) or the donor, that the transferring party or the donor will notify the person as soon as practicable of— 2. any change to or withdrawal of the donor's consent; and 3. any change to the donor's information provided under section 36(3)(e) of the amended ART Act; 4. the person has obtained a written undertaking from— 5. the transferring party that the transferring party will take all reasonable steps to give the donor written notice as soon as practicable of—    1. the name and contact details of the registered ART provider receiving the donor gametes or embryo; or    2. the name and contact details of the doctor carrying out artificial insemination using the donor gametes; or 6. the person receiving the donor gametes or embryo produced from donor gametes (the receiving party) that the receiving party has provided written notice to the donor of— 7. the name and contact details of the registered ART provider receiving the donor gametes or embryo; or 8. the name and contact details of the doctor carrying out artificial insemination using the donor gametes; 9. if the person is a registered ART provider or a doctor carrying out artificial insemination using the donor gametes, the person will use the unique donor identifier from the transferring party so far as is reasonably practicable; 10. the person has sighted— 11. the donor's passport, driver licence or any other identification document displaying the donor's photograph and signature; or 12. a certified copy of the donor's passport, driver licence or any other identification document displaying the donor's photograph and signature; 13. the person has received— 14. the donor's email address (if any); and 15. the donor's postal address; 16. the person has received information about whether the donor has donated, or intends to donate, gametes or an embryo to a person (other than a registered ART provider or a doctor) including an individual for the purposes of self-insemination. |
| **New Regulation 9D inserted**  **Additional matters to be certified before taking donated gametes or embryo produced from donor gametes from Victoria**  **(additional to those in section 36(4) of the Amended ART Act)** | Prescribes the matters that must be certified under section 36(4)(c) of the amended ART Act, in addition to those criteria in section 36(4) of the amended ART Act, where a person is taking donated gametes or embryo produced from donor gametes out of Victoria  These additional criteria are included in the certification form (Schedule 8 of the Amended ART Regulations).  The matters to be certified are as follows (note that ‘the person’ refers to the person making the certification)   1. the person has provided the person receiving the donor gametes or embryo produced from donor gametes (the receiving party) with a copy of the donor's consent under section 16 of the ART Act or evidence that the donor has provided the relevant consent; 2. the person has sighted— 3. the donor's passport, driver licence or any other identification document displaying the donor's photograph and signature; or 4. a certified copy of the donor's passport, driver licence or any other identification document displaying the donor's photograph and signature; 5. the person has provided the receiving party with the following information about the donor— 6. the donor's unique donor identifier (if any); 7. the donor's full name; 8. any other name by which the donor is or has been known; 9. the donor's date of birth; 10. the donor's place of birth (suburb or town and country); 11. the donor's sex; 12. the donor's residential address; 13. the donor's phone number; 14. the date on which the donor produced the gametes; 15. the place at which the donor produced the gametes; 16. the donor's blood group; 17. any known genetic abnormality of the donor and, if available, any results of tests undertaken in relation to that abnormality; 18. the number of women who have given birth to children conceived using the donor's gametes or an embryo produced from the donor's gametes, including any current or former partner of the donor; 19. whether the donor has donated, or intends to donate, gametes or an embryo to any other registered ART provider or to a doctor and, if so— 20. the name and address of that registered ART provider; or 21. the full name and business address of that doctor; 22. if the person is a registered ART provider and the donor gametes were or the embryo produced from the donor's gametes was not produced at the premises of the registered ART provider, the person has provided the receiving party with the date on which the gametes were or the embryo was received by the person; 23. if the person is a registered ART provider, the person has provided the receiving party with the following information about the donor— 24. the date on which the person has sighted— 25. the donor's passport, driver licence or any other identification document displaying the donor's photograph and signature; or 26. (a certified copy of the donor's passport, driver licence or any other dentification document displaying the donor's photograph and signature; 27. the number of children born as a result of a treatment procedure carried out by the person using the donor's gametes or an embryo produced from the donor's gametes; 28. if the person is a doctor carrying out artificial insemination using the donor gametes, the person has provided the receiving party with the following information about the donor— 29. the date on which the donor gametes were received by the person; 30. the date on which the donor received counselling under section 18 of the Act and the name of the counsellor who provided the counselling; 31. the number of children born as a result of artificial insemination carried out by the person using the donor's gametes; 32. the person has received the name and contact details of the receiving party; 33. the person has provided written notice to the donor of the name and contact details of the receiving party; 34. the person has taken all reasonable steps to ensure that, at the time of certification, the limit imposed by section 29 of the ART Act in relation to the use of the gametes or embryo has not been reached. |
| **New Regulation 9E inserted**  **Prescribed form for a certification** | Prescribes the forms for a certification. The form for a person making a certification under section 36(3) of the amended ART Act to bring donor gametes or embryos produced from them into Victoria, is the form in Schedule 7 of the amended ART Regulations. The prescribed form for a person making a certification under section 36(4) of the amended ART Act to take donor gametes or embryos produced from them out of Victoria, is the form in Schedule 8 of the amended ART Regulations. |
| **New Regulation 9F inserted**  **Prescribed form for applying for an exemption under section 37 of the amended ART Act** | Provides that the prescribed form to apply for an exemption under section 37(1) of the amended ART Act is the form in Schedule 9 of the amended ART Regulations. Section 37 of the amended ART Act allows the Secretary to grant an exemption in specified circumstances, in relation to certain provisions of the Act relating to use of gametes and embryos, where donated gametes or embryos formed from donated gametes are moved into or out of Victoria. These exemptions could be granted by the regulator under the Act prior to 1 January 2025, on the same grounds, where approval have been granted by the regulator for movement of the gametes or embryos.  Regulation 9F also prescribes section 37E of the amended ART Act as a prescribed provision for the purposes of section 37(3)(c) of the amended ART Act. This effectively allows for the Secretary to grant exemptions from any prohibition established under new Regulation 9H of the Amended ART Regulations see below). |
| **New Regulation 9G inserted**  **Required record keeping for certification** | Prescribes detail for the purposes of section 37B(2) of the amended ART Act. Under amended ART Act section 37B(1) provides that a person must keep a written record of the matters certified and section 37B(2) provides that a person making a certification must keep prescribed records relating to the certification for a prescribed period. Failure to keep the prescribed records for the prescribed period is an offence.  The prescribed retention period is 25 years from the date of certification.  The prescribed records where person is bringing donated gametes or embryo produced from donor gametes into Victoria are:   1. a copy of the certification; 2. a copy of the donor's consent provided in accordance with section 36(3)(c) of the amended ART Act, or if an exemption has been granted in relation to section 32(2)(c) or (3) of the Act, evidence that any conditions to which the exemption is subject have been complied with; 3. evidence that the donor received counselling in accordance with section 36(3)(d) of the amended ART Act, or if an exemption has been granted in relation to section 18 of the amended ART Act, evidence that any conditions to which the exemption is subject have been complied with; 4. the name and contact details of the person transferring the donor gametes or embryo produced from donor gametes including the country in which the person transferring the donor gametes or embryo produced from the donor gametes is located; 5. the information given by the donor under section 36(3)(e) of the amended ART Act, or if an exemption has been granted in relation to section 19(a) of the amended ART Act, evidence that any conditions to which the exemption is subject have been complied with; 6. details of the donor gametes or embryo produced from donor gametes including— 7. the number of straws, vials or containers of donor sperm; and 8. the number of donor oocytes; and 9. the number of embryos produced from donor gametes; 10. details of the intended transport or movement of the donor gametes or embryo produced from donor gametes into Victoria at the time of certification, including the date and method of transportation or movement.   The prescribed records where person is taking donated gametes or embryo produced from donor gametes out of Victoria are:   1. a copy of the certification; 2. a copy of the donor's consent under section 16 of the Act or evidence that the donor has provided the relevant consent; 3. the name and contact details of the person receiving the donor gametes or embryo produced from donor gametes including the country in which the person receiving the donor gametes or embryo produced from the donor gametes is located; 4. details of the donor gametes or embryo produced from donor gametes including— 5. the number of straws, vials or containers of donor sperm; and 6. the number of donor oocytes; and 7. the number of embryos produced from donor gametes; 8. details of the intended transport or movement of the donor gametes or embryo produced from donor gametes from Victoria at the time of certification, including the date and method of transportation or movement. |
| **New Regulation 9H inserted**  **Prohibited location for importation** | Allows for a prohibition on brining in donor gametes, or embryos formed from them, from specified locations. The Secretary may, by notice in the Government Gazette, declare a country or geographic location to be a prohibited location if in the Secretary's opinion   1. there is ongoing armed conflict or political unrest in the country or geographic location; and 2. it is unlikely that requirements under the Act relating to consent or record-keeping requirements can be complied with because of the ongoing armed conflict or political unrest. |
| **New regulation 18A inserted**  **Prescribed form for a statement of reasons** | Provides that the prescribed form for a statement of reasons submitted by an applicant to the Central Register is at Schedule 10 of the amended ART Regulations. |
| **New regulation 19A inserted**  **Prescribed explanatory material - section 56(4) of the amended ART Act**  **To person who has applied for information from the Central Register** | Prescribes the explanatory material that the Donor Conception Registrar is required to provide under section 56(4) of the amended ART Act - that is, to a person who has applied for information from the Central Register. The person may be a person born as a result of a donor treatment procedure, a parent of a person born as a result of a donor treatment procedure, a person who is descended from a person born as a result of a donor treatment procedure, or a donor.  The prescribed explanatory material is as follows   * + 1. information about the requirements of Part 6 of the Act in relation to the disclosure of identifying information from the Central Register;     2. information about the lodgement of a contact preference by or on behalf of a person whose identifying information is to be disclosed, including any possible consequences for the applicant;     3. information about the requirements of Part 6 of the Act in relation to compliance with a contact preference lodged by a person whose identifying information is to be disclosed;     4. information about the issues which may arise if the applicant intends to contact a person whose identifying information is to be disclosed;     5. information about possible consequences for the applicant if the person whose identifying information is to be disclosed cannot be located or is deceased;     6. if the applicant is a donor, information about possible consequences for the person, whose identifying information is to be disclosed, only becoming aware that the person was born as a result of a donor treatment procedure, as a consequence of the application being made;     7. if the applicant is a parent of a person born as a result of a donor treatment procedure, information about—  1. advising the applicant's child of the child's donor origins; and 2. obtaining information from the Central Register; and 3. the significance to the applicant's child of a biological connection with the donor and the benefits of early disclosure and early connection with any donor siblings; and 4. how to support the applicant's child with the child's sense of identity; and 5. any safety or privacy issues for the applicant's child that may arise if contact is established with the donor; and 6. any issues that may arise if the applicant's child makes contact with donor siblings who are raised in different families;    * 1. if the person whose identifying information is to be disclosed is a donor, information about possible consequences of the donor becoming aware as a consequence of the application being made that a person was born as a result of a donor treatment procedure carried out using the donor's gametes;      2. information about any other adverse consequence of disclosing identifying information from the Central Register;      3. information about the possibility that an applicant's family may not agree with the applicant's plans in relation to making contact;      4. information about counselling services available to the applicant;      5. information about mental health support and intervention services that can provide crisis support and any other support services that might be relevant to the applicant;      6. information about the Donor Conception Registrar's reasons for providing the explanatory material to the applicant;      7. information about the benefits to the applicant of considering the explanatory material before the applicant proceeds with an application under section 56 of the Act;      8. information about how to approach discussions about genetic and medical issues and possible outcomes of those discussions;      9. if the applicant is a donor, information about the possibility that the applicant may be contacted to request information about the applicant's health and medical history, including any hereditary conditions. |
| **Regulation 20 substituted**  **Explanatory material - section 62(1) of the amended ART Act**  **Where Donor Conception Registrar must make all reasonable efforts to notify someone about whom they intend to disclose identifying information (individuals other than a pre-1998 donor or donor conceived person)** | Prescribes the explanatory material to be provided under section 62(1) of the amended ART Act. That is, where the Donor Conception Registrar must make all reasonable efforts to notify someone about whom they intend to disclose identifying information (this applies to individuals other than a pre-1998 donor or a person born as a result of a donor treatment procedure).  The prescribed explanatory material is as follows   1. information about the requirements of Part 6 of the Act in relation to the disclosure of identifying information from the Central Register; 2. information about possible consequences for the person whose identifying information is to be disclosed if that identifying information is disclosed from the Central Register; 3. information about the issues which may arise if the applicant intends to contact the person whose identifying information is to be disclosed; 4. information about mental health support and intervention services that can provide crisis support and any other support services that might be relevant to the person whose identifying information is to be disclosed; 5. information about counselling services available to the person whose identifying information is to be disclosed; 6. information about the issues which may arise for the person whose identifying information is to be disclosed if the person is contacted by another person following the disclosure of the person's identifying information from the Central Register; 7. information about the Donor Conception Registrar's reasons for providing the explanatory material to the person whose identifying information is to be disclosed; 8. information about the benefits to the person whose identifying information is to be disclosed of considering the explanatory material; 9. information about the possibility that the person whose identifying information is to be disclosed may be contacted to request information about the health and medical history of the person whose identifying information is to be disclosed, including any hereditary conditions. |
| **New Regulation 20A inserted**  **Explanatory material - section 62(4) of the amended ART Act**  **Where Donor Conception Registrar must make all reasonable efforts to notify someone of intention to disclose their identifying information from Central Register, (where individual is a donor conceived person or pre-1998 donor)** | Prescribes the explanatory material to be provided under section 62(4) of the amended ART Act. That is, where the Donor Conception Registrar must make all reasonable efforts to notify someone of an intention to disclose their identifying information from the Central Register, where the individual is a person born as a result of a donor treatment procedure or a pre-1998 donor, or if the person is a child, the person's parent or guardian.  The prescribed explanatory material is as follows:   1. information about how to lodge, withdraw and extend a contact preference; 2. information about how to comply with a contact preference; 3. information about possible consequences for the pre-1998 donor ,the person born as a result of a donor treatment procedure or, if the person born as a result of a donor treatment procedure is a child, the person's parent or guardian, if a contact preference is lodged; 4. information about possible consequences for the pre-1998 donor, the person born as a result of a donor treatment procedure or, if the person born as a result of a donor treatment procedure is a child, the person's parent or guardian, if a contact preference is not lodged; 5. information about the requirements of Part 6 of the Act in relation to the disclosure of identifying information from the Central Register; 6. information about mental health support and intervention services that can provide crisis support and any other support services that might be relevant to the pre-1998 donor, the person born as a result of a donor treatment procedure or, if the person born as a result of a donor treatment procedure is a child, the person's parent or guardian; 7. information about counselling services available to the pre-1998 donor, the person born as a result of a donor treatment procedure or, if the person born as a result of a donor treatment procedure is a child, the person's parent or guardian; 8. information about the possibility that the pre-1998 donor, the person born as a result of a donor treatment procedure or, if the person born as a result of a donor treatment procedure is a child, the person's parent or guardian, may be contacted by another person following the disclosure of identifying information from the Central Register and any issues that may arise from that contact; 9. information about the Donor Conception Registrar's reasons for providing the explanatory material to the pre-1998 donor, the person born as a result of a donor treatment procedure or, if the person born as a result of a donor treatment procedure is a child, the person's parent or guardian; 10. information about the benefits to the pre-1998 donor, the person born as a result of a donor treatment procedure or, if the person born as a result of a donor treatment procedure is a child, the person's parent or guardian of considering the explanatory material; 11. if the identifying information to be disclosed relates to a pre-1998 donor, information about the possibility that the pre-1998 donor may be contacted to request information about the pre-1998 donor's health and medical history, including any hereditary conditions; 12. if the identifying information to be disclosed relates to a person born as a result of a donor treatment procedure who is a child, information about— 13. advising the child of the child's donor origins; and 14. obtaining information from the Central Register; and 15. the significance to the child of a biological connection with the donor and the benefits of early disclosure and early connection with any donor siblings; and 16. how to support the child with the child's sense of identity; and 17. any safety or privacy issues that may arise for the child if contact is made with a donor; and 18. any issues that may arise for the child if contact is made with donor siblings who are raised in different families. |
| **New Regulation 20B inserted**  **Explanatory material - section 63A(3)(b) of the amended ART Act**  **To a donor where information has been received about the donor from an applicant to the Central Register** | Prescribes the explanatory material to be provided under section 63A(3)(b) of the amended ART Act – that is the Donor Conception Registrar must make all reasonable efforts to give this material to a pre-1998 donor where information has been received about the donor from an applicant to the Central Register.  The prescribed explanatory material is as follows:   1. information about how to lodge, withdraw and extend a contact preference; 2. information about how to comply with a contact preference; 3. information about possible consequences for the pre-1998 donor if a contact preference is lodged; 4. information about possible consequences for the pre-1998 donor if a contact preference is not lodged; 5. information about the requirements of Part 6 of the Act in relation to the disclosure of identifying information from the Central Register; 6. information about mental health support and intervention services that can provide crisis support and any other support services that might be relevant to the pre-1998 donor; 7. information about counselling services available to the pre-1998 donor; 8. information about the issues which may arise for the pre-1998 donor if the pre-1998 donor is contacted by another person following the disclosure of the pre-1998 donor's identifying information from the Central Register; 9. information about the Donor Conception Registrar's reasons for providing the explanatory material to the pre-1998 donor; 10. information about the benefits to the pre-1998 donor of considering the explanatory material; 11. information about the possibility that the pre-1998 donor may be contacted to request information about the pre-1998 donor's health and medical history, including any hereditary conditions. |
| **New Regulation 20C inserted**  **Explanatory material - section 63E(ab) of the amended ART Act**  **To an impacted applicant when a pre-1998 donor amends a contact preference** | Prescribes the explanatory material to be provided under section 63E(ab) of the amended ART Act – that the material that the Donor Conception Registrar must give to an impacted applicant to the Central Register when a pre-1998 donor amends a contact preference (material to be provided to an applicant to whom the contact preference relates). The prescribed explanatory material is as follows:   1. information about how to comply with an amended contact preference; 2. information about mental health support and intervention services that can provide crisis support and any other support services that might be relevant to the applicant; 3. information about counselling services available to the applicant; 4. information about the issues which may arise for the applicant if the applicant is contacted by another person following the disclosure of that person's identifying information from the Central Register; 5. information about the Donor Conception Registrar's reasons for providing the explanatory material to the applicant; 6. information about the benefits to the applicant of considering the explanatory material; 7. information about how to approach discussions about genetic and medical issues and possible outcomes of those discussions; 8. if the applicant is a parent or guardian of a child born as a result of a donor treatment procedure, information about— 9. advising the child of the child's donor origins; and 10. obtaining information from the Central Register; and 11. the significance to the child of a biological connection with the donor and the benefits of early disclosure and early connection with any donor siblings; and 12. how to support the child with the child's sense of identity; and 13. any safety or privacy issues that may arise for the child if contact is made with a donor; and 14. any issues that may arise for the child if contact is made with donor siblings who are raised in different families. |
| **Regulation 21 substituted**  **Explanatory material – section 63J(3) of the amended ART Act**  **To a donor conceived person or their parent or guardian before they amend a contact preference** | Prescribes the explanatory material to be provided under section 63J(3) of the amended ART Act – that is, the material to be provided to a donor conceived person or their parent or guardian before they amend a contact preference. The prescribed material is as follows:   1. information about how to lodge, withdraw and extend a contact preference; 2. information about how to comply with a contact preference; 3. information about possible consequences for the person born as a result of a donor treatment procedure or, if the person is a child, the person's parent or guardian if a contact preference is lodged; 4. information about possible consequences for the person born as a result of a donor treatment procedure or, if the person is a child, the person's parent or guardian if a contact preference is not lodged; 5. information about the requirements of Part 6 of the Act in relation to the disclosure of identifying information from the Central Register; 6. information about mental health support and intervention services that can provide crisis support and any other support services that might be relevant to the person born as a result of a donor treatment procedure or, if the person is a child, the person's parent or guardian; 7. information about counselling services available to the person born as a result of a donor treatment procedure or, if the person is a child, the person's parent or guardian; 8. information about the issues which may arise for the person born as a result of a donor treatment procedure or, if the person is a child, the person's parent or guardian if the person or the person's parent or guardian is contacted by another person following the disclosure of identifying information from the Central Register; 9. information about the Donor Conception Registrar's reasons for providing the explanatory material to the person born as a result of a donor treatment procedure or, if the person is a child, the person's parent or guardian; 10. information about the benefits to the person born as a result of a donor treatment procedure or, if the person is a child, the person's parent or guardian of considering the explanatory material; 11. information about how to approach discussions about genetic and medical issues and possible outcomes of those discussions; 12. if the person born as a result of a donor treatment procedure is a child, information about— 13. advising the child of the child's donor origins; and 14. obtaining information from the Central Register; and 15. the significance to the child of a biological connection with the donor and the benefits of early disclosure and early connection with any donor siblings; and 16. how to support the child with the child's sense of identity; and 17. any safety or privacy issues that may arise for the child if contact is made with a donor; and 18. any issues that may arise for the child if contact is made with any donor siblings who are raised in different families. |
| **New Regulation 21A inserted**  **Explanatory material – section 63M(3)(ab) of the amended ART Act**  **To an applicant impacted when a donor conceived person amends their contact preference (information to be provided to the applicant to whom the contact preference relates)** | Prescribes the explanatory material to be provided under section 63M(3)(ab) of the amended ART Act – that is, the material to be provided to an applicant to the Central Register who is impacted when a donor conceived person amends their contact preference (information to be provided to the applicant to whom the contact preference relates). The prescribed material is as follows:   1. information about how to comply with an amended contact preference; 2. information about mental health support and intervention services that can provide crisis support and any other support services that might be relevant to the applicant; 3. information about counselling services available to the applicant; 4. information about the issues which may arise if the applicant is contacted by another person following the disclosure of that person's identifying information from the Central Register; 5. information about the Donor Conception Registrar's reasons for providing the explanatory material to the applicant; 6. information about the benefits to the applicant of considering the explanatory material; 7. if the applicant is a donor, information about the possibility that the applicant may be contacted by another person to request information about the applicant's health and medical history, including any hereditary conditions. |
| **New regulation 22A inserted**  **Explanatory material – section 72(2)(b) of the amended ART Act**  **To a person about whom information may be disclosed from the Voluntary Register** | Prescribes the explanatory material to be provided under section 63M(3)(ab) of the amended ART Act – that is, the material to be provided to a person about information may be disclosed from the Voluntary Register. The prescribed information is as follows:   1. information about the requirements of Part 7 of the ART Act in relation to the disclosure of identifying information from the Voluntary Register; 2. information about possible consequences for the person whose name is entered in the Voluntary Register if information about that person is disclosed from the Voluntary Register; 3. information about mental health support and intervention services that can provide crisis support and any other support services that might be relevant to the person whose name is entered in the Voluntary Register; 4. information about counselling services available to the person whose name is entered in the Voluntary Register; 5. information about the issues which may arise for the person whose name is entered in the Voluntary Register if the person is contacted by another person following the disclosure of information from the Voluntary Register about the person whose name is entered in the Voluntary Register; 6. information about the Donor Conception Registrar's reasons for providing the explanatory material to the person whose name is entered in the Voluntary Register; 7. information about the benefits to the person whose name is entered in the Voluntary Register of considering the explanatory material; 8. information about how to approach discussions about genetic and medical issues and possible outcomes of those discussions; 9. if the person whose name is entered in the Voluntary Register is a donor, information about the possibility that the person whose name is entered in the Voluntary Register may be contacted to request information about the health and medical history of the person whose name is entered in the Voluntary Register, including any hereditary conditions 10. if the person whose name is entered in the Voluntary Register is a child, information about— 11. the significance to the child of a biological connection with the donor and the benefits of early disclosure and early connection with any donor siblings; and 12. how to support the child to learn about the child's genetic origins and the child's sense of identity; and 13. any safety or privacy issues that may arise for the child if contact is made with a donor; and 14. any issues that may arise for the child if contact is made with any donor siblings who are raised in different families. |
| **Schedule 2 substituted and new Schedule 2AA inserted** | This reflects the new regulation 8, which distinguishes between the prescribed form of consent required if a donation is made in Victoria (Schedule 2) or outside Victoria (Schedule 2AA). |
| **Information to be recorded in Register kept by registered ART provider** | This regulation is amended to require registered ART providers record the date of the certification given under section 36 of the Amended ART Act, to reflect the amendments made to that section (replacing pre-approval from the regulator with a certification to the regulator).  No other amendments have been made to Schedules 3, 4 and 5, which prescribe information to be kept on registers by registered ART providers and doctors carrying out artificial insemination for the purposes of sections 49, 49A and 50 of the Act. |
| **New Schedules 7 to 10 inserted** | These schedules set out the prescribed forms for the following   * + 1. Certification under section of the 36 amended ART Act -– to bring donor gametes or embryos produced from donor gametes into Victoria     2. Certification under section 36 of the amended ART Act - to take donor gametes or embryos produced from donor gametes from Victoria     3. Application for an exemption under section 37 of the amended ART Act     4. A statement of reasons for the purposes of applications for disclosure of information from the Central Register. (A person will be able to provide additional information in/along with their statement of reasons, should they wish to). |

|  |
| --- |
| To receive this document in another format [email the Department of Health’s Legislative and Regulatory Reform Team](mailto:email%20the%20Department%20of%20Health’s%20Legislative%20and%20Regulatory%20Reform%20Team) at <legandregreform@health.vic.gov.au>.  Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.  © State of Victoria, Australia, Department of Health, December 2024.  **ISBN** 978-1-76131-724-8 **(pdf/online)**  Available at on the Department of Health’s website at [Assisted Reproductive Treatment reform](https://www.health.vic.gov.au/patient-care/assisted-reproductive-treatment-reform) <https://www.health.vic.gov.au/patient-care/assisted-reproductive-treatment-reform> |

1. Provisional members of ANZICA, in order to be eligible for full membership, would be required to provide demonstrated evidence that they meet the comprehensive requirements including client contact hours, training, peer supervision and continuing provisional development, as set out in the ANZICA Membership requirements for upgrade from provisional to full membership. [↑](#footnote-ref-2)