



South Australian Government

RESPONSE TO THE  
INDEPENDENT REVIEW  
OF THE ASSISTED  
REPRODUCTIVE  
TREATMENT ACT 1988

Tabled 29 November 2017

# Introduction

The Government thanks Associate Professor Sonia Allan for her report and recommendations and the many people who contributed to the review findings through written submissions, face to face meetings and engagement with the reviewer.

The Government response is generally supportive of the recommendations of the independent review of the *Assisted Reproductive Treatment Act 1988* (ART Act). The matters addressed in the review are of importance to the Government and it recognises that further work is required to ensure the ART Act is properly operationalised. Government is aware of the need to fulfil its role in the regulatory framework for assisted reproductive treatment and the need to balance that against the regulatory burden on business. Work will commence immediately to ensure this is accomplished.

Some of the recommendations of the review will require additional funding or consultation to implement, particularly the recommendation for the establishment of a donor conception register. The Government is committed to undertaking further work in consultation with clinics and stakeholders to identify how these recommendations can be achieved. To reflect this position, the recommendations that require funding are supported in principle until further investigation has been undertaken.

NO.	RECOMMENDATION	GOVERNMENT RESPONSE
<b>OVERSIGHT OF A.R.T CLINICS</b>		
1	The Minister should seek relevant expert advice and evidence on a periodic basis to ensure that conditions of registration remain current and effective.	Support
2	The Minister should clarify the intention of section 5(2)(a) of the Act regarding health professionals providing assisted insemination who are ‘approved’ by the Minister. In particular the Minister should address the context to which section 5(2)(a) is intended to apply, and stipulate conditions that all such health professionals would be required to meet.	Not supported. The Government is of the view that the intention of section 5(2)(a) is clear. While health professionals are not required to be registered they are required to be approved by the Minister. The Act further provides that the Minister may impose conditions on any approvals. If, or when, a health professional seeks approval to provide assisted insemination, the Minister will impose the appropriate conditions on the approval.
3	Clinics should, in addition to current requirements under the Assisted Reproductive Treatment Act 1988, be required to provide to the Minister the Certification Body’s audit report and recommendation to RTAC for the granting of a licence, including any outline of non-conformance and corrective actions required. Auditing of clinics concerning how any non-conformance has been remedied should be conducted by the Minister.	Support
4	The Minister should establish an A.R.T. Advisory Council—whose role it is to: <ul style="list-style-type: none"> <li>a) Advise the Minister regarding medical, social, scientific, ethical, legal, and moral issues arising from A.R.T, and any necessary directives that need to be issued to clarify acceptable practice in South Australia;</li> <li>b) Monitor compliance with the Act, via receiving annual reports from clinics that include details of the RTAC audit and any recommendations for improvement, and any further reports necessary to inform the Council of action that has been taken in response;</li> <li>c) Consider the results of any inspection or audit undertaken by a suitably qualified person appointed by the Minister, and make recommendations</li> </ul>	Support in principle. Further consideration is also required to determine the most efficient means of implementing the recommendation; the most appropriate membership to form the Council; and the functions of the Council.

	<p>(when necessary) concerning appropriate action to be taken by the Minister;</p> <p>d) Promote and engage in public education and forums concerning A.R.T; promote research, and provide the Minister with information regarding any research that may inform regulation and governance of A.R.T;</p> <p>e) Report annually on the above, as well as upon outcomes of A.R.T. in South Australia, and any other matters decided by the Minister.</p> <p>The Council should include at least one A.R.T. health professional, consumer representatives (for example a donor of gametes, and a recipient of A.R.T.), religious leader representatives, a person born as a result of A.R.T., a person born as the result of donor-conception, a person with legal expertise in A.R.T. and health law, a person with expertise in ethics, a person with relevant expertise in counselling, and a scientific expert(s).</p>	
<b>5</b>	The Minister should ensure that the A.R.T. Advisory Council is supported in its functions by an appropriate Department for Health and Ageing staff member (or members) as required, who in addition undertake functions relevant to the implementation, oversight, monitoring, and enforcement of the Act.	Support in principle.
<b>6</b>	<p>To ensure effective operation of the Act, and that the functions of the A.R.T. Advisory Council may be realised, the Minister should:</p> <p>(1) act upon regulation 8(2)(b) to make it a condition of registration that A.R.T. providers supply an annual report to the Council that includes details of the RTAC audit and any recommendations for improvement, as well as any further reports necessary to inform the Council of action that has been taken in response.</p> <p>(2) Make it a condition of registration that clinics: a) may be subject to auditing by a suitably qualified person appointed by the Minister from time to time for the purposes of ensuring compliance with the requirements of the Act; b) must adhere to directives issued by the Minister;</p> <p>(3) Appoint a suitably qualified person to audit and/or inspect providers of A.R.T. from time to time, for the purposes of ensuring compliance with the requirements under the Act.</p> <p>(4) Issue directives relevant to the practice of A.R.T. in South Australia as the need arises, and/or as advised by the Council.</p>	Support in principle.
<b>7</b>	The Minister should ensure provision in the Act for review of its operation and effectiveness five years after the date of the report from the last review being tabled	Support

	in Parliament.	
<b>PARAMOUNTCY OF THE WELFARE OF THE CHILD</b>		
<b>8</b>	The Minister should conduct audits of clinics from time to time to establish the circumstances in which pre-implantation genetic diagnosis (PGD) has been used, and adherence to the law, conditions of registration, and relevant ethical guidelines.	Support
<b>9</b>	In the interest of upholding the welfare of the child born as a result of A.R.T. as paramount, the Minister should maintain prohibitions on sex selection for social purposes. A statement to this effect should be included in the conditions for registration, or via a directive.	Support
<b>10 (1)</b>	The Minister should provide a directive on requirements pertaining to screening of donors of gametes and/or embryos for heritable disease, disorder or illness; and	Support in principle. Clinics currently have policies and procedures in place to ensure screening for infectious diseases and heritable diseases. Further consideration is required to determine the risk profile of consumers to determine whether the Minister should issue a directive or equivalent.  The Government is of the view that the National Health and Medical Research Council (NHMRC) <i>Ethical guidelines on the use of assisted reproductive technology in clinical practice and research</i> is currently sufficient in providing requirements pertaining to pre-implantation genetic screening of embryos. However the Minister will issue directives or equivalent if necessary.
<b>10 (2)</b>	Disclosure to genetic relatives when such a disease, disorder, or illness is discovered by a donor/donor-conceived person that may pose a threat to the life, health, or safety of a related person—including requirements and processes concerning: a. updating the clinic, and/or donor conception register of health status; b. notification to the person at risk;	Support The National Health and Medical Research Council (NHMRC) <i>Ethical guidelines on the use of assisted reproductive technology in clinical practice and research</i> currently provides some guidance to clinics, donors and recipients relevant to this recommendation however the Minister will issue

	c. provision by the clinic to the person at risk of appropriate support services (such as genetic counselling).	directives or equivalent to clarify responsibilities around disclosure to genetic relatives of disease, disorder or illness.
<b>11</b>	<p>The Minister should develop a directive that provides for a clear and consistent risk assessment framework and process to be used by clinicians/health professionals when assessing applicants and their partners (if any) in relation to any risk they may pose to a child born as a result of providing A.R.T. Such a directive should:</p> <ol style="list-style-type: none"> <li>1) Include criteria to be considered;</li> <li>2) Outline the process to be followed;</li> <li>3) Provide for referral to, and consultation with, external experts, authorities, agencies, and/or support services;</li> <li>4) Make it an offence for applicants to provide false information in relation to the assessment;</li> <li>5) Allow for criminal record, ANCOR and/or child protection order checks in individual cases that raise significant concern; and</li> <li>6) Require information to be given to applicants regarding avenues available to them for judicial review (as appropriate).</li> </ol> <p>A form should also be developed that all providers of treatment must use on which the outcomes of the assessment must be recorded, that may be audited by the Minister from time to time.</p>	<p>Support in principle. The Government agrees with the development of a risk assessment framework but further consideration is required to determine the most effective model.</p>
<b>12</b>	The A.R.T. Advisory Council should consider whether donors of gametes and embryos should be screened in relation to prior criminal history; and the scope, and limits, of the paramountcy of the welfare of the child principle.	<p>Support in principle. In principle support is provided to the Advisory Council considering this matter however this will rely on the implementation of recommendation 4. Consideration will be given to whether a criminal history check will form part of the risk assessment framework under recommendation 11.</p>
<b>13</b>	The Minister should re-establish the promotion of research, and reporting on research and the outcomes of A.R.T. practices, as a required function of the recommended A.R.T. Advisory Council under the Assisted Reproductive Treatment Act 1988 (SA).	<p>Support in principle. This will rely on the implementation of recommendation 4. It will also depend on considerations about the functions of the Council.</p>

14	The Minister should, pursuant to sections 9 and 20 of the Assisted Reproductive Treatment Act 1988, issue regulations, conditions of registration, or directives from time-to-time, informed by research on the short and long term outcomes for people born as a result of A.R.T., that may set the bounds of A.R.T. practice necessary to uphold the principle of the paramountcy of the welfare of the child.	Support in principle.
15	The Minister should consider and act upon the government's ability (if any) to fund and/or support independent research that may contribute to ensuring the health, welfare and safety of children who are born as a result of A.R.T. and donor conception.	Support in principle This will rely on the implementation of recommendation 4. Subject to considerations about the functions of the Council, part of its role may be to consider which areas of A.R.T. are most likely to benefit from research activity.
16	The Minister should amend the statement of principle concerning the paramountcy of the welfare of the child within the Assisted Reproductive Treatment Act 1988 (SA) to include the wording that both the health and welfare of the child born as a result of A.R.T. is paramount.	Support
<b>ESTABLISHMENT OF THE DONOR CONCEPTION REGISTER</b>		
17	The Minister should exercise his powers under section 15 of the Assisted Reproductive Treatment Act 1988 (SA) to establish the donor conception register as a matter of priority.	Support in principle. Establishment of the donor conception register is subject to further investigation into funding options.
18	The Minister should amend section 15 of the Assisted Reproductive Treatment Act 1988 (SA) to state that the Minister must establish the donor conception register – to ensure that the register is maintained into the future.	Support in principle.
19	The Minister should amend section 15(8) of the Assisted Reproductive Treatment Act 1988 to apply to A.R.T. provided both before and after the commencement of section 15 of the Act.	Support in principle.
20	The Minister should, subsequent to amending section 15(8), act pursuant to section 15(6) of the Assisted Reproductive Treatment Act 1988 to provide notice in writing requiring all record(s) held by any person, establishment, organisation, A.R.T. clinic	Support in principle. The relevant data from donor conception records will be required for the donor conception register.

	or otherwise, that relate to A.R.T. and/or donor-conception in South Australia, including (but not limited to) Queen Elizabeth Hospital and Adelaide University/ACN, Repromed, and Flinders Fertility to be transferred to the donor conception register as a matter of priority.	Transfer of the records will only be necessary where the information could not be directly entered into the register by the persons responsible for the records.
21	The Minister should pass legislation prohibiting the destruction of any record that relates to donor conception, and the donation of gametes and/or embryos, as a matter of priority.	Support
22	Access to identifying information by donor-conceived people about donors who donated prior to the requirements for consent to release of such information in South Australia, should be permitted pursuant to regulations (promulgated under section 15(4) of the <i>Assisted Reproductive Treatment Act 1988</i> ) that establish a contact veto/preference system. Such a system should include a careful process that is supportive and respectful of all parties.	Support in principle.
<b>FURTHER MATTERS RELATING TO THE DONOR CONCEPTION REGISTER AND ACCESS TO INFORMATION</b>		
23	The Minister should develop laws and undertake any other measures necessary to enable the donor conception register to be held at the South Australian Attorney General's Department, Births, Deaths, and Marriages (BDM), allowing for recording of all data alongside all other records held on the birth register and access to information concerning a person's birth, biological and legal parentage, to occur in one location.	Support in principle.
24	As part of the establishment of the donor conception register at BDM, the Minister should engage an agency to provide intermediary and support services, and take whatever measures necessary (in law or otherwise) to ensure that the agency be given 'trusted agency' status in relation to all donor conception records.	Support in principle.
25	The Minister should pass regulations that provide that intermediary and support services should be provided on a needs basis, and should not be mandated except as required in relation to intermediary services concerning retrospective access to identifying information; contact vetoes/preferences; and information exchange between recipients and donors concerning people under 18 years of age.	Support in principle.

26	<p>The Minister should issue a directive that clinics must actively notify a donor of gametes or embryos of the birth of a child(ren) that have resulted from the donation, including the number, age and sex of children born; and the number of recipient families that have been formed as a result of the use of the donor's gametes or embryo(s).</p>	<p>Support in principle. Further consideration needs to be given to how notification of donor conception births will be integrated with recommendation 17 to establish and maintain the donor conception register and the role of the register.</p>
27	<p>The Minister should provide in the regulations regarding inspection of the donor conception register that:</p> <ol style="list-style-type: none"> <li>(1) donors are able to contact the donor conception register to access non-identifying information about number, age, and sex of children born as a result of their donation, and the number of recipient families;</li> <li>(2) recipients of donated gametes/embryos with children under the age of 18, and donor-conceived people over the age of 18 or of sufficient maturity, should be able to register their consent on the donor conception register to the release of identifying information.</li> <li>(3) that when a donor requests identifying information about donor-conceived offspring that release of such information can occur only with the registered consent of recipient parents (when the child is under 18) or the donor-conceived person if over 18 or of sufficient maturity.</li> <li>(4) when consent has not been given a donor should be referred to the agency providing intermediary and support services, who may provide support services as required.</li> </ol>	<p>Support in principle.</p>
28	<p>The Minister should provide in the regulations regarding inspection of the donor conception register that:</p> <ol style="list-style-type: none"> <li>(1) Recipient families of donor-conceived children under the age of 18, and donor-conceived people of age 18 or sufficient maturity are able to: <ol style="list-style-type: none"> <li>a) contact the donor conception register to access non-identifying information about number, age, and sex of children born to a common donor, and the number of recipient families (including the donor's own family if any);</li> <li>b) register their consent on the donor conception register to the release of identifying information to siblings.</li> </ol> </li> </ol>	<p>Support in principle.</p>

	<p>(2) When a recipient family of a child under 18, or donor-conceived person over the age of 18 or sufficient maturity requests identifying information about siblings that share a common donor, release of such information can occur only with the registered consent regarding a sibling who is under the age of 18.</p> <p>(3) When consent has not been registered, the requesting party should be referred to the agency providing intermediary and support services, who will determine whether it would be appropriate to contact the parent(s) or sibling(s) to seek such consent.</p> <p>(4) All cases should be made aware of the presence of support services available to them if required.</p>	
<b>29</b>	The Minister in drafting regulations regarding inspection of the register, should provide that voluntary registration by past donors of gametes/embryos and donor-conceived people onto the donor conception register should be possible, subject to any requirements of BDM for confirmation of status.	Support in principle.
<b>30</b>	The Minister should pass regulations pursuant to section 15(2)(d) of the Act to require the recording of comprehensive identifying and non-identifying information regarding the donor on the donor conception register. This is especially important to ensure consistency across clinics, and to ensure the recording of meaningful information about a person's genetic heritage.	Support in principle.
<b>31</b>	<p>To ensure recipient parents of donated gametes or embryos are given information and support regarding the significance of biological connection to genetic parents and siblings, and how to discuss donor-conception with their children, within the context of the recommendations made in this report:</p> <p>(1) BDM and the support services should publicise the donor conception register and how it works;</p> <p>(2) The A.R.T. Advisory Council should exercise its functions to promote and engage in public education and forums via producing information brochures and/or running a yearly 'Time to Tell' seminar;</p> <p>(3) Auditing of clinics from time-to-time should include consideration of what clinics have done to uphold their obligations under the NHMRC Ethical Guidelines and the Act.</p>	<p>Support in principle.</p> <p>Further consideration is required to determine how the donor conception register should be publicised and the role of the Council/BDM/SA Health in this.</p>
<b>32</b>	The Minister should amend the law to require an addendum to a donor-conceived	Support

	person's birth certificate that will notify them at age 18 when they apply for their birth certificate of more information being held on the donor conception register about them.	
<b>33</b>	Provision should be made to maintain recent amendments to section 46 of the Births, Deaths and Marriages Registration Act 1996 (SA), for voluntary inclusion of the name of any biological parent(s) on a second birth certificate of a donor-conceived person at their request, or the request of their legal parent(s) if the donor-conceived person is under the age of 18. The provision should be strengthened to apply to births that occurred before and after the commencement of the section. The option for issuance of a second birth certificate should be available to all donor-conceived people once they turn 18 whether a 'known' donor or clinic based donor was used.	Support
<b>34</b>	Section 14 amendments to the Births Deaths and Marriages Act 1996 that require recording of information on the birth registration statement about 'known' donors should remain.	Support
<b>35</b>	The Minister should include in any changes to the law and/or regulations provision to allow known donors from arrangements outside of clinics to be recorded on the donor conception register, for the addendum to be placed on the resulting child's birth certificate, and for the option of the known donor's name to be placed on a second birth certificate, as per all donor conception arrangements, subject to meeting any BDM requirements.	Support in principle.
<b>36</b>	The Minister should provide (via law/regulations/directive as necessary) for a presumption of legal parentage when an alleged 'known' donor and recipient have been in a prior relationship with each other that resulted in them having a child/ren together for whom the alleged 'donor' is considered the legal parent.	Supported in principle. Further consideration is needed to determine the best way to implement the recommendation.
<b>37</b>	An ongoing levy or yearly fee paid by registered clinics and A.R.T. providers should be established to support the ongoing maintenance and operation of the donor conception register, and provision of intermediary and support services. The Minister should pass any laws or regulations and/or take any other actions necessary to make this possible.	Support in principle.

38	Responsibility for the costs related to the transfer of past records to the donor conception register should be borne by any person, establishment, organisation, A.R.T. clinic or otherwise, that currently holds records that relate to donor-conception in South Australia, unless special dispensation or agreement as to costs is granted by the Minister.	Support
39	The Minister should pass regulations that require clinics to record information at the time of 1) donation (on the donor's record), 2) treatment, including whether a pregnancy has occurred and expected date of delivery (on the donor's and recipient's records), and 3) birth (on the donor's, recipients, and donor-conceived person's record). Such information should be regularly reported to the Minister, as well as relevant information being entered into the donor conception register.	Support
40	The Minister should require, and monitor, adherence to the RTAC technical bulletin 8 concerning counselling, agreement, and reporting on matters related to the use of donor sperm, eggs, or embryos.	Support
<b>ACCESS TO A.R.T.</b>		
41	The Minister should amend section 9 of the Assisted Reproductive Treatment Act 1988 (SA) to provide that a person can access A.R.T. if, in the person's circumstances, they are unlikely to become pregnant other than by an A.R.T. procedure; and include the guiding principle that people seeking to undergo such procedures must not be discriminated against on the basis of their sexual orientation, marital status or religion.	Supported and implemented. Section 9 was amended by the <i>Statutes Amendment (Surrogacy Eligibility) Act 2017</i>
42	The Minister should act to clarify the law regarding the posthumous collection, use and/or transport of gametes to another state when there has not been written consent.	Not supported. The Government is of the view that the Act is sufficiently clear on posthumous use of gametes for A.R.T. Retrieval is permitted only by prior consent or by order of the Supreme Court. The question of retrieval of gametes after a person has died is a tragic, rare, and unusual event. The Government is of the view that it is appropriate that the Supreme

		Court may make an order for the removal of sperm from an unconscious/dead patient where consent has not been explicitly given. The Court is the appropriate place to consider the complex ethical and legal matters associated with such a request.
43	The Minister should seek further evidence and advice from the A.R.T. Advisory Council concerning health factors that may compromise A.R.T., pregnancy and birth outcomes, and increase maternal risk, including but not limited to factors related to Body Mass Index, as well as smoking. Based on such advice the Minister should issue directives, if deemed necessary, so that consistency of practice regarding access to treatment and information in such circumstances occurs in South Australia. The A.R.T. Advisory Council may also assist to encourage public discussion and information regarding effects of such things upon fertility, maternal risks, and pregnancy and birth outcomes.	Support in principle. The Government is of the view that assisted reproductive treatment providers are best placed to use their expertise and discretion in making clinical decisions. If areas of risk, or inconsistent practice are identified the Minister will issue directives if necessary. The role of the Council will depend on considerations about the functions of the Council detailed in response to recommendation 4.
44	The Minister should clarify the age limit requirement currently contained in the conditions for registration for the <i>Assisted Reproductive Treatment Act 1988</i> (SA).	Support
45	Consideration of the order in which patients are subjected to certain inquiry and/or treatments should be had by the recommended A.R.T. Advisory Council, and advice as to whether there should be any directives on the matter is required.	Support in principle. The Government is of the view that assisted reproductive treatment providers are best placed to use their expertise and discretion in making clinical decisions however if areas of risk are identified the Minister will issue directives if necessary. This will rely on the implementation of recommendation 4. The role of the Council will depend on considerations about the functions of the Council detailed in response to recommendation 4.
<b>RECORD KEEPING</b>		
46	The Minister should issue regulations pursuant to section 16 of the Assisted Reproductive Treatment Act 1988 (SA) concerning requirements for record keeping	Support

	and documents in relation to the provision of A.R.T. and donor-conception, the length of required preservation of records, ongoing obligations concerning records should a clinic close, and responsibilities concerning records when a clinic changes hands.	
<b>47</b>	Further to recommendations 4 and 6, the Minister should establish a system of auditing and required reporting that includes (but not limited to) reporting of data supplied to ANZARD, which may inform reflection upon clinical practice of A.R.T. and its outcomes and, regulatory responses and policy development	Support