

Introduction to the Review



REGULATION OF ASSISTED REPRODUCTIVE TREATMENT IN SOUTH AUSTRALIA

Introduction to the Review

On 1 September 2010, the regulation of assisted reproductive treatment (A.R.T.) in South Australia underwent significant changes. Parliament passed the Reproductive Technology (Clinical Practices) (Miscellaneous) Amendment Bill 2009 to amend the *Reproductive Technology (Clinical Practices) Act 1988 (SA)*. Details of what the law is now, and what it was prior to the changes are set out on the following pages of this fact sheet.

The Review

The law provides that the changes to the Act must be reviewed five years after the date of enactment. The time for review is now due. The Minister for Health has appointed Associate Professor Sonia Allan, an expert in the regulation of assisted reproductive technologies and donor conception, to conduct the review as an independent consultant to government.

The review will focus upon the operation and effectiveness of the Act in relation to:

- > the requirement that the welfare of any child born as a consequence of assisted reproductive treatment (A.R.T.) is to be treated as being of paramount importance, and accepted as a fundamental principle, in respect of the operation of the Act, as well as in the provision of assisted reproductive treatment;
- > the replacement of the previous licensing scheme with a registration scheme for A.R.T. clinics;
- > the dissolution of the SA Council on Reproductive Technology and its Code of Ethical Clinical Practice;
- > amending eligibility for access to A.R.T. services—noting that such conditions relate to the circumstances in which, and to whom, A.R.T. may be provided;
- > allowing for the establishment of a donor conception register; and
- > provisions for record keeping and confidentiality.

The review will include examination of research and practice, and invite public submissions relevant to the above matters. It will lead to a report, which will include recommendations regarding the regulation of A.R.T. in South Australia. The report will be tabled in Parliament and made publically available. The recommendations will be considered by the Minister.

The Law prior to 2010

A.R.T. was previously governed in South Australia by *the Reproductive Technology (Clinical Practices) Act 1988 (SA)* and *The Reproductive Technology (Code for Ethical Clinical Practice) Regulations 1995*.

The Act established the South Australian Council on Reproductive Technology (SACRT) whose functions were to:

- > formulate a code of ethical practice to govern artificial fertilisation procedures;
- > provide advice to the Minister on conditions, licenses, and issues relating to reproductive technology;
- > promote research and understanding of the causes of human infertility and ethical and social issues arising from reproductive technology;
- > provide annual reports to the Minister for Health.

The Act and SACRT's Code of Ethical Clinical Practice (which formed the Regulations) provided detailed information about requirements for assisted reproductive treatment in South Australia, including licence provisions, conditions for access to treatment, record keeping and confidentiality provisions.

The 2010 changes

In 2010 the legislation governing A.R.T. in South Australia became known as the *Assisted Reproductive Treatment Act 1988 (SA)*. The oversight and functions of the SACRT were repealed (see Fact Sheet 4). The 2010 changes moved to a framework style of regulation, in which A.R.T. providers are registered by the Minister subject to meeting certain conditions, and otherwise are required to comply with the national self-regulatory accreditation scheme of the Reproductive Technology Accreditation Committee (RTAC), and to adhere to the National Health and Medical Research Council *Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2004 (revised 2007)* (NHMRC Guidelines). RTAC is a committee of the Fertility Society of Australia, the peak body representing all health professionals working in the fertility sector. The NHMRC Guidelines are made and amended at the national level. (See further Fact Sheets 3 and 4).

The 2010 changes also: strengthened the paramountcy of the welfare of a child born from A.R.T. (see Fact Sheet 2); amended the eligibility criteria for accessing A.R.T. treatment (see Fact Sheet 5); provided for a donor conception register (see Fact Sheet 6); and amended record keeping and confidentiality provisions (see Fact Sheet 7).

Please see the Table on the following page for a further summary of the 2010 changes to the regulation of assisted reproductive treatment in South Australia.

Ethics Health Advisory Council

At the time of the amendments it was anticipated that the Ethics Health Advisory Council (EHAC) would provide advice to the Minister on health related ethical issues, including A.R.T.

The current review of the *Assisted Reproductive Treatment Act 1988 (SA)* will include consultation with the EHAC, and with members of the public, about how the EHAC has operated since 2010 in relation to A.R.T.

Other Relevant Legislation

Other legislation relevant to assisted reproductive treatment in South Australia includes the:

- > *Family Relationships Act 1975*, which refers to surrogacy and parenting;
- > *Births, Deaths and Marriages Registration Act 1996*, which provides for registration of births;
- > *Research Involving Human Embryos Act 2002*, which deals with the use of excess A.R.T. embryos.

While these Acts are relevant to A.R.T. in South Australia, they are not the subject of this review. The review does not cover issues related to surrogacy, research involving human embryos or cloning.

Summary Of Changes Relevant To This Review

	Pre-2010	Post- 2010
Relevant South Australian Law	<ul style="list-style-type: none"> > <i>The Reproductive Technology (Clinical Practices) Act 1988</i> > <i>The Reproductive Technology (Code for Ethical Clinical Practice) Regulations 1995</i> 	<ul style="list-style-type: none"> > The Act was renamed the <i>Assisted Reproductive Treatment Act 1988 (SA)</i> > The Code was repealed, and replaced with <i>Assisted Reproductive Treatment Regulations 2010</i>
Licensing/ Registration	<ul style="list-style-type: none"> > Licensing system (That new licenses were only granted if there was an unmet social need not met by existing licensees was seen as anti-competitive) 	<ul style="list-style-type: none"> > Registration Scheme – Clinics register with Minister pursuant to meeting RTAC accreditation, and conditions stipulated in Act and regulations
Oversight	<ul style="list-style-type: none"> > Reproductive Technology Accreditation Committee (RTAC) (via self-regulatory accreditation scheme) > SACRT > Minister 	<ul style="list-style-type: none"> > RTAC (via self-regulatory accreditation scheme) > SACRT dissolved > Minister
Ethical Guidance	<ul style="list-style-type: none"> > SACRT > <i>The Reproductive Technology (Code for Ethical Clinical Practice) Regulations 1995</i> > NHMRC Guidelines > 	<ul style="list-style-type: none"> > SACRT dissolved > SA Code of Ethical Clinical Practice Repealed > NHMRC Guidelines > Ethics Health Advisory Council (mentioned by Parliament, but not in legislation/regulations)
Welfare of the Child	<ul style="list-style-type: none"> > Welfare of the child prescribed as a guiding principle in the provision of A.R.T. 	<ul style="list-style-type: none"> > Welfare of the child provision retained, and strengthened: requiring the welfare of the child born as a result of the use of A.R.T. be considered as paramount and of fundamental importance in the application of the Act and in the provision of assisted reproductive treatment
Access to A.R.T.	<ul style="list-style-type: none"> > Marital requirement (declared void in 1996 in <i>Pearce v South Australian Health Commission</i> (1996) 66 SASR 486) > Infertility > Risk of passing on genetic disease > Counselling requirements in Code (focus on children, outcomes and need for information) > ‘Screening’ - No treatment if prior offences or removal of children; illness that would impact ability to care for children > Stored embryos to be destroyed if husband or wife dies, dissolve their marriage, or revoke consent > Welfare of the child principle > Appeal and review process for access to treatment decisions 	<ul style="list-style-type: none"> > Removed marital requirement > Infertility > Risk of passing on genetic disease > Risk of passing on serious illness > Risk of future infertility of recipients > Post-humous use of sperm permitted (if conditions are met) > A.R.T. not to be provided to woman of greater than or equal to the average age of menopause > Donated gametes must be destroyed after 15 years > Counselling provisions removed (some covered in NHMRC Guidelines). > No ‘screening’ criteria included > Welfare of the child principle > Removed appeal and review processes
Information	<ul style="list-style-type: none"> > Detailed requirements for information recording about recipients and donors > Provisions regarding access to records by recipients > Access to non-identifying information about recipients, and number and sex of children (if any), by donor > Recipients required to be counselled about importance of disclosing to donor-conceived children about their status, and children’s entitlement to non-identifying information about their donors (identifying with consent) > Provision of information to third-parties (e.g. a register) impeded by confidentiality provisions 	<ul style="list-style-type: none"> > Disclosing identifying information dependent upon consent > Provision that Minister may establish a donor register > If register is established provision that <ul style="list-style-type: none"> - enables transfer of data to the register (removing confidentiality impediment) - requires information to be recorded about donors/recipients/ child (without a register, record keeping requirements default to the NHMRC Guidelines)
Record Keeping	<ul style="list-style-type: none"> > Requirements regarding record keeping > Documents and records to be kept for 50 years. > Limited protections for patients’ and donors’ records when clinics were closed or a licence cancelled. 	<ul style="list-style-type: none"> > Section 16 allows regulations to set procedures to ensure records are safely and appropriately stored, transferred and/or destroyed when clinics or other providers of A.R.T. cease to practice. > Conditions of registration require provision be made for transfer or destruction of records should registrant cease to provide A.R.T.
Reporting	<ul style="list-style-type: none"> > Annual reporting by clinics to SACRT required > Annual report by SACRT to the Minister 	<ul style="list-style-type: none"> > Parliament expressed intention to require clinics to provide copies of annual national data reports to Minister, to be further detailed in the regulations. (Not currently operationalised)



Introduction to the Review Fact Sheet 1

Review of the
*Assisted Reproductive
Treatment Act
1988 (SA)*

We Invite You To Make a Submission



Complete the online submission form on the [YourSA](#) website to provide your views in relation to the issues under review.

Email a submission to Associate Professor Sonia Allan at HealthPolicyLegislation@sa.gov.au with subject heading 'A.R.T. Act Review'



Post a submission to

A/Professor Sonia Allan
A.R.T. Act Review,
C/- Policy and Intergovernment Relations Unit,
SA Health, PO Box 287, Rundle Mall,
ADELAIDE SA 5000



Join the discussion on the [YourSA](#) website.

Please note that all submissions are public unless marked 'confidential'. Public submissions will be posted on the [YourSA](#) website, and the author may be cited in the final report. Authors of 'confidential' submissions will not be referred to by name. We cannot accept anonymous submissions.

Submissions close on Friday 15 April 2016.

More Information

For general information on topics relevant to the review of the *Assisted Reproductive Treatment Act 1988 (SA)* see the following Fact Sheets:

[Fact Sheet 1: Introduction to the Review](#)

[Fact Sheet 2: Paramourncy of the Welfare of the Child](#)

[Fact Sheet 3: Registration Scheme for A.R.T. Clinics](#)

[Fact Sheet 4: Dissolution of SA Council on Reproductive Technology, and its Code of Ethical Clinical Practice](#)

[Fact Sheet 5: Access to Assisted Reproductive Treatment](#)

[Fact Sheet 6: Establishment of a Donor Register](#)

[Fact Sheet 7: Record Keeping and Confidentiality](#)

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Prepared by Associate Professor Sonia Allan, for the *Assisted Reproductive Treatment Act 1988 (SA)* review, January 2016.

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