

Record Keeping and Confidentiality Provisions



ASSISTED REPRODUCTIVE TREATMENT: RECORD KEEPING AND CONFIDENTIALITY

Regulation of Assisted Reproductive Treatment in South Australia

In South Australia, the *Assisted Reproductive Treatment Act 1988* and *Assisted Reproductive Treatment Regulations 2010* provide for the regulation and oversight of assisted reproduction by the Minister for Health. The current provisions of the Act and regulations came into effect in 2010.

This Fact Sheet provides brief information on the previous legislation's provisions regarding

- 1) record keeping, and
- 2) confidentiality.

It also provides insight into the changes that occurred in relation to such provisions in 2010. There is also brief discussion of the reasons given for such changes, and of what has happened since.

Record Keeping

Record keeping in relation to assisted reproductive treatment (A.R.T.) is very important. Records may provide information about the types of treatment applied, and the treatment outcomes—for example, the number of cycles of treatment a person undergoes, and whether there is a successful pregnancy and subsequent birth of a healthy child.

Such treatment may involve the use of reproductive materials of the recipient woman, her partner, and/or of donor(s) of gametes (egg or sperm) or embryos. Records about donor-conception including information about the donor(s) of reproductive materials are therefore also important. A child born as a result of A.R.T. that has involved donor-conception and/or surrogacy, may require access to information about all those involved in their conception and birth.

Records may also be important for research on longer term health outcomes for children born as a result of A.R.T.; and health outcomes for recipients and donors.

Records about A.R.T. and its outcomes may also enable consideration of how much personal, and public (eg. via Medicare), expenditure is involved in relation to such treatment and its outcomes. Such information in turn may assist people who wish to access A.R.T. services to decide whether to proceed with such treatment, and/or which clinic they prefer to use. It may also assist in deciding how much funding in the future should be directed toward A.R.T.

Record Keeping – Previous Regulations

Prior to the 2010 changes the South Australian Council on Reproductive Technology (SACRT)'s Code of Ethical Clinical Practice set out strong record keeping requirements relating to recipients of assisted reproductive treatment; donors of reproductive material; clinical standards and procedures. These were removed by the 2010 changes as the Code was repealed. (See Fact Sheet 4 for more information about SACRT and the Code of Ethical Clinical Practice).

Record Keeping – Current Regulations

The current law allows for record keeping conditions to be required of registered providers of A.R.T.

Section 16 of the Act now provides that a person who is registered under the Act to provide A.R.T., or a health professional approved under the Act to provide assisted insemination, must make such records, and keep such documents, as may be required by the regulations in relation to the provision of A.R.T./assisted insemination.

A person who is required to make a record or keep a document under section 16 must retain the record or document in accordance with any requirement set out in the regulations.

There is a maximum penalty of \$50,000 for not doing so.

However, there are currently no regulations regarding the making of records or keeping of documents.

Confidentiality – Prior Legislative Provisions

Provisions regarding confidentiality in the legislation that existed prior to 2010 restricted the provision of information by clinics to a third party – such restrictions would have applied, for example, in the case of a donor conception register or Births, Deaths and Marriages making a request for such information. That is, the release of information to such registers may have been impeded.

Confidentiality – Current Provisions

In the early 2000s, expectations had been raised about a national donor register, or the setting up of a local South Australian register. As such, the changes to the legislation in 2010 were intended by Parliament to remove any impediments to the release of information to a register and to allow South Australia to participate in a donor registration program approved by the Minister for Health.

Section 18 of the *Assisted Reproductive Treatment Act 1988* therefore now provides (among other things) that a person must not disclose the identity of a donor of human reproductive material *except as required or authorised by or under the A.R.T. Act* (or any other legislation) or with the donor's consent.

The *Assisted Reproductive Treatment Regulations 2010* (cl 8(4)) provide that a condition imposed on the registration of a person (whether under the Act or otherwise); or a provision of the National Health and Medical Research Council *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2004 (revised 2007)* (NHMRC Guidelines), that requires or authorises a person to disclose the identity of a donor of human reproductive material; or to divulge confidential information obtained (whether by that person or some other person) for the purpose, or in the course, of providing A.R.T., will be taken to be such a requirement or authorisation under the Act.

Note – As discussed further in Fact Sheet 6, while the confidentiality provisions allow for the release of information if the above provisions were utilised by the Minister, a donor register is yet to be established in South Australia.

Reference to other Codes and Guidelines

To be registered in South Australia clinics must be licensed by the Reproductive Technology Accreditation Committee (RTAC), and must adhere to the NHMRC Guidelines (See further Fact Sheet 3).

The current RTAC Code of Practice (revised August 2015) provides some minimum requirements concerning data monitoring and reporting, and require adherence to the NHMRC Guidelines. The NHMRC Guidelines contain provisions relating to privacy and confidentiality, keeping detailed records, collecting and reporting outcomes data, upholding the right to knowledge about genetic parents and siblings, and prohibit the use of anonymous donors (except in exceptional circumstances). (Note the NHMRC Guidelines are currently under review).

Questions

We are interested in hearing from people about their experience and views concerning record keeping and confidentiality under the Act and regulations. The following questions may help you to inform the review:

1. In your view, are current record keeping practices sufficient?
2. There is provision in the legislation for the regulations to stipulate conditions relating to record keeping, however the regulations do not contain such provisions. Is this satisfactory? Why? What more should be done (if anything)?
3. In your view, should record keeping laws facilitate research into the effectiveness and outcomes of A.R.T. treatment?
4. Do the RTAC Code of Practice and/or the NHMRC Guidelines provide sufficient instructions relevant to a) record keeping; b) confidentiality of information?
5. What conditions (if any) should the regulations stipulate in relation to the release of information relevant to donor-conception? (See also Fact Sheet 6).

Please feel free to comment on anything else that is relevant.

The Review of the Act

The *Assisted Reproductive Treatment Act 1988* provides that a review must take place of the operation and effectiveness of the Act as soon as possible after the fifth anniversary of the changes that came into effect on or after 1st September 2010. The review will particularly 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 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 assisted reproductive treatment in South Australia. The report will be tabled in Parliament and made publically available. The recommendations will be considered by the Minister.

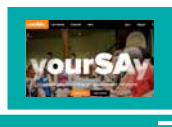




Record Keeping and Confidentiality Provisions Fact Sheet 7

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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