



TECHNICAL BULLETIN

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FSA Disclaimer: The purpose of the RTAC Technical Bulletin is to provide general advice and guidance on matters of educational value to all ART Units. The topics, discussion and suggestions do not constitute requirements or enforceable directives for RTAC accreditation purposes. The recipient assumes all responsibility for any consequences resulting from all uses made of this Technical Bulletin.

Closure of an ART Unit

With the revision of the RTAC Code of Practice (CoP) into a standard that is able to be audited by an external and independent body some important considerations needed to be omitted. Requirements that deal with the closure of an ART unit for any reason are such a case. Such requirements could not be applied within the scheme as conformance with the CoP via the Deed of Agreement only relates to a licensed entity.

It is stated within the introduction to the CoP (version 2008) that:

Patients and their offspring remain the most important consideration in all decisions made about the delivery of fertility services.

In the past and as a direct result of unfortunate experiences, RTAC attempted to ensure that patients and donors and their embryos and gametes were properly cared for when an ART unit closed. The previous version of the CoP approved in 2005 contained requirements related to the closure of any ART unit. Units were required to implement arrangements to:

- Continue storage of embryos and gametes
- Transfer medical records
- Notify relevant authorities

While these matters are covered by legislation in some states, such requirements are not universal within Australia and New Zealand. Consequently, RTAC wishes to remind all ART units of the provisions of the CoP version 2005. We strongly advise all ART units to have a thoroughly documented policy that they would follow in such an event including a detailed risk analysis and management plan within the records and cryostorage sections of their QMS.

It may help to restate the directive in the CoP version 2005 in terms of the evidence RTAC requested when it was informed of the closure of an ART unit:

1. Ongoing storage of gametes and embryos

- Documents detailing arrangements for the ongoing storage of frozen embryos, gametes or ovarian tissue.
- Information relating to the number of patients with frozen embryos, gametes or ovarian tissue in storage and details of the location of the material.
- The name and address of the ART unit agreeing to accept storage of the frozen gametes, embryos and ovarian tissue, the name of the medical director responsible for the storage of the



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material if it is being transferred to another ART unit, and a letter from the medical director accepting responsibility for storage.

- Copies of the communication to patients who have material in storage, outlining their options and costs for future storage.
- A copy of procedures for consenting to the transfer of embryos/gametes to another ART unit, including the consent forms.
- Details of provision for the ongoing storage of medical records.

2. Transfer of medical records

- A copy of procedures for consenting for the transfer of medical records to another doctor, including the consent forms.

3. Notification of relevant authorities

- Confirmation that a representative from the ART unit has notified the Health Insurance Commission and any other relevant authorities within 30 days of the closure of the ART unit.

It should be noted that it is vitally important to include gamete donors within the definition of patients in this extract from the 2005 version of the CoP.

Attention to all these factors should provide an appropriate framework when developing policy in this area. Care for the patients, donors and potential offspring in such situations is paramount.

A handwritten signature in black ink, appearing to read 'Ossie Petrucco', written in a cursive style.

A/Prof Ossie Petrucco
Chair - Reproductive Technology Accreditation Committee (RTAC)