

TECHNICAL BULLETIN 3

DONOR ISSUES

April 2011

From time to time RTAC will become aware of issues, questions or comments where it may consider assisting units enhance the quality of their service to patients. A Technical Bulletin is an educational communication to all units, and Bodies certifying units to the RTAC Code of Practice, offering advice and guidance. It is not enforceable.

Introduction

This Technical Bulletin extends and replaces Technical Bulletin 2 entitled 'Obtaining donor sperm outside Australia and New Zealand' issued in July 2009. It has been promoted by recent:

- Letters from RTAC-licenced IVF units asking FSA and RTAC about the legality of importing donor sperm into Australia
- Concerns raised by people making submissions to the Australian Senate inquiry into 'Donor conception practices in Australia' and covered in the Committee's report
- The Committee's report stating that units are confused about the interpretation of some aspects of the RTAC Code of Practice

This Technical Bulletin gives advice to units on interpretation of the RTAC Code of Practice, and requests auditors of Certifying Bodies (CB) to pay particular attention to certain aspects of the RTAC Code of Practice during surveillance audits in 2011-2012 to answer concerns raised in the Senate inquiry report.

Advice to units

1. Units are reminded that the NHMRC 'Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research', 2004 revised June 2007, are an integral part of the RTAC Code of Practice, and contained within Critical Criterion 1.

Hence:

- **Donors must be identifiable** to their donor offspring (NHMRC 6.1, 7.1), which means the donors recruited from 2002 must consent to the release of identifying information to offspring or their parents.
- **Comprehensive non-identifying information** must be collected about each donor, including the items covered in NHMRC sections 6.10 and 10.3
- Units must have **written donor-recipient linking procedures** (NHMRC 6.11, 6.13)

2. **Donors from outside Australia** must meet the same requirements as if they donated in Australia. This applies, but is not limited to, donor sperm sourced from outside Australia.

Use of imported donor sperm should be supported by written independent legal opinion specific to the origin of the donor sperm, State and Federal requirements for the State where the sperm is used, and the unit's clinical practice using this sperm. This legal advice should be available to auditors upon request. The legal opinion should cover the type and amount of 'reimbursement' given to the sperm donor by the sperm bank, the availability of identifying and other information for offspring and their parents, retention of records, and the maximum number of offspring or donor families possible from each donor.

3. The Senate inquiry reported that some units were confused about the RTAC Code of Practice and NHMRC guidelines relating to the maximum number of offspring for a donor and 'reasonable expenses'.

Where State legislation does not apply, the following are advised:

- **A maximum of ten donor families per sperm donor.** This is based on the highest limit in existing State legislation (Victoria). The **number of families** per donor includes all families wherever the donor's sperm is used, not just the number of families from one unit, in one city, or in one country. This interpretation is based on the definition in existing State legislation.
- **Reasonable expenses** be based on the principles in the Surrogacy Act 2010 of NSW, which applying to sperm donation would cover:
 - o Reasonable medical, travel or accommodation costs associated with offering to be a donor and associated with donation
 - o Receiving any legal advice associated with donation

A cost is reasonable only if the cost is actually incurred and the amount of the cost can be verified by receipts or other documentation. For the convenience of donors and units, it is suggested that units may decide to waive requiring receipts for individual items below \$50.

4. Where State legislation does not apply, **key information relating to a donor** who has donor offspring or to a recipient who has donor offspring must not be destroyed. The key information that must be retained about the donor includes his or her identity, last known address, and relevant medical history about the individual and his or her immediate family. Key information to be retained about the offspring includes the identity of the donor used.

Advice to auditors

5. Auditors are reminded that the NHMRC guidelines are an integral part of the RTAC Code of Practice and are audited as part of Critical Criterion 1. Auditors are requested to pay particular attention in 2011-2012 surveillance audits to:

- Donors being identifiable
- Donor records, especially that identifying and non-identifying information about donors is available to offspring and their parents
- Retention of medical records of donors and donor offspring
- The existence and use of donor-recipient linking policies
- Policies and their implementation concerning the maximum number of families per donor
- Policies and their implementation concerning payment of 'reasonable expenses' to donors

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