Overview of Amendments to the Human Reproductive Technology Directions

The amendments to the *Human Reproductive Technology Directions* (Directions 2021) deal with a narrow range of matters, which are intended to give effect to some recommendations in the Sonia Allan Review of the *Human Reproductive Technology Act 1991* (HRT Act) and *Surrogacy Act 2008*, pending wider regulatory reforms.

Directions Part 1: Personnel, premises and minimum standards of practice

There are no changes to Part 1 of the Directions.

Directions Part 2: Records and reporting

New Direction 2.5

The main amendment in this section relates to submission of data to the Department of Health for inclusion in the Reproductive Technology (RT) Registers.

Directions 2.5 to 2.9 of the HRT Directions 2004 specified the information that licensees were required to provide to the Department of Health CEO (CEO) for inclusion in the Department's RT Registers. The Directions 2004 detailed the manner, form and times when this information was to be provided.

The amendments delete Directions 2.5 to 2.9 in the Directions 2004 and replace them with a new Direction 2.5. This now refers to 'Data Specification Submission' which is a Department of Health document that provides instructions and sets how, when and in what form the required data and information are to be provided. The information to be reported is as follows:

(a) data relating to reproductive technology treatments carried out by the licensee for donor insemination, oocyte pickup, storage or fertilisation and embryo storage or transfer including information –
  (i) the licensee is required to submit to the Australian and New Zealand Assisted Reproduction Database (ANZARD) for use by the Fertility Society of Australia (FSA); and
  (ii) that describes the donor of any gametes or embryos used in treatments by the licensee.

(b) identifying particulars of participants, surrogates, and donors of gametes and embryos;

(c) demographic information that is non-identifying about all donors of gametes and embryos; and

(d) identifying and other particulars of live births from donated material exported from Western Australia by the licensee, including information about the recipient of the donated material.

This provides for a more contemporaneous and responsive approach to reporting.

There are two new notification requirements in this part of the Directions relating to notification of adverse events (Direction 2.14 – as below) and provision of annual audit reports from the certifying body (Direction 2.15 – as below).

New Directions 2.14 and 2.15

Direction 2.14 Notification of Serious Adverse Events

The licensee must –

(a) notify the CEO of any serious adverse event or serious notifiable adverse event within 7 days of its occurrence or within 7 days of becoming aware of its occurrence; and

(b) provide the CEO with information about any investigations undertaken by the licensee into the serious adverse event or serious notifiable adverse event notified under direction 2.14(a), and any corrective actions taken by the licensee within 6 weeks of the occurrence of the serious adverse event or serious notifiable adverse event.

Direction 2.15 Copy of Annual RTAC Audit Report to be provided to the CEO

The licensee must provide the CEO with the following reports within 7 days of their receipt –

(a) a copy of its annual audit report on its compliance with the RTAC Code of Practice received from a certifying body of the RTAC; and

if there are non-compliance issues identified in the annual audit report, a copy of any stand-alone reports of any follow-up on-site audits received from a certifying body of the RTAC once the non-conformities have been closed out by the certifying body.

These amendments ensure the notification of a serious adverse event or serious notifiable event are brought to the attention of the CEO in a timely manner and that there is oversight on corrective actions.

Method of required notification

Direction 2.21 in the HRT Directions 2004 has been replaced with new Direction 2.16 to update the method of notification. Notifications to the Western Australian Reproductive Technology Council (RTC) will now be made via the Department of Health Licensing and Accreditation Unit (LARU), either by email or registered post as given below.

Direction 2.16

Executive Officer

Western Australian Reproductive Technology Council

VIA the Licensing and Accreditation Regulatory Unit

Department of Health

189 Royal Street, East Perth WESTERN AUSTRALIA 6004

Email: LARUReception@health.wa.gov.au

OR such other address as may be provided.

Directions Part 3 – Consent

Consent for gamete storage every five years has been removed (Direction 3.1 HRT Directions 2004) because the requirement for a gamete storage limit has been removed from Part 6 of the Directions 2021. The period of storage will be determined between the participant and fertility clinic as per the National Health and Medical Research Council *Ethical guidelines for the use of assisted reproductive technology in clinical practice and research* 2017 (NHMRC Guidelines 2017) – see Part 6 below.

However, licensees are still required to comply with the requirements for transfer and storage of gametes under Part 6 of the Directions.

Directions Part 4 – Information

The requirement for licensees to provide information to persons 'in a form approved by Council' in relation to patient consent forms and information sheets has been removed from Directions 4.1 to 4.3. The requirement for licensees to submit consent forms and information sheets remains in Part 9 of the Directions.

Directions Part 5 – Assistance with decision making and counselling

The Directions in this part have been amended to remove reference to "approved counsellors" and replace it with "counsellor". The term "counsellor" has been defined to mean a person who is eligible for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA). The requirement for the RTC to 'approve' counsellors is outdated and has been superseded by professional registration and the ANZICA requirements for counsellors.

There are no changes to the standards of counselling required in the HRT Directions 2021.

This amendment will ensure consistency between these Directions and the amendments made to the *Surrogacy Regulations 2009*.

Directions Part 6 – Transfer and storage of gametes

Direction 6.8 has been deleted. The storage period of up to 15 years for gametes, approval of the RTC for further storage periods, and the requirement for renewed consent every five years have been removed from the Directions.

It has been deleted because the scientific, legal and social landscape has changed significantly since the HRT Directions 2004 commenced. In the early days it was not certain what prolonged freezing would do to gametes. There have been social changes since then such as delayed parenthood, freezing gametes for social reasons, more awareness of options for fertility preservation for medical reasons, and intergenerational oocyte donation (such as Turner's syndrome).

The emerging view is that long-term storage is a matter for personal and clinic consideration and clinics should set policy to guide clinicians' determinations.

It is the responsibility of the licensee to ensure the proper and safe storage of gametes. Clinics are required to comply with the RTAC Code of Practice and the NHMRC Guidelines (2017) as a condition of licensing under the HRT Act.

The licensee is required to submit a gamete storage policy to the RTC, with reference to the NHMRC Guidelines (2017) noting that indefinite storage is not an option.

Directions Part 7 – Eligibility and assessment

No change.

Directions Part 8 – Specific clinical practice issues

Directions 8.7 and 8.8 have been deleted. The restrictions on egg collections, where there are more than three embryos in storage and the requirement for licensees to make applications to the RTC to approve the collection of more eggs are no longer relevant to current clinical practice. Increased numbers of people are interested in genetic testing of embryos and delaying pregnancy until later in life. These applications create an administrative burden for clinics and potential delays to patient treatment.

Service providers must comply with the NHMRC Guidelines (2017) in that the provision of Assisted Reproductive Technology (ART) must be underpinned by policies that support effective and efficient practices that minimise interventions.

Directions Part 9 – Approval of laboratory and clinical procedures

There are no substantive changes to this part of the Directions. However, the requirement for routine documentation about procedures to be provided to the RTC on request has been removed from Part 2 Schedule 4 and placed in Part 9.2 (b) of the Directions 2021.

SCHEDULES

The schedules have been amended and restructured to align with amendments to the various Directions. Some schedules have been deleted entirely or in part where they are no longer required. The remaining schedules are as follows:

Schedule 1 – Forms

The forms have been renumbered and redundant forms removed. Electronic versions will be available on the RTC website.

Schedule 2 – Annual Reporting

Annual reporting by clinics is a requirement of the HRT Act with reporting required by financial year. The information requested for the annual returns in the new Directions has been streamlined and simplified.

Schedule 3 – Psychosocial Preparation

The cooling off period for the use of donated material from a known donor has been amended to three months.

Schedule 4 – Protocol Manuals

There have been no substantive changes to this part of the Directions. However, the requirement for routine documentation about procedures to be provided to the RTC on request has been removed from this Schedule and placed in Part 9.2 (b) of the Directions 2021.