ASSISTED REPRODUCTIVE TREATMENT ACT 1988

Flinders Reproductive Medicine Pty Ltd (trading as Flinders Fertility)

Conditions of Registration to provide assisted reproductive treatment in South Australia

Pursuant to section 9 of the *Assisted Reproductive Treatment Act 1988* (the Act) and section 38 of the *Legislation Interpretation Act 2021*, I **CHRIS PICTON**, Minister for Health and Wellbeing **HEREBY VARY** the Conditions of Registration to provide Assisted Reproductive Treatment (ART) in South Australia imposed on **Flinders Reproductive Medicine Pty Ltd (trading as Flinders Fertility) dated 19 July 2019**.

These varied Conditions of Registration come into effect on 26 February 2025 and are a consolidated copy.

***Flinders Reproductive Medicine Pty Ltd* (Trading as Flinders Fertility) (the Registrant)** is registered to provide ART (as defined in s 3 of the Act)

The Registrant's registration is subject to the following conditions:

Compliance with the Law and Regulatory Documents

1) The Registrant must comply with the Act and the Assisted Reproductive Treatment Regulations 2024 (the Regulations) as amended from time to time.

2) The Registrant must ensure that it meets and maintains the minimum standards required by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia for practice, personnel and premises.

3) The Registrant must comply with the National Health and Medical Research Council's *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (2017) as amended from time to time.

Accreditation

4) The Registrant must hold a current Reproductive Technology Accreditation Committee (RTAC) licence and maintain RTAC accreditation.
5) The Registrant must notify the Minister as soon as practicable and within 14 days of inspection by RTAC of:

   a) the status of its accreditation; and

   b) any reservations or conditions which apply to the accreditation, and any action being taken by the Registrant to address any reservations or conditions; and

   c) the date of expiry of its current licence.

6) The Registrant must provide the Minister with a copy of its RTAC Accreditation, Audit and Surveillance reports and conditions, any corrective action plans and any other documents related to non-conformity with the RTAC Code of Practice.

7) The Registrant shall ensure that laboratories (including external providers) conducting diagnostic testing are, and continue to be, accredited by the National Association of Testing Authorities (NATA).

Notification to the Minister

8) The Registrant must notify the Minister of:

   a) any actual or potential contravention of the Act, Regulations or Conditions of Registration within 14 days of becoming aware of the occurrence;

   b) any incident that is reported to RTAC as part of its accreditation requirements, within 14 days of such notification being made to RTAC.

9) The Registrant must notify the Minister in writing as soon as is practicable and within 28 days if any of the following events occur:

   a) the corporation becomes insolvent (as that term is defined in section 9 of the *Corporations Act 2001* (Cth));

   b) there is any change in constitution of the board of directors;

   c) there is any change in key personnel (senior management staff) including Chief Executives, Medical Director, Scientific Director, Nurse Manager and Senior Counsellor;

   d) there is any change in shareholding of the corporation (where private) or a takeover bid (as that term is defined in section 9 of the *Corporations Act 2001)* is made or announced with respect to all or any of the shares on issue to the Registrant (if publicly listed).

Provision of Services

10) The Registrant must not undertake sex selection except to reduce the risk of transmission of a serious genetic condition, disease or abnormality.

11) The Registrant must ensure that donated gametes, and donated embryos, are destroyed, or allowed to succumb, after 15 years from the time of donation, unless approval from the Minister is obtained for ongoing storage and use.

12) Prior to using donated gametes, the Registrant must be satisfied that the gamete donor's consent for the use remains valid. Consent for use of donated material should be sought annually at a minimum.

13) The Registrant must ensure that the number of families born from a single donor is limited to 10. In determining the number of families the Registrant must consider whether the donor has already donated gametes at another clinic (including families created who reside outside of South Australia, but within Australia). If gametes are imported from another country, the Registrant must ensure that no more than 10 families are created in South Australia and less than 10 if the Registrant is aware that the gametes have been used elsewhere in Australia.

14) The Registrant must only provide ART in accordance with its RTAC accreditation and only in the following circumstances:

a) if it appears to be unlikely that, in the person's circumstances, the person will become pregnant other than by an assisted reproductive treatment;

b) if there appears to be a risk that a serious genetic defect, serious disease or serious illness would be transmitted to a child conceived naturally;

c) if the human reproductive material –

- in the case of human semen or a human ovum – was collected from a person who has died (the donor); or

- in the case of a human embryo – was created from gametes of a person who has died (the donor); and

a. before the donor died, the donor consented to the use of the human reproductive material after their death in the provision of the proposed ART; and

b. if the donor gave any directions in relation to the use of the human reproductive material – the directions have, as far as is reasonably practicable, been complied with; and

c. the ART is provided for the benefit of a person who, immediately before the death of the donor, was living with the donor on a genuine domestic basis (whether the treatment is carried out on that person or another person for the purposes of a lawful surrogacy agreement);

d) for the purposes of a recognised surrogacy arrangement in accordance with the Surrogacy Act 2019; and

e) where a woman who would be the mother of any child born as a consequence of the ART; or a man who is living with a woman (on a genuine domestic basis) who would be the mother of any child born as a consequence of the ART, is suffering from an illness or other medical condition that may result in, or the appropriate treatment of which may result in, the woman or the man becoming infertile at a future time.

15) The Registrant (other than a **registered objector**) must not refuse to provide assisted reproductive treatment to another on the basis only of the others sexual orientation or gender identity, marital status, or religious beliefs.

16) The Registrant must comply with any policies and/or directives issued by the Minister from time to time.

17) The Registrant must not provide assisted insemination or in vitro fertilisation to a woman whose age is greater than, or equal to, the average age of menopause.

18) The Registrant must at all times carry policies of insurance that accord with industry standards in respect of ART.

Audits

19) The Registrant must allow any audits by an independent auditor (who is RTAC accredited) appointed by the Minister, as required by the Minister from time to time.

20) Where the Minister considers that the provider's processes, policies, procedures and/or systems may pose a risk to patient welfare and/or result in a contravention of the Act, regulations or conditions of registration, the Minister may request the Registrant engage an external auditor (who is RTAC accredited), as approved by the Minister, at its own expense to conduct an audit in relation to the identified risk/s. The Registrant must provide the audit report to the Minister within 14 days after completion.

Record Keeping

21) Donor conception records must be kept indefinitely and in accordance with the Act.

Reporting Requirements

22) The Registrant must provide the following report to the Minister:

- ANZARD's annual feedback report of clinic data.

23) The Registrant must provide specified information as requested by the Minister from time to time in a manner and form determined by the Minister.

Transitional Provisions where Registrant Ceases to Operate

24) If for any reason the Registrant ceases to provide ART, it must make provision for the transfer or destruction of any stored human reproductive material.

25) Where stored human reproductive material is unable to be transferred it must not be destroyed until the Minister has been consulted.

NOTE: These varied Conditions of Registration are imposed pursuant to section 38 of the *Legislation Interpretation Act 2021* and do not take effect until 26 February 2025.
For the avoidance of doubt the Conditions of Registration signed by the Minister on 19 July 2019 remain in place until this date.

Signed ……

MINISTER FOR HEALTH AND WELLBEING

Dated ……10th……day of ……February……..year……2025……