Conditions of Registration
to provide assisted reproductive treatment in South Australia

Pursuant to the *Assisted Reproductive Treatment Act 1988* (the Act),

***Adelaide Fertility Centre Pty Ltd* (trading as Repromed) (the Registrant)** is registered to provide assisted reproductive treatment (as defined in s 3 of the Act) (ART) at:

Repromed Adelaide, 180 Fullarton Road, Dulwich, and;

Ashford Hospital, 55 Anzac Highway, Ashford, and;

Adelaide Obstetrics, 38 King William Road, Goodwood, and;

266 Melbourne Street, North Adelaide, (added 25 March 2020) and;

8b Light Common, Mawson Lakes, as of 1 July 2019.

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 2010* (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 are, and continue to be, (including external providers of laboratory testing) accredited by the National Association of Testing Authorities (NATA) where the laboratory conducts diagnostic testing. (Embryology labs do not require NATA accreditation.)

Notification to the Minister

8) The Registrant must notify the Minister, within 14 days of becoming aware of the occurrence, of:

   a) any actual or potential contravention of the Act, Regulations or Conditions of Registration;

   b) any incident that is reported to RTAC as part of its accreditation requirements.

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 the 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 should make reasonable attempts to contact the donor of the gametes to ensure that consent for use remains valid. Additionally consent for use of donated material should be sought annually.

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 donor of the relevant human semen has died and before the donor died—

1. the donor's semen was collected; or

2. a human ovum (being the ovum of a woman who, immediately before the death of the deceased, was living with the donor on a genuine domestic basis) was fertilised by means of ART using the donor's semen; or

3. an embryo had been created as a consequence of such assisted reproductive treatment; and

4. the donor consented to the use of the semen, fertilised ovum or embryo (as the case requires) after the donor's death in the provision of the proposed ART; and

5. if the donor gave any directions in relation to the use of the semen, ovum or embryo (as the case requires)—the directions have, as far as is reasonably practicable, been complied with; and

6. the ART is provided for the benefit of a woman who, immediately before the death of the donor, was living with the donor on a genuine domestic basis.

d) for the purposes of a recognised surrogacy arrangement and in accordance with s10HA of the Family Relationships Act 1975; and

e) where a woman, or a man who is living with a woman (on a genuine domestic basis as her husband), 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 man becoming infertile 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 within 14 days after completion.

Record Keeping

21) Donor conception records must be kept indefinitely.

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:
    a. stored human reproductive material; and
    b. records of patients who have been treated, and are being treated, particularly as they relate to the use of donated human reproductive material.

25) Where stored human reproductive material or patient records are unable to be transferred they must not be destroyed until the Minister has been consulted. Records relating to the use of donated human reproductive material must not be destroyed.

Signed .....

MINISTER FOR HEALTH AND WELLBEING

Dated twenty-ninth **day of** April **year** 2020