LICENCE CONDITIONS FOR

LICENSEES PROVIDING ASSISTED REPRODUCTION SERVICES

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1. Application

1.1 These licence conditions ("**LCs**") apply to all persons which have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide an assisted reproduction service (such persons referred to as "**Licensees**").

1.2 A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:

(a) suspension or revocation of the Licensee's license to provide an assisted reproduction service;

(b) shortening the term of the Licensee's licence to provide an assisted reproduction service;

(c) directing the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or

(d) directing the Licensee to pay a financial penalty.

1.3 For avoidance of doubt:

(a) the defined terms as used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated;

(b) the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, codes of practice made thereunder; and

(c) these LCs do not override a healthcare professional's duty to make clinical decisions that are in the best interests of each patient.

2. Requirements relating to certification

With reference to Regulation 9 of the Healthcare Services (Assisted Reproduction Service) Regulations 2023 ("**AR Regulations**") (Licensee must be certified)

2.1. The Licensee shall, for the duration of the licensee's licence, have a certificate of conformity from a "certifying body" recognised by the Reproductive Technology Accreditation Committee as listed on the Joint Accreditation System of Australia and New Zealand's Internet website at https://register.jas-anz.org/accredited-bodies.

3. Requirements relating to personnel

3.1. The Licensee shall deploy an adequate number of nurses to, at all times, monitor the patients in any approved permanent premises to ensure that there is prompt recognition of and the delivery of appropriate medical intervention or treatment to a patient whose condition requires medical intervention or treatment.

3.2. The Licensee shall ensure that —

(a) there is an adequate number of nurses at each of the Licensee's approved permanent premises to monitor every patient at those premises who has undergone an assisted reproduction procedure; and

(b) there is an adequate number of qualified assisted reproduction practitioners at each of the licensee's approved permanent premises to assess every patient at those premises and provide medical care or intervention if necessary.

3.3. The Licensee shall appoint one or more persons to oversee the nursing care provided in the course of the Licensee's provision of the assisted reproduction service, each of whom must be a registered nurse who has at least 6 months of experience with a relevant acute hospital licensee or assisted reproduction licensee.

4. Pre-procedural waiting area

4.1. The Licensee must ensure that each approved permanent premises includes an area that is designated for the use of patients undergoing preparation before an assisted reproduction procedure.

5. Post-discharge follow up

5.1. The Licensee shall ensure that —

(a) where necessary, appropriate instructions for follow-up care are provided to a patient who has been assessed fit for discharge; and

(b) the Licensee's personnel gives the patient or the patient's caregiver information on the appropriate person to contact if the patient has an emergency medical need arising from the relevant procedure or the administration of anaesthetics.

6. Requirements relating to consent

With reference to Regulation 25 of the AR Regulations (Written consent required for any procedure on a patient)

6.1. The Licensee shall ensure that they minimally provide, as part of the possible consequences and side effects of the assisted reproduction procedure, the following information before obtaining written consent from the patient, and the patient's husband, where applicable, for the assisted reproduction procedure:

(a) the possibility of ovarian hyperstimulation syndrome; and

(b) the possibility of multiple births and the medical, social, financial and other consequences of such births.

6.2. The Licensee shall ensure that they minimally provide the following information, as part of the additional information or increased risks (including risks to the child conceived through the assisted reproduction procedure) that are relevant based on the age of the patient or the number of stimulated cycles the patient has already undergone, before obtaining written consent for the assisted reproduction procedure from the patient and the patient's husband (where applicable):

(a) the success rates of the assisted reproduction procedure, taking into account:

(i) the patient's age,

(ii) where donor reproductive cells are used in the creation of an embryo, the age of the donor at the point of collection; and

(iii) where a donor embryo is used, the age of the donor at point of collection of the reproductive cells used in the creation of the donor embryo.

(b) for patients above 35 years old, the increased risk of genetic anomalies in the foetus e.g. Down's Syndrome;

(c) for patients above 40 years old, the lower chances of success and higher risks associated with assisted reproduction procedures performed on such patients;

(d) for patients aged 45 and above:
    (i) the risks of assisted reproduction procedures and pregnancy at that patient's age;

    (ii) the prevailing assisted reproduction success rates for patients at that patient's age at the specific Licensee; and

    (iii) the potential impact of advanced parental age on the welfare of the child, including consideration of the couple's physical and financial ability to care for the child during their old age before the child reaches adulthood;

(e) for patients considering their 11th treatment cycle and beyond:
    (i) the risks of undergoing more treatment cycles based on that patient's age;

    (ii) the relative success rates of assisted reproduction procedures of different age groups; and

    (iii) the fact that there is no guarantee of successful pregnancy with more treatment cycles.

6.3. The Licensee shall ensure that they minimally provide the following information to patients undergoing elective oocyte storage, before obtaining written consent from the patient:

(a) the limitations of oocyte freezing, including that it does not guarantee motherhood;

(b) the indicative costs of the procedure to retrieve oocytes, including that there are no available subsidies for the elective procedure itself;

(c) the indicative costs for any subsequent assisted reproduction procedures, including any applicable subsidies;

(d) the procedure's invasive nature;

(e) potential health risks, including the risk of ovarian hyperstimulation syndrome;

(f) the lower chances of success and higher risks associated with assisted reproduction procedures and pregnancy at an advanced maternal age;

(g) challenges of older parenthood; and

(h) storage and insurance costs of egg freezing.

6.4. The Licensee shall ensure that they use the acknowledgement form provided in Annex 1 to obtain a written acknowledgment from the patient and her husband, where the patient is of 45 years of age or older on the day of the assisted reproduction procedure.

With reference to Regulation 28 of the AR Regulations (Additional requirements where donor reproductive cells or embryos used)

6.5. For patients who require or are using donor embryos or reproductive cells for assisted reproduction procedures, the Licensee shall inform the patient and the patient's husband of the requirements under section 13 of the Human Cloning and Other Prohibited Practices Act 2004 ("**HCOPPA**"), before obtaining written consent from the patient.
For the purposes of these LCs, allowable "reasonable expenses" under section 13 of the HCOPPA may include expenses relating to the:

(a) preparation, preservation and quality control of the oocyte or sperm; and

(b) preparation, preservation and quality control of the embryo.

With reference to Regulation 29 of the AR Regulations (Other requirements relating to obtaining consent)

6.6. The Licensee shall ensure that each signed consent form contains the following:

(a) the name, signature and unique identification number (such as the national registration identification number, foreign identification number or passport number) of:
(i) the person giving consent; and
(ii) the witness; and

(b) the name, signature and Singapore Medical Council registration number of the medical practitioner who obtained the consent.

7. Marital Status

With reference to Regulation 31 of the AR Regulations (When assisted reproduction service may be provided)

7.1. A Licensee must not provide a restricted procedure to a patient unless —

(a) the patient is legally married to a man; and

(b) the patient's husband consents to the restricted procedure.

7.2. In these LCs, "restricted procedure", in relation to a patient, means any of the following assisted reproduction procedures:

(a) the fertilisation of the oocytes collected from the patient with the sperm of any man by IVF or ICSI;

(b) the transfer of any oocyte or embryo into the body of the patient.

8. Requirements relating to referral for counselling

8.1. The Licensee shall ensure that a medical practitioner who is the Licensee's personnel:

(a) before providing any assisted reproduction procedure, asks each patient and the patient's husband whether they would like to receive counselling from a counsellor in relation to any aspect of the assisted reproduction procedure; and

(b) refers the patient or the patient's husband to an appropriate counsellor:

(i) where the patient or the patient's husband informs the Licensee's personnel that he or she wishes to receive counselling; or

(ii) where the patient or the patient's husband is assessed at any point in the provision of an assisted reproduction service to the patient or the patient's husband to require counselling.

8.2. For the purpose of this LCs, "counsellor" includes:

(a) a medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in psychiatry; and

(b) a clinical psychologist.

9. Embryo and Foetal Sexing

9.1. The Licensee shall ensure that no sex-revealed embryo is to be transferred into the body of a woman without prior written approval from the Director-General of Health ("**DGH**").

9.2. In relation to paragraph 9.1, the Licensee shall ensure that prior written approval from the DGH is obtained before any transfer of a sex-revealed embryo into the body of a patient. The Licensee shall provide the DGH with all available information on the patient and her husband's circumstances for the DGH's consideration on a case-by-case basis.

10. Requirements relating to the disposal of reproductive cells or embryos

With reference to Regulation 42 of the AR Regs (Storage and disposal in accordance with terms of consent)

10.1. The Licensee shall ensure that the disposal of any reproductive cell or embryo, termination of the development of any reproductive cell or embryo, and the disposal of any associated material is handled ethically and sensitively.

11. Counterchecking

With reference to Regulation 46 of the AR Regulations (Counterchecking procedures)

11.1. The Licensee shall ensure that they have counterchecking protocols in place to counter check the identification of the specimens, the patient, the patient's husband and the donor at all critical points of the clinical and laboratory procedures. These checks must be completed and documented at the time the relevant clinical or laboratory procedure takes place.

11.2. The critical points mentioned in paragraph 11.1 are:

(a) Sperm collection

(i) when sperm is collected from the known donor or the patient's husband (the Licensee shall also ensure that the patient's husband is asked to confirm and provide written acknowledgment that the specimen is his own);

(b) Sperm preparation

(i) when sperm from the sperm pot is transferred to the washing tube;

(ii) after recovery of the swim-up;

(iii) when sperm is transferred to the final sperm tube;

(c) Oocyte Retrieval

(i) before the patient undergoes oocyte retrieval;

(ii) when oocytes are transferred into the petri dish during oocyte retrieval;

(iii) when all the oocytes are finally transferred to the culture dish after oocyte retrieval;

(d) Insemination (IVF and ICSI)

(i) before commencing an insemination (prior to bringing oocytes and sperm to insemination or ICSI dishes; for ICSI, this refers to the period before the oocyte is removed from the culture dish containing the fertilisation droplets);

(ii) when oocytes are removed for denuding and before transferring denuded oocytes to the culture dish before ICSI and after IVF insemination;

(iii) when the oocytes are transferred to the culture dish for overnight culture after ICSI;

(e) Fertilisation Checks

(i) before commencing transfer of fertilised oocytes (prior to transfer of the fertilised oocytes to the new culture dish and before the fertilised oocytes are transferred into the patient);

(ii) before commencing the changing of culture medium during embryo culture on any day (the culture dish to which the embryos are transferred shall also be checked that it is correctly labelled);

(f) Embryo Transfer (ET)

(i) before the patient undergoes embryo transfer;

(ii) before commencing transfer of embryo from culture dish to ET dish;

(iii) before loading into the ET catheter from the ET dish;

(g) Cryopreservation of reproductive cells or embryos

(i) when transferring reproductive cells or embryos from the tubes and dishes;

(ii) during straw/vitrification device/cryo vial labelling;

(iii) after freezing and when the straws/vitrification devices/cryo vials are transferred to the liquid nitrogen tank;

(h) Embryo thawing

(i) when removing the straws/vitrification devices from the liquid nitrogen tank;

(ii) when labelling thawed dish or tubes;

(iii) when performing thawing of embryos;

(iv) after thawing, when the thawed embryos are transferred to the culture dish;

(i) Discarding of reproductive cells or embryos

(i) before removal of the gametes/embryos from their storage devices for the purpose of discarding; and

(j) Transporting reproductive cells or embryos

(i) before removal of reproductive cells or embryos from their respective storage devices for the purpose of transporting them.

12. Tests for diseases

12.1. The Licensee shall ensure that screening for the following diseases is carried out:

(a) Rubella

(i) The Licensee shall screen the patient for rubella at least once before the patient undergoes her first assisted reproduction procedure with the Licensee, except where:

(A) the patient has within 6 months before undergoing her first assisted reproduction procedure with the Licensee received rubella vaccination or recovered from a rubella infection; or

(B) the patient has been screened for rubella at least once before the patient undergoes her first assisted reproduction procedure with the Licensee, by (1) a person who holds a licence under the HCSA authorising the person to provide a clinical laboratory service; or (2) a person who operates a clinical laboratory outside Singapore that is accredited by an accreditation body approved by the Director- General.

(ii) The Licensee shall ensure that the attending assisted reproduction practitioner orders additional rubella screening(s) for the patient where required, including screenings to assess if the patient has adequate antibodies before she undergoes her first assisted reproduction procedure.

(iii) The Licensee shall not carry out any assisted reproduction procedures unless the patient and her husband have been adequately counselled and informed of:

(A) the need for rubella immunisation one month prior to conception if the patient has tested negative for rubella; and

(B) the risks to the foetus if a patient who has tested negative for rubella contracts a rubella infection during pregnancy.

(b) Cytomegalovirus (CMV)

(i) The Licensee shall screen:

(A) all donors for CMV within 6 months before the collection of the reproductive cell from the donor; and

(B) all recipients using donor gametes or embryos (called in this paragraph "the recipient") for CMV at least once within 6 months before the recipient undergoes the first assisted reproduction procedure with the Licensee.

(ii) Notwithstanding, the Licensee need not carry out the screening referred to in (b)(i)(A) on the patient or the patient's husband, if the patient and the patient's husband intend to donate any excess embryos remaining from their assisted reproduction treatment to another patient and the other patient's husband.

(iii) The Licensee shall ensure that the attending assisted reproduction practitioner orders additional screening(s) for the donor or the recipient where appropriate.

(iv) Where:

(A) the donor's CMV status is unknown or positive, and

(B) the recipient's CMV status is negative,

and the donated gametes/embryos have to be used, the attending authorised medical practitioner shall inform the patient and her husband of the risks of infection. The Licensee shall ensure that that express written consent is obtained from both the patient and her husband.

(c) Thalassaemia

(i) Where neither the patient nor her husband has tested positive for Thalassaemia, but the Licensee assesses that either the patient and/or her husband are at risk of Thalassaemia, the Licensee shall screen the patient and/or her husband before the patient and/or her husband undergoes her/his first assisted reproduction procedure with the Licensee;

(ii) Where the patient and/or her husband has tested positive for Thalassaemia, the Licensee shall counsel the patient and/or her husband on the risks and consequences of having a child with Thalassaemia before any assisted reproduction procedure is carried out.

12.2. Where a relevant person tests positive for any one of the diseases mentioned in paragraph 12.1 (a) and (c), or tests positive or unknown for the disease mentioned in 12.1 (b), the Licensee must do the following:

(a) inform the following persons of the positive or unknown test status:

(i) the proposed recipient of a reproductive cell collected from the relevant person and the proposed recipient's husband;

(ii) the proposed recipient of an embryo that is created from a reproductive cell collected from the relevant person and the proposed recipient's husband;

(b) explain to the persons mentioned in sub-paragraph (*a*)(i) or (ii) (as the case may be) the risk of the child or the persons mentioned in (a)(i) or (ii) (as the case may be) themselves contracting the disease or developing any related condition;

(c) obtain from each of the persons mentioned in sub-paragraph (*a*)(i) or (ii) (as the case may be) —

(i) a signed written declaration that the Licensee has explained, and the person is aware of, the risk mentioned in sub-paragraph (*b*); and

(ii) a signed written consent for the transfer of the reproductive cell or embryo.

12.3. Where the test result of a relevant person is positive or unknown for any one of the diseases mentioned in paragraph 12.1 (a) and (b), the Licensee must ensure that any reproductive cell collected from the relevant person or embryo that created from a reproductive cell collected from the relevant person is stored in a manner that minimises the risk of cross-contamination with reproductive cells or embryos from persons who have tested negative for the disease.

13. Requirements relating to embryology laboratory

With reference to Regulation 56 of the AR Regulations (Requirements relating to embryology laboratory)

13.1. The Licensee shall ensure that where equipment or facilities affect critical processing or storage parameters such as temperature, CO_2 pressure, particle

counts, microbial contamination levels, the Licensee shall identify and monitor the same to ensure that the critical parameters are maintained within acceptable limits at all times.

13.2. The Licensee shall ensure that all equipment used for critical measurements are calibrated against a traceable standard if available.

13.3. The Licensee shall ensure that the controlled environment has an appropriate air quality to ensure the quality and safety of the assisted reproduction procedures. In these LCs, “appropriate air quality” refers to the air quality in critical work areas being at least Grade C, and the air quality in background environments being at least Grade D, as set by the Good Manufacturing Practices Standards for Cleanroom (Grade C and D cleanroom) and ISO standard 14644:2015(E) (Class 7 and Class >7).

14. Requirements relating to laboratory procedures

With reference to Regulation 57 of the AR Regulations (Requirements relating to laboratory processes)

14.1. The Licensee shall ensure that in relation to the transferring of sperm, before transferring sperm into an ICSI dish, the sperm is dispensed into a petri dish by using a graduated pipette or Pasteur pipette before drawing the sperm into the pipette tip e.g. Eppendorf tip. For the avoidance of doubt, the pipette tip shall not be inserted directly into the test tube to aspirate the sperm.

14.2. The Licensee shall ensure that only single-use disposable consumables are used when processing all specimens, and such consumables are not re-used.

15. Requirements relating to provision of data

15.1. The Licensee shall submit such information as the Ministry of Health (MOH) may require on each of its patients undergoing AR procedures (including patients who consented to research in relation to such procedures) to MOH. The Licensee shall ensure that such information is submitted through MOH’s Healthcare Application and Licensing Portal in a timely and accurate manner.

ANNEX 1

ACKNOWLEDGMENT FORM FOR COUPLES UNDERGOING ASSISTED REPRODUCTION PROCEDURES
(WHERE THE PATIENT IS AGED 45 YEARS OLD AND ABOVE)

We,_____(Husband)
(Name) (NRIC/Passport No.) (Age)

and_____(Patient)
(Name) (NRIC/Passport No.) (Age)

of_____(Address)

have been counselled by _____ and acknowledge the following in relation to our decision to undergo AR procedures: -

(a) The risks and possible consequences of the procedure, including the possibility of ovarian hyperstimulation syndrome, multiple births and the medical, social, financial and other consequences of such births;
(b) The lower success rates for patients aged 45 years and above;
(c) The success rates for patients aged ____ years old carried out at _____;
(AR Centre)

(d) The increased risks involved with a pregnancy in patients aged 45 years and above, including the increased risk of genetic anomalies; and possible health or mental or physical impairment(s) of any child conceived or born as a result of the procedure due to advanced maternal age during pregnancy;

(e) Our physical and financial ability to care for the child during old age before the child reaches adulthood, taking into account our health and the cost of raising a child as the child grows older;

(f) The potential impact on the welfare of the child due to parenthood at an older age, bearing in mind:

i. social acceptance of the child having older parents, including the large age gap between ourselves and the child; and

ii. the possibility of the child having to care for aged / ill parents or having to face the loss of one / both parent(s) during their schooling years or early in their careers.

Patient
Signature _____
Name _____
Date _____

Husband
Signature _____
Name _____
Date _____

Doctor
Signature _____
Name _____
Date _____
MCR No._____

Witness
Signature _____
Name _____
Date _____
Unique ID No._____