

Code of Practice on Reproductive Technology and Embryo Research

Council on Human Reproductive Technology
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**CODE OF PRACTICE ON REPRODUCTIVE TECHNOLOGY
AND EMBRYO RESEARCH**

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CODE OF PRACTICE ON REPRODUCTIVE TECHNOLOGY AND EMBRYO RESEARCH

Chapter I — Introduction

Preamble

1.1 The Council on Human Reproductive Technology (the Council) was established under section 4 of the Human Reproductive Technology Ordinance (Cap. 561) (the Ordinance) in April 2001. It takes a multidisciplinary approach and provides a framework to ensure the safe and informed practice of reproductive technology (RT) in a way which respects human life, the role of the family, the rights of service users and the welfare of children born through RT.

1.2 Under section 8 of the Ordinance, the Code of Practice on Reproductive Technology and Embryo Research (the Code) has been produced in consultation with, and provides detailed guidelines for RT service providers and embryo researchers.

1.3 The Code provides guidance for good practice, as described in subsequent chapters, which aim to support proper clinical and scientific procedures, to safeguard the health and interests of service users and to protect the welfare of children born through RT. Professionals concerned should still follow the codes of practice and professional ethics of their individual disciplines. The Code is not meant to supersede these.

Application of the Code

1.4 The Code came into effect on 1st August 2007.¹ The Code will be reviewed and updated as necessary to keep up with developments in RT.² Although a failure on the part of any person to observe any provision of the Code shall not of itself render the person liable to any proceedings, the Council, which is the licensing authority for RT services and embryo research, shall take into account any observance of or failure to observe the provisions of the Code when considering granting, renewal, variation, revocation or suspension of licences.³ The person may also become liable to legal or disciplinary proceedings if the act of non-observance also constitutes a breach of any statutory provision and/or code of conduct of any profession and/or civil duty of care.

Interpretation of the Human Reproductive Technology Ordinance and Promulgation of the Code

1.5 All personnel involved in the provision of RT procedures or embryo research are advised to familiarize themselves with the Ordinance. Reference should be made to the Ordinance for definitions of specific terms.

1.6 The Code must be construed in a manner consistent with the

¹ s.8(6) of the Human Reproductive Technology Ordinance (the Ordinance)

² s.8(3) of the Ordinance

³ s.9 of the Ordinance

provisions of the Ordinance.

1.7 Since artificial insemination by husband (AIH) is regarded as a relatively simple RT procedure, the Council considers that a simpler code is sufficient when AIH is being performed. The Supplementary Code of Practice on Reproductive Technology – Artificial Insemination by Husband (AIH) (attached herewith as **Annex I** and forms part and parcel of the Code) is prepared for compliance when AIH is performed by a RT service provider (whether or not other RT procedures are provided by the same service provider). However, when RT procedures other than AIH are performed by the RT service provider, he should comply with the provisions of the Code.

Chapter II — Staff

General

2.1 As required by the Ordinance, no person shall carry on RT activities and embryo research except pursuant to a licence.⁴

Person Responsible

2.2 The “person responsible”, in relation to a licence, refers to the individual specified in the licence as the individual under whose supervision the activities authorised by the licence shall be carried on.⁵

2.3 It shall be the duty of the person responsible to ensure that -⁶

- (a) the other persons to whom the licence applies⁷ are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the relevant activity authorised by the licence; for licensed centres with satellite centres/associated doctors (see Note), the person responsible of the centre is fully responsible for the acts of his/her satellite centres/associated doctors. Therefore, person responsible must play a supervisory and proactive role to ensure that his/her satellite centres/associated doctors provide the relevant RT services authorised by the licence in compliance with the Ordinance and its subsidiary legislation, the Code, the Licensing Manual for Reproductive Technology Centres, and the terms and conditions to which the licence is subject;
- (b) proper equipment is used;
- (c) proper arrangements are made for the keeping of gametes and embryos and for the disposal of gametes and embryos that have been allowed to perish;
- (d) proper practices are used in the course of that activity; and
- (e) the conditions of the licence are complied with.

2.4 The person responsible should ensure that this Code is made known to all staff involved.

Licensee

2.5 The “licensee”, in relation to a licence, is the holder of the licence as defined in the Ordinance.⁸

2.6 It is the duty of the licensee to ensure that the person responsible discharges his/her duty. The discharge of the duty by the person responsible should not be prejudiced if the licensee and the person responsible are the same person.⁹

⁴ s.13 of the Ordinance

⁵ s.2(1) of the Ordinance - interpretation of the term “person responsible”

⁶ s.24(1) of the Ordinance

⁷ s.24(3) of the Ordinance

⁸ s.2(1) of the Ordinance - interpretation of the term “licensee”

⁹ s.23(3) and s.24(2) of the Ordinance

Medical Practitioners

2.7 The overall clinical responsibility for RT procedures should be held by registered medical practitioner¹⁰ with relevant training and experience and with post-graduate qualifications recognised by the Hong Kong College of Obstetricians and Gynaecologists or the Hong Kong College of Surgeons, and recognised as an accredited specialist in Obstetrics & Gynaecology, Surgery or Reproductive Medicine under the Specialist Register kept by the Registrar of Medical Practitioners under the Medical Registration Ordinance (Cap. 161). Licensed centres should promptly report to the Council any change(s) of personnel(s) involving medical practitioner(s) and/or person(s) occupying the role of accredited specialist(s). Centres performing intravaginal or intracervical insemination only are exempted from this requirement.

2.8 Medical staff in a training capacity shall only carry out such procedures under supervision.

Nursing Staff/Healthcare Assistants

2.9 All nursing staff employed by licensed centres must be registered nurses or enrolled nurses under the Nurses Registration Ordinance (Cap. 164) and be appropriately trained for the duties they carry out. Licensed centres should promptly report to the Council any change(s) of personnel(s) involving person(s) occupying the role of nurse-coordinator(s). Other healthcare assistants should work under the supervision of the medical practitioner and be appropriately trained for the duties they carry out.

Staff Engaged in Scientific/Laboratory Services

2.10 The person in charge of a RT laboratory should have an appropriate scientific or medical degree, plus a period of experience in a RT laboratory sufficient to qualify him/her to take full charge of the laboratory.

2.11 Scientific or laboratory staff should have a degree or higher qualification in a relevant discipline, plus a period of experience sufficient to qualify them to perform the duties of the respective RT procedures. Licensed centres should promptly report to the Council any change(s) of personnel(s) involving person(s) occupying the role of embryologist(s)-in-charge.

Counsellors

2.12 Counselling may be provided by doctors, nurses, social workers, clinical psychologists or other persons with suitable experience and/ or qualifications as appropriate. Please refer to **Chapter VII** for details on counselling services. Licensed centres should promptly report to the Council any change(s) of personnel(s) involving person(s) occupying the role of counsellor(s)-in-charge.

Fitness to Practise

2.13 In the case of medical practitioners, reference should also be made to guidance laid down by the Medical Council of Hong Kong on fitness to

¹⁰ a medical practitioner registered in accordance with s.14 of the Medical Registration Ordinance (Cap. 161)

practise.

Note:

Satellite centres or associated doctors of a licensed centre are those centres, clinics or medical practitioners, not being part and parcel of the organization of the licensed centre, but which/who carry out reproductive technology treatment/procedures or other supporting services in the centre on a contractual basis, and which/who have been named as such in the licence application form of the centre, as updated and informed to the Council from time to time.

Chapter III — Facilities and Equipment

General Standard of Clinical and Laboratory Facilities in Licensed Centres

3.1 The person responsible must secure that proper facilities and equipment are used and maintained.¹¹ Licensed centres should promptly report to the Council any change(s) involving critical equipment related to RT procedures which will lead to any circumstance where the licence may be revoked/temporarily suspended.

3.2 Backup and/or emergency support facilities should be arranged and made available for each technique practised in the licensed centre. The extent and readiness of such facilities must be commensurate with the degree of risk involved. Licensed centres should promptly report to the Council any change(s) involving contingency plan(s) to be adopted by them.

3.3 A laboratory manual and logbook, and maintenance records of essential equipment must be properly kept and maintained and be available for inspection by persons authorised by the Council.

Minimum Requirements for Licensed Centres Offering IVF Services

3.4 The minimum facilities and equipment required for licensed centres offering in vitro fertilization (IVF) services include the following -

- (a) laboratory facilities for semen analysis at least up to the specifications laid down in the World Health Organisation's (WHO) current laboratory manual for examination of human semen, including light microscopes with phase-contrast optics, a haemocytometer, counting chambers, and the necessary reagents for determining sperm viability and morphology;
- (b) a completely separate laboratory for handling gametes and embryos, which should be equipped with carbon dioxide incubator, safety cabinet with dissection microscope, inverted microscope, appropriate equipment for cryopreservation of embryos or gametes and liquid nitrogen tank, micromanipulator, refrigerator, upright microscope, centrifuge and other necessary equipment;
- (c) culture media and purified water, which can either be bought ready-made or be prepared in the laboratory. The water should be sterile and deionised;
- (d) hormonal assay facilities, which should be readily available either at the licensed centre or at another laboratory which is able to provide the required service as well as the assay results in a timely manner;
- (e) ultrasound equipment, which should be readily available in the licensed centre for monitoring ovarian stimulation and ultrasonically guided retrieval of ova through the vagina;
- (f) a procedure room properly set up and equipped for the purpose of oocyte collection, vacuum aspiration of the follicles and embryo transfer; and
- (g) facilities for resuscitation should be available for the procedure of oocyte collection. A properly equipped operating theatre is

¹¹ s.24(1)(b) of the Ordinance

required if general anaesthesia is used for oocyte collection. Facilities for emergency laparotomy must be made readily available.

3.5 The embryology laboratory should be in close proximity to the egg collection room.

3.6 Licensed centres should ensure a continuous supply of electricity.

3.7 In licensed centres undertaking research as well as providing services, additional and more sophisticated equipment may be required.

Storage Facilities for Gametes and Embryos

3.8 A proper and safe storage facility must be provided to preserve the viability of gametes and embryos, to minimise chances of accident, loss or contamination.

Counselling Facilities

3.9 If counselling is carried out in the licensed centre, there should be a designated place with privacy and comfort for counselling, where discussion can take place undisturbed.

Chapter IV — Assessment of Clients, Donors and Welfare of Children

4.1 Under the Ordinance, any RT procedure may be provided only to persons who are the parties to a marriage¹², except where the RT procedure is¹³

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- (a) provided to a surrogate mother pursuant to a surrogacy arrangement;
- (b) continued to be provided to persons who were the parties to a marriage when gametes were, or an embryo was, placed in the body of a woman pursuant to the procedure; however, no further gametes or further embryos may be placed in the body of that woman pursuant to such procedure; or
- (c) for obtaining gametes.

4.2 Furthermore, as stipulated in the preamble of the Ordinance, the provision of RT procedures should be confined to infertile couples, subject to any express provision to the contrary in this Code.

Assessment of Clients

4.3 Clients should be offered fair and unprejudiced assessment. Clients' medical conditions should be fully assessed to determine the most appropriate treatment option. For clients undergoing treatments involving the use of donated gametes/embryos, licensed centres are advised that for best practice all potential recipients should be screened against infectious disease with reference to the guidelines for screening at **Appendix I**.

4.4 In assessing clients' suitability for RT procedure, the welfare of the child is of paramount importance. The assessment should take into account the clients' physical, mental and social well-being, including the following factors -

- (a) their commitment to having and bringing up a child or children;
- (b) their ability to provide a stable and supportive environment for any child born as a result of treatment;

¹² The term "parties to a marriage" has not been defined under the Human Reproductive Technology Ordinance. For his/her own protection, if a service provider is asked to provide RT services to a couple married outside Hong Kong, he/she should ensure that the marriage was celebrated or contracted in accordance with the law in force at the time and in the place where the marriage was performed and recognized by such law as involving the voluntary union for life of one man and one woman to the exclusion of all others. Please refer, in this regard, to the definition of "monogamous marriage" under section 2 of the Matrimonial Causes Ordinance (Cap. 179). The Council is of the view that the term "parties to marriage" applies to marriages celebrated or contracted in places which allow monogamous as well as polygamous marriages **as long as the marriage of the client couple involves the voluntary union for life of one man and one woman to the exclusion of all others**. The Council also considers that evidence such as a statutory declaration made by the client couple before a Commissioner of Oaths or solicitors that their marriage was the union for life of one man and one woman to the exclusion of all others or documents of proof issued by Consular Officers, etc., declaring that "*the marriage was celebrated or contracted in accordance with the law in force at the time and in the place where the marriage was performed and recognized by such law as involving the voluntary union for life of one man and one woman to the exclusion of all others*" are reasonable proofs for the purpose, unless otherwise exist any contrary facts known, or should have been reasonably known by the RT service providers. It is nevertheless the duty and role of individual licensed centres, as RT service providers, to decide whether the requirements of the Ordinance and the Code regarding "parties to marriage" have been fulfilled in a particular case (please also see para. 4 of Appendix IX for good practice on record keeping).

¹³ s.15(5), 15(6), 15(7) & 15(8) of the Ordinance

- (c) their medical histories and the medical histories of their families;
- (d) their ages and likely future ability to look after or provide for a child's needs;
- (e) their ability to meet the needs of any child or children who may be born as a result of treatment, including the implications of any possible multiple births or disability;
- (f) any risk of harm to the child or children who may be born, including the risk of transmission of infectious diseases as screened for the recipients undergoing treatments using donated gametes/embryos, risk of inherited disorders, problems during pregnancy and of neglect or abuse;
- (g) in cases where donated gametes or embryos are used, the possible attitudes of other members of the family towards the child;
- (h) the result of counselling; and
- (i) if clients with intellectual disability are involved, prior assessment should be made on their ability to understand and give consent to undergo the relevant RT procedures. Licensed centres are advised to engage additional professionals, such as social workers, clinical psychologists, psychiatrists or other persons with suitable experience and/or qualifications for a more precise assessment of the suitability of clients with special needs to undergo the relevant RT procedures (please also see para. 7.1) if deemed necessary.

Proper Counselling

4.5 Proper counselling should be provided to the commissioning couple and concerned parties before RT procedure is provided. If clients with special needs (e.g. persons with physical and/or intellectual disability) are involved, licensed centres are advised to engage additional professionals, such as social workers, clinical psychologists, psychiatrists or other persons with suitable experience and/or qualifications, who can best address the needs of such clients to offer and provide the relevant counselling service (please also see paras. 7.5-7.9)

Assessment of Donors of Gametes and Embryos

4.6 Licensed centres must ensure that all potential donors are carefully screened to prevent transmission of infectious diseases. Donors should also be assessed for any personal or family history of hereditary disorders.

4.7 The necessity and implications of the screening procedure must be explained to potential donors so that they understand screening may reveal previously unknown diseases such as HIV infection.

4.8 Guidelines for screening are at **Appendix I**. Unless fresh ova/embryos are used (please also see para. 9.12), gamete or embryo donors must be tested again to ensure that they are free of HIV antibody 6 months after donation before their donated gametes or embryos could be considered safe for use. The use of fresh sperm is prohibited.

4.9 As a matter of good clinical practice, licensed centres must ensure that the most up-to-date guidelines for screening against infectious diseases and hereditary disorders are followed. Re-screening and the inclusion of any other appropriate tests as may be indicated for a particular case should be adopted in

line with professional standards of the relevant specialties.

4.10 Female donors should be below the age of 35 and male donors should be under 55 (see Note 1). These age limits may be exceeded in appropriate circumstances. For female donors, the age limit of 35 might be exceeded in appropriate circumstances and only under exceptional circumstances it might exceed 40. The reasons for waiving the age limit should be explained in the treatment record.

4.11 Gametes should not be taken from anyone under the age of 18 unless in exceptional cases where the gametes are for their own or their spouse's treatment (see Note 2).

4.12 Gametes must not be taken from anyone incapable of giving a valid consent.

4.13 Proper counselling should also be provided to potential donors of gametes or embryos. (please also see para. 7.10)

Persons Considered Unsuitable as Donors or to Undergo RT Treatments

4.14 If the licensed centre decides that it is unsuitable for a person to be a donor or to undergo RT treatments, the reasons for the decision should be recorded and explained to the person. Appropriate counselling and referral for treatment or assistance should be arranged where necessary.

Note 1 :

An upper age limit for gamete or embryo donation is set because the risk of chromosomal abnormalities in gametes increases with age. The age limits for the male and female donors from whom the gametes are obtained to form the donated embryos should follow the age limits set out in para. 4.10.

Note 2 :

The lower age limit of 18 aims to protect minors who may not be mature enough to fully understand the implications of gamete or embryo donation.

Chapter V — Information to Clients and Donors

General

5.1 Licensed centres should devise a mechanism to ensure that relevant information is given to persons seeking RT procedure and those who want to donate gametes or embryos. Licensed centres should provide clients and donors with information on the services offered.

Information to Clients

5.2 Persons seeking RT procedure should be informed of the following -

- (a) explanation of the procedure, possible discomfort, side effects, complications of treatment and associated risks such as the risks of surgical gamete retrieval procedures, to the woman and the resulting pregnancy including, where relevant, risk of ovarian hyperstimulation syndrome or multiple pregnancy and indications for embryonic reduction;
- (b) for storage of gametes or embryos, the relevant information on the decline in pregnancy rates associated with aging of women and use of stored gametes and/or embryos in bringing about human reproduction by artificial means at advanced maternal age, the risks of pregnancy at an advanced maternal age, the impacts of delayed childbearing, the arrangements upon cessation of storage and the storage period policy of the licensed centre, if any;
- (c) limitations and possible outcomes of the treatment;
- (d) any other options available; and
- (e) charges for services.

5.3 Licensed centres should also advise clients who intend to undergo treatments involving donor gametes/embryos about information disseminated by the Council on matters relating to legal provisions under the Ordinance and the Parent and Child Ordinance (Cap. 429) such as -

- (a) the legal status of the child and parents¹⁴;
- (b) the child's right to access to information about whether he/she was born in consequence of RT involving donated gametes or donated embryos and non-identifying information about the donor on reaching the age of 16¹⁵; and
- (c) the legal obligation of licensed centres to report information to the Council in accordance with the Ordinance and its subsidiary legislation.¹⁶

Information to Donors of Gametes or Embryos

5.4 Donors of gametes or embryos should be informed of the following -

¹⁴ s.9 – s.12 of the Parent and Child Ordinance

¹⁵ s.33(3)(a), s.33(4), s.33(5) and s.33(7) of the Ordinance

¹⁶ s.33(1) and s.33(2) of the Ordinance and Human Reproductive Technology (Licensing) Regulation (Cap 561 sub. leg. A)

- (a) the procedures involved and the associated discomfort, pain and risks, including the risk of ovarian hyperstimulation syndrome for egg (oocyte) donors;
- (b) the screening tests to be performed and the implications of having the HIV antibody test (also see para. 4.8 and **Appendix I**);
- (c) the purpose(s) for which their gametes or embryos may be used;
- (d) a child may be born disabled as a result of the donor's failure to disclose defects, about which he or she knows or should reasonably have known; and
- (e) a donor's donated gametes or embryos may not be allowed to bring about more than 3 live birth events to minimise risk of inadvertent incest in the offspring.

5.5 A "live birth event" for the purposes of this Code shall mean an event of the birth in Hong Kong of one or more than one live child from one single pregnancy. The birth of live twins, triplets and so on will therefore be considered as a single "live birth event". A "live birth event" will be assumed after the use of a donor's gametes or embryos for RT procedure has been reported to the Council, unless the Council is informed otherwise.

5.6 Licensed centres should also advise donors on other relevant information disseminated by the Council such as -

- (a) protection provided under the Ordinance regarding the anonymity of donors and the confidentiality of patients seeking RT treatment¹⁷;
- (b) the fact that, under the Laws of Hong Kong¹⁸, donors will not be regarded as the parents of child(ren) born from their donated gametes/embryos;
- (c) the fact that, under the Ordinance and its subsidiary legislation¹⁹, licensed centres are required to register with the Council certain information on the donors; and
- (d) the fact that reimbursement may only be made in accordance with the provisions of the Ordinance²⁰ (please see paras. 5.7 and 5.8 and **Appendix II** for details).

Payment to Donors

5.7 Under the Ordinance, donors should not be paid for the supply of gametes or embryos, except for reimbursing or defraying -²¹

- (a) the cost of removing, transporting or storing an embryo or gamete to be supplied; and
- (b) any expenses or loss of earnings incurred by the donor.

5.8 Guidelines for payment to donors are at **Appendix II**. Licensed centres shall follow the guidelines strictly such that gamete donors shall not be paid more than the maximum daily payment level.

¹⁷ s.34 of the Ordinance

¹⁸ s.9 – s.12 of the Parent and Child Ordinance

¹⁹ s.33(1) and s.33(2) of the Ordinance and Human Reproductive Technology (Licensing) Regulation (Cap 561 sub. leg. A)

²⁰ s.2(1) of the Ordinance - interpretation of the term "payment" and s.16(1)(a)

²¹ s.2(1) of the Ordinance - interpretation of the term "payment" and s.16(1)(a)

Chapter VI — Consent

Informed Consent

6.1 Informed consent with respect to receiving RT procedure, and to donating gametes or embryos must be obtained in writing. Such consent must be obtained before commencement of any active treatment procedures for each cycle of treatment, but not earlier than 6 months prior to carrying out of the treatment cycle. For the use of appropriate consent forms for this purpose, please see para. 6.10 below.

6.2 RT practitioners are advised to refer to the *Code of Professional Conduct for the Guidance of Registered Medical Practitioners* issued by the Medical Council of Hong Kong for consent to surgical procedures.

Consent of Husband in Cases of Donor Insemination

6.3 In accepting appropriate recipients of donor insemination, the person responsible should always consider the welfare of the child.

6.4 The legitimacy of children born by donor insemination is protected by law. Sections 9-11 of the Parent and Child Ordinance (Cap. 429) have provided for this. The parentage of children born by donor insemination is to be determined in accordance with the law.

6.5 Licensed centres should obtain the written consent of the commissioning woman's husband to avoid any disputes about the fatherhood of the child born of donor insemination.

Consent to Use of Gametes and Embryos

6.6 Clients/Donors must consent in writing and specify the purpose(s) for which the gametes or embryos may be used. Consent in writing may be given for one or more of the following purpose(s) -

- (a) to provide treatment for themselves or their spouse;
- (b) to be donated for treating other infertile couples; or
- (c) for research and/or use of embryos for quality control and training purposes.

For (b) and (c) above, consent cannot be revoked once the gametes or embryos have been donated.

Consent to Storage of Gametes and Embryos

(This section is not applicable to anonymous donors and designated donors)

6.7 Clients who consent to the storage of their gametes or embryos at the beginning of storage and at every time when a consent is required under para. 6.8 must -

- (a) receive proper counselling and acknowledge in their consent form receipt of the relevant information on the decline in pregnancy rates associated with aging of women and use of stored gametes and/or embryos in bringing about human reproduction by artificial means at advanced maternal age, the risks of pregnancy at an advanced

- maternal age and the impacts of delayed childbearing, the arrangements upon cessation of storage, and also the storage period policy of the licensed centre if any; and
- (b) state what is to be done with the gametes or embryos if he or she dies or becomes incapable of varying or revoking his or her consent (details on posthumous arrangement are described in **Chapter X**).

6.8 Clients should be informed that they are required to give a written notice of extension of consent to the licensed centre every 2 years within the first 5 years of storage. After the initial storage period of 5 years and every 2 years thereafter, clients are required to receive proper counselling and sign a new consent form, together with an acknowledgement of the relevant information pursuant to section 6.7(a) above before extension of storage. In the absence of written notice of extension, or failure to attend counselling and signing new consent form as required, or failure to pay for the storage fees, or loss of contact, licensed centres by giving their clients 3 months' notice, may dispose of or donate the stored gametes or embryos as follows:

- (a) dispose of the stored gametes or embryos;
- (b) donate them for treatment of other infertile couple(s);
- (c) donate for research; or
- (d) donate for quality control and/or training,

in accordance with the instruction given by the clients in the latest consent form.

6.9 Clients may vary or withdraw their consent at any time in writing provided that the gametes or embryos have not already been used in treatment or donated.

Consent Forms

6.10 Licensed centres are required to make use of the appropriate sample consent forms²² at **Annex II** unless there are justifiable reasons why they should not be used or should be departed from or modified. For subsequent treatment cycles involving the use of frozen-thawed embryos, in relation to which no donor gametes/embryos or surrogacy arrangement is involved, licensed centres may use a simplified consent form (Consent Form (18)) instead of the full consent form. For renewal of storage after the initial 5 years storage period and every 2 years thereafter, Consent Form (19) should be used for the case of gamete(s) and Consent Form (20) should be used for the case of embryo(s).

²² s.15(6) of the Human Reproductive Technology (Licensing) Regulation (Cap 561 sub. leg. A)

Chapter VII — Counselling

General

7.1 Counselling service must be recommended and made available to all clients and donors. Counselling service may be provided by doctors, nurses, social workers, clinical psychologists or other persons with suitable experience and/or qualifications. For RT procedures involving donation of gamete(s) or embryo(s) from person(s) other than the couple who seeks treatment, counselling service should be provided by an independent person who is not involved in the treatment or clinical decision-making process.

7.2 Counselling services provided pursuant to para. 7.1 above should be non-directional and should include discussions on the implications of the RT procedure intended to be undertaken as well as consideration of other options (including adoption). Couples seeking treatment should be given adequate time to consider the matter after counselling before they make a decision as to whether to undergo the RT procedure. If necessary, more than 1 session of counselling ought to be provided. Counselling service should also be recommended and provided to the patient after commencement or completion of the RT procedure (e.g. to address the consequences of treatment and to cope with the emotional stress and social adjustment) if the situation so warrants.

7.3 Information obtained during counselling must be kept in confidence.

7.4 Proper records should be kept of the counselling service offered and provided. If clients with special needs are involved, on top of keeping a standard counselling checklist based on the implications listed in para. 7.5, licensed centres should record the observations on and the responses from such clients during counselling.

Counselling for Potential Clients of RT Services

7.5 Counsellors should ask potential clients to consider carefully all possible implications before receiving RT services, such as -

- (a) the implications of the RT procedure on themselves, their family and relatives, their social life, and any resulting or existing children;
- (b) the financial implications of the RT procedure (e.g. there is the possibility of multiple pregnancy);
- (c) their feelings about manipulation of their own gametes or embryos outside their bodies, and the possible storage and disposal of gametes or embryos;
- (d) the chances that treatment may fail;
- (e) the possibility of the need of embryonic/foetal reduction;
- (f) the alternative of adoption of a child;
- (g) the possibilities that the implications of and feelings about their RT procedure may change as personal circumstance changes;
- (h) all the terms and conditions set out in the consent form; and
- (i) the submission of their particulars to the register(s) kept by the Council in accordance with the Ordinance and its subsidiary legislation.²³ They should also be informed that a child born from RT procedure may apply to the Council when he/she reaches the

²³ s.33(1) and s.33(2), s.45(2)(c) and s.45(2)(d) of the Ordinance

age of 16 to check whether he/she was born in consequence of a RT procedure involving gametes or embryos not solely from his/her parents.²⁴

Counselling for Clients Storing Gametes or Embryos

7.6 For storage of gametes or embryos, to ensure that clients are fully informed of the associated medical risks and to prevent them from having unreasonable expectations and missing the optimal time of childbearing before engaging in the storage of gametes or embryos for their own use, proper counselling services tailored to clients' individual circumstances, at the beginning of storage, as well as after the initial 5 years of storage and every 2 years thereafter, are required before extension of the storage period for a maximum of 2 years at a time. Counselling services should cover relevant information on the decline in pregnancy rates associated with aging of women and use of stored gametes and/or embryos in bringing about human reproduction by artificial means at advanced maternal age, the risks of pregnancy at an advanced maternal age and the impacts of delayed childbearing. Clients should acknowledge the receipt of such information by signing appropriate consent form. Licensed centres shall properly maintain the relevant counselling records for checking by the Council when necessary.

Counselling for Clients where Donated Gametes or Embryos are to be Used

7.7 In cases where donated gametes or embryos are used, clients should also be advised to consider -

- (a) their own feelings, and that of their spouse, about not being the genetic parent of the child;
- (b) the desirability of revealing the history of gamete/embryo donation to their future child and the possible reaction of the child;
- (c) the desirability of informing their future child of the right to check information in Register A before marriage (please see para. 7.5(i) above) to avoid incest; and
- (d) the importance of reporting to the licensed centres any successful births so that donated gametes or embryos will not be used to bring about more than 3 live birth events to avoid the possibility of inadvertent incest in the offspring (please also see para. 9.6).

Counselling for Clients Undergoing Infertility Treatment

7.8 Counselling must be available to help clients to cope with consequences of infertility and RT services. Counselling should be offered to support infertile people who are not suitable for RT procedure or those whose treatment has failed to allow them to adjust their expectation and to accept the situation.

7.9 When indicated, the clients should be referred for specialist counselling or support group counselling as appropriate.

Counselling for Potential Donors of Gametes or Embryos

7.10 Counsellors should ask potential donors of gametes or embryos to

²⁴ s.33(3), s.33(4) and s.33(5) of the Ordinance

consider all possible implications such as -

- (a) their reasons for wanting to donate gametes or embryos;
- (b) implications of the procedure for themselves, their spouse, their family and relatives, their social circle and any resulting child;
- (c) their feelings about manipulation of their gametes or embryos outside the human body and the possible storage and disposal of gametes or embryos;
- (d) their willingness to forego knowledge of and responsibility for the resulting children;
- (e) the feelings of their spouse or sex partner;
- (f) their attitudes to allowing embryos which have been produced from their gametes to be used for research; and
- (g) the submission of their particulars to the register(s) kept by the Council in accordance with the Ordinance and its subsidiary legislation.²⁵ They should also be informed that a child born from RT procedure may apply to the Council when he/she reaches the age of 16 to check whether he/she was born in consequence of a RT procedure involving gametes or embryos not solely from his/her parents.²⁶

²⁵ s.33(1) and s.33(2), s.45(2)(c) and s.45(2)(d) of the Ordinance

²⁶ s.33(3), s.33(4) and s.33(5) of the Ordinance

Chapter VIII — Treatment Method

General Standards

8.1 The attending clinician must ensure that the treatment method offered is the one which best suits the couple's particular medical indication.

8.2 Established laboratory standards and clinical practices accepted by the professional association of the relevant specialty should be adopted to safeguard the health and safety of clients and donors. Licensed centres should promptly report to the Council any change(s) in their clinical and laboratory protocols.

8.3 New reproductive technology and techniques must be scientifically validated and subject to ethical sanction by the Ethics Committee of the Council prior to introduction into clinical practice.

8.4 Indication for selecting a particular RT procedure must be stated in each case.

8.5 Side effects and complications arising from RT procedure must be recorded for each case.

Embryonic/Foetal Reduction

8.6 Whenever possible, RT practitioners must take measures to prevent high multiple pregnancies. This is to avoid the known risks of foetal mortality and retarded growth development in such cases, the health hazards to the mother and the possible psychological and practical consequences for both parents.

8.7 For IVF techniques, no more than 3 embryos should be placed at a time. The Council will require additional information from clinics reporting high rates of multiple pregnancies.

8.8 If a pregnancy involving multiple foetuses should occur despite the above-mentioned precautions having been taken, and if the prognosis for the foetuses is so unfavourable, a procedure of foetal reduction may be necessary. The carrying out of foetal reduction procedure should comply with section 47A of the Offences Against the Person Ordinance (Cap. 212). The possibility of foetal reduction should be included in the pre-treatment counselling. Parents should be clearly informed of the reasons for embryonic/foetal reduction and the possible risks involved, and the procedure may not be carried out without their consent.

8.9 Embryonic/foetal reduction should not be carried out simply to comply with the request of the parents who prefer to have a fewer number of children from the pregnancy.

Pre-implantation Genetic Testing (PGT)

8.10 Pre-implantation genetic testing (PGT), including Pre-implantation genetic testing – aneuploidy (PGT-A) and Pre-implantation genetic testing for monogenic defects/chromosomal structural rearrangement (PGT-M/SR), may be conducted only if there are clinical indications for screening of the embryos; and in which event, licensed centres need to provide the Council a report (see **Annex VII**) within 3 months after the completion of the procedure detailing –

- (a) the clinical indication(s)/ the nature of the genetic condition/ abnormality;
- (b) the likely impact(s) on the embryo(s);
- (c) the anticipated risk of transmission; and
- (d) the effectiveness of PGT in the circumstances.

For this purpose, the date of completion of the procedure shall not be later than the date of issue of the PGT analysis report by the genetic diagnostic laboratory.

When PGT-M/SR or PGT-A is used to combine with IVF as a means of avoiding the transmission of a genetic abnormality or disease, the medical practitioners shall follow the principles of the Ethical Guidelines on PGT at **Appendix III** (please also see para. 6 of Appendix III for the reporting requirements).

Sperm-washing

8.11 Laboratories licensed by the Council performing sperm- washing for other licensed centres must ensure that the referring practitioner/centre is permitted to carry on a relevant activity.

8.12 These licensed laboratories are required to have a proper procedure in place to ensure that sperm samples are not mixed up during the entire period of time when such samples are within their custody, care or control.

Chapter IX — Use of Gametes and Embryos

Collection of Gametes or Embryos

9.1 Collection of sperm for donation purpose and retrieval of eggs or embryos should only take place at a licensed centre.

Screening and Selection of Gametes or Embryos

9.2 Only cryopreserved semen should be used for donor insemination (DI) to allow time for the screening process of donors and to reduce the possibility of incest. For artificial insemination by husband (AIH), both cryopreserved and fresh semen can be used.

9.3 Gametes and embryos which have been subject to procedures which carry an actual or unreasonable risk or harm to their developmental potential should not be used for treatment.

Local Transfer of Gametes or Embryos between Licensed Centres

9.4 In the case of local transfer of gametes or embryos between licensed centres, the guidelines at **Appendix IV** should be observed.

Importation of Gametes or Embryos

9.5 Gametes or embryos should not be imported for infertility treatment or embryo research unless the following conditions have been fulfilled -

- (a) the use of imported embryos must follow the Ordinance and the laws of Hong Kong. No embryo that is created for research should be imported. Information as required in data collection forms (DC Forms) 5 and 6 of **Annex III** has to be submitted to the Council (please see para. 14.5);
- (b) the supplier has fulfilled all statutory health and export requirements of the exporting country;
- (c) the supplier has not breached the code of practice in relation to RT or embryo research of the exporting country;
- (d) the supplier is from a credible institution with good track records;
- (e) the supplier certifies that the donated gametes or embryos have been screened against communicable diseases and hereditary disorders in compliance with international professional standards, taking into account the epidemiological pattern of diseases of the population from whom they are collected; and
- (f) the supplier and RT practitioner concerned ensure that the safety and quality of the gametes or embryos are protected during the transport process, in which -
 - (i) a reputable courier should be employed;
 - (ii) the container must be securely sealed to avoid contamination and prevent tampering;
 - (iii) suitable cold storage to preserve the gametes or embryos should be ensured; and
 - (iv) a specified person should be assigned to collect the gametes or embryos upon arrival.

Limitation on Number of Times Donated Gametes or Embryos may be Used

9.6 Gametes or embryos from any single donor should not be used to produce more than 3 “live birth events”. The person responsible is required to obtain clearance from the Council before the commencement of any RT treatment involving the use of donor gametes/embryos, by submitting to the Council the application form at **Annex V** (AF Form 1 for donor gametes; AF Form 2 for donor embryos) as appropriate, with Part I of the form duly filled in.

9.7 Upon approval, and after the donor gametes/embryos concerned have actually been used for the treatment of the recipient specified in the application form, licensed centres are required to inform the Council within 1 week of the date when a donor’s gametes or embryos are used (DC Forms 5 and 6 at **Annex III** are relevant) and report on any successful pregnancy and birth resulting from donor’s gametes or embryos via DC Forms 2 or 3 and 4 at **Annex III** respectively. The corresponding approval number given by the Council for the use of donor gametes/embryos should be quoted in all subsequent DC Forms submitted to the Council.

9.8 In case of imported gametes or embryos, only live birth events achieved in Hong Kong will be counted.

9.9 If the donor has specified a limit lower than 3 live birth events, this must be observed if practicable.

Limitation on Number and Source of Eggs or Embryos that may be Placed in a Woman

9.10 No more than 3 oocytes or embryos should be placed in a woman in any one cycle.

9.11 Women should not be treated with gametes or with embryos derived from the gametes of more than one man or woman during any treatment cycle.

Fresh Ovum Donation

9.12 Fresh ova should only be used and embryo transfer should only be performed after full discussion with the concerned parties on the respective risks of HIV transmission involved in the use of fresh ova/embryos and thawed embryos. The donor must have been screened negative for HIV status before the donation.

Exportation of Gametes or Embryos²⁷

9.13 No embryo should be exported after the appearance of the primitive streak. The primitive streak shall be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored.

9.14 If the donated gametes or embryos are intended to be exported for use by persons overseas, this should be specified in the consent form for donation.

9.15 A donor’s gametes or embryos which have produced 3 live birth

²⁷ s.45(2)(g) of the Ordinance

events in Hong Kong should not be exported for treatment of infertile patients overseas. Licensed centres should check with the Council on the number of live birth event when licensed centres handle exportation requests involving donor gametes/embryos.

9.16 Licensed centres should require their clients to confirm by way of a statutory declaration that they have read and understood the prohibitions set out in sections 15, 16 and 17 of the Ordinance and that they do not have the intention to use any of the gametes/embryos to be exported for any purpose in contravention with any of these prohibitions. Please see **Appendix IV** for further information to be included in the statutory declaration. Licensed centres should report to the Council within 3 months after they have exported any gametes or embryos. Information should include the personal particulars of the donor, or client/couple exporting the gamete(s)/embryo(s), destinations, date of export and the reason for export, etc.

Chapter X — Storage and Disposal of / Donation of Gametes and Embryos^{27a}

Security

10.1 The storage facility must be properly designed and maintained at a secure location with controlled access and away from possible sources of contamination.

10.2 The person responsible should allow access only to designated individuals in the licensed centre for whom such access is essential for their work.

10.3 The source of gametes and embryos should be accurately recorded and labelled in a manner which is not susceptible to unauthorised or undetectable alteration.

Ensuring Quality of Gametes and Embryos

10.4 Licensed centres are responsible for maintaining the gametes and embryos in good condition through periodic review of the status of the storage equipment and records.

Disposal of Gametes and Embryos

10.5 The ways by which surplus gametes and embryos will be disposed of should be discussed with the donors or clients and consent obtained in relation thereto vide the appropriate consent form(s). The guidelines on disposal of gametes or embryos at **Appendix V** should be observed.

Storage Period for **Donated Gametes or Embryos**

(A) Anonymous Donation

10.6 The maximum storage period for anonymous donation involving gametes or embryos should be 10 years or when the donated gametes or embryos have brought about 3 live birth events, whichever is earlier. The storage period should be counted starting from the day on which the gamete or embryo is donated (or fertilised if the donated gametes are subsequently used for creation of embryos), **irrespective of the premises in which it is stored**. Licensed centres may formulate their own policy for a maximum storage period of less than 10 years. Licensed centres are advised to remind the recipients every time when storage period is being extended of -

- (a) the need for timely plans for future RT treatments; and
- (b) the licensed centres' responsibility to dispose of or donate the stored gametes or embryos in accordance with the instructions indicated in their consent forms upon expiry of the maximum storage period.

(B) Designated Donation

^{27a} For safe handling and storage of ovarian tissues, licensed centres are advised to observe the good practice and protocols recommended in the *Guidance for Cell and Tissue Products* issued by the Department of Health in August 2021 or the latest version thereafter issued by the Department of Health.

10.7 Designated donations²⁸ of gametes or embryos should not be permitted unless under special circumstances (please also see para. 14.9 for reporting information to the Council on such cases). The maximum storage period for donated gametes or embryos for a designated recipient should not exceed 2 years. Except under special circumstances (in which event reporting to the Council is required, please also see para. 14.10 for reporting information to the Council on such cases), the maximum storage period for embryos produced from fertilizing donated gamete(s) with the gamete(s) from a designated recipient should also be 2 years. The storage period should be counted starting from the day on which the gamete or embryo is donated (or fertilised if the donated gametes are subsequently used for creation of embryos), **irrespective of the premises in which it is stored**. Application for use of remaining embryos produced from a designated recipient after one live birth event has been achieved must be made in writing to the Council **before the expiry of the maximum storage period of 2 years** (please also see Annex V). Late application will not be accepted.

Storage Period for Gametes or Embryos for Patients' Own Use

10.8 Whilst there is no statutory maximum storage period for gametes or embryos stored for patients' own use in a RT procedure, subject to the requirements under paras. 6.7, 6.8 and 7.6 above, licensed centres may formulate and inform patients of their own policy on the maximum storage period and the arrangements upon cessation of storage having considered the needs of individual patients. Licensed centres are advised to remind their patients every time when storage period is being extended of –

- (a) the need for timely plans for future RT treatments;
- (b) the licensed centres' responsibility to dispose of or donate the stored gametes or embryos in accordance with the instructions indicated in their consent forms upon expiry of the maximum storage period (please also see para. 10.10 (d)); and
- (c) for storage of gametes or embryos, relevant information on the decline in pregnancy rates associated with aging of women and use of stored gametes and/or embryos in bringing about human reproduction by artificial means at advanced maternal age, the risks of pregnancy at an advanced maternal age, and the impacts of delayed childbearing.

Storage of Embryos for Married Persons Only

10.9 Embryos may be stored in licensed premises only for and on behalf of the parties to a marriage. A single person should not be allowed to store embryos created by using his/her own gametes including such embryos created outside Hong Kong since creation of embryos involves RT procedures which should not be provided to a single person under the Ordinance.²⁹

General Principles to be Observed in the Storage of Gametes and Embryos

10.10 In general, the following guiding principles should be observed while storage services in relation to gametes and embryos are provided -

²⁸ s.15(6) of the Human Reproductive Technology (Licensing) Regulation (Cap 561 sub. leg. A)

²⁹ s.15(5) of the Ordinance

- (a) the welfare of the child is of paramount importance;
- (b) appropriate counselling on all possible implications must be provided by service providers before patients make their decision as to whether to store their gametes or embryos;
- (c) all clients/donors must consent in writing and specify the purpose(s) for which their gametes or embryos may be used. Consent in writing may be given for one or more of the following purpose(s) -
 - (i) to provide treatment for themselves or their spouse;
 - (ii) to be donated for treating other infertile couples;
 - (iii) for research
- (d) for gametes or embryos stored for patients' own use in a RT procedure, the storage period should be counted starting from the day on which the gamete or embryos begins to be stored, irrespective of the premises in which it is stored. For donated gametes or embryos, the storage period should be counted starting from the day on which the gamete or embryo is donated (or fertilised if the donated gametes are subsequently used for creation of embryos). Licensed centres should ensure that the stored gametes or embryos are promptly disposed of or donated in accordance with the instructions indicated in the latest consent forms as and when appropriate. They must state what is to be done with the gametes or embryos (i.e. whether to donate them to other infertile couples or for research or to let them perish or for quality control or training) if they die or become incapable of revoking their consent. In the case of storage of embryos, the patient should also state in the consent form what is to be done with the stored embryos if the patient divorces or becomes legally separated;
- (e) a couple should have joint authority to determine what is to be done to the embryos created from their gametes or donors' gametes. Their conjoint decision in this regard should be obtained in writing before gametes collection and fertilization;
- (f) gametes or embryos stored for the client's or commissioning couple's own use should not be stored beyond the death of the client or either one of the commissioning couple, except that the gametes of the surviving spouse may still be retained for storage. If it is the wish of the client or commissioning couple and their written (conjoint) consent is obtained, the stored gametes or embryos may be donated for research or for treatment of other infertile couples or for quality control or training. Such donated gametes or embryos for treatment of other infertile couples have to be properly screened before use to ensure that no genetic or infectious disease would be transmitted. (please see paras. 4.6-4.9 on screening of donors); and
- (g) a client/patient may, by giving a written notice to the licensed centre, collect his or her own gametes or embryos stored in the centre for the transfer of these gametes or embryos to –
 - (i) another local licensed centre; or
 - (ii) an overseas centre,for own use in RT procedure, donation to other couple(s) for use in RT procedure, or for donation for research, or for quality control or training.

10.11 Gametes stored on behalf of a patient should only be used for the treatment of the patient when the patient is married. Besides, in determining whether a certain RT procedure may be appropriately carried out for a patient, the patient's suitability for the procedure must be properly assessed in

accordance with the principles set out in paras. 4.3 and 4.4. In the case of the use of gametes or embryos stored on behalf of cancer or other patients rendered infertile as a result of chemotherapy, radiotherapy, surgery or other medical treatment, service providers must consider whether the patient has sufficiently recovered. The appropriate timing for insemination or gamete/embryo transfer is a matter for clinical judgment. Service providers are required to seek opinion from experts of the relevant discipline where necessary. Proper counselling should also be provided for these patients who should be informed of the possible consequences of undergoing insemination or gamete/embryo transfer in his/her then medical conditions, and the possible implications for the child to be born. Arrangements to bring about a posthumous child should not be allowed.³⁰ Besides, persons responsible and licensees are reminded that, according to section 20 of the Ordinance, no person who has a conscientious objection to participating in a relevant activity authorized by a licence shall be under any duty, howsoever arising, to do so.

Posthumous Arrangement

10.12 Under the Parent and Child Ordinance (Cap. 429), where the sperm of a man was used after his death, or where an embryo was used after the death of the man with whose sperm the embryo was created, that man is not to be regarded as the father of the child for the purposes of the law of succession.³¹

10.13 Given the complexities and potential consequences of posthumous use of gametes or embryos, **stored gametes or embryos should not be used to bring about a posthumous child**. In cases where gametes or embryos are for the patient's or the commissioning couple's own use, upon the death of the patient/either one of the commissioning couple, the stored gametes or embryos should be disposed of, except that the gametes of the surviving spouse may still be retained for storage. However, if the patient has given written consent, or the commissioning couple has given conjoint written consent, the stored gametes or embryos can be donated for research or for treatment of other infertile couples or for quality control or training.

³⁰ s.45(3) of the Ordinance

³¹ s.10(7)(a) and s.10(7)(b) of the Parent and Child Ordinance

Chapter XI — Research and Use of Embryos for Quality Control and Training Purposes

Basic Principles

11.1 The Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects at **Appendix VI** should be observed.

11.2 No person shall bring about the creation of a human embryo for the purpose of research.³²

11.3 All researches which involve the development, storage, manipulation and usage of human embryos outside human body must be licensed by the Council.³³

11.4 Research protocols on human embryo research must be approved by the institution's own research ethics committee before it is submitted to the Council for licence. Licensed centres should promptly report to the Council any change(s) in their research protocols.

11.5 One of the factors that the Council will take into account in deciding whether to grant a licence for an embryo research project is the purpose for which the proposed project is carried out. Under normal circumstances, the Council will not grant a licence unless the project is considered necessary or desirable for the furtherance of one or more of the following purposes -

- (a) to promote advances in the treatment of infertility;
- (b) to increase knowledge about the causes or treatment of congenital diseases;
- (c) to increase knowledge about the causes or treatment of miscarriages;
- (d) to develop more effective techniques of contraception;
- (e) to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation;
- (f) to increase knowledge about the development of embryos;
- (g) to increase knowledge about serious diseases; and
- (h) to enable such knowledge to be applied in the development of treatments to combat serious diseases.

Prohibitions in Connection with Embryos

11.6 The following activities in relation to human embryos are prohibited under the Ordinance -³⁴

- (a) to bring about the creation of a human embryo for the purpose of embryo research;
- (b) to combine human and non-human gametes or embryos or any part thereof such as to give rise to a 2-cell zygote for the purpose of research (under such restriction, the Hamster Test may be performed under licence);
- (c) to keep or use an embryo after the appearance of the primitive streak;

³² s.15(1)(a)(i) of the Ordinance

³³ s.2(1) (definition of “relevant activities” and “reproductive technology procedure”) and s.13 of the Ordinance

³⁴ s15(1)(a) to (f) of the Ordinance

- (d) to place any non-human gamete or embryo or any part thereof in any human;
- (e) to place any human gamete or embryo or any part thereof in any animal;
- (f) to replace the nucleus of a cell of an embryo with a nucleus taken from any other cell; and
- (g) to clone any embryo.

Use of Embryos for Research

11.7 Where excess embryos are donated for research, written consent from the donors of the embryo must be obtained.

11.8 The standard of care provided to infertile couple should not be affected by their decision to donate or not to donate embryos for research.

11.9 No inducement or payment³⁵ may be offered to potential donors to influence their decision.

11.10 No staff should be under any obligation to participate in embryo research if they have conscientious objection.³⁶

11.11 Each institution involved in embryo research must maintain a multi-disciplinary institutional research ethics committee. Before permitting research, the institutional research ethics committee must satisfy itself -

- (a) on the validity of the research;
- (b) that the objectives of the proposed research cannot be achieved in any other way; and
- (c) that the researchers have the necessary facilities and skills.

11.12 The institutional research ethics committee has the duty to monitor the progress of the research.

Use of Human Embryonic Stem Cell for Research

11.13 Researchers should note that extraction of embryonic stem cell would be regarded as use or manipulation of embryo and any research which involves the creation, use or manipulation of an embryo is an embryo research. Thus, the combination of human embryonic stem cells with non-human embryos, for the purpose of embryo research, is prohibited under section 15(1)(a)(ii) of the Ordinance. Any person involving in the research relating to the use of human embryonic stem cell shall observe and follow the Ethical Guidelines for Human Embryonic Stem Cell Research at **Appendix VII**.

Use of Foetal Ovarian or Testicular Tissue

11.14 The use of foetal ovarian or testicular tissue for infertility treatment is prohibited under the Ordinance.³⁷

11.15 In the case of embryo research, the use of foetal ovarian or testicular

³⁵ s.2(1) (see interpretation of the term “payment”) and s.16(1)(a) of the Ordinance

³⁶ s.20(1) of the Ordinance

³⁷ s.15(2) of the Ordinance

tissue is acceptable subject to the following controls -

- (a) any activity prohibited under the Ordinance is strictly banned, including the prohibition under section 15(1)(a)(i) of the Ordinance that no person shall, for the purpose of embryo research, bring about the creation of an embryo;
- (b) any embryo research activity not prohibited by law must be vetted by the applicant's own institutional ethics committee before it is submitted to the Council for approval to carry on the relevant activity under licence;
- (c) written consent must be obtained from the mother of the foetus;
- (d) written consent should be obtained from the spouse or sex partner (if unmarried) of the mother of the foetus where practicable; and
- (e) there should be no financial reward for donating foetal tissue.

11.16 The decision to carry out an abortion must be reached without consideration of the benefits of subsequent use of the aborted foetal tissue for embryo research purposes.

11.17 The management of the pregnancy of any mother should not be influenced by any potential use of the foetal tissue for embryo research purposes.

Genetic Manipulation

11.18 Any research which involves alteration of the genetic structure of gametes or embryos must be approved by the institutional research ethics committee before it is submitted to the Council for licence.

11.19 An intervention or research seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

11.20 Germ-line gene therapy should not be performed.

Prohibition Against Commercial Dealings

11.21 Commercial dealings in gametes, embryos or foetal ovarian or testicular tissues are prohibited under the Ordinance.³⁸

Terms of Reference and Membership of Institutional Research Ethics Committee

11.22 The institutional research ethics committee should be responsible for scrutinizing research proposals involving human gametes or embryos before the proposals are submitted to the Council. In considering any such research proposal, guidelines relating to the use of human gametes, embryos or foetal tissues as provided in the Code should be followed.

11.23 An institution performing embryo research should have a research ethics committee, such committee should be formed and operated in accordance with the principles of the Declaration of Helsinki. As a general guideline, the following terms of reference could be considered -

³⁸ s.16 of the Ordinance

- (a) to advise the appointing institution on the ethics of the methodology involved in research involving human gametes or embryos;
- (b) to keep under review such guidelines on the ethical requirements in research involving human gametes or embryos;
- (c) to consider individual research protocols submitted to the committee, to advise the investigators and other bodies in the light of approved guidelines and where appropriate to certify that ethical requirements have been fulfilled, to enable researchers to state in their publications that ethical problems have received independent consideration; and
- (d) to seek advice as appropriate from specialist advisers.

11.24 The membership of research ethics committees should allow for a sufficiently broad range of experience and expertise so that the committee can take account of the scientific and medical aspects as well as the ethical implications of a research proposal. Co-option of members should be allowed where appropriate. Members should be required to declare any interest for each proposal submitted.

General Principles to be Observed for Use of Excess Embryos for Quality Control and Training Purposes

11.25 In general, the following guiding principles should be observed while using embryos for quality control and training purposes -

- (a) the number of embryos to be used should be kept to a minimum;
- (b) use of the embryos must be reasonably incidental to quality control and training purposes; and
- (c) under the direct supervision of embryologist(s) and/or qualified embryology laboratory staff.

Chapter XII — Surrogacy

12.1 Commercial surrogacy is prohibited under the Ordinance. Its arrangement or advertising is a criminal offence.³⁹

12.2 RT procedure may be provided pursuant to a surrogacy arrangement only if -

- (a) the gametes used in the procedure are those of the parties to a marriage⁴⁰; and
- (b) the wife in that marriage is unable to carry a pregnancy to term and no other treatment option is practicable for her.

12.3 The suitability of a woman to be a surrogate mother should be assessed by a registered medical practitioner⁴¹, who is not responsible for the RT procedures regarding the surrogacy, by taking into account the following considerations -

- (a) marital status;
- (b) history of pregnancy; and
- (c) physical and mental fitness to carry a baby

of the woman. A woman who is at a higher risk of suffering from complications of pregnancy should not be allowed to be a surrogate mother.

12.4 A woman under the age of 21 shall not act as a surrogate mother.

12.5 Surrogacy should require the consent of both the surrogate mother and her husband if she is currently married.

12.6 The commissioning couple and surrogate mother should be informed that the surrogacy arrangement is unenforceable under law.⁴²

12.7 Counselling must be provided by a multi-disciplinary team of the licensed centre for the commissioning couple and surrogate mother and her husband (if any) to ensure that all parties concerned understand the medical, social, legal, moral and ethical implications of surrogacy. The multi-disciplinary team for counselling in surrogacy should at least comprise -

- (a) 2 non-attending registered medical practitioners who both recommended the arrangement to explain the medical implications and consequences;
- (b) a legal advisor familiar with family matters to explain the legal implications to both the surrogate mother and the commissioning couple;
- (c) a social worker familiar with medical related issues to explain the social and moral impacts;
- (d) and/or a clinical psychologist when appropriate to make assessment.

³⁹ s.17 of the Ordinance

⁴⁰ s.14 of the Ordinance

⁴¹ a medical practitioner registered in accordance with s.14 of the Medical Registration Ordinance (Cap. 161)

⁴² s.18 of the Ordinance

12.8 In assessing surrogate mother (and her husband if any) and the commissioning couple, the welfare of the child is of paramount importance. The assessment should take into account their physical, mental and social well-being, including the following factors -

- (a) their commitment to having and bringing up a child or children;
- (b) their ability to provide a stable and supportive environment for any child born as a result of surrogacy;
- (c) their medical histories and the medical histories of their families;
- (d) their ages and likely future ability to look after or provide for a child's needs;
- (e) their ability to meet the needs of any child or children who may be born as a result of surrogacy, including the implications of any possible multiple births or disability;
- (f) any risk of harm to the child or children who may be born, including the risk of inherited disorders, problems during pregnancy and of neglect or abuse; and
- (g) the possible attitudes of other members of the family towards the child.

12.9 Recommendations of surrogacy with reasons and details of the counselling should be recorded properly.

12.10 Licensed centres should report to the Council on cases of surrogacy within 3 months after completion of the procedure for each treatment cycle. It is advisable to submit this report together with DC Form 1 at **Annex III** as required in para. 14.8. Information to be reported should include the personal particulars of the commissioning couple and surrogate mother (and her husband if any), their relationship and detailed justifications.

Chapter XIII — Gender Selection

13.1 The use of RT procedures for the purpose of foetal sex selection for avoidance and prevention of the birth of a child with a severe sex-linked genetic disease should only be offered in cases where not less than 2 registered medical practitioners each state in writing that such selection is for the aforesaid purpose and that the disease sought to be avoided or prevented would be sufficiently severe to a person suffering it to justify such selection.⁴³

13.2 Sex selection for social reasons or for reasons other than the avoidance or prevention of the birth of a child with a severe sex-linked genetic disease is prohibited under the Ordinance.⁴⁴

13.3 Counselling should be provided to clients to facilitate their informed decision on sex selection or other available options.

13.4 Sex selection may be conducted only for the purpose of avoiding a sex-linked genetic disease specified in **Schedule 2**⁴⁵ to the Ordinance which may prejudice the health of the embryo. Each disease in the schedule by itself is not a conclusive indication for sex selection. The schedule is at **Appendix VIII** for reference. In addition, due to the technological advancement in PGT and prenatal testing, many sex-linked genetic diseases could be accurately detected without resorting to sex selection of gametes or embryos. Sex selection should be the **last resort** to prevent sex-linked genetic diseases, as they could potentially be detected by PGT or prenatal testing (see Note).

13.5 Patients/clients should be advised to take into account the following factors when considering whether sex selection is an option to avoid the birth of a child with a severe sex-linked genetic disease -

- (a) the probability of having an affected child;
- (b) the chance of the child being physically or mentally handicapped;
- (c) the natural history of the disease;
- (d) the life expectancy of an affected child;
- (e) whether the affected child needs to go through life long and/or invasive medical procedures/treatment;
- (f) the perception of the parents of having an affected child;
- (g) the ability of the parents to cope with an affected child; and
- (h) the family and social support available for the parents.

13.6 Sperm treatment with sex-selective insemination has variable effectiveness. If this is recommended for cases which have a clear medical indication, the lack of reliability of any technique used should be disclosed to the patient.

13.7 PGT with sex-selective embryo transfer should only be carried out on medical grounds and in compliance with the requirement laid down in this part. PGT technique applied to determine normality of the embryo shall not be used for the purpose of sex selection.

⁴³ s.15(3)(b) of the Ordinance

⁴⁴ s.15(3)(b) of the Ordinance

⁴⁵ s.15(3)(a) and Schedule 2 of the Ordinance

Note In general, PGT and similar techniques should be adopted to detect genetic diseases in embryos. Sex selection should be considered as the last resort, and only when these tests are not feasible.

13.8 Prenatal diagnosis with sex-selective abortion without medical grounds contravenes sections 46-47B of the Offences Against the Person Ordinance (Cap. 212) and renders the offender liable to criminal prosecution.

13.9 Licensed centres should report to the Council on cases of sex selection achieved through RT (e.g. using sperm treatment with sex-selective insemination or PGT with sex-selective embryo transfer) within 3 months after the procedure has taken place. Information should include the personal particulars of the commissioning couple, the indication, the choice of technique and the outcome of sex selection procedure. The Council may make regulation specifying any other information to be submitted to the Council.⁴⁶

13.10 Licensed centres should also report to the Council on cases which resort to sex-selective abortion within 3 months after the abortion. Information should include the personal particulars of the couple, details of the indication as well as the sex of the abortus. Service providers are reminded to comply with section 47A of the Offences Against the Person Ordinance (Cap. 212) in relation to medical termination of pregnancy.

⁴⁶ s.45(2)(d) of the Ordinance

Chapter XIV — Record Keeping and Information Management

Accuracy and Confidentiality of Information

14.1 Licensed centres must ensure personal records with identifying information are kept in confidence with controlled access and disclosed only in circumstances permitted by the Ordinance.⁴⁷ Persons responsible should familiarize themselves with the Guidance Note on Data Security Measures for Information and Communications Technology issued by the Office of Privacy Commissioner for Personal Data.

Keeping of Record

14.2 Licensed centres must keep medical records containing the names, correspondence addresses, identity card/passport numbers of all patients, donors and recipients of gametes and embryos. The record should include information on RT procedures performed, outcomes of RT procedures, the storage of gametes and embryos and the offspring produced as far as it is practicable. Derivations from the licensed centres' clinical protocols must be properly justified and documented (e.g. in the medical records of the patients concerned). Licensed centres should also properly and adequately monitor their associated doctors so as to ensure due compliance with the licensed centres' clinical protocols. The registers and records required to be kept and maintained by licensed centres are listed at **Appendix IX**. Licensed centres must ensure that these registers and records are readily accessible for inspection by persons authorized by the Council and/or upon lawful request by other persons (Please also see **Appendix X**). If these registers and records are kept in electronic form, licensed centres are required to put in place protocol on how to ensure records would be readily accessed for inspection.

14.3 General medical record kept and maintained under a treatment licence should be retained by the licensed centres for at least 6 years after the patient ceases to be a client of the licensed centre. Record concerning the usage of donated gametes or embryos should be kept by licensed centres, associated doctors or satellite centres for at least 80 years. Licensed centres with research licence should keep record for at least 3 years after the report of the related research project was finalized and submitted to the Council.

Submission of Information to Council

14.4 Licensed centres are required to submit to the Council any information as required by it.

(A) Register A

14.5 Under section 33 of the Ordinance, the Council is required to keep and maintain a register, called Register A⁴⁸, which shall contain any information obtained by the Council that -

- (a) relates to the provision of a RT procedure where a child born or

⁴⁷ s.34, s.35 and s.36 of the Ordinance

⁴⁸ s.33(1) and s.33(2) of the Ordinance and Human Reproductive Technology (Licensing) Regulation (Cap 561 sub. leg. A)

- intended to be born in consequence of the procedure was not created from the gametes solely of the parents of the child; and
- (b) the child, any of the parties to the marriage, or any individual whose gametes have been used, or any combination thereof, can be identified from the information.

14.6 The information required in para. 14.5 above should be submitted in the prescribed format using the DC Forms 2, 3, 4, 5 and 6 at **Annex III**.

(B) RT Procedures not Involving Use of Donated Gametes or Embryos

14.7 For RT procedures not involving the use of donated gametes or donated embryos, licensed centres are required to submit to the Council non-identifying information about RT treatments provided to clients on a quarterly basis.

14.8 The information required in para. 14.7 above should be submitted in the prescribed format using the DC Forms 1 and 4 at **Annex III**.

(C) Designated Donation

14.9 Designated donations of gametes/embryos should not be permitted unless under special circumstances. Licensed centres should report to the Council on such cases in writing within 3 months after completion of the procedure for each treatment cycle. It is advisable to submit this report together with the appropriate DC Forms (as in **Annex III**), as required in para. 14.6. Information should include personal particulars of the donor(s) and the recipient couple, the approval number for the use of donor sperm/egg/embryos as provided by the Council, their relationship and detailed justifications as to why the donation has to be designated.

14.10 Embryos produced from fertilizing donated gamete(s) with the gamete(s) from a designated recipient should not be stored for more than 2 years except under special circumstances. In case embryo(s) produced from fertilizing donated gamete(s) with the gamete(s) from a designated recipient, and which has/have been stored for more than 2 years, is/are used, the licensed centres concerned should submit a report to the Council within 3 months after completion of the procedure for each treatment cycle. It is advisable to submit this report together with the appropriate DC Forms. The period for which the embryo(s) has been stored before use, together with the reasons and justifications for the use of embryo(s) which exceed the maximum storage period of 2 years, should be clearly stated in the report.

(D) Others

14.11 Detailed information on the following should also be submitted to the Council on each case -

- (a) use of donor gametes/embryos (para. 9.6 and Annex V);
- (b) exportation of gametes and embryos (para. 9.16);
- (c) surrogacy (para. 12.10);
- (d) sex selection (paras. 13.9 and 13.10)
- (e) pre-implantation genetic testing (PGT) (para. 6 of Appendix III);
- (f) tissue typing in conjunction with PGT-M/SR (para. 9 of Appendix III); and

- (g) local transfer involving donor gametes or embryos (para. 8 of Appendix IV).

(E) Annual Statistics

14.12 Other non-identifying data in the prescribed format at **Annex IV** should be submitted on an annual basis to the Council by end of March every year. The use of uniform definitions should be adopted. (please refer to the glossary of common terms used in RT in this Code).

Disclosure of Information in Register A

14.13 Under section 34 of the Ordinance, no person who is or has been an authorized person or a person to whom a licence applies or the holder of a licence shall disclose any information contained or required to be contained in Register A, except under one or more of the circumstances specified in **Appendix X**.⁴⁹

Access to Information

14.14 Donors and recipients of gametes or embryos should be advised that a person who has attained the age of 16 may apply to the Council to ascertain whether or not that person was or may have been born in consequence of a RT procedure involving donated gametes or donated embryos.⁵⁰

Handling of Personal Data under the Personal Data (Privacy) Ordinance

14.15 The Personal Data (Privacy) Ordinance (Cap. 486) enables individuals to request access to and correction of personal data held by data users. RT service providers are advised that the rules and principles stipulated in the Personal Data (Privacy) Ordinance on the collection, retention, use, disposal, access to and correction of the personal data should be complied with.

Disclosure of Personal Information

14.16 Licensed centres should clearly explain to their clients (patients, donors, surrogate mothers and their spouses) that the personal data that they provide in connection with the provision of RT procedure(s)/donation may be disclosed for the purposes as stipulated by the Ordinance and the Code published from time to time by the Council. The relevant consent form pertaining to the respective RT procedures contains provisions drawing clients' attention to such disclosures by reference to **Appendix X** (for procedures involving the use of donor gametes or embryos only) and **Appendix XI** (for all RT procedures) where appropriate. Licensed centres should ensure that clients understand and consent to such disclosures. Should the clients, by not taking the option in the Consent Form, refuse to release all medical records, including their medical history, kept by the licensed centre and its doctor(s) or associated doctor(s) on them to the Council for the purpose of inspection and use in the course of discharging its regulatory functions under the Ordinance and the Code, licensed centres are responsible to keep separate records for RT and non-RT procedures, or to make prior arrangement as appropriate to cover up the non-RT parts of the records for inspection.

⁴⁹ s.33, s.34, s.35 and s.36 of the Ordinance

⁵⁰ s.33(3) of the Ordinance

14.17 If a licensed centre engages the service of another laboratory licensed by the Council for the purpose to carry out sperm washing or PGT procedure for a client, a copy of the relevant consent form duly signed by the client must be provided to the laboratory.

14.18 The laboratory whose service is engaged as mentioned in para. 14.17 above must in turn comply with all requirements in relation to the confidentiality, access and disclosure of the personal information, information and records of the client as stipulated by the Ordinance and this Code.

Chapter XV — Handling of Complaints

Complaints against Licensed Centres

15.1 Licensed centres should have in place an administrative arrangement with a designated staff at the appropriate level to acknowledge receipt of complaints and to take charge of investigations. The outcome of the investigation should be recorded and explained to the complainant.

15.2 If the complainant is dissatisfied with the outcome of investigation by the licensed centre, he/she should be advised of other channels of airing their grievances including, if appropriate, the Investigation Committee of the Council or the Medical Council of Hong Kong (for matters relating to possible professional misconduct of medical practitioners) or other regulatory professional bodies in Hong Kong.

Breach of Code of Practice

15.3 Any complaints of breach of the Code will be investigated by the Investigation Committee of the Council.⁵¹ Failure to co-operate with the Investigation Committee will be taken into account by the Council in assessing whether there is a ground for revocation, variation and/or suspension of the licence.

15.4 Professionals concerned are reminded that they are also bound by the codes of practice or ethics of their respective professional disciplines.

⁵¹ Schedule 1 s.6(c) of the Ordinance

References

In drawing up this Code, references have been made to the following documents -

1. Final Report of the Committee on Scientifically Assisted Human Reproduction, 1993, Hong Kong.
2. Code of Practice of the Human Fertilization & Embryology Authority, United Kingdom.
3. Code of Practice for Units Using In Vitro Fertilization and Related Reproductive Technology of the Fertility Society of Australia.
4. “Proceed with Care” - Final Report of the Royal Commission on New Reproductive Technologies, 1993, Canada.
5. Code of Professional Conduct for the Guidance of Registered Medical Practitioners by the Medical Council of Hong Kong.
6. Guidelines for the Use of Semen Donor Insemination. American Fertility Society 1990.
7. World Medical Association Statement on Ethical Aspects of Embryonic Reduction, adopted by the 47th WMA General Assembly, Bali, Indonesia, September 1995.
8. World Health Organisation. WHO Technical Report Series 820. Recent Advances in Medically Assisted Conception. Report of a WHO Scientific Group. Geneva 1992.
9. Review of the Guidance on the Research Use of Fetuses and Fetal Materials (The Polkinghorne Report), July 1989. Her Majesty’s Stationery Office. ISBN 0 10 107622 3.
10. Report of the Committee on the Ethics of Gene Therapy (The Clothier Report), January 1992. Her Majesty’s Stationery Office. ISBN 0 10 117882 4.
11. Peter S Harper, Practical Genetic Counselling, 4th Edition. Butterworth Heinmann, 1993.
12. 2008 Guidelines for Gamete and Embryo Donation, the American Society for Reproductive Medicine.

Glossary of Abbreviations in the Code and Common Terms Used in RT

Abbreviations in the Code

1. **RT** reproductive technology
2. **the Ordinance** the Human Reproductive Technology Ordinance
3. **the Code** the Code of Practice on Reproductive Technology and Embryo Research
4. **the Council** the Council on Human Reproductive Technology

Common Terms Used in RT

1. **Artificial insemination (AI)**
This refers to the placing of sperm inside a woman's vagina or uterus (i.e. womb) by means other than sexual intercourse. In artificial insemination by husband (AIH), the husband's sperm is used. In artificial insemination by donor (AID or DI), sperm collected from a man who is not the woman's husband is used.
2. **Cell**
The basic unit of all living organisms. Complex organisms such as humans are composed of somatic (body) cells and germ line (reproductive) cells.
3. **Chromosome**
A threadlike structure of DNA and associated proteins found coiled tightly together in the cell nucleus which carries genetic information in the form of genes. In humans each somatic cell contains 46 chromosomes (23 pairs); one of each chromosome in the pair is of maternal and one of paternal origin. Of these 22 are matching pairs and 1 pair determines sex (XX=female, XY=male).
4. **Cloning**
The production of two or more genetically identical individuals by nucleus substitution ("fusion cloning") or by mechanical division of a cleaving zygote to yield identical cells each of which can form a new individual.
5. **Cryopreservation**
The freezing of gametes or embryos, usually in liquid nitrogen at -196°C, in order to store them for subsequent use.
6. **Dispose of**
The term "dispose of" used in this Code in relation to gametes or embryos refers to the process of thawing, being left to perish and disposal.
7. **DNA**
Deoxyribonucleic acid, the major constituent of the chromosomes, and the hereditary material of most living organisms.
8. **Ectogenesis**
The complete development of an embryo outside the body.

9. **Ectopic pregnancy**
A pregnancy in which implantation has taken place outside the uterine cavity.
10. **Egg donation**
Process where a fertile woman donates an egg to be fertilized in vitro with the semen of the spouse of a woman who no longer produces eggs.
11. **Embryo**
The product of human conception, often understood to cover the period from fertilization to the end of the eighth week of pregnancy, during which time all the main organs are formed. “Pre-embryo” is sometimes used to cover the first 14 days’ development after fertilization. Around this point the “primitive streak” develops.
12. **Embryo (or ovum) transfer**
Placement into the uterus of an embryo at any embryonic stage from day 1 to day 7 after IVF or ICSI. Embryos from day 1 to day 3 can also be transferred into the fallopian tube.
13. **Epididymal sperm aspiration (ESA)**
A technique which aims to treat male infertility due to absence of sperm in the semen as a result of a blockage of the duct system. Such patients can have an operation to collect their sperm directly from the collection ducts behind the testicle (known as the epididymis).
14. **Fallopian tube**
The organ which carries an egg from the ovary to the womb.
15. **Fallopian replacement of eggs with delayed insemination (FREDI)**
Eggs of any maturity are placed in the fallopian tube without spermatozoa, which are supplied later by high intrauterine insemination (IUI) at a time when the eggs are judged to be fully mature.
16. **Fertilization**
The fusing together of the maternal and paternal genetic material from the sperm and the egg.
17. **Foetus**
The product of conception from end of embryonic stage (8 weeks after fertilization) until birth.
18. **Gametes**
The reproductive cells, sperm and egg, which fuse to form a zygote. Each human gamete contains a basic set of 23 chromosomes - a haploid set; on fusion of egg and sperm a full (diploid) set of 46 chromosomes results. All other (somatic) cells in the body contain 46 chromosomes in their nuclei.
19. **Gamete micromanipulation**
These methods aim to enable those couples where the husband has a low sperm count or poor quality sperm to use the husband’s sperm rather than donated sperm.

The objective of many of these techniques is to bypass the zona pellucida (protein shell) which surrounds the egg, as this layer often prevents sperm which have poor motility or morphology from penetrating and fertilizing the egg. Examples of these micromanipulation techniques include Zona Drilling (ZD), Partial Zona Dissection (PZD), Sub Zonal Insemination (SUZI) and Intra Cytoplasmic Sperm Injection (ICSI).

20. **Germ-line gene therapy**
A kind of gene therapy which would entail “foreign” genes into fertilized eggs; the inserted genes would be distributed among somatic cells (cells that form the non-genetic component of an organism) and germ cells (cells that constitute the reproductive or genetic material of an organism) and would be transmitted into future generations.
21. **Implantation**
The process whereby the embryo becomes burrowed in the lining of the uterus.
22. **Intra cytoplasmic sperm injection (ICSI)**
A method of gamete micromanipulation by which a single sperm is injected into the inner cellular structure of the egg.
23. **In vitro**
Literally, in glass. More commonly to describe a biological event that occurs in a laboratory or in an artificial environment.
24. **In vivo**
Describing a biological event that occurs in an intact animal or in the natural environment.
25. **In vitro fertilization (IVF)**
This technique is used mainly where a woman has no fallopian tubes or they are blocked. It has also been used in dealing with some types of male infertility and where the cause of infertility is unknown. Eggs are taken from the woman’s ovaries when judged to be ripe and before they are released naturally. It is then mixed with sperms in a dish (in vitro) so that fertilization can occur. Once the fertilized egg has started to develop it is transferred back to the woman’s womb. The embryo must implant in the womb for a pregnancy to be established.
26. **Laparoscopy**
Examination of the pelvic or other abdominal organs with a fibre optic telescope inserted surgically below the navel. During laparoscopy, suction applied to the needle can be used in the recovery of eggs from follicles in the ovary.
27. **Microinjection intra-fallopian transfer (MIFT)**
The process of laparoscopic transfer of microinjected oocytes to the fallopian tube.
28. **Ovary**
The female reproductive organ in which oocytes are produced from pre-existing germ cells.

- 29. **Ovulation**
The release of an egg from a follicle in the ovary.
- 30. **Ovum**
Egg; female gamete.
- 31. **Primitive streak**
A groove which develops in the embryo about 14-15 days after fertilization. This is the rudimentary nervous tissue of the embryo.
- 32. **Sperm**
A mature male germ cell, produced in the testicles.
- 33. **Sperm-washing**
A process in which spermatozoa are separated from seminal plasma.
- 34. **Superovulation**
The medical stimulation of the ovary with hormones so that a woman produces more eggs than usual in a monthly cycle.
- 35. **Uterus**
The womb; the female organ in which the foetus grows during pregnancy.
- 36. **Zygote**
The cell formed by the union of sperm and egg.

Appendix I

Guidelines for Screening of Potential Gamete/Embryo Donors and Recipients Against Infectious Diseases

1. The following guidelines for screening potential gamete/embryo donors and recipients aim at decreasing the potential hazard of transmission of infectious diseases through gamete/embryo donation. They are modified from the “2008 Guidelines for Gamete and Embryo Donation” issued by the American Society for Reproductive Medicine. Modifications are required because local conditions differ.

Guidelines for Screening Potential Semen Donor

2. The main purposes of these guidelines are to decrease the potential hazard for transmitting infectious agents by the use of frozen semen samples that have been adequately quarantined.

Medical History

3. The donors should be generally healthy and in general give no history to suggest hereditary and familial diseases.

4. A complete sexual history should be obtained to exclude as donors individuals who might be at high risk for HIV and/or who have multiple sex partners.

Physical Examination

5. The donor should have a complete physical examination including evaluation for urethral discharge, genital warts and genital ulcers, as well as routine laboratory screening, including blood group and Rh factor testing, before enlisting him in the programme.

6. Donor should have follow-up examinations for urethral discharge, genital warts, and genital ulcers and not be utilised if any of these findings are present.

Laboratory Screening

7. There is no absolute method of completely ensuring that infectious agents will not be transmitted by donor insemination, but the following guidelines, in addition to adequate history-taking and exclusion of individuals at high risk for HIV, should minimise the risk. The following serological tests should be performed -

- (a) serologic tests for syphilis should be obtained initially on blood serum and need not be repeated unless clinically indicated;
- (b) serum hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc) (immunoglobulin G (IgG) and immunoglobulin M (IgM)) and hepatitis C antibody should be tested initially and 6 months afterwards for each batch of stored gametes/embryos;
- (c) semen, urine or urethral cultures should be obtained initially for *Neisseria gonorrhoeae*. Either urethral or urinary testing for *Chlamydia trachomatis* should be performed. These cultures should be repeated at 6-month intervals or more frequently if clinically indicated;
- (d) serum antibody tests (IgG and IgM) for CMV should be obtained -

- (i) if the antibody tests are positive for active infection, the semen sample should not be used;
- (ii) if the antibody tests are positive without active infection, it is suggested that the donor should only be used with recipients who are CMV-positive;
- (iii) if the titers are negative, the donor should have CMV titers done at 6-month intervals; quarantined semen samples should not be released if the donor develops an antibody titer suggesting recent CMV infection;
- (iv) the donor should also be monitored for any development of heterophil-negative mononucleosis-type illness;
- (e) an initial serum screening for HIV antibodies should be performed -
 - (i) a positive assay should be verified with a Western Blot test before notifying the potential donor;
 - (ii) if the test is negative, semen samples may be collected and prepared for cryopreservation;
 - (iii) the donor should be tested again in 180 days for HIV, and the specimen should be released for use only if the results are negative; and
- (f) haematological tests on MCV screening for thalassaemia should be performed initially. Patients with low MCV should be subject to Haemoglobin pattern test.

Guidelines for Screening Potential Egg Donors

8. The main purposes of these guidelines are to decrease the potential hazard for transmitting infectious agents by the use of donated eggs.

Medical History

9. The donors should be generally healthy and in general give no history to suggest hereditary and familial diseases.

10. A complete sexual history should be obtained to exclude as donors individuals who might be at high risk for HIV and/or who have multiple sex partners.

Physical Examination

11. The donor should have a complete physical examination including evaluation for urethral discharge, genital warts and genital ulcers, as well as routine laboratory screening, including blood group and Rh factor testing, before enlisting her in the programme. If the use of donor eggs creates the potential of an Rh incompatibility, couples should be informed about the obstetrical significance of this condition.

12. Donor should have follow-up examinations for urethral discharge, genital warts, and genital ulcers and not be utilised if any of these findings are present.

Laboratory Screening

13. There is no absolute method of completely ensuring that infectious agents will not be transmitted via egg donation, but the following guidelines, in addition to adequate history-taking and exclusion of individuals at high risk for HIV, should minimise the risk. The following serological tests should be performed -

- (a) serologic tests for syphilis should be obtained initially on blood serum and need not be repeated unless clinically indicated;
- (b) serum hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc) (immunoglobulin G (IgG) and immunoglobulin M (IgM)) and hepatitis C antibody should be tested initially and at 6-month intervals;
- (c) Cervical cultures on urine or a swab obtained from the cervix, urethral meatus, or vagina for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. These cultures should be repeated at 6-month intervals or more frequently if clinically indicated;
- (d) serum antibody tests (IgG and IgM) for CMV should be obtained -
 - (i) if the antibody tests are positive for active infection, the donated eggs should not be used;
 - (ii) if the antibody tests are positive without active infection, it is suggested that the donor should only be used with recipients who are CMV-positive;
 - (iii) if the titers are negative, the donor should have CMV titers done at 6-month intervals;
 - (iv) the donor should also be monitored for any development of heterophil-negative mononucleosis-type illness;
- (e) an initial serum screening for HIV antibodies should be performed -
 - (i) a positive assay should be verified with a Western Blot test before notifying the potential donor;
 - (ii) the donor should be tested again in 180 days for HIV; and
- (f) haematological tests on MCV screening for thalassaemia should be performed initially. Patients with low MCV should be subject to Haemoglobin pattern test.

Use of fresh eggs

14. Fresh eggs should only be used after adequate counselling to the recipients about the risk of possible transmission of infectious diseases. The donor must have been screened negative for HIV status before the donation. In addition, hepatitis C nucleic acid test and HIV nucleic acid test are advisable in every donation involving the use of fresh eggs.

Freezing and quarantining of donated eggs or embryos fertilized from donor eggs

15. Fresh eggs should normally be used unless there are situations making the use of frozen eggs necessary.

16. In case donated eggs are frozen, they should be quarantined for at least 180 days before being used for fertilization.

17. Couples entering an egg donation arrangement should be -

- (a) informed that the use of fresh eggs for fertilization carries a risk, albeit a low risk, of acquiring HIV;
- (b) asked whether they are willing to assume such risk;
- (c) asked whether, alternative to (a) above and in order to avoid the said risk, they would like to have the donated eggs fertilized, the resulting embryos frozen and quarantined, and the donor recalled and retested for HIV 6 months after donation before undergoing embryo transfer; and
- (d) asked whether they would like to use frozen eggs if there are situations

making the use of frozen eggs necessary.

Guidelines for Screening Embryo Donors

18. The respective donors of the sperm and the egg in embryo donation should undergo screening according to the guidelines described in paras. 2-17 above.

Guidelines for Screening Recipients Undergoing Treatment Involving Donation

19. As a best practice, the recipient is advisable to undergo the same screening tests for infectious diseases as the donor, as mentioned in paras. 7 and 13 above.

Appendix II

Guidelines for Payment to Donors

1. This appendix provides guidance to licensed centres when paying gamete donors.
2. Under the Ordinance, donors should not be paid for the supply of gametes or embryos, except for reimbursing or defraying⁵²-
 - (a) the cost of removing, transporting or storing an embryo or gamete to be supplied; and
 - (b) any expenses or loss of earnings incurred by the donor.
3. Donors should only be reimbursed for all accountable expenses or loss of earning incurred by the donor as a result of donation.
4. There should be **NO payment** for supernumerary semen/egg donation.
5. The cost of removing, transporting or storing of gametes would not be borne by the donors.
6. The total expense for the donors is classified into 3 categories -
 - (a) loss of earnings;
 - (b) other accountable expenses; and
 - (c) medical expenses (for egg donors only).

Loss of Earnings

7. Payment for loss of earnings should be made on daily basis. The total daily amount that can be claimed under this category cannot exceed **HK\$630**. Licensed centres might at their discretion decide on the amount of payment for loss of earnings subject to detailed evidence provided by the donor.

Other Accountable Expenses

Travelling Expenses

8. Semen/egg donors can be reimbursed a fixed sum of **HK\$450** to cover the travelling expenses incurred in getting to the RT centre including the return trip.
9. For egg donation, the travelling expenses of the person accompanying the donor on the day of egg collection can also be reimbursed at the same rate i.e. **HK\$450**.

⁵² s.2(1) (see interpretation of the term “payment”) and s. 16(1)(a) of Human Reproductive Technology Ordinance (Cap. 561)

Minding Services

10. The donor may claim for expenses incurred for employing minding services for persons to be taken care by the donor like children, parents or grandparents etc. However, the donor is not eligible to claim for minding services if such services are not employed solely for the purpose of donation.

11. A certifying receipt or letter on the expenses signed by the provider of minding service should be provided to the licensed centre.

12. To prevent the abuse of the claim for minding services, the daily amount that can be reimbursed for employing minding services cannot exceed **HK\$360**. A donor who claims for defrayal or reimbursement for loss of earnings and/or expenses for substitute worker is not allowed to claim reimbursement for minding services.

Miscellaneous Expenses

13. The donor can be reimbursed for other expenses incurred by the donor for the purpose of donation, which may include payment by the donor to someone to cover his/her temporary absence from his/her work for the purpose of donation. The claim should be supported by receipt signed by the substitute worker.

14. The total daily amount that can be claimed by the donor under this section cannot exceed **HK\$630**.

Medical Expenses (For Egg Donor Only)

15. The egg donor is eligible to claim for medical expenses for treatment of medical implications arising from egg donation; no matter they are incurred during or after the donation procedure.

16. The donor should not be required to bear any medical expenses incurred as a result of donation. All medical expenses should be borne by the licensed centre so long as the medical expense is incurred as a result of the donation.

17. The egg donor should be advised to return to the original licensed centre where donation process is carried out for follow-up medical treatment. **The egg donor should not be charged for the medical expenses related to donation regardless of the duration.**

18. Where the egg donor receives medical treatment from other clinics, she should provide the original licensed centre with the attending doctor's supporting letter and receipt certifying the type of medical treatment and medical expenses for reimbursement.

19. There is **NO maximum payment** set for medical expenses incurred by the egg donor.

20. The egg donor is also eligible to claim for the loss of earnings and other accountable expenses incurred (same as sperm donor).

Maximum Daily Payment for Donation

21. Subject to the limit for each item of expenses as specified above, the maximum **daily** amount that may be paid to each donor for expenses or loss incurred is **HK\$1,710**. Such amount may be increased to **HK\$2,160** for expenses or loss incurred by an egg donor on the day of egg collection (to cover additional travelling expenses if the egg donor is accompanied to the donation centre by other person(s)), excluding medical expenses for which there is no upper limit.

Appendix III

Ethical Guidelines on Pre-implantation Genetic Testing (PGT)

General Principles

1. Pre-implantation genetic testing (PGT), including pre-implantation genetic testing for aneuploidy (PGT-A) and pre-implantation genetic testing for monogenic (or single gene) defects/chromosomal structural rearrangement (PGT-M/SR), is a test that may be used to combine with IVF as a means of avoiding the transmission of a genetic abnormality or disease. PGT must be conducted in accordance with the following basic ethical principles -

- (a) human life in all its forms warrants respect and special moral consideration;
- (b) the welfare of the child is of paramount importance;
- (c) personal autonomy, individual liberty and human integrity must be duly safeguarded;
- (d) basic community values such as responsible parenthood, parental love and the family should be recognized; and
- (e) use of resources must be based on the principles of care, equality, justice and accountability and a reasonable balance must be sought between individual and collective interests to protect vulnerable parties from harm or exploitation.

Application of PGT

2. PGT should only be used for the detection of serious genetic conditions or abnormalities that significantly affect the health of an individual who might be born. Due attention should be given to the differing views in society about seriousness of genetic conditions or abnormalities, and the potential development in medicine that may shift the boundaries defining seriousness of genetic conditions or abnormalities.

3. PGT should not be used with the intention to enable parents to select a baby with some desired social, physical or psychological characteristics.

Preparation for PGT Procedures

4. The use of PGT should be a matter of discussion between those seeking PGT (i.e. the parents) and the clinical team on the seriousness of the genetic condition or abnormality and their experience and perception of abnormality.

5. For PGT-M/SR, the clinical team should consist of 2 doctors, one of whom should have proper training in clinical genetics and/or genetic counselling.

6. The licensed centre, having discussed with the persons seeking PGT and determined the condition to be sufficiently serious to warrant PGT, need to provide the Council with a report (see **DC Form 9 of Annex III** of the Code) within 3 months after completion of the procedure, detailing -

- (a) the clinical indication(s)(for PGT-A)/the nature of the genetic condition/abnormality (for PGT-M/SR);
- (b) the likely effect of the genetic condition;
- (c) the anticipated risk of transmission; and
- (d) the effectiveness of the testing.

For this purpose, the date of completion of the procedure shall not be later than the date of issue of the PGT analysis report by the genetic diagnostic laboratory.

7. The licensed centre should follow the detailed reporting requirements as specified under the Human Reproductive Technology Ordinance, its regulations, and the legal notices and government notices issued from time to time by the Council on Human Reproductive Technology.

8. It is also necessary for the clinical team to provide the person seeking PGT with appropriate counselling and adequate information on the other genetic testing options.

Tissue Typing in Conjunction with PGT-M/SR

9. In addition to using PGT-M/SR to avoid serious genetic abnormalities or diseases, PGT-M/SR can be used together with histocompatibility leukocyte antigen (HLA) tissue typing to identify embryos which match a living sibling with a genetic condition, with the intention that when the matched embryo develops into a baby, blood can be harvested from its umbilical cord to provide stem cells for transplantation to the sibling. Practitioners who intend to undertake PGT-M/SR together with HLA have to seek prior approval from the Council on a **case by case basis**. Only applications for the harvest of cord blood or bone marrow would be considered, and the harvesting of non-regenerative organs is not acceptable. Tissue typing in conjunction with PGT-M/SR would be considered case by case with regard to compliance with the following basic ethical principles -

- (a) all other possibilities of treatment and existing sources of tissue for the affected child should have been explored;
- (b) the condition of the affected child should be severe or life-threatening;
- (c) the parents cannot be the intended tissue recipient and the primary intended tissue recipient should be a sibling;
- (d) embryos should not be genetically modified to provide a tissue match; and
- (e) appropriate pre-treatment and follow-up counselling should be provided to the couple to whom treatment is provided or intended to be provided. The counsellor should clearly explain to the couple that if the child is wanted for his/her own worth, the treatment might be justifiable. If the child is conceived solely for the purpose of creating a donor of stem cells for an existing sibling, the child's dignity is violated and the treatment is not justifiable.

10. Implications counselling should be provided by the centres offering pre-implantation tissue typing and the following factors should be considered -

- (a) the motivation and level of understanding of the parents (in particular the woman undertaking the IVF treatment) seeking to have additional child;
- (b) the condition of the existing child such as the degree of suffering associated with the condition of the affected child, the prognosis for the affected child in relation to all treatment options available;
- (c) the possible consequences of the child to be born (such as the risks associated with embryo biopsy for the child to be born, the likely long term emotional and psychological implications for the child to be born, whether the treatment of the affected child is likely to require intrusive surgery for the child to be born);

- (d) the family circumstances of the people seeking treatment such as the perception of the family on the consequences of the unsuccessful outcome, the issue which might arise when the birth of a child does not resolve the genetic condition of the existing child; and
- (e) the extent of social support available.

11. A clinical report in addition to that mentioned in para. 6 should be submitted to the Council with the application for the tissue typing procedure which should include the details of the condition of the existing child, prognosis for the affected child in relation to all treatment options available and evidences showing that the guiding principles of the above are strictly followed.

Appendix IV

Guidelines for Transfer of Stored Gametes or Embryos

Local Transfer of Gametes or Embryos between Licensed Centres

1. Gametes or embryos which have been stored in a licensed centre (the Original Centre) must only be transferred to another licensed centre (the Receiving Centre) for the purposes of carrying out relevant activities subject to the licence approved by the Council on Human Reproductive Technology (the Council).
2. If gametes or embryos are to be transferred between licensed centres, adequate arrangements should be made to protect their quality and security. Both the Original Centre and the Receiving Centre must make every endeavour to ensure that the correct gametes or embryos are being transferred.
3. Licensed centres must ensure that the gametes or embryos, which are to be transferred, are kept in such manner that their condition would not deteriorate. The containers shall be labelled in such a way as to make them easily identifiable according to the information provided by the Original Centre below. Above all, access to them should be restricted to the authorized persons and persons to whom the licence applies.
4. The Original Centre should keep a record of the centre to which the gametes or embryos were supplied and the date on which they were supplied. The Receiving Centre should keep a record of the centre from which the gametes or embryos were received and the date on which they were received.

Information to be Provided by Original Centre to Receiving Centre

5. The Original Centre should keep the original and provide a copy of the following documents to the Receiving Centre -
 - (a) a copy of the consent form(s) that relate to the gametes or embryos being supplied or transferred;
 - (b) if donated gametes or embryos are being supplied, a copy of the donor's record; and
 - (c) if patient's gametes or embryos are being transferred, a copy of the treatment records.
6. It is the responsibility of the Receiving Centre to ensure that effective consents have been given to the use and storage of any gametes or embryos that are being transferred to the centre. If the patient's own gametes or embryos are being transferred, the Receiving Centre must obtain consents from the patient for providing storage and treatment services.
7. The Original Centre should also provide a document certifying that the gametes or embryos have been collected and screened in accordance with the Code published by the Council.

Information to be Provided to the Council

8. If the transfer involves donor gametes or embryos, the **Original Centre** should report to the Council within 2 weeks after the completion of the transfer.

Information to be provided to the Council should include -

- (a) the name and licence number of the Original Centre;
- (b) the name and licence number of the Receiving Centre;
- (c) the purpose of transfer;
- (d) the donor's clinical record number;
- (e) the date of transfer and receipt;
- (f) the type and quantity of material being transferred (the Original Centre should state whether there is a partial or complete transfer of the gametes or embryos of a particular donor stored in the centre); and
- (g) approval number provided by the Council (for cases involving use of donor gametes/embryos only).

9. The **Receiving Centre** should also report to the Council by completing the DC Forms 5 or 6, and returning it/them to the Council upon the use of the gametes or embryos.

Payment for Transfer or Supply of Gametes or Embryos

10. The Original Centre could charge the Receiving Centre on the reasonable expenses incurred for the transfer or supply of the gametes or embryos. These may include defraying or reimbursing for ⁵³-

- (a) the cost of removing, transporting or storing an embryo or gamete to be supplied; and
- (b) any expenses or loss of earnings incurred by a person and attributable to the person supplying an embryo or gamete from the person's body.

Transfer of Gametes or Embryos to Overseas Centres

11. Clients may transfer gametes or embryos which have been stored in a licensed centre in Hong Kong to an overseas centre licensed or established according to the law where it is situated. Licensed centres should require their clients to confirm by way of a statutory declaration that they have read and understood the prohibitions set out in sections 15, 16 and 17 of the Ordinance and that they do not have the intention to use any of these gametes/embryos to be exported for any purpose in contravention with any of the prohibitions. The statutory declaration should also include (i) the name of the client; (2) Hong Kong Identity Card/Passport Number of the client; (3) address of the client; (4) name of the licensed centre from which the gametes/embryos are to be transferred; and (5) name of the overseas receiving centre to which the gametes/embryos are to be transferred (please see Annex VI to the Code for details). In making the transfer arrangement, the principles of paras. 2-4 of these guidelines should be observed. A reputable courier should be commissioned to carry out the transfer, and the requirements of exportation of gametes or embryos in paras. 9.13-9.16 of the Code should be complied with.

⁵³ Human Reproductive Technology Ordinance (Cap. 561) s.2(1) interpretation of the term "payment"

Guidelines on Disposal of Gametes or Embryos

1. Gametes or embryos may be disposed of in accordance with this appendix with the consent of the person/couple entitled to them.
 2. Gametes or embryos may be disposed of by allowing the gametes or embryos in its container to stand at room temperature, in a secure area, for a period of not less than 24 hours.
 3. The centre should follow the relevant Ordinances in the Laws of Hong Kong and any practice notes issued by the Government concerning the method of disposal.
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Appendix VI

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964,
and amended by the:

29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington 2002 (Note of Clarification on
paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

PREAMBLE

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

GENERAL PRINCIPLE

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
5. Medical progress is based on research that ultimately must include studies involving human subjects.
6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights.
8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.
9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.
10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.
11. Medical research should be conducted in a manner that minimises harm to the environment.
12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.
13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.
14. Physicians may combine medical research with medical care should involves their patients in research only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.

17. All medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs and priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.
22. The design and performance of each research study involving human subjects must be clearly described in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committees

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.
26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.
28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.
30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.
31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.
32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, analysis, storage and/or reuse. There may be exceptional situations where consent would be impossible or impractical to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Use of Placebo

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention(s), except in the following circumstances:

Where no current proven intervention exists, the use of placebo, or no intervention, is acceptable; or

Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention

and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to any additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

Post-Trial Provisions

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.
36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

October 2013*

* Please refer to the up-to-date version of the Helsinki Declaration at the website of the World Medical Association at <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

Ethical Guidelines for Human Embryonic Stem Cell Research

Preamble

1. Research on the early human embryo has long been recognized as essential to progress in a host of biomedical areas, from reproductive medicine to the treatment of paediatric cancers. Nowadays, with the possibility of stem cell research and cell replacement therapies, embryo research holds out the promise of cures for many serious disease conditions, such as diabetes and Alzheimer's disease. Stem cell has been the focus of discussion in the science circle. It also raises a lot of ethical issues, such as reproductive cloning.

2. In Hong Kong, the Human Reproductive Technology Ordinance (Cap. 561) (the Ordinance), which was enacted in June 2000, is the only piece of legislation governing the use of technologies on assisted reproduction and the use of embryo for research. The Council on Human Reproductive Technology (the Council), a statutory body formed under this ordinance, has recognized the importance of the science and application of stem cell technologies. A Working Group on New Developments in Reproductive Technology, which was formed under the Council to look into the development of advances in reproductive technology, has discussed the issues on human embryonic stem cells research. The Ethics Committee of the Council has also looked into the ethical issues of human embryonic stem cell research.

3. On the basis of the recommendations from the Ethics Committee, the Council adopted the following ethical guidelines for compliance by embryo researchers.

Human Embryonic Stem Cell Research

4. An underlying intermediate position with regard to the moral status of the human embryo is adopted. The intermediate position neither accords the embryo full moral status from the moment of its conception nor considers it void of any moral status. Instead, it accords the embryo moral respect, which increases relative to its biological development.

5. The potential benefits of embryonic stem cell research are sufficient justification of such research. Based on the intermediate position, the use of embryos or fetal tissues as sources for generating stem cells is ethically justified subject to the options as stated in paras. 6-11 below.

Options for Deriving Human Embryonic Stem Cells

6. As the embryo represents human life in its early form, its potential use for research must be commensurate with its moral status. In accordance with the intermediate position, it is ethically permissible to use "excess RT embryos" (see Note) for the derivation of stem cell lines and research.

7. Before "excess RT embryos" are used for deriving embryonic stem cells, it is necessary to first find out, in so far as is practicable, whether at present any stem cell lines exist in Hong Kong and to what extent they would meet present research needs.

8. Alternatively, the possibility of importing stem cell lines should be

examined. If human embryonic stem cells are to be imported into Hong Kong, it will be necessary to ensure that the Ordinance, its regulations and other relevant Ordinances are followed and that those stem cells are not derived from cloned embryos or embryos created for research purposes.

9. It is also worthy to consider whether adult stem cells could first be used before resorting to embryonic stem cells, given the fact that greater potential is increasingly being discovered with adult stem cells. Nevertheless, the apparent greater plasticity of embryonic stem cells compared to adult stem cells in developing into various types of cells needs to be taken into consideration as well as the fact that, at present, the yield of adult stem cells is insufficient.

10. Should none of these options meet research needs, it is ethically justified to generate stem cells from “excess RT embryos” in Hong Kong subject to certain restrictions.

11. Only the minimum number of excess RT embryos may be used for research.

Conditions for Human Embryonic Stem Cell Research

12. The purposes and the therapeutic benefits of human embryonic stem cell research must be sufficiently significant, non-trivial and well-founded. They must be commensurate with the respect due to the human embryo. Non-medical research with human embryonic stem cells (including eugenic enhancement and cosmetic research) is considered ethically unjustified.

13. There should be no commercial transactions or benefits with regard to embryo donation.

14. The morality of the process of donation must be ensured. This implies that the roles of persons conducting embryonic stem cell research and the persons providing IVF treatment should be separated and that documented, free and informed consent must be obtained. Due to the specific nature of embryonic stem cells and their virtual “immortality”, such consent should be obtained before donation for embryonic stem cell research. Donors should be protected against inducement, coercion or undue influence. Measures should be taken to provide for the reasonable protection and safeguarding of donor identity.

15. Fair access to and sharing of research results among researchers should be possible so as not to unduly restrict further research and adversely affect the development of therapeutic benefits.

Somatic Cell Nuclear Replacement

16. From both the scientific and ethical point of view, the Council considers that the “embryo” created by somatic cell nuclear replacement (SCNR) should be regarded as an embryo since it has the full potential to develop into a human being, regardless of the means of its creation (i.e. whether it has been formed by fertilization or not).

17. As section 15(1)(a) of the Ordinance prohibits the creation of an embryo for the purposes of embryo research, the creation of an embryo by SCNR for embryo research is therefore prohibited.

Research involving Mixing of Human Embryonic Stem Cells with Non-human Embryos or Vice Versa

18. Regarding research involving the mixing of human embryonic stem cells with non-human embryos or vice versa, the relevant provision is section 15(1)(a)(ii) of the Ordinance.

19. For the purpose of embryo research, combining human and non-human gametes or embryos or any part thereof such as to give rise to a 2 cell zygote is prohibited in section 15(1)(a)(ii) of the Ordinance. Since any embryonic stem cell forms part of the embryo, the mixing of human embryonic stem cells with non-human embryo or vice versa for the purpose of embryo research is not allowed.

Patenting of Embryonic Stem Cell Lines

20. The patenting of inventions involving elements of human origin leads to the question of morality as it tends to devalue human dignity. The bottom line drawn in the Hong Kong Patents Ordinance is that “patenting must not be contrary to public order and morality”. The following principles for patenting of human embryonic stem cell lines should be observed -

- (a) in accordance with the ethical principle of the non-commercialization of the human body, embryos should not be used for commercial or industrial purposes;
- (b) no remuneration should be paid to the persons who donate embryos for research purposes except for the reimbursement of necessary expenses;
- (c) based on the general distinction between discovery (not patentable) and invention (patentable), neither the human body itself, nor knowledge related to the human body or its elements (e.g. unmodified stem cells) are patentable. Embryonic stem cell lines with identified functions may, however, be patentable;
- (d) a just balance should be sought between the interests of the inventors and the interests of society so that access to health care will not be adversely affected; and
- (e) embryo donors should be provided with complete and specific information on how the donated embryo will be used, in particular the potential patenting of the embryonic stem cells extracted from the donated embryos and that they will not participate in the profit made from it. Informed and free consent needs to be obtained when embryos are donated and when the embryos are actually used for research to cultivate stem cell lines.

Use of Human Embryonic Stem Cell Lines

21. In order to minimize the destructive use of human embryos for the generation of embryonic stem cells and avoid unnecessary duplication of research, researchers should obtain information on existing stem cell lines and make best use of the resources available, both locally and from overseas.

Note:

The term “excess RT embryos” is defined as human embryos that-

- (a) were produced, by reproductive technology (RT) procedures, for use in treatment of a woman; and
- (b) are excess to the needs of -
 - (i) the woman for whom they were produced for RT treatment; and
 - (ii) her spouse at the time the embryos were produced by RT procedures.

Appendix VIII

Sex-linked Genetic Diseases ⁵⁴

-
- | | |
|--|---|
| 1. 46XY sex reversal 2 | 30. Hypophosphatemic rickets, X-linked |
| 2. Aarskog-Scott syndrome | 31. Incontinentia pigmenti |
| 3. Adrenal hypoplasia,, congenital | 32. Intellectual developmental disorder, X-linked 1 |
| 4. Adrenoleukodystrophy | 33. Intellectual developmental disorder, X-linked 109 |
| 5. Agammaglobulinemia, X-linked | 34. Kallmann syndrome 1 |
| 6. Albinism, ocular, type 1 | 35. Keratosis follicularis spinulosa decalvans, X-linked |
| 7. Alport syndrome 1, X-linked | 36. Lesch-Nyhan syndrome (hypoxanthine-guanine-phosphoribosyl transferase 1 deficiency) |
| 8. Amelogenesis imperfecta, type 1E | 37. Lowe oculocerebrorenal syndrome |
| 9. Androgen insensitivity | 38. Menkes disease |
| 10. Anemia, sideroblastic, 1 | 39. Microphthalmia, syndromic 1 |
| 11. Arts syndrome | 40. Mucopolysaccharidosis type II |
| 12. Cataract 40, X-linked | 41. Muscular dystrophy, Becker type |
| 13. Charcot-Marie-Tooth disease, X-linked recessive, 5 | 42. Muscular dystrophy, Duchenne type |
| 14. Charcot-Marie-Tooth neuropathy, X-linked dominant, 1 | 43. Myopathy, centronuclear, X-linked |
| 15. Choroideraemia | 44. Night blindness, congenital stationary, X-linked |
| 16. Coffin-Lowry syndrome | 45. Norrie disease |
| 17. Deafness, X-linked | 46. Ornithine transcarbamylase deficiency |
| 18. Diabetes insipidus, nephrogenic, 1, X-linked | 47. Orofaciodigital syndrome I |
| 19. Dyskeratosis congenita, X-linked | 48. Phosphoglycerate kinase 1 deficiency |
| 20. Ectodermal dysplasia 1, hypohidrotic, X-linked | 49. Phosphoribosylpyrophosphate synthetase superactivity |
| 21. Emery-Dreifuss muscular dystrophy 1, X-linked | 50. Retinitis pigmentosa, X-linked |
| 22. Fabry disease | 51. Retinoschisis 1, X-linked, juvenile |
| 23. Focal dermal hypoplasia | 52. Severe combined immunodeficiency, X-linked |
| 24. Fragile X syndrome | 53. Spastic paraplegia 2, X-linked |
| 25. Glycogen storage disease, type IXa1 and type IXa2 | 54. Spinal and bulbar muscular atrophy, X-linked 1 |
| 26. Granulomatous disease, chronic, X-linked | 55. Spinocerebellar ataxia, X-linked 1 |
| 27. Haemophilia A | 56. Spondyloepiphyseal dysplasia tarda, X-linked |
| 28. Haemophilia B | 57. Thrombocytopenia, X-linked |
| 29. Hydrocephalus, congenital, X-linked | 58. Wiskott-Aldrich syndrome |
-

⁵⁴ Schedule 2 to the Ordinance

Records to be Kept and Maintained by Licensed Centres

1. Under section 45(2) of the Human Reproductive Technology Ordinance (Cap. 561) (the Ordinance), the Council may make regulation to specify the registers and other records to be kept and maintained by licensed centres.

Registers to be Kept and Maintained by Licensed Centres

2. Licensed centres are required to keep and maintain the following -
 - (a) a Donors Register which contains information on every donor of gametes or embryos stored in the licensed premises at any time on or after the commencement of the Human Reproductive Technology (Licensing) Regulation (the Regulation). Types of information to be kept in the Donors Register should include, but not limited to -
 - (i) donor's clinic record number;
 - (ii) type of donated material stored in the centre;
 - (iii) date when the material was stored;
 - (iv) date when all the stored material was removed from storage or utilized; and
 - (v) outcome of treatment in which the donated material was used to facilitate checking the live birth events brought about by the material donated by any single donor.

As the Donors Register is keeping records of donors whose donated gametes or embryos are stored in the licensed premises, information on donors whose gametes or embryos are used immediately after donation and have not been stored at the licensed centre are not required to be entered into the Register;
 - (b) a Patients Register which contains -
 - (i) information on every person who undergoes a RT procedure in the licensed premises at any time on or after the commencement of the Regulation;
 - (ii) where the person is a woman, information on the person who was her husband when gametes were, or an embryo was, placed in her body pursuant to that procedure; and
 - (iii) where the person is a man, information on the person who was his wife when gametes were obtained from him.

Types of information to be kept in the Patients Register should include, but not limited to -

 - (i) patient's clinic record number;
 - (ii) name;
 - (iii) gender;
 - (iv) spouse's name;
 - (v) dates and types of RT procedures for every treatment cycle (see Note); and
 - (vi) whether the treatment involves donated gametes/embryos.
 - (c) a Children Register which contains information, if available, on every child born in consequence of a RT procedure provided in the licensed premises at any time on or after the commencement of the Regulation. Types of information to be kept in the Children Register should include, but not limited to -

- (i) clinic record numbers of parents;
- (ii) gender; and
- (iii) date of birth.

Records to be Kept and Maintained by Licensed Centres

3. Licensed centres are required to keep and maintain the following records -
- (a) assessment of donors and patients on suitability for RT procedure;
 - (b) counselling services provided to donors and patients;
 - (c) consents and withdrawals of consent to the storage and removal from storage of gametes or embryos at the centre;
 - (d) collection and storage of gametes or embryos at the centre;
 - (e) diagnosis of collected and stored gametes or embryos at the centre;
 - (f) any amounts paid to donors in respect of donations made at the centre;
 - (g) creation or attempted creation of embryos in vitro at the centre;
 - (h) destruction or disposal at the centre of any stored gametes or embryos created in vitro;
 - (i) RT procedures carried out on a woman at the centre;
 - (j) use of gametes or embryos in a RT procedure or research at the centre;
 - (k) outcome of a RT procedure, such as clinical pregnancy, miscarriage or death of an embryo or foetus, if this information is available at the centre;
 - (l) transfer of gametes or embryos to/from another licensed centre;
 - (m) importation and exportation of any gametes or embryos from/to overseas licensed centres;
 - (n) surrogacy arrangement carried out at the centre;
 - (o) fetal reduction carried out at the centre;
 - (p) gender selection carried out at the centre;
 - (q) any complaints received by the centre; and
 - (r) any other records as determined by the Council in accordance with the Ordinance and its regulations.
4. It is good practice for licensed centres to adopt the following -
- (a) Essential Information of Marriage Certificates of Client Couples to be Recorded –
 - (i) The photocopies of marriage certificates of client couples made by licensed centres for record purpose should clearly show the following essential information establishing their legal marriage status –
 - 1) First name and surname of the bride and groom;
 - 2) Date of marriage;
 - 3) Name and location of the registration office of the marriage; and
 - 4) Name of the issue authority.
 - (ii) If available, the names of the witnesses, the registration number and the chop of the issuing authority on the marriage certificate should also be photocopied for record purpose.
 - (b) Marriage Certificates in Languages other than Chinese and English

While the client couples have the responsibility to make endeavour to prove the validity of their marriage certificates, in the event that a marriage certificate is

written in a language other than Chinese and English, the official languages of Hong Kong, licensed centres should ensure that there is a translation of the whole certificate in Chinese or English provided by translator(s) in Hong Kong or elsewhere. If there is any doubt about the authenticity of a marriage certificate presented by the client couple, the licensed centre concerned is advised to obtain certification of the marriage certificate from a notary public appointed in Hong Kong or elsewhere, or from the relevant consulate in Hong Kong.

Note:

Types of procedures -

- (1) In vitro fertilization (IVF)
- (2) Artificial insemination by husband (AIH)
- (3) Artificial insemination by donor (AID)/Donor insemination (DI)
- (4) Removal of oocytes from ovaries
- (5) Retrieval of sperm from testis
- (6) Retrieval of sperm from epididymis
- (7) Frozen-thawed/ fresh embryo transfer (ET)
- (8) Microinjection intra-fallopian transfer (MIFT)
- (9) Fallopian replacement of eggs with delayed insemination (FREDI)
- (10) Intra cytoplasmic sperm injection (ICSI)
- (11) Pre-implantation genetic testing (PGT)
- (12) Sperm sorting technique
- (13) Sperm washing
- (14) In vitro maturation of oocytes
- (15) Storage of semen/sperm
- (16) Storage of oocyte
- (17) Storage of embryo
- (18) Storage of testicular tissue
- (19) Storage of ovarian tissue
- (20) Embryo donation
- (21) Oocyte donation
- (22) Assisted hatching
- (23) Embryo micromanipulation (other than assisted hatching)
- (24) Sex selection
- (25) Surrogacy arrangement
- (26) Other micromanipulation (please specify)
- (27) Others (please specify)

**Information Sheet on Disclosure of Information
Contained or to be Contained in Register A
(For Reproductive Technology Procedures Involving
the Use of Donor Gametes or Embryos Only)**

Keeping of Register A

1. Under section 33 of the Human Reproductive Technology Ordinance (Cap. 561) (the Ordinance), the Council on Human Reproductive Technology (the Council) shall keep and maintain a register, namely Register A.
2. Information contained in Register A shall be kept for 80 years.

Information Contained in Register A

3. The register shall contain⁵⁵-
 - (a) information related to the provision of a RT procedure where a child born or intended to be born in consequence of the procedure involving donated gametes or donated embryos; and
 - (b) identifying information of the child born, the parties to a marriage who will be the parents of the child and any individual whose gametes have been used.

Disclosure of Information

4. Under sections 34(2) & (3) of the Ordinance, disclosure of any information contained or required to be contained in Register A is allowed in the following circumstances -
 - (a) disclosure to a member of the Council, a member of its Committees or a designated public officer designated by the Secretary for Health (the Secretary) is allowed;
 - (b) disclosure to the following persons for the purposes of performing their functions in such capacities is allowed -
 - (i) the licensee who is holder of a licence, which permits the licensee to carry out activities which consist of or involve provision of a RT procedure, conducting of embryo research or handling, storing or disposing of a gamete or embryo used or intended to be used in the RT procedure or embryo research;
 - (ii) the person responsible under a licence;
 - (iii) any person designated in a licence or in a notice duly given to the Council by the persons in (i) and (ii) above; and
 - (iv) any person acting under the direction of the person responsible or of any person so designated;
 - (c) disclosure may be allowed where no individual to whom the information relates can be identified;
 - (d) any adult (age 16 or above) may request the Council to state whether or not

⁵⁵ s.33(2) of the Ordinance

the information contained in Register A shows that⁵⁶ -

- (i) a person other than his/her parents, would or might be his/her parent; and if yes then
 - (ii) a person whom the adult proposes to marry, would or might be related;
 - (iii) any information that the Council is required to give pursuant to regulations made by the Secretary. However, no information that identifies the donors of gametes or embryos shall be given if such information was provided at a time when the Council could not have been required to give such information;
- (e) disclosure is allowed when it is made pursuant to a court order made in the interests of justice, in any proceeding where the court has to determine whether a person is or is not the parent of a child by virtue of sections 9, 10 and 11 of the Parent and Child Ordinance (Cap. 429). However, such an order may not require the Council to disclose any information which may identify the donor(s) whose gamete(s) was/were used in the RT procedure;
- (f) the Council shall disclose to the Registrar of Births and Deaths or any deputy registrar of births and deaths upon their notice requesting the Council to disclose whether any information in Register A tends to show that a man may be the father of a child by virtue of section 10 of the Parent and Child Ordinance and, if so, disclose that information;
- (g) disclosure concerning an individual who undergoes a RT procedure may be made pursuant to consent in writing given by him/her before the provision of the procedure;
- (h) disclosure concerning an individual who undergoes a RT procedure may be made if -
- (i) he/she gives a permission in writing before the provision of the procedure that he/she may be contacted after the provision of the procedure to ascertain whether he/she will consent to a disclosure of information relating to the provision of the procedure to him/ her, either generally or in circumstances specified in the permission; and
 - (ii) consent in writing is obtained from the individual in accordance with the said permission in writing;
- (i) disclosure is allowed in any proceedings relating to application for a parental order under section 12(1) of the Parent and Child Ordinance for establishing whether -
- (i) the child has been carried by a surrogate mother; or
 - (ii) the gametes of either or both the parties to the marriage were used to bring about the creation of the embryo.

⁵⁶ s.33(4) of the Ordinance

**Information Sheet on Personal Data Collected in Connection with
the Provision of Reproductive Technology/Donation Procedure**

Purposes for which Personal Data may be Used

1. The personal data that a licensed centre (“the Centre”) collects in connection with the provision of RT /donation procedure may be used for the following purposes -

- (a) all procedures (including administrative and treatment procedures) appertaining to the provision of the relevant RT /donation procedure;
- (b) the keeping and maintaining of register(s) and/or record(s), and the provision of documents, records, data and information to the Council on Human Reproductive Technology (“the Council”) and other governmental or statutory bodies, as may be required under the Human Reproductive Technology Ordinance (Cap. 561) (“the Ordinance”) and its subsidiary legislation (including the Human Reproductive Technology (Licensing) Regulation), other laws of Hong Kong, and/or the code of practice published from time to time by the Council;
- (c) the communication between the licensed centre and its clients;
- (d) where the service of another laboratory licensed by the Council for the purpose is engaged for the carrying out of sperm washing/pre-implantation genetic testing for monogenic defects/chromosomal structural rearrangement (PGT-M/SR) procedure, the provision of documents, records, data and information to the said laboratory for such purpose;
- (e) revelation to persons duly authorized by the Council in inspection(s) conducted by the Council for the purpose of determining whether to grant or renew licence(s) to the Centre;
- (f) revelation to persons duly authorized by the Council for the purpose of investigation or inquiry into complaints or information with which the Centre is involved; and
- (g) in the event that the licence of the Centre is revoked or suspended, or in the event that the Centre for any reason becomes unable to continue to provide reproductive technology services to its clients, the provision of documents, records, data and information to a backing up centre appointed by the Centre and/or the Council for follow-up arrangements to be made.

Classes of Persons to whom Personal Data May be Transferred

2. The personal data provided to the licensed centre may be transferred to the Council and/or other parties who become necessary recipient(s) thereof for the purposes mentioned in the first paragraph above.

Whether the Supply of Personal Data Obligatory

3. The supply of such personal data to the licensed centre as it may require is obligatory. If the client fails or refuses to supply the data, the licensed centre may refuse to carry out the RT procedure requested.

Access to Personal Data

4. The provider(s) of the data has/have the right of access and correction with respect to the personal data provided, as provided for under sections 18 and 22 and Principle 6 of Schedule 1 to the Personal Data (Privacy) Ordinance (Cap. 486). Such right of access may include the right to obtain a copy of such data.

Enquiries

5. Reference of enquiries (name, address and telephone no. of contact person) concerning the personal data collected by the licensed centre, including access thereto and correction thereof, should be provided to the parties providing the data.

**Supplementary Code of
Practice on Reproductive
Technology - Artificial
Insemination by Husband
(AIH)**

Council on Human Reproductive Technology

**SUPPLEMENTARY CODE OF PRACTICE ON REPRODUCTIVE
TECHNOLOGY - ARTIFICIAL INSEMINATION BY HUSBAND (AIH)**

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SUPPLEMENTARY CODE OF PRACTICE ON REPRODUCTIVE TECHNOLOGY - ARTIFICIAL INSEMINATION BY HUSBAND (AIH)

I. Introduction

Preamble

1.1 Since artificial insemination by husband (AIH) is regarded as a relatively simple RT procedure, the Council considers that a simpler code is sufficient for AIH procedures. This Supplementary Code of Practice on Reproductive Technology - Artificial Insemination by Husband (AIH) (the Supplementary Code) is prepared for compliance when AIH is performed by a RT service provider (whether or not other RT procedures are provided by the same service provider). However, when RT procedures other than AIH are performed by the RT service provider, he should also comply with the provisions of the Code of Practice on Reproductive Technology and Embryo Research (the Code) in relation to the other RT procedures.

1.2 This Supplementary Code provides guidance for good practice, as described in subsequent paragraphs, which aim to support proper clinical and scientific procedures, to safeguard the health and interests of service users and to protect the welfare of children born through AIH. Professionals concerned should still follow the codes of practice and professional ethics of their individual disciplines. This Supplementary Code is not meant to supersede these.

Application of the Supplementary Code

1.3 The Supplementary Code is annexed to the Code and forms part and parcel thereof. The Code came into effect on 1st August 2007.¹ It will be reviewed and updated as necessary to keep up with developments in RT.² The Council, which is the licensing authority for RT services and embryo research, shall take into account any observance of or failure to observe the provisions of the Supplementary Code when considering granting, renewal, variation, revocation or suspension of licences relating to the practice of AIH.³

Interpretation of the Human Reproductive Technology Ordinance and Promulgation of the Supplementary Code

1.4 All personnel involved in the provision of AIH procedure are advised to familiarize themselves with the Human Reproductive Technology Ordinance (the Ordinance). Reference should be made to the Ordinance for definitions of specific terms.

1.5 The Supplementary Code must be construed in a manner consistent with the provisions of the Ordinance.

¹ s.8(6) of the Human Reproductive Technology Ordinance (the Ordinance)

² s.8(3) of the Ordinance

³ s.9 of the Ordinance

II. Procedure of Artificial Insemination by Husband (AIH)

2.1 In this Supplementary Code, AIH refers to the placement of the husband's sperm into the vagina or uterus of his wife otherwise than by sexual intercourse. Sperm washing may be performed before the husband's sperm is used for this purpose. Ovarian stimulation may be used with appropriate monitoring. Every care should be made to minimize the risk of multiple pregnancies and reference should be made to the Hong Kong College of Obstetricians and Gynaecologists Guidelines Number 1.

Classification of AIH

2.2 The Council considers it appropriate to broadly categorize AIH into three types, namely **intravaginal**, **intracervical** and **intrauterine** insemination. Intravaginal insemination refers to the placement of sperm into the vagina. Intracervical insemination refers to the placement of sperm at the cervical os. Intrauterine insemination refers to the placement of sperm (usually after processing) into the uterine cavity. Respective guidelines for the three types of AIH are shown in the ensuing paragraphs.

III. Staff

General

3.1 As required by the Ordinance, no person shall carry on RT activities except pursuant to a licence.⁴

Person Responsible

3.2 The "person responsible", in relation to a licence, refers to the individual specified in the licence as the individual under whose supervision the activities authorized by the licence shall be carried on.⁵

3.3 It shall be the duty of the person responsible to ensure that -⁶

- (a) the other persons to whom the licence applies⁷ are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the relevant activity authorized by the licence (For persons responsible of licensed centres with satellite centres/ associated doctors, the requirement as stipulated in para. 2.3(a) of the main code should also be followed.);
- (b) proper equipment is used;
- (c) proper arrangements are made for the keeping of semen/sperm and for the disposal of semen/sperm that have been allowed to perish;
- (d) proper practices are used in the course of that activity; and

⁴ s.13 of the Ordinance

⁵ s.2(1) of the Ordinance - interpretation of the term "person responsible"

⁶ s.24(1) of the Ordinance

⁷ s.24(3) of the Ordinance

- (e) the conditions of the licence are complied with.

3.4 The person responsible should ensure that this Supplementary Code is made known to all staff involved.

Licensee

3.5 The “licensee”, in relation to a licence, is the holder of the licence as defined in the Ordinance.⁸

3.6 It is the duty of the licensee to ensure that the person responsible discharges his/her duty. The discharge of the duty by the person responsible should not be prejudiced if the licensee and the person responsible are the same person.⁹

Medical Practitioners

3.7 Artificial insemination should be administered or supervised by a registered medical practitioner. Subject to this paragraph and para. 3.9 below, intrauterine insemination should be performed by a registered medical practitioner recognised as an accredited specialist in Obstetrics & Gynaecology or Reproductive Medicine under the Specialist Register of the Medical Council of Hong Kong. Medical practitioners in training may also carry out intrauterine insemination procedure under supervision of such specialists.

3.8 When ovarian stimulation with gonadotrophin is used for any of the three insemination procedures, it should be done or supervised by a specialist in Obstetrics & Gynaecology or Reproductive Medicine.

Nursing Staff/Healthcare Assistants

3.9 Nursing staff employed by licensed centres¹⁰ should be registered nurses or enrolled nurses under the Nurses Registration Ordinance (Cap. 164) and be appropriately trained for the duties they carry out. Nursing staff with appropriate training may also perform intrauterine insemination procedures under the supervision of a specialist who possesses the qualifications set out in para. 3.7 above. Other healthcare assistants should work under the supervision of the medical practitioner and be appropriately trained for the duties they carry out.

Counsellors

3.10 Counselling may be provided by doctors, nurses, social workers, clinical psychologists or other persons with suitable experience and/or qualifications as appropriate.

Fitness to Practise

3.11 In the case of medical practitioners, reference should also be made to the

⁸ s.2(1) of the Ordinance - interpretation of the term “licensee”

⁹ s.23(3) and s.24(2) of the Ordinance

¹⁰ Licensed centres refer to the hospitals or centres or clinics providing AIH services

Code of Professional Conduct for the Guidance of Registered Medical Practitioners laid down by the Medical Council of Hong Kong on fitness to practise.

IV. Facilities and Equipment

4.1 The person responsible must ensure that proper facilities and equipment are used and maintained.¹¹ Hormonal assay facilities should be available if needed.

4.2 The minimum facilities and equipment required for licensed centres offering intrauterine insemination service should include-

- (a) ultrasound equipment, which should be readily available in the licensed centre for monitoring ovarian stimulation; and
- (b) sperm washing facilities, which should be readily available either at the licensed centre itself or at another laboratory which is licensed for the purpose and which is able to provide the required service in a timely manner.

4.3 If counselling is carried out in the licensed centre, it should be provided in a place with privacy and comfort where discussion can take place undisturbed.

V. Assessment of Clients

5.1 In accordance with the Ordinance, AIH procedures should only be provided to persons who are the parties to a marriage¹².

5.2 The clients concerned should be offered fair and unprejudiced assessment. Clients' medical conditions should be fully assessed to determine the most appropriate treatment option.

¹¹ s.24(1)(b) of the Ordinance

¹² The term "parties to a marriage" has not been defined under the Human Reproductive Technology Ordinance. For his/her own protection, if a service provider is asked to provide RT services to a couple married outside Hong Kong, he/she should ensure that the marriage was celebrated or contracted in accordance with the law in force at the time and in the place where the marriage was performed and recognized by such law as involving the voluntary union for life of one man and one woman to the exclusion of all others. Please refer, in this regard, to the definition of "monogamous marriage" under section 2 of the Matrimonial Causes Ordinance (Cap. 179). The Council is of the view that the term "parties to marriage" applies to marriages celebrated or contracted in places which allow monogamous as well as polygamous marriages **as long as the marriage of the client couple involves the voluntary union for life of one man and one woman to the exclusion of all others**. The Council also considers that evidence such as a statutory declaration made by the client couple before a Commissioner of Oaths or solicitors that their marriage was the union for life of one man and one woman to the exclusion of all others or documents of proof issued by Consular Officers, etc., declaring that *"the marriage was celebrated or contracted in accordance with the law in force at the time and in the place where the marriage was performed and recognized by such law as involving the voluntary union for life of one man and one woman to the exclusion of all others"* are reasonable proofs for the purpose, unless otherwise exist any contrary facts known, or should have been reasonably known by the RT service providers. It is nevertheless the duty and role of individual licensed centres, as RT service providers, to decide whether the requirements of the Ordinance and the Code regarding "parties to marriage" have been fulfilled in a particular case (please also see para. 4 of Appendix IX for good practice on record keeping).

VI. Information to Clients

6.1 Licensed centres should devise a mechanism to ensure that relevant information is given to persons seeking AIH treatment. Licensed centres should provide clients with information on the services offered.

6.2 Persons seeking AIH treatment should be informed of the following -

- (a) explanation of the procedure;
- (b) possible discomfort, side effects and complications of treatment to the woman and the resulting pregnancy including, where relevant, risk of ovarian hyperstimulation syndrome or multiple pregnancies and indications for embryonic/fetal reduction;
- (c) limitations and possible outcomes of the treatment;
- (d) any other options available; and
- (e) charges for services.

VII. Consent

7.1 Informed consent with respect to receiving AIH treatment must be obtained in writing. Such consent must be obtained before commencement of any active treatment procedures for each cycle of treatment, but not earlier than 6 months prior to the AIH treatment.

7.2 Licensed centres are required to make use of the sample Consent Form (14) at **Annex II** of the Code unless there are justifiable reasons why they should not be used or should be departed from or modified.

VIII. Counselling

General

8.1 The clients concerned should be provided with counselling by doctors, nurses, social workers, clinical psychologists or other persons with suitable experience and/or qualifications as appropriate.

8.2 Non-directional counselling on the implications of the AIH procedure and consideration of other options must be offered to clients before they consent to AIH procedure. Couples seeking treatment should be given adequate time to consider the issue.

8.3 Information obtained during counselling must be kept in confidence.

8.4 Proper records should be kept of the counselling service offered and provided.

Counselling for Potential Clients of AIH Service

8.5 Counsellors should ask potential clients to consider carefully all possible implications before receiving AIH service especially when ovarian stimulation has to be done, such as -

- (a) the financial implications of the AIH treatment (e.g. there is the possibility of multiple pregnancies);
- (b) their feelings about manipulation of the husband's sperm outside his body, and the possible storage and disposal of the sperm;
- (c) the chances that treatment may fail;
- (d) the possibility of the need of embryonic/fetal reduction;
- (e) the alternative of adoption of a child;
- (f) the possibilities that the implications of and feelings about their AIH treatment may change as personal circumstance changes; and
- (g) all the terms and conditions set out in the consent form.

IX. Treatment Method

9.1 The attending clinician must ensure that the treatment method offered is the one which best suits the couple's particular medical indication.

9.2 Established clinical practices and laboratory standards should be adopted to safeguard the health and safety of clients.

9.3 The indication for selecting the AIH procedure must be stated in each case.

9.4 Side effects and complications arising from the AIH procedure must be recorded for each case.

9.5 When ovarian stimulation has to be carried out, RT practitioners must take measures to prevent high multiple pregnancies whenever possible. This is to avoid the known risks of fetal mortality and morbidity in such cases, the health hazards to the mother and the possible psychological and practical consequences for both parents.

9.6 If a pregnancy involving multiple fetuses should occur despite the above-mentioned precautions having been taken, and if the prognosis for the fetuses is so unfavourable, a procedure of fetal reduction may be necessary. The carrying out of fetal reduction procedure should comply with section 47A of the Offences Against the Person Ordinance (Cap. 212). The possibility of embryonic/fetal reduction should be included in the pre-treatment counselling. Parents should be clearly informed of the reasons for embryonic/fetal reduction and the possible risks involved, and the procedure may not be carried out without their consent.

9.7 Embryonic/fetal reduction should not be carried out simply to comply with the request of the parents who prefer to have a fewer number of children from the pregnancy.

X. Screening and Selection of Sperm

10.1 For AIH, both cryopreserved and fresh semen/sperm of the husband can be used. If licensed centres store semen/sperm for their clients, a proper and safe storage facility must be provided to preserve the viability of semen/sperm and to minimize the chance of accident, loss or contamination. In the case that the semen/sperm is stored at a licensed centre and is transferred to another licensed centre where AIH is to be performed, the guidelines as contained in **Appendix IV** regarding the local transfer of stored gametes between licensed centres should be observed.

10.2 Semen/sperm which has been subject to procedures carrying an actual or unreasonable risk or harm to its developmental potential should not be used for treatment.

10.3 Intrauterine insemination should be carried out or supervised by an obstetrician or gynaecologist or a specialist in reproductive medicine, or by registered medical practitioners under training or nursing staff with appropriate training, and under supervision of the specialist as mentioned above. Sperm washing should also be performed as part and parcel of the procedure, and should be carried out either at the licensed centre itself by a person who has undergone the appropriate training, or at another laboratory licensed for the purpose.

10.4 If the semen is cryopreserved for storage, appropriate measures should be taken to minimize the risk of contamination of the semen stored.

XI. Record Keeping and Information Management

Accuracy and Confidentiality of Information

11.1 Licensed centres must ensure that personal records with identifying information are kept in confidence with controlled access and disclosure of such should be in circumstances permitted by the Ordinance.¹³

Keeping of Record

11.2 Licensed centres must keep medical records containing the names, correspondence addresses, identity card/passport numbers of all patients. The record should include information on the AIH procedure performed and outcomes of the procedure as far as it is practicable. The registers, namely Patients Register and Children Register, and records required to be kept and maintained by licensed centres are listed at **Appendix IX**.

11.3 General medical record kept and maintained under an AIH licence should be retained by the licensed centres for at least 6 years after the patient ceases to be a client of the licensed centre.

¹³ s.34, s.35 and s.36 of the Ordinance

Submission of Information to Council

11.4 Licensed centres are required to submit to the Council non-identifying information on AIH treatments provided to clients on a quarterly basis. The information required should be submitted in the prescribed format using the DC Forms 4 and 7 at **Annex III**.

11.5 Other non-identifying data in the prescribed format, i.e. annual statistics form (AS Form) 7 at **Annex IV**, should be submitted on an annual basis to the Council by end of March every year. The use of uniform definitions should be adopted (please refer to the glossary of abbreviations and common terms used in RT and the explanatory notes for completing the forms on annual statistics on RT treatment in the Code).

Handling of Personal Data under the Personal Data (Privacy) Ordinance

11.6 The Personal Data (Privacy) Ordinance (Cap. 486) enables individuals to request access to and correction of personal data held by data users. RT service providers are advised that the rules and principles stipulated in the Personal Data (Privacy) Ordinance on the collection, retention, use, disposal, access to and correction of the personal data should be complied with.

Disclosure of Personal Information

11.7 Licensed centre should clearly explain to the patients and their spouses that the personal data they provide in connection with the provision of RT procedure(s) may be disclosed for the purposes as stipulated by the Ordinance and the Code published from time to time by the Council. Consent Form (14) (please note also para. 7.2 above) contains provisions drawing clients' attention to such disclosures by reference to **Appendix XI** of this Code. Licensed centres should ensure that clients understand and consent to such disclosures.

11.8 If a licensed centre engages the service of another laboratory licensed by the Council for the purpose to carry out sperm washing procedure for a client, a copy of the consent form (14) duly signed by the client must be provided to the laboratory.

11.9 The laboratory whose service is engaged as mentioned in para. 11.8 above must in turn comply with all requirements in relation to the confidentiality, access and disclosure of the personal information, information and records of the client as stipulated by the Ordinance and this Code.

XII. Handling of Complaints

Complaints against Licensed Centres

12.1 Licensed centres should have in place an administrative arrangement with a designated staff at the appropriate level to acknowledge receipt of complaints and to take charge of investigations. The outcome of the investigation should be recorded and explained to the complainant.

12.2 If the complainant is dissatisfied with the outcome of investigation by the licensed centre, he/she should be advised about other avenues of complaint including, if appropriate, the Investigation Committee of the Council or the Medical Council of Hong Kong (for matters relating to possible professional misconduct of medical practitioners) or other regulatory professional bodies in Hong Kong.

Breach of the Supplementary Code

12.3 Any complaints of breach of the Supplementary Code will be investigated by the Investigation Committee of the Council.¹⁴ Failure to co-operate with the Investigation Committee will be taken into account by the Council in assessing whether there is a ground for revocation, variation and/or suspension of licence.

12.4 Professionals concerned are reminded that they are also under codes of practice or ethics of their respective professional disciplines.

XIII. References

13.1 In interpreting the terms used in the Supplementary Code, reference should be made to the glossary of abbreviations and common terms used in RT and the explanatory notes for completing the forms on annual statistics on RT treatment in the Code.

¹⁴ Schedule 1 s.6(c) of the Ordinance

Consent Form (1) (Revised in 2025)**Consent to Freezing and Storage of Gametes**
(for own use at the beginning of storage)

1. I _____
(Surname, Given Names) (ID No.)
(Single/Married*) of _____
_____ (address) DO HEREBY
AUTHORISE _____ (name of the
licensed centre) (hereinafter called "the Centre") to freeze and store the
sperm/eggs(oocytes)* produced from me and provided by me to the Centre, in a manner
which accords with the practice and procedure adopted from time to time by the Centre
("the Programme").
2. I acknowledge that the nature, procedures and possible complications of the Programme,
together with the relevant information on the decline in pregnancy rates associated with
aging of women and use of stored gametes and/or embryos in bringing about human
reproduction by artificial means at advanced maternal age, the risks of pregnancy at an
advanced maternal age, the impacts of delayed childbearing, the arrangements upon
cessation of storage; and also the storage period policy of the Centre* have been clearly
explained to me by _____ and I have been given the
opportunity to ask any question I wish. I have also been offered a suitable opportunity to
take part in counselling with _____ about the
implications of the Programme¹.
3. I consent that my sperm/eggs(oocytes)* will be stored for an initial period of 2 years
/ _____ (please specify the storage period if shorter than 2 years)* from the date of freezing
of the sperm/eggs(oocytes)* and that the storage period will be extended thereafter 2 years
at a time only if I give a written notice of extension. I understand that the said notice of
extension must reach the Centre at least 1 month before the expiry of the period of storage
concerned. I understand that, after the initial 5 years of storage of my
sperm/eggs(oocytes)* and every 2 years thereafter, I am required to receive proper
counselling and give a fresh consent by signing a Consent Form (19), together with an
acknowledgment of the relevant information stated in para. 2 above before further extension
of storage.
4. I consent that in the absence of a written notice of extension or a fresh consent by signing a
Consent Form (19) upon expiry of the storage period concerned, or if I fail to pay the storage
fees, or am not contactable by the Centre, the Centre by giving me 3 months' notice in
advance, may dispose of or donate my sperm/eggs(oocytes)* in accordance with my latest
instructions set out in para. 5 below.

¹I have been separately informed about the possible discomfort, side effects, complications of treatment and
associated risks such as the risks of surgical gamete retrieval procedures if applicable.

5. I understand that, subject to the giving of proper notice(s) of extension or a fresh consent by signing a Consent Form (19) as mentioned in para. 3 above, my sperm/eggs(oocytes)* will be frozen and stored until the time that I indicate to withdraw from or terminate the Programme, or upon expiry of the time limit / maximum storage period set by the Centre*, or upon my death, whichever occurs earlier in time, I consent that the sperm/eggs(oocytes)* stored may be (please tick one) -

☐ disposed of in accordance with the “Guidelines on disposal of gametes or embryos” (“the Guidelines”) in the Code of Practice on Reproductive Technology and Embryo Research published from time to time by the Council on Human Reproductive Technology.

☐ donated anonymously for the treatment of other infertile couples, in which event my sperm/eggs(oocytes)* would not be used to produce more than a total of 1/2/3* live birth events (failing which the Centre may dispose of the stored sperm/eggs(oocytes)* in accordance with the Guidelines).

☐ donated for research (failing which the Centre may dispose of the stored sperm/eggs(oocytes)* in accordance with the Guidelines).

☐ donated for quality control and/or training (failing which the Centre may dispose of the stored sperm/eggs(oocytes)* in accordance with the Guidelines).

6. I understand that my stored sperm/eggs(oocytes)* will be used for insemination or other reproductive technology procedures only if I am a married person at the time of use of the sperm/eggs(oocytes)*, except in circumstances specified otherwise by the law or by the Code of Practice. Furthermore, upon my death, my stored sperm/eggs(oocytes)* cannot be used by my spouse to bring about any posthumous child(ren) .

7. I understand that I can withdraw from and terminate the Programme at any time by giving a written notice to the Centre stating my intention to withdraw and terminate, and indicating to the Centre whether I would like the sperm/eggs(oocytes)* then stored with the Centre to be -

- (a) transferred to another local licensed centre;
- (b) exported to an overseas centre; or
- (c) disposed of or be donated in accordance with my instructions set out in para. 5 above.

In the event that I withdraw from or terminate the Programme without giving any indication as aforesaid, the Centre will dispose of or donate the stored sperm/eggs(oocytes)* in accordance with my instructions as set out in para. 5 above.

8. I understand that I am required to immediately inform the Centre of any change of my address and/or contact details.

9. I fully understand and accept that -

- (a) my stored sperm/eggs(oocytes)* may not produce any successful pregnancy;
- (b) the procedures of freezing, thawing and storage of my sperm/eggs(oocytes)* may be associated with a higher incidence of carrying abnormal children as compared with

a pregnancy without such procedures. There may also be an increase in preterm deliveries in pregnancies and that any child conceived or born following in vitro fertilization using such sperm/eggs(oocytes)* may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary, fertility problems or other reasons compared to a natural or spontaneous pregnancy, as reported in some studies;

- (c) the quality of the sperm/eggs(oocytes)* stored depends to a large extent on the quality of the specimen submitted for storage;
- (d) the quality of the sperm/eggs(oocytes)* may deteriorate following the freezing and thawing procedures and may not be found to be suitable for subsequent use; and
- (e) the Centre will not be responsible for damage to or deterioration of the sperm/eggs(oocytes)* due to whatever cause which is beyond its control or because of unforeseen circumstances.

10. I acknowledge that the Information Sheet at Appendix XI of the Code of Practice on Reproductive Technology and Embryo Research has been read by me/explained to me*. I fully understand the contents of the Information Sheet and I agree that my personal data and information may be used for the purposes as set out in para. 1 of the Information Sheet.

- [] (Please tick if agreed) I also consent to the release of all medical records, including my medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on me from the time when my suitability for RT procedure(s) is being assessed or the provision of any RT service to me (whenever the earlier) until one year after the time when the last RT service is being provided to me or the completion of my RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ Day of _____
(Month) (Year)

Signed _____
(Patient's Signature)

Name _____
(in Block Letters)

(in Chinese)

Spouse's Name # _____
(in Block Letters)

(in Chinese)

Marriage Certificate No. # _____

Signed _____
(Signature of Attending Doctor)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

Position _____

- * Delete whichever is inapplicable
- # To be completed if the patient is married.

Consent Form (2) (Revised in 2025)

Consent to Freezing and Storage of Embryos
(for married couples' own use at the beginning of storage)

1. We _____ (husband's name)
(Surname, Given Names) (ID No.)
(hereinafter called "the Husband") and _____
(Surname, Given Names) (ID No.)
(wife's name) (hereinafter called "the Wife"), of _____
_____ (address),
DO HEREBY AUTHORISE _____
(name of the licensed centre) (hereinafter called "the Centre") to freeze and store the embryos produced from our gametes, in a manner which accords with the practice and procedure adopted from time to time by the Centre ("the Programme").
2. We acknowledge that the nature, procedures and possible complications of the Programme, together with the relevant information on the decline in pregnancy rates associated with aging of women and use of stored gametes and/or embryos in bringing about human reproduction by artificial means at advanced maternal age, the risks of pregnancy at an advanced maternal age, the impacts of delayed childbearing, the arrangements upon cessation of storage; and also the storage period policy of the Centre* have been clearly explained to us by _____ and we have been given the opportunity to ask any question we wish. We have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the Programme.
3. We understand that, where a written notice from us is required under the Programme, the notice is only valid if it bears both our signatures.
4. We consent that our embryos will be stored for an initial period of 2 years / _____ (please specify the storage period if shorter than 2 years)* from the date of freezing of the embryos and that the storage period will be extended thereafter 2 years at a time only if we give a written notice of extension. We understand that the said notice of extension must reach the Centre at least 1 month before the expiry of the period of storage concerned. We understand that, after the initial 5 years of storage of our embryos and every 2 years thereafter, we are required to receive proper counselling and give a fresh consent by signing a Consent Form (20) by both of us, together with an acknowledgment of the relevant information stated in para. 2 above before further extension of storage.
5. We consent that in the absence of a written notice of extension or a fresh consent by signing a Consent Form (20) by both of us upon expiry of the storage period concerned, or if we fail to pay the storage fees, or are not contactable by the Centre, the Centre by giving us 3 months' notice in advance, may dispose of or donate our embryos in accordance with our latest instructions set out in para. 6 below.
6. We understand that, subject to the giving of proper notice(s) of extension or a fresh consent by signing a Consent Form (20) by both of us as mentioned in para. 4 above, our embryos

will be frozen and stored until the time that we indicate to withdraw from or terminate the Programme, or upon expiry of the time limit / maximum storage period set by the Centre*, or upon the death of either of us, or in the event of divorce or legal separation, or upon one of us becoming incapable of revoking his or her consent, whichever occurs earlier in time, we consent that our stored embryos may be (please tick one) -

- ☐ disposed of in accordance with the “Guidelines on disposal of gametes or embryos” (“the Guidelines”) in the Code of Practice published from time to time by the Council on Human Reproductive Technology.
 - ☐ donated anonymously for the treatment of other infertile couples, in which event our embryos would not be used to produce more than a total of 1/2/3* live birth events (failing which the Centre may dispose of the stored embryos in accordance with the Guidelines).
 - ☐ donated for research (failing which the Centre may dispose of the stored embryos in accordance with the Guidelines).
 - ☐ donated for quality control and/or training (failing which the Centre may dispose of the stored embryos in accordance with the Guidelines).
7. We understand that our stored embryos will only be used for reproductive technology procedures when we are the parties to a marriage, except in circumstances specified otherwise by the law or by the Code of Practice on Reproductive Technology and Embryo Research. Furthermore, upon the death of either of us, our stored embryos cannot be used by the surviving spouse to bring about any posthumous child(ren).
8. We understand that we can withdraw from and terminate the Programme at any time by giving a written notice to the Centre stating our intention to withdraw and terminate, and indicating to the Centre whether we would like the embryos then stored with the Centre to be -
- (a) transferred to another local licensed centre;
 - (b) exported to an overseas centre; or
 - (c) disposed of or be donated in accordance with our instructions set out in para. 6 above.
- In the event that we withdraw from or terminate the Programme without giving any indication as aforesaid, the Centre will dispose of or donate the stored embryos in accordance with our instructions as set out in para. 6 above.
9. We understand that we are required to immediately inform the Centre of any change of our address and/or contact details, or our marital relationship.
10. We fully understand and accept that -
- (a) the stored embryos may not produce any successful pregnancy;
 - (b) the procedures of freezing, thawing and storage of our embryos may be associated with a higher incidence of carrying abnormal children as compared with a pregnancy without such procedures. There may also be an increase in preterm deliveries in pregnancies and that any child conceived or born following in vitro fertilization using

[p.3 of Form (2)]

such embryos may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary, fertility problems or other reasons compared to a natural or spontaneous pregnancy, as reported in some studies;

- (c) the quality of the embryos stored depends to a large extent on their quality prior to freezing;
- (d) the quality of the embryos may deteriorate following the freezing and thawing procedures and may not be found to be suitable for subsequent use; and
- (e) the Centre will not be responsible for damage to or deterioration of the embryos due to whatever cause which is beyond its control or because of unforeseen circumstances.

11. We acknowledge that the Information Sheet at Appendix XI of the Code of Practice on Reproductive Technology and Embryo Research has been read by us/explained to us *. We fully understand the contents of the Information Sheet and we agree that our personal data and information may be used for the purposes as set out in para. 1 of the Information Sheet.

[] (Please tick if agreed) We also consent to the release of all medical records, including our medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on us from the time when our suitability for RT procedure(s) is being assessed or the provision of any RT service to us (whenever the earlier) until one year after the time when the last RT service is being provided to us or the completion of our RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____ Signed _____
(Husband's Signature) (Wife's Signature)

Name _____ Name _____
(in Block Letters) (in Block Letters)

(in Chinese) (in Chinese)

Marriage Certificate No. _____

Signed _____ Signed _____
(Signature of Attending Doctor) (Signature of Witness)

Name _____ Name _____
(in Block Letters) (in Block Letters)

Position _____

* Delete whenever is inapplicable

Consent Form (3) (Revised in 2025)

Consent to Anonymous Donation of Sperm

1. I _____
(Surname, Given Names) (ID No.)
(Single/Married*), DO HEREBY CONSENT to donating my sperm anonymously to _____ (name
of licensed centre) (hereinafter called “the Centre”) with the understanding that sperm
donated by me will be used for the treatment of infertile couples* or for research project*
and that this consent cannot be revoked or varied once my sperm has been donated.
2. I consent that sperm donated by me may be stored and/or disposed of by the Centre in
such way(s) as the Centre may at its discretion deem appropriate.
3. I consent that sperm donated by me should only be used to produce 1/2/3* live birth
events.
4. I have/have not*, prior to my donation to the Centre on this occasion, donated my sperm
on _____ previous occasions. Details of my previous donations are as
follows -

*(please state name(s) of the centre(s) to which donation was made, date of donation(s)
and other relevant information.)*
5. I acknowledge that the nature and implications of my donation have been explained to
me by _____ and I have been given the opportunity to
ask any question I wish. I have also been offered a suitable opportunity to take part in
counselling with _____ about the implications of my
donation.
6. I understand that under the Parent & Child Ordinance (Cap. 429), I shall not be the legal
father of the child(ren) born from sperm donated by me. I also agree never to seek to
make any claim over such child(ren) in any circumstance whatsoever.
7. I understand that the identity of any recipient of my donation and of any child(ren) born
from sperm donated by me will not be disclosed to me. I shall also remain anonymous.
8. To the best of my knowledge and belief -
 - (a) I am in good health and have no communicable disease or hereditary disorder,
except as follows -

 - (b) None of my relatives has ever suffered from any inheritable disease, except as
follows -

9. For the purpose of determining whether I am suitable as a donor of sperm, I consent to undergoing such blood tests (including HIV test) and medical examinations as shall be prescribed by the Centre.

10. I acknowledge that the Information Sheets at Appendices X and XI of the Code of Practice on Reproductive Technology and Embryo Research have been read by me/explained to me*. I fully understand the contents of the Information Sheets and I agree that my personal data and information may be used for the purposes as set out therein.

[] (Please tick if agreed) I also consent to the release of all medical records, including my medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on me from the time when my suitability for RT procedure(s) is being assessed or the provision of any RT service to me (whenever the earlier) until one year after the time when the last RT service is being provided to me or the completion of my RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

11. I do / do not* consent to sperm donated by me to be exported out of Hong Kong SAR.

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Donor's Signature)

Name _____
(in Block Letters) (in Chinese)

Date of Birth _____
(dd/mm/yy)

Signed _____
(Signature of the one who explained
the nature & implications)

Name _____
(in Block Letters)

Position _____

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Position _____

* Delete whichever is inapplicable.

Consent Form (4) (Revised in 2025)

Consent to Anonymous Donation of Eggs (Oocytes)

1. I _____
(Surname, Given Names) (ID No.)
(Single/Married*), DO HEREBY CONSENT to donating my eggs (oocytes) anonymously to _____
(name of licensed centre) (hereinafter called “the Centre”), with the understanding that eggs (oocytes) donated by me will be used for the treatment of infertile couples* or for research project* and that this consent cannot be revoked or varied once my eggs (oocytes) have been donated.
2. I consent to -
 - (a) be prepared for egg (oocytes) retrieval including the use of drugs for hyperstimulation;
 - (b) the removal of eggs (oocytes) from my ovaries with the aid of laparoscopy/ultrasound; and
 - (c) the administration of appropriate drugs and/or anaesthetics to me if necessary for the procedure(s).
3. I consent that eggs (oocytes) donated by me may be stored and/or disposed of by the Centre in such way(s) as the Centre may at its discretion deem appropriate.
4. I consent that eggs (oocytes) donated by me should only be used to produce 1/2/3* live birth events.
5. I have/have not*, prior to my donation to the Centre on this occasion, donated my eggs (oocytes) on _____ previous occasions. Details of my previous donations are as follows -

(please state name(s) of the centre(s) to which donation was made, date of donation(s) and other relevant information.)
6. I acknowledge that the nature, procedures and possible complications associated with my donation have been explained to me by _____ and I have been given the opportunity to ask any question I wish. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of my donation and associated procedures.
7. I understand that under the Parent & Child Ordinance (Cap. 429), I shall not be the legal mother of the child(ren) born from eggs (oocytes) donated by me. I also agree never to seek to make any claim over any such child(ren) under any circumstance whatsoever.
8. I understand and agree that the identity of any recipient of my donation and of any

child(ren) born from egg(s) [oocyte(s)] donated by me will not be disclosed to me. I shall also remain anonymous.

9. To the best of my knowledge and belief -

(a) I am in good health and have no communicable disease or hereditary disorder, except as follows -

(b) None of my relatives has ever suffered from any inheritable disease, except as follows -

10. For the purpose of determining whether I am suitable as a donor of eggs (oocytes), I consent to undergoing such blood tests (including HIV test) and medical examinations as shall be prescribed by the Centre.

11. I acknowledge that the Information Sheets at Appendices X and XI of the Code of Practice on Reproductive Technology and Embryo Research have been read by me/explained to me*. I fully understand the contents of the Information Sheets and I agree that my personal data and information may be used for the purposes as set out therein.

[] (Please tick if agreed) I also consent to the release of all medical records, including my medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on me from the time when my suitability for RT procedure(s) is being assessed or the provision of any RT service to me (whenever the earlier) until one year after the time when the last RT service is being provided to me or the completion of my RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

12. I do / do not* consent to egg (oocytes) donated by me to be exported out of Hong Kong SAR.

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Donor's Signature)

Name _____
(in Block Letters) (in Chinese)

Date of Birth _____
(dd/mm/yy)

Signed _____
(Signature of Attending Doctor)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

Position _____

*Delete whichever is inapplicable.

Consent Form (5) (Revised in 2025)

Consent to Anonymous Donation of Embryos

1. We _____
(Surname, Given Names) (ID No.)
(husband's name) (hereinafter called "the Husband"), and _____
(Surname, Given Names)
_____ (wife's name) (hereinafter called "the Wife"),
(ID No.)
of _____ (address),
DO HEREBY CONSENT to donating our embryo(s) anonymously to _____ (name of
licensed centre) (hereinafter called "the Centre"), with the understanding that embryos
donated by us will be used for the treatment of other infertile couples* or for research
projects* and that this consent cannot be revoked or varied.
2. We consent that embryos donated by us may be stored and/or disposed of by the Centre
in such way(s) as the Centre may at its discretion deem appropriate.
3. We consent that embryos donated by us should only be used to produce 1/2/3* live birth
events.
4. We have/have not*, prior to our donation to the Centre on this occasion, donated our
embryo(s) on _____ previous occasions. Details of our previous donations
are as follows -

*(please state name(s) of the centre(s) to which donation was made, date of donation(s)
and other relevant information.)*
5. We acknowledge that the nature and implications of our donation have been explained
to us by _____ and we have been given the opportunity
to ask any question we wish. We have also been offered a suitable opportunity to take
part in counselling with _____ about the implications of
our donation.
6. We understand that under the Parent & Child Ordinance (Cap. 429), we shall not be the
legal parents of the child(ren) born from embryo(s) donated by us. We also agree never
to seek to make any claim over any such child(ren) under any circumstance whatsoever.
7. We understand and agree that the identity of any recipient of our donation and of any
child(ren) born from embryos donated by us will not be disclosed to us. We shall also
remain anonymous.

8. To the best of our knowledge and belief -

- (a) We are in good health and have no communicable disease or hereditary disorder, except as follows -

- (b) None of our relatives has ever suffered from any inheritable disease, except as follows -

9. For the purpose of determining whether we are suitable as donors of embryos, we consent to undergoing such blood tests (including HIV test) and medical examinations as shall be prescribed by the Centre.

10. We acknowledge that the Information Sheets at Appendices X and XI of the Code of Practice on Reproductive Technology and Embryo Research have been read by us/explained to us*. We fully understand the contents of the Information Sheets and we agree that our personal data and information may be used for the purposes as set out therein.

[] (Please tick if agreed) We also consent to the release of all medical records, including our medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on us from the time when our suitability for RT procedure(s) is being assessed or the provision of any RT service to us (whenever the earlier) until one year after the time when the last RT service is being provided to us or the completion of our RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

11. We do / do not* consent to embryos donated by us to be exported out of Hong Kong SAR.

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Husband's Signature)

Signed _____
(Wife's Signature)

Name _____
(in Block Letters)

(in Chinese)

Name _____
(in Block Letters)

(in Chinese)

Marriage Certificate No. _____

Signed _____
(Signature of Attending Doctor)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

Position _____

*Delete whichever is inapplicable.

Consent Form (6) (Revised in 2025)

Consent to Donor Insemination

PART I PATIENT'S CONSENT

1. I _____, of
(Surname, Given Names) (ID No.)
_____ (address),
being lawfully married and desirous of having a child, DO HEREBY AUTHORISE
_____ (name of licensed centre)
(hereinafter called "the Centre"), to perform the treatment of donor insemination for me.
2. I understand that appropriate drugs will be administered to me if necessary for the treatment.
3. I understand that the donor shall remain anonymous* *(please delete this sentence if the donation is designated)*. Under the Parent & Child Ordinance (Cap. 429), the donor shall not be the legal father of any child(ren) born from the aforesaid treatment procedure.
4. I acknowledge that the nature, procedures and possible complications of the aforesaid treatment procedure have been explained to me by _____ and I have been given the opportunity to ask any question I wish. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the treatment procedure.
5. I fully understand and accept that -
 - (a) the aforesaid treatment procedure may not result in a successful pregnancy;
 - (b) I may not be able to carry the pregnancy to term; and
 - (c) there may be an increase in preterm deliveries in pregnancies and that any child conceived or born following the procedures may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary, fertility problems or other reasons compared to a natural or spontaneous pregnancy, as reported in some studies.
6. I understand that -
 - (a) this consent cannot be revoked or varied once insemination has been performed; and
 - (b) the procedure of donor insemination will not be performed if my husband revokes or varies his consent prior to insemination.
7. I acknowledge that the Information Sheets at Appendices X and XI of the Code of Practice on Reproductive Technology and Embryo Research have been read by me/explained to me*. I fully understand the contents of the Information Sheets and I agree that my personal data and information may be used for the purposes as set out

therein.

- [☐] (Please tick if agreed) I also consent to the release of all medical records, including my medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on me from the time when my suitability for RT procedure(s) is being assessed or the provision of any RT service to me (whenever the earlier) until one year after the time when the last RT service is being provided to me or the completion of my RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Patient's Signature)

Name _____
(in Block Letters) (in Chinese)

Signed _____ Signed _____
(Signature of Attending Doctor) (Signature of Witness)

Name _____ Name _____
(in Block Letters) (in Block Letters)

Position _____

PART II HUSBAND'S CONSENT

8. I _____ am
(Surname, Given Names) (ID No.)
the husband of _____ and I consent to the
course of treatment outlined above. I understand that I will be the legal father of any
child(ren) born from the treatment.
9. I understand that this consent cannot be revoked or varied once the insemination has
been performed. Any revocation or variation of this consent will not be effective until
actual receipt by the Centre in writing.
10. I acknowledge that the Information Sheets at Appendices X and XI of the Code of
Practice on Reproductive Technology and Embryo Research have been read by
me/explained to me*. I fully understand the contents of the Information Sheets and I
agree that my personal data and information may be used for the purposes as set out
therein.
- [] (Please tick if agreed) I also consent to the release of all medical records, including
my medical history, except those specified separately otherwise, kept by the Centre
and its doctor(s) or associated doctor(s) on me from the time when my suitability
for RT procedure(s) is being assessed or the provision of any RT service to me
(whenever the earlier) until one year after the time when the last RT service is being
provided to me or the completion of my RT treatment (whenever the later) to the
Council on Human Reproductive Technology for the purpose of inspection and use
in the course of discharging its regulatory functions under the Human Reproductive
Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Husband's Signature)

Name _____
(in Block Letters) (in Chinese)

Marriage Certificate No. _____

*Delete whichever is inapplicable.

Consent Form (7) (Revised in 2025)

Consent to In Vitro Fertilization/Embryo Transfer

To be used for every treatment cycle involving

**(i) fresh embryo transfer; or (ii) the use of donor gametes/embryos
(whether such embryos are transferred in a fresh or frozen-thawed state)**

PART I PATIENT'S CONSENT

1. I _____, of _____ (Surname, Given Names) _____ (ID No.) _____ (address), being lawfully married and desirous of having a child, DO HEREBY AUTHORISE _____ (name of licensed centre) (hereinafter called "the Centre"), to perform the treatment of in-vitro fertilization/embryo transfer for me.
2. I also hereby consent that the Centre may proceed with the following reproductive technology procedures for me (please tick as appropriate) -

☐ in vitro fertilization & embryo transfer;
☐ others (please specify) _____.
3. I consent to -

(a) be prepared for egg (oocytes) retrieval including the use of drugs for hyperstimulation;
(b) the removal of eggs (oocytes) from my ovaries with the aid of laparoscopy/ultrasound;
(c) the administration of appropriate drugs and/or anaesthetics to me if necessary for the said procedure(s); and
(d) the transfer of gametes/embryos to my body .
- 4.^{Note} I consent to the mixing of the gametes of _____ with those of _____. (please specify the reference no. of man who provides the sperm and woman who provides the eggs (oocytes))
5. I understand that the donor(s) of the gamete(s)/embryo(s) shall remain anonymous* (please delete this sentence if the donation is designated). Under the Parent & Child Ordinance (Cap. 429), the donor(s) shall not be the legal parent(s) of any child(ren) born from the aforesaid treatment procedure.* (please delete the entire paragraph if no donated gamete(s)/embryo(s) are involved)
6. I acknowledge that the nature, procedures and possible complications of the treatment procedure and associated risks such as the risks of surgical gamete retrieval procedures have been explained to me by _____ and I have been given the opportunity to ask any question I wish. I have also been offered a suitable

opportunity to take part in counselling with _____ about the implications of the treatment procedure.

7. I fully understand and accept that -
- (a) the aforesaid treatment procedures may not result in a successful pregnancy;
 - (b) I may not be able to carry the pregnancy to term;
 - (c) I may suffer from illness(es) or complications arising out of or consequent upon a pregnancy resulting from in-vitro fertilization/embryo transfer; and
 - (d) there may be an increase in preterm deliveries in pregnancies and that any child conceived or born following the procedures may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary, fertility problems or other reasons compared to a natural or spontaneous pregnancy, as reported in some studies.
8. I understand that the procedures as listed in para. 2 will not be performed if my husband revokes or varies his consent before the transfer of gamete(s) or embryo(s) to me.
9. I consent that unfertilised eggs (oocytes) obtained from me and/or excess embryos produced in the course of the procedures listed in para. 2 above may be (please tick one) -
- ☐ disposed of in accordance with the “Guidelines on disposal of gametes or embryos” (“the Guidelines”) in the Code of Practice on Reproductive Technology and Embryo Research published from time to time by the Council on Human Reproductive Technology.
 - ☐ donated anonymously for the treatment of other infertile couples, in which event my gametes or embryos would not be used to produce more than a total of 1/2/3* live birth events (failing which the Centre may dispose of the stored gametes or embryos in accordance with the Guidelines).
 - ☐ donated for research (failing which the Centre may dispose of the stored gametes or embryos in accordance with the Guidelines).
 - ☐ donated for quality control and/or training (failing which the Centre may dispose of the stored gametes or embryos in accordance with the Guidelines).
10. I acknowledge that the Information Sheet(s) at Appendix X* (*delete this appendix for cases not involving use of donor gametes/embryos*) and/or Appendix XI of the Code of Practice on Reproductive Technology and Embryo Research has/have been read by me/explained to me*. I fully understand the contents of the Information Sheet(s) and I agree that my personal data and information may be used for the purposes as set out therein.

- [] (Please tick if agreed) I also consent to the release of all medical records, including my medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on me from the time when my suitability for RT procedure(s) is being assessed or the provision of any RT service to me (whenever the earlier) until one year after the time when the last RT service is being provided to me or the completion of my RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Patient's Signature)

Name _____
(in Block Letters)

Signed _____
(Signature of Attending Doctor)

Name _____
(in Block Letters)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Position _____

PART II HUSBAND'S CONSENT

11. I _____ am
(Surname, Given Names) (ID No.)
the husband of _____ and I consent to the
course of treatment outlined above. I understand that I will be the legal father of any
child(ren) born from the treatment.
12. I understand that this consent cannot be revoked or varied once the gamete(s) or
embryo(s) has/have been transferred to my wife. Any revocation or variation of this
consent will not be effective until actual receipt by the Centre in writing.
13. I consent that excess embryos produced in the course of the procedures listed in the para.
2 above may be disposed of or donated in accordance with my wife's instructions, as set
out in para. 9 hereof.
14. I acknowledge that the Information Sheet(s) at Appendix X* (*delete this appendix for
cases not involving use of donor gametes/embryos*) and/or Appendix XI of the Code of
Practice on Reproductive Technology and Embryo Research has/have been read by
me/explained to me*. I fully understand the contents of the Information Sheet(s) and I
agree that my personal data and information may be used for the purposes as set out
therein.
- [] (Please tick if agreed) I also consent to the release of all medical records, including
my medical history, except those specified separately otherwise, kept by the Centre
and its doctor(s) or associated doctor(s) on me from the time when my suitability
for RT procedure(s) is being assessed or the provision of any RT service to me
(whenever the earlier) until one year after the time when the last RT service is being
provided to me or the completion of my RT treatment (whenever the later) to the
Council on Human Reproductive Technology for the purpose of inspection and use
in the course of discharging its regulatory functions under the Human Reproductive
Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Husband's Signature)

Name _____
(in Block Letters) (in Chinese)

Marriage Certificate No. _____

* Delete whichever is inapplicable.

Note: Under normal circumstances, gametes from the husband and wife should be used.
The use of donated gamete(s) would be subject to proof of difficulties in obtaining
normal gametes from either the husband or the wife.

Consent Form (8) (Revised in 2025)

Consent to Designated Donation of Sperm

Part I DONOR'S CONSENT

1. I _____ (name of donor) (hereinafter
(Surname, Given Names) (ID No.)
called "the Donor"), DO HEREBY CONSENT to donating my sperm to the following
couple (hereinafter called "the Recipients"), _____
(Surname, Given Names) (ID No.)
(husband's name), and _____ (wife's name),
(Surname, Given Names) (ID No.)
with the understanding that sperm donated by me will be used for the treatment of the
Recipients and that this consent cannot be revoked or varied once my sperm has been
donated, subject to any written agreement to the contrary between the Donor and the
Recipients.
2. I acknowledge that the nature and implications of my donation have been explained to
me by _____ and I have been given the opportunity to
ask any question I wish. I have also been offered a suitable opportunity to take part in
counselling with _____ about the implications of my
donation.
3. I understand that sperm donated by me will be stored for a maximum period of 2 years
from the day of my donation. I consent that sperm donated by me should only be used
to produce 1 / 2 / 3* live birth events. If the aforesaid treatment of the Recipients cannot
be successfully carried out within that period, or if before the expiry of the said maximum
storage period, it becomes impossible for any reason whatsoever for the aforesaid
treatment to be successfully carried out, or if excess sperm remains after the completion
of the aforesaid treatment, I consent that stored sperm may be (please tick one) -

☐ disposed of in accordance with the "Guidelines on disposal of gametes or embryos"
("the Guidelines") in the Code of Practice on Reproductive Technology and
Embryo Research published from time to time by the Council on Human
Reproductive Technology.

☐ donated anonymously for the treatment of other infertile couples, in which event
sperm donated by me would not be used to produce more than a total of 1/2/3* live
birth events, including the event of the designated donation, if successful (failing
which the Centre may dispose of the stored sperm in accordance with the
Guidelines).

☐ donated for research (failing which the Centre may dispose of the stored sperm in
accordance with the Guidelines).

☐ donated for quality control and/or training (failing which the Centre may dispose
of the stored sperm in accordance with the Guidelines).

- 4.# I understand that the embryo(s) produced from the fertilization of sperm donated by me will be used for the infertility treatment of the Recipients. If the aforesaid treatment cannot be successfully carried out, or if it becomes impossible for any reason whatsoever for the aforesaid treatment to be successfully carried out, or if excess embryo(s) remain after the completion of the aforesaid treatment, I consent that the embryo(s) produced from the aforesaid fertilization may be disposed of or donated in accordance with the Recipients' instructions, as set out in para. 13 hereof.
5. I understand that under the Parent & Child Ordinance (Cap. 429), I shall not be the legal father of the child(ren) born from sperm donated by me. I also agree never to seek to make any claim over such child(ren) under any circumstance whatsoever.
6. To the best of my knowledge and belief -
- (a) I am in good health and have no communicable disease or hereditary disorder, except as follows -
- _____
- _____
- (b) None of my relatives has ever suffered from any inheritable disease, except as follows -
- _____
- _____
7. For the purpose of determining whether I am suitable as a donor of sperm, I consent to undergoing such blood tests (including HIV test) and medical examinations as shall be prescribed by the Centre.
8. I acknowledge that the Information Sheets at Appendices X and XI of the Code of Practice on Reproductive Technology and Embryo Research have been read by me/explained to me*. I fully understand the contents of the Information Sheets and I agree that my personal data and information may be used for the purposes as set out therein.
- [☐] (Please tick if agreed) I also consent to the release of all medical records, including my medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on me from the time when my suitability for RT procedure(s) is being assessed or the provision of any RT service to me (whenever the earlier) until one year after the time when the last RT service is being provided to me or the completion of my RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).
9. I do / do not* consent to sperm donated by me to be exported out of Hong Kong SAR.

Dated the _____ day of _____ (Month) _____ (Year)

Signed _____ (Donor’s Signature)

Name _____ (in Block Letters) _____ (in Chinese)

Date of Birth _____ (dd/mm/yy)

Signed _____ (Signature of Attending Doctor)

Signed _____ (Signature of Witness)

Name _____ (in Block Letters)

Name _____ (in Block Letters)

Position _____

Part II RECIPIENTS' CONSENT

10. We (the Recipients), _____ (husband's name),
(Surname, Given Names) (ID No.)
and _____ (wife's name),
(Surname, Given Names) (ID No.)
of _____
_____ (address),
being lawfully married and desirous of having a child, DO HEREBY CONSENT to
receiving the sperm donated by _____
(Surname, Given Names) (ID No.)
(the Donor) for infertility treatment.

11. We acknowledge that the nature and implications of the aforesaid treatment have been explained to us by _____ and we have been given the opportunity to ask any question we wish. We have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the donation.

12. We fully understand and accept that -

- (a) the aforesaid treatment procedure may not result in a successful pregnancy;
- (b) the wife may not be able to carry the pregnancy to term; and
- (c) there may be an increase in preterm deliveries in pregnancies and that any child conceived or born following the procedures may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary, fertility problems or other reasons compared to a natural or spontaneous pregnancy, as reported in some studies.

13.# We understand that the embryo(s) produced from the fertilization of the gametes of

_____ *(please specify names of persons from whom the gametes are obtained)*
will be used for the aforesaid infertility treatment and stored for such purpose for a maximum period of 2 years from the day on which the embryo(s) is/are fertilised, unless there are special circumstances justifying a longer storage period. If the aforesaid treatment cannot be successfully carried out within that period, or if, before the expiry of the said maximum storage period, it becomes impossible for any reason whatsoever for the aforesaid treatment to be successfully carried out, or if excess embryo(s) remain after completion of the aforesaid treatment, we consent that the embryo(s) produced from the aforesaid fertilization may be (please tick one) -

- ☐ disposed of in accordance with the "Guidelines on disposal of gametes or embryos" ("the Guidelines") in the Code of Practice on Reproductive Technology and Embryo Research published from time to time by the Council on Human Reproductive Technology.
- ☐ donated anonymously for the treatment of other infertile couples, in which event the embryo(s) would not be used to produce more than a total of 1/2/3 * live birth events^{Note}, including the event of the designated donation, if successful (failing

which the Centre may dispose of the stored embryo(s) in accordance with the Guidelines).

☐ donated for research (failing which the Centre may dispose of the stored embryo(s) in accordance with the Guidelines).

☐ donated for quality control and/or training (failing which the Centre may dispose of the stored embryo(s) in accordance with the Guidelines).

14. We understand that under the Parent & Child Ordinance (Cap. 429), we shall be the legal parents of the child(ren) born from the aforesaid treatment procedure.

15. We acknowledge that the Information Sheets at Appendices X and XI of the Code of Practice on Reproductive Technology and Embryo Research have been read by us/explained to us*. We fully understand the contents of the Information Sheets and we agree that our personal data and information may be used for the purposes as set out therein.

☐ (Please tick if agreed) We also consent to the release of all medical records, including our medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on us from the time when our suitability for RT procedure(s) is being assessed or the provision of any RT service to us (whenever the earlier) until one year after the time when the last RT service is being provided to us or the completion of our RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Husband's Signature)

Signed _____
(Wife's Signature)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

(in Chinese)

(in Chinese)

Marriage Certificate No. _____

Signed _____
(Signature of Attending Doctor)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

Position _____

* Delete whichever is inapplicable.

To be completed only if the embryo(s) were produced from the wife's egg(s) (oocytes).

Note : If the Donor has indicated to donate surplus or unused sperm to other infertile couple, the limit of "live birth event" specified by the donor in para. 3 should also be considered for the case which the Recipients indicate to donate the surplus or unused embryos to other infertile couple. The total no. of live birth events produced by the excess sperm and embryos subsequently created should not be more than 3.

Consent Form (9) (Revised in 2025)

Consent to Designated Donation of Eggs (Oocytes)

Part I DONOR'S CONSENT

1. I _____ (name of donor) (hereinafter called
(Surname, Given Names) (ID No.)
"the Donor"), DO HEREBY CONSENT to donating my eggs (oocytes) to the following
couple (hereinafter called "the Recipients"),

(Surname, Given Names) (ID No.)

(wife's name), with
(Surname, Given Names) (ID No.)
the understanding that eggs (oocytes) donated by me will be used for the treatment of
the Recipients and that this consent cannot be revoked or varied once my eggs (oocytes)
have been donated, subject to any written agreement to the contrary between the Donor
and the Recipients.
2. I consent to -
 - (a) be prepared for egg (oocytes) retrieval including the use of drugs for hyperstimulation;
 - (b) the removal of eggs (oocytes) from my ovaries with the aid of laparoscopy/ultrasound;
 - (c) the administration of appropriate drugs and/or anaesthetics to me if necessary for the procedure(s).
3. I acknowledge that the nature and implications of my donation have been explained to me by _____ and I have been given the opportunity to ask any question I wish. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of my donation.
4. I understand that eggs (oocytes) donated by me will be stored for a maximum period of 2 years from the day of my donation. I consent that eggs (oocytes) donated by me should only be used to produce 1 / 2 / 3* live birth events. If the aforesaid treatment of the Recipients cannot be successfully carried out within that period, or if, before the expiry of the said maximum storage period, it becomes impossible for any reason whatsoever for the aforesaid treatment to be successfully carried out, or if excess eggs (oocytes) remain after completion of the aforesaid treatment, I consent that the stored eggs (oocytes) may be (please tick one) -

[] disposed of in accordance with the "Guidelines on disposal of gametes or embryos" ("the Guidelines") in the Code of Practice on Reproductive Technology and Embryo Research published from time to time by the Council on Human Reproductive Technology.

- ☐ donated anonymously for the treatment of other infertile couples, in which event eggs (oocytes) donated by me would not be used to produce more than a total of 1/2/3* live birth events, including the event of the designated donation, if successful (failing which the Centre may dispose of the stored eggs (oocytes) in accordance with the Guidelines).
- ☐ donated for research (failing which the Centre may dispose of the stored eggs (oocytes) in accordance with the Guidelines).
- ☐ donated for quality control and/or training (failing which the Centre may dispose of the stored eggs (oocytes) in accordance with the Guidelines).
- 5.# I understand that the embryo(s) produced from fertilization of egg(s) [oocyte(s)] donated by me will be used for the infertility treatment of the Recipients. If the aforesaid treatment cannot be successfully carried out, or if it becomes impossible for any reason whatsoever for the aforesaid treatment to be successfully carried out, or if excess embryo(s) remain after completion of the aforesaid treatment, I consent that the embryo(s) produced from the aforesaid fertilization may be disposed of or donated in accordance with the Recipients' instructions, as set out in para. 14 hereof.
6. I understand that under the Parent & Child Ordinance (Cap. 429), I shall not be the legal mother of the child(ren) born from egg(s) [oocyte(s)] donated by me. I also agree never to seek to make any claim over such child(ren) under any circumstance whatsoever.
7. To the best of my knowledge and belief -
- (a) I am in good health and have no communicable disease or hereditary disorder, except as follows -
- (b) None of my relatives has ever suffered from any inheritable disease, except as follows -
-
-
8. For the purpose of determining whether I am suitable as a donor of eggs (oocytes), I consent to undergoing such blood tests (including HIV test) and medical examinations as shall be prescribed by the Centre.
9. I acknowledge that the Information Sheets at Appendices X and XI of the Code of Practice on Reproductive Technology and Embryo Research have been read by me/explained to me*. I fully understand the contents of the Information Sheets and I agree that my personal data and information may be used for the purposes as set out therein.
- ☐ (Please tick if agreed) I also consent to the release of all medical records, including my medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on me from the time when my suitability for RT procedure(s) is being assessed or the provision of any RT service to me

(whenever the earlier) until one year after the time when the last RT service is being provided to me or the completion of my RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

10. I do / do not* consent to eggs (oocytes) donated by me to be exported out of Hong Kong SAR.

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Donor's Signature)

Name _____
(in Block Letters) (in Chinese)

Date of Birth _____
(dd/mm/yy)

Signed _____
(Signature of Attending
Doctor)

Name _____
(in Block Letters)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Position _____

which the Centre may dispose of the stored embryo(s) in accordance with the Guidelines).

☐ donated for research (failing which the Centre may dispose of the stored embryo(s) in accordance with the Guidelines).

☐ donated for quality control and/or training (failing which the Centre may dispose of the stored embryo(s) in accordance with the Guidelines).

15. We understand that under the Parent & Child Ordinance (Cap. 429), we shall be the legal parents of the child(ren) born from the aforesaid treatment procedure.

16. We acknowledge that the Information Sheets at Appendices X and XI of the Code of Practice on Reproductive Technology and Embryo Research have been read by us/explained to us*. We fully understand the contents of the Information Sheets and we agree that our personal data and information may be used for the purposes as set out therein.

☐ (Please tick if agreed) We also consent to the release of all medical records, including our medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on us from the time when our suitability for RT procedure(s) is being assessed or the provision of any RT service to us (whenever the earlier) until one year after the time when the last RT service is being provided to us or the completion of our RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Husband's Signature)

Signed _____
(Wife's Signature)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

(in Chinese)

(in Chinese)

Marriage Certificate No. _____

Signed _____
(Signature of Attending Doctor)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

Position _____

* Delete whichever is inapplicable.

To be completed only if the embryo(s) were produced from the husband's sperm.

Note: If the Donor has indicated to donate surplus or unused eggs (oocytes) to other infertile couple, the limit of "live birth event" specified by the donor in para. 4 should also be considered for the case which the Recipients indicate to donate the surplus or unused embryos to other infertile couple. The total no. of live birth events produced by the excess eggs (oocytes) and embryos subsequently created should not be more than 3.

Consent Form (10) (Revised in 2025)

Consent to Designated Donation of Embryos

PART I DONORS' CONSENT

1. We (the Donors), _____ (husband's name),
(Surname, Given Names) (ID No.)
and _____ (wife's name)
(Surname, Given Names) (ID No.)
(hereinafter jointly called "the Donors"), DO HEREBY CONSENT to donating the
embryo(s) produced from our gametes to the following couple (hereinafter called "the
Recipients"), _____ (husband's name),
(Surname, Given Names) (ID No.)
and _____ (wife's name), with
(Surname, Given Names) (ID No.)
the understanding that embryos donated by us will be used for the treatment of the
Recipients and that this consent cannot be revoked or varied.
2. We acknowledge that the nature and implications of our donation have been explained to
us by _____ and we have been given the opportunity to
ask any question we wish. We have also been offered a suitable opportunity to take part
in counselling with _____ about the implications of our
donation.
3. We understand that embryo(s) donated by us will be stored for a maximum period of 2
years from the day of our donation. We consent that our embryos should only be used to
produce 1 / 2 / 3* live birth events. If the aforesaid treatment of the Recipients cannot be
successfully carried out within that period, or if, before the expiry of the said maximum
storage period, it becomes impossible for any reason whatsoever for the aforesaid
treatment to be successfully carried out, or if excess embryo(s) remain after completion of
the aforesaid treatment, we consent that embryo(s) donated by us may be (please tick one)
-

☐ disposed of in accordance with the "Guidelines on disposal of gametes or embryos"
("the Guidelines") in the Code of Practice on Reproductive Technology and
Embryo Research published from time to time by the Council on Human
Reproductive Technology.

☐ donated anonymously for the treatment of other infertile couples, in which event
embryos donated by us will not be used to produce more than a total of 1/2/3* live
birth events, including the event of the designated donation, if successful (failing
which the Centre may dispose of the stored embryos in accordance with the
Guidelines).

☐ donated for research (failing which the Centre may dispose of the stored embryos
in accordance with the Guidelines).

☐ donated for quality control and/or training (failing which the Centre may dispose
of the stored embryos in accordance with the Guidelines).

4. We understand that under the Parent & Child Ordinance (Cap. 429), we shall not be the legal parents of the child(ren) born from embryo(s) donated by us. We also agree never to seek to make any claim over such child(ren) under any circumstance whatsoever.
5. To the best of our knowledge and belief -
- (a) We are in good health and have no communicable disease or hereditary disorder, except as follows -
- _____
- _____
- (b) None of our relatives has ever suffered from any inheritable disease, except as follows -
- _____
- _____
6. For the purpose of determining whether we are suitable as donors of embryos, we consent to undergoing such blood tests (including HIV test) and medical examinations as shall be prescribed by the Centre.
7. We acknowledge that the Information Sheets at Appendices X and XI of the Code of Practice on Reproductive Technology and Embryo Research have been read by us/explained to us*. We fully understand the contents of the Information Sheets and we agree that our personal data and information may be used for the purposes as set out therein.
- ☐ (Please tick if agreed) We also consent to the release of all medical records, including our medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on us from the time when our suitability for RT procedure(s) is being assessed or the provision of any RT service to us (whenever the earlier) until one year after the time when the last RT service is being provided to us or the completion of our RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).
8. We do / do not* consent to embryos donated by us to be exported out of Hong Kong SAR.

Dated the _____ day of _____ (Month) _____ (Year)

Signed _____ Signed _____
(Husband's Signature) (Wife's Signature)

Name _____
(in Block Letters)

(in Chinese)

Name _____
(in Block Letters)

(in Chinese)

Marriage Certificate No. _____

Signed _____
(Signature of Attending Doctor)
Name _____
(in Block Letters)

Signed _____
(Signature of Witness)
Name _____
(in Block Letters)
Position _____

RT procedure(s) is being assessed or the provision of any RT service to us (whenever the earlier) until one year after the time when the last RT service is being provided to us or the completion of our RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Husband's Signature)

Signed _____
(Wife's Signature)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

(in Chinese)

(in Chinese)

Marriage Certificate No. _____

Signed _____
(Signature of Attending Doctor)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

Position _____

* Delete whenever is inapplicable.

Consent Form (11) (Revised in 2024)

Consent to Disposal of Stored Gametes/Embryos

1. I _____ (hereinafter called “the Patient”)*
(Surname, Given Names of unmarried patient (ID No.)
/ We _____ (hereinafter called “the Husband”),
(Surname, Given Names of husband) (ID No.)
and _____ (hereinafter called “the Wife”)*,
(Surname, Given Names of wife) (ID No.)
of _____ (address),
DO HEREBY CONSENT AND AUTHORISE
_____ (name of the reproductive technology
centre) (hereinafter called “the Centre”), to dispose of the stored gametes / embryos for
which a consent form on gametes / embryo storage was previously signed by me / us on
_____ (dd/mm/yy).

2. I / We acknowledge that the nature and the implications of the disposal have been explained
to me / us by _____ and I / we have been given the opportunity
to ask any question I / we wish. I / We have also been offered a suitable opportunity to
take part in counselling with _____ about the implications
of the disposal.

☐ (Please tick if agreed) I / We also consent to the release of all medical records,
including my / our medical history, except those specified separately otherwise, kept
by the Centre and its doctor(s) or associated doctor(s) on me / us from the time when
our suitability for RT procedure(s) is being assessed or the provision of any RT
service to me / us (whenever the earlier) until one year after the time when the last
RT service is being provided to me / us or the completion of my / our RT treatment
(whenever the later) to the Council on Human Reproductive Technology for the
purpose of inspection and use in the course of discharging its regulatory functions
under the Human Reproductive Technology Ordinance (Cap. 561).

* Delete whichever is inapplicable

Note : If no conjoint consent is obtained from the Husband and the Wife the Centre will keep
the stored embryos until the maximum storage period expires.

Dated the _____ day of _____
(Day) (Month) (Year)

Signed* _____ Signed*^ _____
(Patient’s Signature) (Husband’s Signature) (Wife’s Signature)

Name _____ Name _____
(in Block Letters) (in Block Letters) (in Block Letters)

(in Chinese) (in Chinese) (in Chinese)

Marriage Certificate No.# _____

Signed	_____	Signed	_____
	(Signature of Attending Doctor)		(Signature of Witness)
Name	_____	Name	_____
	(in Block Letters)		(in Block Letters)
		Position	_____

^ Disposal of gamete requires consent from the patient only while conjoint consent from both the wife and the husband is required for disposal of embryos.

To be completed if the patient is married

Consent Form (12) (Revised in 2025)

Consent to Surrogacy Arrangement

PART I COMMISSIONING COUPLE'S CONSENT

1. We (hereinafter called "the Commissioning Couple")

(Surname, Given Names) (ID No.)
and _____ (wife's name),
(Surname, Given Names) (ID No.)
DO HEREBY CONSENT to commissioning

(Surname, Given Names) (ID No.)
(surrogate mother's name) (hereinafter called "the Surrogate Mother") to act as the surrogate mother in the surrogacy arrangement herein, with the understanding that only our own gametes and embryo(s) will be used for the surrogacy arrangement.
2. We acknowledge that the nature and implication of the arrangement and the procedures involved have been explained to us by _____ and we have been given the opportunity to ask any question we wish. We have also been offered a suitable opportunity to take part in counselling with a multi-disciplinary team about the implications of the surrogacy arrangement.
3. We acknowledge that our attending physician, _____, has explained to us that surrogacy arrangement is the only approach that may assist us in having a baby of our own, after discussing with us our clinical condition and confirming with us that other methods of assisted reproduction are not applicable.
4. We understand that under the Parent & Child Ordinance (Cap. 429), we shall not be the legal parents of the child(ren) born from the surrogacy arrangement unless the court makes a parental order in favour of us upon our application within 6 months of the birth of the said child(ren).
5. We understand that under the Human Reproductive Technology Ordinance (Cap. 561) -
 - (a) no surrogacy arrangement involving the making or receiving of any payment is allowed; and
 - (b) no surrogacy arrangement is enforceable by or against any of the persons making it.
6. For the purpose of determining whether we are medically suitable for the surrogacy arrangement, we consent to undergoing such blood tests (including HIV test) and medical examinations as shall be prescribed by _____ (the Centre).
(name of the reproductive technology centre)

7. We fully understand and accept that -

- (a) the medical procedure carried out pursuant to the surrogacy arrangement may not result in a successful pregnancy;
- (b) the Surrogate Mother may not be able to carry the pregnancy to term; and
- (c) there may be an increase in preterm deliveries in pregnancies and that any child conceived or born following the procedures may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary, fertility problems or other reasons compared to a natural or spontaneous pregnancy, as reported in some studies.

8. I _____ (the wife's name), consent to -
(Surname, Given Names) (ID No.)

- (a) be prepared for egg (oocytes) retrieval including the use of drugs for hyperstimulation;
- (b) the removal of eggs (oocytes) from my ovaries with the aid of laparoscopy/ultrasound; and
- (c) the administration of appropriate drugs and/or anaesthetics to me if necessary for the procedure(s);

and acknowledge that the nature, procedures and possible complications of the egg (oocyte) collection procedures mentioned above have been explained to me by _____ and I have been given the opportunity to ask any question I wish. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the procedures.

9. We consent that unfertilized gamete(s) and/or excess embryo(s) obtained from us in the course of procedures carried out pursuant to the surrogacy arrangement may be (please tick one) -

- ☐ disposed of in accordance with the "Guidelines on disposal of gametes or embryos" ("the Guidelines") in the Code of Practice on Reproductive Technology and Embryo Research published from time to time by the Council on Human Reproductive Technology.
- ☐ donated anonymously for the treatment of other infertile couples, in which event our gametes or embryos would not be used to produce more than a total of 1/2/3* live birth events, including the event of the aforesaid surrogacy arrangement, if successful (failing which the Centre may dispose of the stored embryos in accordance with the Guidelines).
- ☐ donated for research (failing which the Centre may dispose of the stored embryos in accordance with the Guidelines).
- ☐ donated for quality control and/or training (failing which the Centre may dispose of the stored embryos in accordance with the Guidelines).

10. We acknowledge that the Information Sheet at Appendix XI of the Code of Practice on Reproductive Technology and Embryo Research has been read by us/ explained to us*.

We fully understand the contents of the Information Sheet and we agree that our personal data and information may be used for the purposes as set out in paragraph 1 of the Information Sheet.

- [] (Please tick if agreed) We also consent to the release of all medical records, including our medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on us from the time when our suitability for RT procedure(s) is being assessed or the provision of any RT service to us (whenever the earlier) until one year after the time when the last RT service is being provided to us or the completion of our RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Husband's Signature)

Signed _____
(Wife's Signature)

Name _____
(in Block Letters)

(in Chinese)

Name _____
(in Block Letters)

(in Chinese)

Marriage Certificate No. _____

Signed _____
(Signature of Attending Doctor)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

Position _____

PART II SURROGATE MOTHER'S CONSENT

11. I, _____
(Surname, Given Names) (ID No.)
(name of the surrogate mother) (hereinafter called "the Surrogate Mother") DO HEREBY
CONSENT to act as the surrogate mother for the Commissioning Couple,

(Surname, Given Names) (ID No.) (husband's name),
and _____ (wife's name),
(Surname, Given Names) (ID No.)
with the understanding that gametes/embryos* of the Commissioning Couple would be
used for the surrogacy arrangement.
12. I acknowledge that the nature and implications of the surrogacy arrangement have been
explained to me by _____ and I have been given the
opportunity to ask any question I wish. I have also been offered a suitable opportunity to
take part in counselling with a multi-disciplinary team about the implications of the
surrogacy arrangement.
13. I understand that under the Parent & Child Ordinance (Cap. 429), I shall be the legal
mother of the child(ren) born from the surrogacy arrangement unless the court makes a
parental order in favour of the Commissioning Couple upon their application within 6
months of the birth of the said child(ren).
14. I consent that the Centre may transfer gametes/embryos* of the Commissioning Couple to
me by any one or more than one of the following reproductive technology procedures
(please tick as appropriate) -

() embryo transfer;
() others (please specify) _____
15. I acknowledge that the nature, procedures and possible complications of the above
reproductive technology procedures have been explained to me by
_____ and I have been given the opportunity to ask any
question I wish. I have also been offered a suitable opportunity to take part in counselling
with _____ about the implications of the procedures.
16. I fully understand and accept that -

(a) the aforesaid procedures may not result in successful pregnancy;
(b) I may not be able to carry the pregnancy to term;
(c) I may suffer from illness(es) or complications arising out of or consequent upon a
pregnancy resulting from the embryo transfer or other reproductive technology
procedures; and
(d) there may be an increase in preterm deliveries in pregnancies and that any child
conceived or born following the procedures, may suffer from defect(s) of health or
mental or physical impairment(s) as a result of congenital, hereditary, fertility
problems or other reasons, compared to a natural or spontaneous pregnancy, as
reported in some studies.

17. For the purpose of determining whether I am medically suitable to act as a surrogate mother, I consent to undergoing such blood tests (including HIV test) and medical examinations as shall be prescribed by the Centre.

18. I acknowledge that the Information Sheet at Appendix XI of the Code of Practice on Reproductive Technology and Embryo Research has been read by me/explained to me*. I fully understand the contents of the Information Sheet and I agree that my personal data and information may be used for the purposes as set out in paragraph 1 of the Information Sheet.

[☐] (Please tick if agreed) I also consent to the release of all medical records, including my medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on me from the time when my suitability for RT procedure(s) is being assessed or the provision of any RT service to me (whenever the earlier) until one year after the time when the last RT service is being provided to me or the completion of my RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Surrogate Mother's
Signature)

Name _____
(in Block Letters) (in Chinese)

Signed _____
(Signature of Attending Doctor)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

Position _____

PART III# HUSBAND OF THE SURROGATE MOTHER'S CONSENT

19. I, _____, am the
(Surname, Given Names) (ID No.)
husband of _____ (name of the
(Surname, Given Names) (ID No.)
surrogate mother) and I consent to the surrogacy arrangement outlined above. I understand that under the Parent & Child Ordinance (Cap. 429), I shall be the legal father of any child(ren) born from the said arrangement unless the court makes a parental order in favour of the Commissioning Couple upon their application within 6 months of the birth of the said child(ren).
20. I understand that this consent cannot be revoked or varied once the procedures as listed in para. 14 above have been performed.
21. I acknowledge that the nature and implications of the surrogacy arrangement have been explained to me by _____ and I have been given the opportunity to ask any question I wish. I have also been offered a suitable opportunity to take part in counselling with a multi-disciplinary team about the implications of the surrogacy arrangement.
22. I acknowledge that the Information Sheet at Appendix XI of the Code of Practice on Reproductive Technology and Embryo Research has been read by me/explained to me*. I fully understand the contents of the Information Sheet and I agree that my personal data and information may be used for the purposes as set out in paragraph 1 of the Information Sheet.
- [] (Please tick if agreed) I also consent to the release of all medical records, including my medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on me from the time when my suitability for RT procedure(s) is being assessed or the provision of any RT service to me (whenever the earlier) until one year after the time when the last RT service is being provided to me or the completion of my RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Husband of the Surrogate Mother's Signature)

Name _____
(in Block Letters) (in Chinese)

Marriage Certificate No.# _____

Signed _____
(Signature of Attending Doctor)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

Position _____

* Delete whichever is inapplicable

To be completed if the surrogate mother is a party to a marriage when making the surrogacy arrangement.

Consent Form (13) (Revised in 2025)

**Consent to Use of Reproductive Technology Procedures for
Purposes of Gender Selection on Medical Ground**

1. We _____ (husband's name), (hereinafter
(Surname, Given Names) (ID No.)
called "the Husband"), and _____
(Surname, Given Names) (ID No.)
(wife's name), (hereinafter called "the Wife"), of _____
_____, (address),
DO HEREBY CONSENT AND AUTHORISE _____
_____ (name of the reproductive technology centre), (hereinafter
called "the Centre"), to apply gender selection technique on our gametes/embryos* for fetal
gender selection, with the understanding that only our own gametes will be used.
2. We also hereby consent that the Centre may proceed with the following RT procedures
(please tick as appropriate) -

☐ sperm treatment with sex-selective insemination
☐ in-vitro fertilization
☐ preimplantation genetic testing with sex-selective embryo transfer
☐ prenatal diagnosis with sex-selective abortion
☐ others (please specify) _____
3. We understand that the reproductive technology procedures mentioned in para. 2 can result
in the gender of our foetus being selected and that the procedure is necessary to avoid a
sex-linked genetic disease, called _____, which is
specified in Schedule 2 to the Human Reproductive Technology Ordinance (Cap.561), and
which may prejudice the health of the embryo. The nature and implication of the sex-linked
genetic disease has been explained to us by _____.
4. We acknowledge that the nature and implications of fetal gender selection have been
explained to us by _____ and
we have been given the opportunity to ask any question we wish. We have also been
offered a suitable opportunity to take part in counselling with
_____ about the implications of the treatment.
5. We fully understand and accept that -

 - (a) the wife may not become pregnant;
 - (b) the wife may not be able to carry the pregnancy to term;
 - (c) the wife may suffer from illness(es) or complications arising out of or consequent
upon a pregnancy resulting from the in-vitro fertilization/embryo transfer*;
 - (d) there may be an increase in preterm deliveries in pregnancies and that any child
conceived or born following the procedures may suffer from defect(s) of health or any
mental or physical impairment(s) as a result of congenital, hereditary, fertility
problems or other reasons compared to a natural or spontaneous pregnancy, as
reported in some studies; and
 - (e) any RT technique in fetal gender selection has variable effectiveness and the resulting
child(ren) born may not possess the correct gender as we have chosen.

6. I _____ (the Wife's name), consent to -
(Surname, Given Names) (ID No.)

- (a) be prepared for egg (oocyte) retrieval including the use of drugs for hyperstimulation;
- (b) the removal of eggs (oocytes) from my ovaries with the aid of laparoscopy/ultrasound; and
- (c) the administration of appropriate drugs and/or anaesthetics to me if necessary for the procedure(s),

and acknowledge that the nature, procedures and possible complications for egg (oocyte) collection procedures as mentioned above have been explained to me by _____ and I have been given the opportunity to ask any question I wish. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the procedures.

7. We acknowledge that the Information Sheet at Appendix XI of the Code of Practice on Reproductive Technology and Embryo Research has been read by us/explained to us*. We fully understand the contents of the Information Sheet and we agree that our personal data and information may be used for the purposes as set out in paragraph 1 of the Information Sheet.

[] (Please tick if agreed) We also consent to the release of all medical records, including our medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on us from the time when our suitability for RT procedure(s) is being assessed or the provision of any RT service to us (whenever the earlier) until one year after the time when the last RT service is being provided to us or the completion of our RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____ Signed _____
(Husband's Signature) (Wife's Signature)

Name _____ Name _____
(in Block Letters) (in Block Letters)

(in Chinese) (in Chinese)

Marriage Certificate No. _____

Signed _____ Signed _____
(Signature of Attending Doctor) (Signature of Witness)

Name _____ Name _____
(in Block Letters) (in Block Letters)

Position _____

* Delete whichever is inapplicable

Consent Form (14) (Revised in 2025)

Consent to Artificial Insemination by Husband (AIH)

PART I WIFE'S CONSENT

1. I _____, of
(Surname, Given Names) (ID No.)
_____ (address),
being lawfully married and desirous of having a child, DO HEREBY AUTHORISE
_____ (name of reproductive
technology centre) (hereinafter called "the Centre") to perform the treatment of
intravaginal/intracervical/intrauterine* insemination on me, using the sperm from my
husband ^{Note}.
2. I acknowledge that the nature, procedures and possible complications of the said treatment
have been explained to me by _____ and I have been
given the opportunity to ask any question I wish. I have also been offered a suitable
opportunity to take part in counselling with _____ about the
implications of the treatment.
3. I fully understand and accept that -
 - (a) the said treatment procedure may not result in a successful pregnancy;
 - (b) I may not be able to carry the pregnancy to term; and
 - (c) there may be an increase in preterm deliveries in pregnancies and that any child
conceived or born following the procedure may suffer from defect(s) of health or
mental or physical impairment(s) as a result of congenital, hereditary, fertility problems
or other reasons compared to a natural or spontaneous pregnancy, as reported in some
studies.
4. I understand that -
 - (a) this consent cannot be revoked or varied once the insemination has been performed;
and
 - (b) the insemination will not be performed if my husband revokes or varies his consent
prior to insemination.
5. I acknowledge that the Information Sheet at Appendix XI of the Code of Practice on
Reproductive Technology and Embryo Research has been read by me/explained to me*. I
fully understand the contents of the Information Sheet and I agree that my personal data and
information may be used for the purposes as set out in paragraph 1 of the Information Sheet.

[] (Please tick if agreed) I also consent to the release of all medical records, including
my medical history, except those specified separately otherwise, kept by the Centre
and its doctor(s) or associated doctor(s) on me from the time when my suitability for
RT procedure(s) is being assessed or the provision of any RT service to me
(whenever the earlier) until one year after the time when the last RT service is being
provided to me or the completion of my RT treatment (whenever the later) to the
Council on Human Reproductive Technology for the purpose of inspection and use
in the course of discharging its regulatory functions under the Human Reproductive
Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Wife's Signature)

Name _____
(in Block Letters)

Signed _____
(Signature of Attending Doctor)

Name _____
(in Block Letters)

(in Chinese)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Position _____

PART II HUSBAND'S CONSENT

(For the first cycle, the husband should sign the consent form in the presence of the attending doctor, while for the subsequent cycles, the signing of the consent form by the husband in the presence of a witness would suffice.)

6. I _____ am the
(Surname, Given Names) (ID No.)
husband of _____ and I consent to the course
of treatment outlined above. I understand that I will be the legal father of any child(ren) born
from the treatment.

7. I understand that this consent cannot be revoked or varied once the insemination has been
performed. Any revocation or variation of this consent will not be effective until actual
receipt by the Centre in writing.

8. I acknowledge that the Information Sheet at Appendix XI of the Code of Practice on
Reproductive Technology and Embryo Research has been read by me/explained to me*. I
fully understand the contents of the Information Sheet and I agree that my personal data and
information may be used for the purposes as set out in paragraph 1 of the Information Sheet.

[] (Please tick if agreed) I also consent to the release of all medical records, including
my medical history, except those specified separately otherwise, kept by the Centre
and its doctor(s) or associated doctor(s) on me from the time when my suitability for
RT procedure(s) is being assessed or the provision of any RT service to me
(whenever the earlier) until one year after the time when the last RT service is being
provided to me or the completion of my RT treatment (whenever the later) to the
Council on Human Reproductive Technology for the purpose of inspection and use
in the course of discharging its regulatory functions under the Human Reproductive
Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Husband's Signature)

Name _____
(in Block Letters) (in Chinese)

Signed _____
(Signature of Attending Doctor/Witness*)

Name _____
(in Block Letters)

Marriage Certificate No. _____

* Delete whichever is inapplicable.

Note: Intravaginal insemination refers to the placement of sperm into the vagina.
Intracervical insemination refers to the placement of sperm at the cervical os. Intrauterine
insemination refers to the placement of sperm (usually after processing) into the uterine cavity.

OBSOLETE

Consent to Disclosure of Personal Data in Connection with Reproductive Technology Procedure/ Donation

Introduction

The Reproductive Technology Centre (the “Centre”) is subject to the Code of Practice published by the Council on Human Reproductive Technology (the “Council”) from time to time and to all laws which are or will be in force including the Human Reproductive Technology Ordinance (Cap. 561) (the “Ordinance”) which requires or will require, amongst other things, the supply of information on the particulars of the patients / donors to the Council.

This form documents your consent to disclosure of your personal data / information in connection with the reproductive technology procedure / donation under circumstances as specified below.

Consent

*To be filled by Patients (and Spouses)/ Donors / Surrogate Mothers (and Spouses)**

1. I/we * _____
(Surname, given names of client) (ID No.)

(Surname, given names of client’s spouse) (ID No.)

consent that -

- (a) all data and information relating to me/ us* may be provided by the Centre to the Council or other governmental or statutory bodies in accordance with the requirements of -
- (i) the Ordinance;
 - (ii) the Code of Practice published and amended from time to time by the Council; and
 - (iii) other statutory provisions in Hong Kong;
- (b) all data and information relating to me/ us* may be provided by the Centre to the Council for the purpose of compiling, keeping and/or maintaining of register(s) established by regulation(s) made by the Secretary for Food and Health under section 45(1)(a) of the Ordinance;
- (c) all documents, records, data and information relating to me/ us* may be shown, provided and revealed by the Centre to persons duly authorized by the Council in inspection(s) conducted by the Council for the purpose of determining whether to grant or renew licence(s) to the Centre;

OBSOLETE

- (d) all documents, records, data and information relating to me/ us* may be shown, provided and revealed by the Centre to persons duly authorised by the Council for the purpose of investigation or inquiry into complaints or information with which the Centre is involved, in accordance with regulations made by the Council pursuant to section 45(2)(h), (i), (j) and/or (k) of the Ordinance.
- (e) in the event that the licence of the Centre is revoked or suspended, or in the event that the Centre for any reason whatsoever becomes unable or unsuitable to continue to provide treatment to me/ us* or to store my / our gametes or embryos, all documents, records, data and information relating to me/ us* (together with my gametes or embryos) may be transferred to and/or taken over by a backing up centre appointed by the Centre and/or the Council. I / we *also consent that in such event, the backing up centre may contact me for follow-up arrangements concerning the treatment and the storage of my/ our* gametes or embryos;
(please delete this paragraph for anonymous donors)
- (f) I / we* may be contacted at any time by the Centre and/or the Council for the purpose of ascertaining whether or not I/ we* will consent to the disclosure or use of data or information relating to me/ us*, in addition to the disclosure or use set out above.
(please delete part or whole of this paragraph if the patient(s) / donor(s) / their spouses donot want to be contacted by the Centre and/ or the Council)

Dated the _____ day of _____
(Month) (Year)

Signed _____ Signed _____
(Client's Signature) (Client's Spouse Signature)*

Name _____ Name _____
(in Block Letters) (in Block Letters)

(in Chinese) (in Chinese)

Signed _____ Signed _____
(Signature of Attending Doctor* (Signature of Witness)
or the one who explained the

nature & implications of the RT
procedure / donation*)

Name _____ Name _____
(in Block Letters) (in Block Letters)

Position _____

Note: * Delete whichever is inapplicable

2012

Consent to Checking on Previous Record of Donation of Gametes

1. I (donor of sperm/ eggs (oocytes)*),

(Surname, Given Names)

(ID No.)

of _____

(address),

DO HEREBY CONSENT that -

(name of
reproductive technology centre to which donation is presently made) (hereinafter called
“the Centre”), may contact -

(a) _____

(b) _____

(c) _____

(names of reproductive technology centres to which donations were previously made)
(hereafter collectively called “the Previous Centres”) or any of them to enquire about the
number of live birth events that have been produced from the sperm / eggs (oocytes)*
that I previously donated to the Previous Centres.

2. I consent that the Previous Centres, any one of them, may disclose to the Centre the
number of live birth events that have been produced from the sperm/ eggs (oocytes)*
that I previously donated to them. Also, the Centre and the Previous Centres may at any
time make mutual enquiries of and mutual disclosures to each other as to the number of
live birth events that have been produced from the sperm/ eggs (oocytes)* that I
previously donated to them.

Dated the _____ day of _____
(Month) (Year)

Signed OBSELETE
(Donor's Signature)

Name _____
(in Block Letters)

(in Chinese)

Signed _____
(Signature of Attending Doctor*
or the one who explained the
nature & implications of the
donation*)

Name _____
(in Block Letters)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Position _____

Note: * Delete whichever is inapplicable.

2012

Consent Form (17)

Consent to Checking on Previous Record of Donation of Embryo(s)

1. We, _____ (husband's name)
(Surname, Given Names) (ID No.)
and _____ (wife's name)
(Surname, Given Names) (ID No.)

of _____
_____ (address),

DO HEREBY CONSENT that: _____
(name of reproductive technology centre to which donation is presently made)
(hereinafter called "the Centre"), may contact -

- (a) _____
(b) _____
(c) _____

(names of reproductive technology centres to which donations were previously made) (hereinafter collectively called "the Previous Centres") or any of them to enquire about the number of live birth events that have been produced from the embryo(s) that we previously donated to the Previous Centres.

2. We consent that the Previous Centres, or any one of them, may disclose to the Centre the number of live birth events that have been produced from the embryo(s) that we previously donated to them. Also, the Centre and the Previous Centres may at any time make mutual enquiries of and mutual disclosures to each other as to the number of live birth events that have been produced from the embryo(s) that we previously donated to them.

Dated the _____ day of _____
(Month) (Year)

OBSOLETE

Signed _____ Signed _____
(Husband's Signature) (Wife's Signature)

Name _____ Name _____
(in Block Letters) (in Block Letters)

(in Chinese) (in Chinese)

Marriage Certificate No. _____

IN

Signed _____ Signed _____
(Signature of Attending Doctor* or the one who explained the nature & implications of the donation*) (Signature of Witness)

2012

Name _____ Name _____
(in Block Letters) (in Block Letters)

Position _____

Note: * Delete whichever is inapplicable.

Consent to Transfer of Frozen-thawed Embryos
(ONLY to be used for subsequent treatment cycles
involving transfer of frozen-thawed embryos
but NOT involving donor gametes/embryos or surrogacy arrangement)

PART II HUSBAND'S CONSENT (to be signed in the presence of witness)

3. I _____, of
(Surname, Given Names) (ID No.)
_____(address),
being lawfully married to _____,
(Surname, Given Names of the Wife) (ID No.)
hereby confirm that all the consent that I gave vide my earlier consent form dated
_____ (the date of signing the consent form for the first treatment cycle), in
relation to the performance of the reproductive technology procedures therein stated,
remains valid, and shall be fully valid and applicable to the new treatment cycle that my
wife is about to receive.

4. I acknowledge that the Information Sheets at Appendices X and XI of the Code of Practice
on Reproductive Technology and Embryo Research have been read by me/explained to me*.
I fully understand the contents of the Information Sheets and I agree that my personal data
and information may be used for the purposes as set out therein.

[] (Please tick if agreed) I also consent to the release of all medical records, including
my medical history, except those specified separately otherwise, kept by the Centre
and its doctor(s) or associated doctor(s) on me from the time when my suitability for
RT procedure(s) is being assessed or the provision of any RT service to me
(whenever the earlier) until one year after the time when the last RT service is being
provided to me or the completion of my RT treatment (whenever the later) to the
Council on Human Reproductive Technology for the purpose of inspection and use
in the course of discharging its regulatory functions under the Human Reproductive
Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____
(Husband's Signature)

Name _____
(Name of Husband in Block Letters) (Name of Husband in Chinese)

Signed _____
(Signature of Witness)

Name _____
(Name of Witness in Block Letters)

Marriage Certificate No. _____

Consent Form (19) (2025)

Consent to Renewal of Storage of Gametes
(for own use after 5 years of storage and every 2 years thereafter)

1. I _____
(Surname, Given Names) (ID No.)
(Single/Married*) of _____
_____ (address) DO HEREBY
AUTHORISE _____ (name of the
licensed centre) (hereinafter called "the Centre") to continue to store the
sperm/eggs(oocytes)* produced from me and provided by me to the Centre, in a manner
which accords with the practice and procedure adopted from time to time by the Centre
("the Programme").
2. I acknowledge that the nature, procedures and possible complications of the Programme,
together with the relevant information on the decline in pregnancy rates associated with
aging of women and use of stored gametes and/or embryos in bringing about human
reproduction by artificial means at advanced maternal age, the risks of pregnancy at an
advanced maternal age, the impacts of delayed childbearing, the arrangements upon
cessation of storage; and also the storage period policy of the Centre* have been clearly
explained to me by _____ and I have been given the
opportunity to ask any question I wish. I have also been offered a suitable opportunity to
take part in counselling with _____ about the
implications of the Programme.
3. I consent that my sperm/eggs(oocytes)* will be stored for a further 2 years and that the
storage period will be extended thereafter 2 years at a time only if I have received proper
counselling and signed a new consent form, together with an acknowledgment of the
relevant information stated in para. 2 above. I understand that I have to receive proper
counselling and sign a new consent form as arranged by the Centre at least 1 month before
the expiry of the current period of storage.
4. I consent that in the absence of attending proper counselling and signing of a new consent
form as stated in para. 3 above, or if I fail to pay the storage fees, or am not contactable by
the Centre, the Centre by giving me 3 months' notice in advance, may dispose of or donate
my sperm/eggs(oocytes)* in accordance with my instructions set out in para. 5 of the
Consent Form (1)* / Consent Form (19)* signed by me on _____, which would
be superseded by my latest instructions set out in para. 5 below*.
5. I understand that, subject to the receipt of proper counselling and signing of a new consent
form as mentioned in para. 3 above, my sperm/eggs(oocytes)* will be frozen and stored
until the time that I indicate to withdraw from or terminate the Programme, or upon expiry
of the time limit / maximum storage period set by the Centre*, or upon my death, whichever
occurs earlier in time, I consent that the sperm/eggs(oocytes)* stored may be disposed of
or be donated in accordance with the instruction indicated in the Consent Form (1)* /
Consent Form (19)* signed by me on _____, which would be superseded by

my latest instructions set out below. (please tick one)*

- ☐ disposed of in accordance with the “Guidelines on disposal of gametes or embryos” (“the Guidelines”) in the Code of Practice on Reproductive Technology and Embryo Research published from time to time by the Council on Human Reproductive Technology.
 - ☐ donated anonymously for the treatment of other infertile couples, in which event my sperm/eggs(oocytes)* would not be used to produce more than a total of 1/2/3* live birth events (failing which the Centre may dispose of the stored sperm/eggs(oocytes)* in accordance with the Guidelines).
 - ☐ donated for research (failing which the Centre may dispose of the stored sperm/eggs(oocytes)* in accordance with the Guidelines).
 - ☐ donated for quality control and/or training (failing which the Centre may dispose of the stored sperm/eggs(oocytes)* in accordance with the Guidelines).
6. I understand that my stored sperm/eggs(oocytes)* will be used for insemination or other reproductive technology procedures only if I am a married person at the time of use of the sperm/eggs(oocytes)*, except in circumstances specified otherwise by the law or by the Code of Practice. Furthermore, upon my death, my stored sperm/eggs(oocytes)* cannot be used by my spouse to bring about any posthumous child(ren) .
7. I understand that I can withdraw from and terminate the Programme at any time by giving a written notice to the Centre stating my intention to withdraw and terminate, and indicating to the Centre whether I would like the sperm/eggs(oocytes)* then stored with the Centre to be -
- (a) transferred to another local licensed centre;
 - (b) exported to an overseas centre; or
 - (c) disposed of or be donated in accordance with my instructions set out in para. 5 above.

In the event that I withdraw from or terminate the Programme without giving any indication as aforesaid, the Centre will dispose of or donate the stored sperm/eggs(oocytes)* in accordance with my instructions as set out in para. 5 above.

8. I understand that I am required to immediately inform the Centre of any change of my address and/or contact details.
9. I fully understand and accept that -
- (a) my stored sperm/eggs(oocytes)* may not produce any successful pregnancy;
 - (b) the procedures of freezing, thawing and storage of my sperm/eggs(oocytes)* may be associated with a higher incidence of carrying abnormal children as compared with a pregnancy without such procedures. There may also be an increase in preterm deliveries in pregnancies and that any child conceived or born following in vitro fertilization using such sperm/eggs(oocytes)* may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary, fertility problems or other reasons compared to a natural or spontaneous pregnancy, as

- reported in some studies;
- (c) the quality of the sperm/eggs(oocytes)* stored depends to a large extent on the quality of the specimen submitted for storage;
 - (d) the quality of the sperm/eggs(oocytes)* may deteriorate following the freezing and thawing procedures and may not be found to be suitable for subsequent use; and
 - (e) the Centre will not be responsible for damage to or deterioration of the sperm/eggs(oocytes)* due to whatever cause which is beyond its control or because of unforeseen circumstances.

10. I acknowledge that the Information Sheet at Appendix XI of the Code of Practice on Reproductive Technology and Embryo Research has been read by me/explained to me*. I fully understand the contents of the Information Sheet and I agree that my personal data and information may be used for the purposes as set out in para. 1 of the Information Sheet.

[] (Please tick if agreed) I also consent to the release of all medical records, including my medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on me from the time when my suitability for RT procedure(s) is being assessed or the provision of any RT service to me (whenever the earlier) until one year after the time when the last RT service is being provided to me or the completion of my RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ Day of _____
(Month) (Year)

Signed _____
(Patient's Signature)

Name _____ Spouse's Name # _____
(in Block Letters) (in Block Letters)

(in Chinese) (in Chinese)

Marriage Certificate No. # _____

Signed _____
(Signature of Attending Doctor)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

Position _____

- * Delete whichever is inapplicable
To be completed if the patient is married.

Consent to Freezing and Storage of Embryos
(for married couples' own use after 5 years of storage
and every 2 years thereafter)

1. We _____ (husband's name)
(Surname, Given Names) (ID No.)
(hereinafter called "the Husband") and _____
(Surname, Given Names) (ID No.)
(wife's name) (hereinafter called "the Wife"), of _____
_____ (address),
DO HEREBY AUTHORISE _____
(name of the licensed centre) (hereinafter called "the Centre") to freeze and store the embryos produced from our gametes, in a manner which accords with the practice and procedure adopted from time to time by the Centre ("the Programme").
2. We acknowledge that the nature, procedures and possible complications of the Programme, together with the relevant information on the decline in pregnancy rates associated with aging of women and use of stored gametes and/or embryos in bringing about human reproduction by artificial means at advanced maternal age, the risks of pregnancy at an advanced maternal age, the impacts of delayed childbearing, the arrangements upon cessation of storage; and also the storage period policy of the Centre* have been clearly explained to us by _____ and we have been given the opportunity to ask any question we wish. We have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the Programme.
3. We consent that our embryos will be stored for a further 2 years and that the storage period will be extended thereafter 2 years at a time only if we have received proper counselling and signed a new consent form by both of us, together with an acknowledgement of the relevant information stated in para. 2 above. We understand that we have to receive proper counselling and sign a new consent form by both of us as arranged by the Centre at least 1 month before the expiry of the current period of storage.
4. We consent that in the absence of attending proper counselling and signing of a new consent form by both of us as stated in para. 3 above, or if we fail to pay the storage fees, or are not contactable by the Centre, the Centre by giving me 3 months' notice in advance, may dispose of or donate our embryos in accordance with our instructions set out in para. 6 of the Consent Form (2)* / para. 5 of the Consent Form (20)* signed by us on _____, which would be superseded by our latest instructions set out in para. 5 below*.
5. We understand that, subject to receipt of proper counselling and signing of a new consent form by both of us as mentioned in para. 4 above, our embryos will be frozen and stored from the date of freezing of the embryos until the time that we indicate to withdraw from or terminate the Programme, or upon expiry of the time limit / maximum storage period set by the Centre*, or upon the death of either of us, or in the event of divorce or legal

separation, or upon one of us becoming incapable of revoking his or her consent, whichever occurs earlier in time, we consent our stored embryos may be disposed of or be donated in accordance with the instruction indicated in the Consent Form (2) */ Consent Form (20)* signed by us on _____, which would be superseded by our latest instructions set out below. (please tick one)* –.

☐ disposed of in accordance with the “Guidelines on disposal of gametes or embryos” (“the Guidelines”) in the Code of Practice published from time to time by the Council on Human Reproductive Technology.

☐ donated anonymously for the treatment of other infertile couples, in which event our embryos would not be used to produce more than a total of 1/2/3* live birth events (failing which the Centre may dispose of the stored embryos in accordance with the Guidelines).

☐ donated for research (failing which the Centre may dispose of the stored embryos in accordance with the Guidelines).

☐ donated for quality control and/or training (failing which the Centre may dispose of the stored embryos in accordance with the Guidelines).

6. We understand that our stored embryos will only be used for reproductive technology procedures when we are the parties to a marriage, except in circumstances specified otherwise by the law or by the Code of Practice on Reproductive Technology and Embryo Research. Furthermore, upon the death of either of us, our stored embryos cannot be used by the surviving spouse to bring about any posthumous child(ren).

7. We understand that we can withdraw from and terminate the Programme at any time by giving a written notice to the Centre stating our intention to withdraw and terminate, and indicating to the Centre whether we would like the embryos then stored with the Centre to be -

- (a) transferred to another local licensed centre;
- (b) exported to an overseas centre; or
- (c) disposed of or be donated in accordance with our instructions set out in para. 5 above.

In the event that we withdraw from or terminate the Programme without giving any indication as aforesaid, the Centre will dispose of or donate the stored embryos in accordance with our instructions as set out in para. 5 above.

8. We understand that we are required to immediately inform the Centre of any change of our address and/or contact details, or our marital relationship.

9. We fully understand and accept that -

- (a) the stored embryos may not produce any successful pregnancy;
- (b) the procedures of freezing, thawing and storage of our embryos may be associated with a higher incidence of carrying abnormal children as compared with a pregnancy without such procedures. There may also be an increase in preterm deliveries in pregnancies and that any child conceived or born following in vitro fertilization using

such embryos may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary, fertility problems or other reasons compared to a natural or spontaneous pregnancy, as reported in some studies;

- (c) the quality of the embryos stored depends to a large extent on their quality prior to freezing;
- (d) the quality of the embryos may deteriorate following the freezing and thawing procedures and may not be found to be suitable for subsequent use; and
- (e) the Centre will not be responsible for damage to or deterioration of the embryos due to whatever cause which is beyond its control or because of unforeseen circumstances.

10. We acknowledge that the Information Sheet at Appendix XI of the Code of Practice on Reproductive Technology and Embryo Research has been read by us/explained to us *. We fully understand the contents of the Information Sheet and we agree that our personal data and information may be used for the purposes as set out in para. 1 of the Information Sheet.

[] (Please tick if agreed) We also consent to the release of all medical records, including our medical history, except those specified separately otherwise, kept by the Centre and its doctor(s) or associated doctor(s) on us from the time when our suitability for RT procedure(s) is being assessed or the provision of any RT service to us (whenever the earlier) until one year after the time when the last RT service is being provided to us or the completion of our RT treatment (whenever the later) to the Council on Human Reproductive Technology for the purpose of inspection and use in the course of discharging its regulatory functions under the Human Reproductive Technology Ordinance (Cap. 561).

Dated the _____ day of _____
(Month) (Year)

Signed _____ Signed _____
(Husband's Signature) (Wife's Signature)

Name _____ Name _____
(in Block Letters) (in Block Letters)

(in Chinese) (in Chinese)

Marriage Certificate No. _____

Signed _____ Signed _____
(Signature of Attending Doctor) (Signature of Witness)

Name _____ Name _____
(in Block Letters) (in Block Letters)

Position _____

* Delete whenever is inapplicable

CONFIDENTIAL

Council on Human Reproductive Technology

DC Form 1

REPRODUCTIVE TECHNOLOGY TREATMENT FORM

(For treatment NOT involving donor gametes/embryos) ^{Note 1}

Quarterly Return: Reporting period –

Month : *Jan – Mar / Apr – Jun / Jul – Sep / Oct – Dec; Year : _____

For Official Use

No.

Form received on

____/____/____
Day Month YearPlease complete the form in block letters

1. Name of centre :
 2. Licence number : 3. Patient's clinic record number ^{Note 2}:

4. Age of wife : 5. Age of husband :

6. Infertility Diagnosis (please tick the appropriate option(s)) :

☐ Male ☐ Tubal ☐ Endometriosis ☐ Immunologic
☐ Tubo-peritoneal ☐ Ovulatory ☐ Unexplained
☐ Others (please specify) :

7. Details of treatment carried out for the patient in this reporting period

		1	2	3	4
(i)	Treatment cycle (i.e. 1 st /2 nd /3 rd cycle for this couple)				
(ii)	Date of Treatment	 Day Month	 Day Month	 Day Month	 Day Month
(iii)	Procedure involved (please tick in the appropriate box)				
	Gamete transfer/embryo replacement				
	Elective cryopreservation of all embryos ^{Note 3}				
	Cycle abandonment ^{Note 3}				
(iv)	Ovarian stimulation	Yes ___ No ___	Yes ___ No ___	Yes ___ No ___	Yes ___ No ___
(v)	Embryos developed (please insert number into the box)				
	Number of embryos developed in this cycle				
	Number developed from fresh eggs				
	Number developed from frozen eggs				
(vi)	Type of treatment (please tick in the appropriate box)				
	IVF				
	ICSI with IVF				
	ICSI with MIFT				
	ICSI with PROST				
	Frozen-thawed ET				
	Surrogacy ^{Note 4}				
	Other micromanipulation(please specify)				
	Others (please specify)				
(vii)	Embryos transferred (please insert number)				
	Number of embryos transferred				
	Number developed from fresh embryos				
	Number developed from frozen/thawed embryos				
(viii)	Egg transferred (please insert number into the box)				
	Number of eggs (oocytes) transferred				
	Number of fresh eggs(oocytes) transferred				
	Number of frozen eggs (oocytes) transferred				

		1	2	3	4
(ix)	Number of embryos discarded in this cycle				
(x)	Excess embryos after replacement (please insert number into the box)				
	Number stored for treatment of patient				
	Number donated for treatment of others				
	Number donated for research ^{Note 5}				
	Number donated for quality control/ training				
(xi)	Outcome of treatment (please tick in the appropriate box)				
	No pregnancy				
	Ongoing pregnancy				
	Miscarriage				
	Ectopic pregnancy				
	Heterotopic pregnancy ^{Note 6}				
	Pregnancy terminated				
	Hydatidiform mole				
	Lost to follow up				
(xii)	Number of embryos/fetuses involved in the pregnancy				
(xiii)	Embryonic/fetal reduction				
	Embryonic/fetal reduction carried out	Yes ___ No ___	Yes ___ No ___	Yes ___ No ___	Yes ___ No ___
	Number of embryos/fetuses reduced				

* Please delete whichever is inapplicable.

- Notes :**
- (1) Please complete 1 form for each couple reporting their RT treatments received in a quarter, and submit the form to HRT Council within 1 month after the quarter. Please also complete DC Form 4 within 12 months after treatment to report on details concerning outcome of pregnancy.
 - (2) "Patient's clinic record number" should be a record number used by the centre for identification of the patient. Same patient who has undergone several treatment cycles at a centre should have the same record number.
 - (3) Please do not make any entries under Items (vii), (viii), (x), (xi), (xii) and (xiii) of Part 7 if either "Elective cryopreservation of all embryos" or "Cycle abandonment" is selected and entered under Item 7(iii).
 - (4) For surrogacy cases, please refer to para. 12.10 of the Code of Practice on Reproductive Technology and Embryo Research and report the case with detailed information including detailed justifications to the HRT Council within 3 months after the treatment.
 - (5) When stored embryos are used or stored for research, please report the usage in AS Form 8 and return to the HRT Council as required.
 - (6) Heterotopic pregnancy refers to simultaneous existence of intrauterine and ectopic pregnancy. For such a case, please only tick against "heterotopic pregnancy" and need not tick against "ectopic pregnancy".

CONFIDENTIAL**DC Form 2**

REPRODUCTIVE TECHNOLOGY TREATMENT FORM
(For RT treatment involving donor gametes/embryos
[other than donor insemination]) ^{Note 1}

For Official Use
 No.
 Form received on
 ___ / ___ / ___
 Day Month Year

Please complete the form in block letters

1. Name of centre :	
2. Licence number :	3. Patient's clinic record number ^{Note 2} :
4. Approval number for the use of donor gametes/embryos:	
5. Name of centre where treatment started, if different:	
6. FULL NAME of patient : (Surname first)	
7. Date of birth : Day Month Year	8. *HKID Card / Passport / Other Entry Permit Number ^{Note 3} :
9. FULL NAME of husband : (Surname first)	
10. Date of birth : Day Month Year	11. *HKID Card / Passport / Other Entry Permit Number ^{Note 3} :
12. Infertility Diagnosis (please tick the appropriate option(s)) : ☐ Male ☐ Tubal ☐ Endometriosis ☐ Immunologic ☐ Tubo-peritoneal ☐ Ovulatory ☐ Unexplained ☐ Others (please specify):	
13. Does the treatment involve donated sperm : YES ☐ NO ☐ donor's clinic record no.:	
14. Does the treatment involve donated eggs : YES ☐ NO ☐ donor's clinic record no.:	
15. Does the treatment involve donated embryos : YES ☐ NO ☐ donor's clinic record no.:	
16. Donor(s) centre licence number(s) (if gamete/embryo is obtained from another licensed centre) : sperm donor egg donor embryo donor	
17. The donation is *anonymous/designated. (If the donation is designated, please refer to para. 14.9 of the Code of Practice on Reproductive Technology and Embryo Research and report the case with detailed information including detailed justifications to the HRT Council within 3 months after the treatment.)	
Treatment cycle : (e.g. 1 st /2 nd /3 rd cycle for this couple)	
18. Type of treatment :	IVF ☐ ICSI with IVF ☐ ICSI with MIFT ☐ ICSI with PROST ☐ Other Micromanipulation (please specify) Frozen-thawed ET ☐ Others (please specify)
19. Ovarian stimulation :	Yes ☐ No ☐
20. Number of embryos developed in this cycle :	Developed from: Fresh eggs (oocytes) Frozen eggs (oocytes)

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21. Date of *gamete transfer/embryo replacement or *elective cryopreservation of all embryos ^{Note 4} or *Date when cycle was abandoned ^{Note 4} :	 Day Month Year	
22. Embryos transferred :	Number of embryos transferred : Developed from : Fresh embryos Frozen/thawed embryos	
23. Number of eggs (oocytes) transferred :	 Fresh eggs (oocytes) Frozen eggs (oocytes)	
24. Number of embryos discarded in this cycle		
25. Excess embryos after replacement:	Number stored for treatment of patient Number donated for treatment of others Number donated for research ^{Note 5} Number donated for quality control/training	
26. Outcome of treatment :	No pregnancy ☐ Miscarriage ☐ Ectopic pregnancy ☐ Heterotopic pregnancy ^{Note 6} ☐ Pregnancy terminated ☐ Ongoing pregnancy ☐ Hydatidiform mole ☐ Lost to follow up ☐	
27. No. of embryos/fetuses involved in the pregnancy:		
28. Embryonic/fetal reduction	Embryonic/fetal reduction carried out: Yes ☐ No ☐ No. of embryos/fetuses reduced:	

* Please delete whichever is inapplicable.

Notes : (1) Please complete 1 form for each couple for each treatment cycle and submit the form to HRT Council within 3 months after the treatment. Please also complete DC Form 4 within 12 months after treatment to report on details concerning outcome of pregnancy.

- (2) "Patient's clinic record number" should be a record number used by the centre for identification of the patient. Same patient who has undergone several treatment cycles at a centre should have the same record number.
- (3) Please fill in the HKID Card number of patient/husband, or Passport / Other Entry Permit number for non-HKID Card holder. "Other Entry Permit" refers to official document which the patient/husband is holding in entering Hong Kong.
- (4) Please do not make any entries under Items 22, 23, 25, 26, 27 and 28 if either "Date of elective cryopreservation of all embryos" or "Date when cycle was abandoned" is selected and entered under Item 21.
- (5) When stored embryos are used or stored for research, please report the usage in AS Form 8 and return to the HRT Council as required.
- (6) Heterotopic pregnancy refers to simultaneous existence of intrauterine and ectopic pregnancy. For such a case, please only tick against "heterotopic pregnancy" and need not tick against "ectopic pregnancy".

DONOR INSEMINATION TREATMENT FORM ^{Note 1}

For Official Use No. Form received on ____ / ____ / ____ Day Month Year
--

Please complete the form in block letters

1. Name of centre :

2. Licence number : 3. Patient's clinic record number ^{Note 2}:

4. Approval number for the use of donor gametes:

5. Name of centre where treatment started, if different:

6. FULL NAME of patient :
(Surname first)7. Date of birth : 8. *HKID Card / Passport / Other Entry Permit Number ^{Note 3}:
Day Month Year9. FULL NAME of husband :
(Surname first)10. Date of birth : 11. *HKID Card / Passport / Other Entry Permit Number ^{Note 3}:
Day Month Year

12. Reasons for treatment :	Obstructive azoospermia	YES	☐	NO	☐
	Nonobstructive azoospermia	YES	☐	NO	☐
	Severe deficits in semen quality in couples who do not wish to undergo intracytoplasmic sperm injection	YES	☐	NO	☐
	Genetic	YES	☐	NO	☐
	Infectious disease in the male partner (such as HIV)	YES	☐	NO	☐
	Severe rhesus isoimmunisation	YES	☐	NO	☐
	Others (please specify)				

13. Donor's clinic record number :

14. Donor centre licence number if different from item 2 above :

15. The donation is *anonymous/designated. (If the donation is designated, please refer to para. 14.9 of the Code of Practice on Reproductive Technology and Embryo Research and report the case with detailed information including detailed justifications to the HRT Council within 3 months after the treatment.)

Treatment cycle : (e.g. 1st/2nd/3rd cycle for this couple)16. Dates of insemination (if more than 1 insemination per treatment cycle, give all dates) :
Day Month Year
.....
.....
.....

17. Ovarian stimulation :	Yes ☐	No ☐
18. Outcome of treatment :	No pregnancy ☐ Ectopic pregnancy ☐ Pregnancy terminated ☐ Hydatidiform mole ☐	Miscarriage ☐ Heterotopic pregnancy ^{Note 4} ☐ Ongoing pregnancy ☐ Lost to follow up ☐
19. No. of embryos/fetuses involved in the pregnancy :		
20. Embryonic/fetal reduction :	Embryonic/fetal reduction carried out: Yes ☐ No ☐ No. of embryos/fetuses reduced:	

* Please delete whichever is inapplicable.

- Notes :
- (1) Please complete 1 form for each couple for each treatment cycle and submit the form to HRT Council within 3 months after the treatment. Please also complete DC Form 4 within 12 months after treatment to report on details concerning outcome of pregnancy.
 - (2) “Patient’s clinic record number” should be a record number used by the centre for identification of the patient. Same patient who has undergone several treatment cycles at a centre should have the same record number.
 - (3) Please fill in the HKID Card number of patient/husband, or Passport / Other Entry Permit number for non-HKID Card holder. “Other Entry Permit” refers to official document which the patient/husband is holding in entering Hong Kong.
 - (4) Heterotopic pregnancy refers to simultaneous existence of intrauterine and ectopic pregnancy. For such a case, please only tick against “heterotopic pregnancy” and need not tick against “ectopic pregnancy”.

PREGNANCY OUTCOME FORM ^{Note 1}

For Official Use
No.
Form received on
____/____/____
Day Month Year

Please complete the form in block letters

1. Name of centre :
2. Licence number : 3. Patient's clinic record number ^{Note 2}:
4. Approval number for the use of donor gametes/embryos (if applicable):
5. Date of *gamete transfer / embryo replacement / insemination resulting in pregnancy:
Day Month Year

6. Pregnancy outcome :	Fetal heart / Pregnancy sac 1	Fetal heart / Pregnancy sac 2	Fetal heart / Pregnancy sac 3	Fetal heart / Pregnancy sac 4	Fetal heart / Pregnancy sac 5
miscarriage	☐	☐	☐	☐	☐
ectopic pregnancy	☐	☐	☐	☐	☐
pregnancy terminated	☐	☐	☐	☐	☐
reason for termination					
hydatidiform mole	☐	☐	☐	☐	☐
embryo reduction	☐	☐	☐	☐	☐
still birth	☐	☐	☐	☐	☐
live birth	☐	☐	☐	☐	☐
neonatal death	☐	☐	☐	☐	☐
lost to follow up	☐	☐	☐	☐	☐
others (describe)					
(Please complete item 7 if outcome is live birth)					

7. Baby born :	Baby 1	Baby 2	Baby 3	Baby 4	Baby 5
gestation (weeks)					
weight (grammes)					
sex	M ☐ F ☐	M ☐ F ☐	M ☐ F ☐	M ☐ F ☐	M ☐ F ☐
date of delivery	 Day Month Year	 Day Month Year	 Day Month Year	 Day Month Year	 Day Month Year
method of delivery					

8. Congenital abnormalities if present please describe :					
					

* Please delete whichever is inapplicable.

Notes : (1) This form should be returned to the HRT Council within 12 months after the treatment.

(2) "Patient's clinic record number" should be a record number used by the centre for identification of the patient. Same patient who has undergone several treatment cycles at a centre should have the same record number.

DONOR INFORMATION FORM (For Gamete Donors)

For Official Use No. Form received on ____ / ____ / ____ Day Month Year

Please complete the form in block letters

The form should be returned to the Council within 1 week of the date when a donor's gametes are used by a licensed centre. Treatment form (i.e. DC Form 2 or 3) should be returned to the Council within 3 months after treatment to report treatment outcome.

A new DC Form 5 should be completed and returned to the Council each time when a donor's gametes are used.

1. Name of centre :

2. Licence number : 3. Donor's clinic record number :

4. Approval number for the use of donor gametes:

5. FULL NAME of donor :
(Surname first)

6. Sex : Male ☐ Female ☐

7. Date of Birth :
Day Month Year

8. *HKID Card / Passport / Other Entry Permit Number ^{Note 1} :

9. Full Correspondence Address and Contact Telephone Number:

Room/Flat: Floor: Block:

Name of Building:

No. & Name of Street:

District: ☐ HK ☐ KLN ☐ NT

Country (if outside Hong Kong):

Tel. Number (Home): Tel. Number (Mobile):

(Please leave this item blank if the donor does not want to be contacted after donation.)

10. Date of *gamete transfer/ embryo replacement/ insemination:
Day Month Year

Date of donation:
Day Month Year

Patient's clinic record number:

This is the(e.g. 1st/2nd/3rd/...) time of use in this centre.

No. of live birth events produced in the previous use in this centre:

11. If this is for designated recipients ^{Note 2}, give names of the couple and their HKID Card / Passport / Other Entry Permit Numbers :

FULL NAME of wife :

*HKID Card / Passport / Other Entry Permit Number ^{Note 1}:

Relationship with donor:

FULL NAME of husband :

*HKID Card / Passport / Other Entry Permit Number ^{Note 1}:

Relationship with donor:

Particulars of donor:

12. Height (cm) : 13. Weight (kgs) : 14. Ethnic group : Chinese ☐

Other, describe

15. Eye Colour : Brown ☐

Other, describe

16. Hair Colour : Black ☐

Other, describe

17. Occupation :

18. The maximum no. of live birth events the donor has consented to using his/her gamete to produce as indicated in the consent form signed :

* Please delete whichever is inapplicable.

Notes : (1) Please fill in the HKID Card number of donor/recipients, or Passport / Other Entry Permit number for non-HKID Card holder. "Other Entry Permit" refers to official document which the donor/recipient is holding in entering Hong Kong.

(2) For designated donation, please submit a report providing detail justifications as to why donation has to be designated (paragraph 14.9 of the Code of Practice on Reproductive Technology & Embryo Research).

CONFIDENTIAL**DC Form 6**

DONOR INFORMATION FORM
(For Embryo Donors)

For Official Use No. Form received on ____ / ____ / ____ Day Month Year
--

Please complete the form in block letters

The form should be returned to the Council within 1 week of the date when donors' embryos are used by a licensed centre. Treatment form (i.e. DC Form 2) should be returned to the Council within 3 months after treatment to report treatment outcome.

A new DC Form 6 should be completed and returned to the Council each time when donors' embryos are used.

1. Name of centre :
2. Licence number : 3. Donor's clinic record number :
4. Approval number for the use of donor embryos:

5. FULL NAME of female donor :
(Surname first)
6. Date of birth : 7. *HKID Card / Passport / Other Entry Permit Number ^{Note 1}:
Day Month Year

8. FULL NAME of male donor :
(Surname first)
9. Date of birth : 10. *HKID Card / Passport / Other Entry Permit Number ^{Note 1}:
Day Month Year

11. Full Correspondence Address and Contact Telephone Number:

Room/Flat: Floor: Block:

Name of Building:

No. & Name of Street:

District: ☐ HK ☐ KLN ☐ NT

Country (if outside Hong Kong):

Tel. Number (Home): Tel. Number (Mobile):

(Please leave this item blank if the donor does not want to be contacted after donation.)

12. Date when embryos of the donors were used :
Day Month Year

Date of donation:
Day Month Year

Patient's clinic record number:

This is the(e.g. 1st/2nd/3rd/...) time of use in this centre.

No. of live birth events produced in the previous use in this centre:

13. If this is for designated recipients ^{Note2}, give names of the couple and their HKID Card / Passport / Other Entry Permit Numbers:

FULL NAME of wife :

*HKID Card / Passport / Other Entry Permit Number ^{Note 1}:

Relationship with donor:

FULL NAME of husband :

*HKID Card / Passport / Other Entry Permit Number ^{Note 1}:

Relationship with donor:

CONFIDENTIAL**DC Form 6(2)****Particulars of female donor :**

14. Height (cm) :	15. Weight (kgs) :
16. Ethnic group : Chinese ☐	Other, describe
17. Eye Colour : Brown ☐	Other, describe
18. Hair Colour : Black ☐	Other, describe
19. Occupation :	
20. The maximum no. of live birth events the donor has consented to using her gametes/embryos to produce as indicated in the consent form signed :	

Particulars of male donor :

21. Height (cm) :	22. Weight (kgs) :
23. Ethnic group : Chinese ☐	Other, describe
24. Eye Colour : Brown	Other, describe
25. Hair Colour : Black ☐	Other, describe
26. Occupation :	
27. The maximum no. of live birth events the donor has consented to using his gametes/embryos to produce as indicated in the consent form signed :	

* Please delete whichever is inapplicable.

Notes : (1) Please fill in the HKID Card number of donors/recipients, or Passport / Other Entry Permit number for non-HKID Card holder. "Other Entry Permit" refers to official document which the donor/recipient is holding in entering Hong Kong.

(2) For designated donation, please submit a report providing detail justifications as to why donation has to be designated (paragraph 14.9 of the Code of Practice on Reproductive Technology & Embryo Research).

ARTIFICIAL INSEMINATION BY HUSBAND (AIH) TREATMENT FORM ^{Note 1}

Quarterly Return: Reporting period –

Month : *Jan – Mar / Apr – Jun / Jul – Sep / Oct – Dec; Year : _____

For Official Use
No.
Form received on
____/____/____
Day Month Year

Please complete the form in block letters

1. Name of centre :
2. Licence number : 3. Patient's clinic record number ^{Note 2}:
4. Age of wife : 5. Age of husband :
6. Infertility Diagnosis (please tick the appropriate option(s)) :
☐ Male ☐ Endometriosis ☐ Ovulatory ☐ Unexplained
☐ Others (please specify) :
7. Details of treatment carried out for the patient in this reporting period

		1	2	3	4
(i)	Date of insemination/cycle abandonment (if more than 1 insemination per treatment cycle, give all dates)	*Insemination / *cycle abandoned on Day Month 	*Insemination / *cycle abandoned on Day Month 	*Insemination / *cycle abandoned on Day Month 	*Insemination / *cycle abandoned on Day Month
(ii)	Type of AIH ^{Note 3} (please tick in the appropriate box)				
	Intravaginal (IVI)				
	Intracervical (ICI)				
	Intrauterine (IUI)				
(iii)	Treatment cycle (i.e. 1 st /2 nd /3 rd cycle for this couple)				
(iv)	Ovarian stimulation	Yes ___ No ___	Yes ___ No ___	Yes ___ No ___	Yes ___ No ___
(v)	Sperm washing	Yes ___ No ___	Yes ___ No ___	Yes ___ No ___	Yes ___ No ___
(vi)	Outcome of treatment (please tick in the appropriate box)				
	No pregnancy				
	Ongoing pregnancy				
	Miscarriage				
	Ectopic pregnancy				
	Heterotopic pregnancy ^{Note 4}				
	Pregnancy terminated				
	Hydatidiform mole				
	Lost to follow up				
(vii)	Number of embryos/fetuses involved in the pregnancy				
(viii)	Embryonic/fetal reduction				
	Embryonic/fetal reduction carried out	Yes ___ No ___	Yes ___ No ___	Yes ___ No ___	Yes ___ No ___
	Number of embryos/ fetuses reduced				

* Please delete whichever is inapplicable.

- Notes :
- (1) Please complete 1 form for each couple for a quarter and submit the form to HRT Council within 1 month after the quarter. Please also complete DC Form 4 within 12 months after treatment to report on details concerning outcome of pregnancy.
 - (2) "Patient's clinic record number" should be a record number used by the centre for identification of the patient. Same patient who has undergone several treatment cycles at a centre should have the same record number.
 - (3) Intravaginal insemination refers to the placement of sperm into the vagina. Intracervical insemination refers to the placement of sperm at the cervical os. Intrauterine insemination refers to the placement of sperm (usually after processing) into the uterine cavity.
 - (4) Heterotopic pregnancy refers to simultaneous existence of intrauterine and ectopic pregnancy. For such a case, please only tick against "heterotopic pregnancy" and need not tick against "ectopic pregnancy".

CONFIDENTIAL

**REPORTING FORM ON THE
DISPOSAL OF EXCESS EMBRYOS AFTER
END OF REPRODUCTIVE TECHNOLOGY TREATMENT**

For Official Use
No.
Form received on
____/____/____
Day Month Year

Please complete the form in block letters

This form is to report, upon cessation of treatment in relation to a particular patient (i.e., when all treatment cycles have been completed/aborted and it is anticipated that no further treatment will be provided to the patient concerned), the manner in which embryos stored for the patient since the last treatment cycle reported in DC Form 1 or 2 have been disposed of. Licensed centre should return this form to the Council within 3 months after completion of all treatment cycles.

1. Name of centre :

2. Licence number : 3. Patient's clinic record number ^{Note} :

4. Approval number for the use of donor gametes/embryos (if applicable):

5. Age of wife : 6. Age of husband :

7. Last reported DC Form 1 or 2:	Date of *embryo replacement or *elective cryopreservation of all embryos or *Date when cycle was abandoned Day Month Year
----------------------------------	--

8. Disposal of excess cryoperserved embryos after end of RT treatment:	Total number of excess embryos stored at the end of RT treatment: - <u>Manner of disposal of excess embryos</u> Number donated for treatment of others : Number donated for research : Number donated for quality control or training: Number discarded :
--	---

* Please delete whichever is inapplicable.

Note : "Patient's clinic record number" should be a record number used by the centre for identification of the patient. This record number should refer to the one reported in the previous DC Form 1 or 2 for the same patient.

RESTRICTED

DC Form 9

REPORT FORM ON PRE-IMPLANTATION GENETIC TESTING¹

For official use

Date of receipt:

Report ref no.:

Part II (please update items F to G within one month after the quarter of the embryo transfer³)

Serial no:	S/N (Ref. No. PGT/ /)				
	PGT Report	Subsequent Updates			
Report Submission Date ^{2, 3}	dd/mm/yyyy	dd/mm/yyyy	dd/mm/yyyy	dd/mm/yyyy	dd/mm/yyyy

A. Information about the RT centre

	Treatment Licence	PGT Licence
License number ⁷		

B. Information about the patient

Clinical record number ⁷	
-------------------------------------	--

F. Post-PGT Procedures and Outcome

	1 st	2 nd	3 rd	4 th
Date of transfer / disposal of biopsied embryo(s) ⁸	dd/mm/yyyy	dd/mm/yyyy	dd/mm/yyyy	dd/mm/yyyy
Number of biopsied embryo(s) transferred	[pls. select]	[pls. select]	[pls. select]	[pls. select]
PGT results per biopsied embryo transferred	1 [pls. select]	[pls. select]	[pls. select]	[pls. select]
	2 [pls. select]	[pls. select]	[pls. select]	[pls. select]
	3 [pls. select]	[pls. select]	[pls. select]	[pls. select]
Number of biopsied embryo(s) stored ⁹				
Number of biopsied embryo(s) disposed of ¹⁰				
- Discarded				
- Donated for treatment of others/ research/quality control or training				
G. Outcome of embryo transfer	[pls. select]	[pls. select]	[pls. select]	[pls. select]

Remarks: ☒ Please check the appropriate box(es).

Notes to the Pre-implantation Genetic Testing (PGT) Report Form

1. Please refer to the International Glossary on Infertility and Fertility Care 2017, published in September 2017 by the International Committee for Monitoring Assisted Reproductive Technologies (ICMART), for the definitions on Preimplantation Genetic Testing for Monogenic/Single Gene Defects/Chromosomal Structural Rearrangements (PGT-M/SR) and Preimplantation Genetic Testing for Aneuploidies (PGT-A). The tests were previously known as Pre-implantation Genetic Diagnosis (PGD) and Pre-implantation Genetic Screening (PGS) respectively.
2. According to **para. 6 of Appendix III** in the Code of Practice on Reproductive Technology and Embryo Research (the Code), the clinical team, having discussed with the persons seeking PGT and determined the condition to be sufficiently serious to warrant PGT, need to provide the Council on Human Reproductive Technology (the Council) with a report **within 3 months** after completion of the procedure, i.e. biopsy date, test date or laboratory report date, in item D of this report form. This date should not be later than the date when the report was issued by the genetic diagnostic laboratory.
3. To facilitate the Council to have a full picture on the processing position of the PGT performed embryos, the licensed treatment centre(s) should submit the relevant report with updated information for items F to G to the Council **within one month after the quarter** of the embryo transfer, and indicate the use of PGT biopsied embryos in the corresponding DC forms.
4. The age of the patient should be counted as at the date of PGT or the start of the treatment cycle.
5. According to **para. 4 of Appendix III** in the Code, the use of PGT should be a matter of discussion between those seeking PGT (i.e. the patients) and the clinical team on the seriousness of the genetic condition or abnormality and their experience and perception of abnormality. *The clinical team for PGT-M/SR should consist of two doctors, one of whom should have proper training in clinical genetics and/or genetic counselling. The team, having discussed with the patients seeking PGT, would determine the condition to be sufficiently serious to warrant PGT.*
6. If it is impracticable to ascertain the actual date of test(s) performed, a date of a related procedure, such as date of embryo biopsy or date when the analysis report of embryos was issued by the genetic diagnostic laboratory could be provided. This date should not be later than the date when the report was issued by the genetic diagnostic laboratory.
7. Please copy the relevant information from Parts A & B of Page 1.
8. Please report the date and the number of the biopsied embryo(s) disposed of if **none** of the embryos were genetically suitable for transfer.
9. Biopsied embryos stored should include those awaiting for transfer and awaiting to be disposed of for various reasons, such as QC failure or amplification failure etc.
10. Please report the number of embryos disposed of after each cycle so that the Secretariat can have the latest positions of all biopsied embryo(s).
11. NA = Not available

**Explanatory Notes for Completing
Annual Statistics Forms on Reproductive Technology Treatments
for submission to the Council on Human Reproductive Technology**

- All cases whose monitoring or ovarian stimulation started some time in the year (i.e. from January 1 to December 31 of the year) should be included.
- There are 9 individual forms numbered as follows -
 1. IVF-ET
 2. Frozen-thawed ET
 3. ICSI
 4. Use of Reproductive Technology for Surrogacy Arrangement
 5. Use of Reproductive Technology for Gender Selection to Avoid Sex-linked Diseases
 6. Others
[for any other programmes outside those numbered from 1 to 5. Please give the name of the programme in the bracket.]
 7. Artificial Insemination by Husband (AIH)
 8. Storage of Gametes/Embryos
 9. Number of patients who stored gametes / embryos for own use
- For the brackets or spaces with ‘±’ sign on each form, please provide mean ‘±’ SD (standard deviation) value.
- For “Infertility duration”, if a patient has undergone more than 1 treatment cycle in the year, the infertility duration should be counted up to the initiation of the first treatment cycle within the reporting year.
- In the cases where diagnosis(es) is (are) not mentioned under the block-heading of “Infertility Diagnosis” in the forms, tick the “Others” box and state the diagnosis in the space provided.
- The following terminologies used in annual statistics forms (AS Form 1-9) should be observed and followed –

Clinical pregnancy

A pregnancy documented by 1 or more gestational sacs on ultrasound or the histological confirmation of gestational products in miscarriages or ectopic pregnancies.

Clinical Pregnancy rate

The percentage of treatment cycles that result in a clinical pregnancy, including ectopic pregnancies, spontaneous and induced abortions, and viable pregnancies of at least 20 weeks' gestation but excluding biochemical pregnancies. Pregnancy rates should be expressed per 100 treatment cycles started/commenced or per 100 cycles reaching the stage of attempted oocyte recovery/retrieval or embryo transfer.

Ectopic pregnancy

A pregnancy in which implantation has taken place outside the uterine cavity.

Heterotopic pregnancy

Heterotopic pregnancy refers to simultaneous existence of intrauterine and ectopic pregnancy.

Neonatal death

A death of a liveborn infant within 28 days of birth.

Oocyte recovery (retrieval)

Procedure undertaken in an attempt to collect oocyte(s) from a woman.

Ongoing pregnancy

Ongoing pregnancy with fetal cardiac activity during the period of the year being reported on.

Ongoing pregnancy rate

Ongoing pregnancy rates expressed per 100 treatment cycles started/commenced or per 100 cycles reaching the stage of attempted oocyte retrieval or embryo transfer.

Miscarriage

Loss of embryos or foetuses detected clinically or by ultrasound, before 24 weeks' gestation (as estimated with reference to the day of embryo transfer or day of ovulation).

Stillbirth

In-utero death at or after 24 weeks' gestation (as estimated with reference to the day of embryo transfer or day of ovulation).

Treatment cycle

The process in which a reproductive technology (RT) procedure is carried out, where a woman has undergone ovarian stimulation or monitoring with the intent of having RT procedure, or frozen embryos have been thawed with the intent of transferring them to a woman. A treatment cycle starts (a) on the day when superovulatory drugs were commenced or (b) from the date of the last menstrual period.

Number of cycles started (for AS Form 7)

Total number of treatment cycles started during the reporting period, including cycles which finally lead to insemination treatment and the canceled cycles (which do not lead to insemination treatment).

Number of cycles proceeded to IUI (for AS Form 7)

Number of treatment cycles started which finally lead to the intrauterine insemination.

AS Form 1

For Official Use
No. _____
Form received on _____
_____/_____/_____
Day Month Year

		Day	Month	Year			to	Day	Month	Year
Period covered	:	1	1					3	1	2

1. IVF-ET (In-Vitro Fertilization & Embryo Transfer)

Patients' Characteristics

No. of patients	[	]	Age, women	[	±	]	
Infertility duration (yr)	[	±	]	Age, men	[	±	]

Infertility Diagnosis		Stimulation Protocol	
Male	[cycles]	Natural	[cycles]
Male plus tubal	[cycles]	Stimulated	[cycles]
Endometriosis	[cycles]	Cycles ending up with ovarian hyperstimulation	[cycles]
Male plus endometriosis	[cycles]		
Immunologic	[cycles]		
Tubo-peritoneal	[cycles]		
Ovulatory	[cycles]		
Male plus ovulatory	[cycles]		
Tubal plus ovulatory	[cycles]		
Unexplained	[cycles]		
Others (please specify):	[cycles]	Donor semen	[patients]
()		Donor oocyte	[patients]

Clinical Results

	Natural cycle	Stimulated cycle
No. of cycles		
No. of oocyte recoveries (/cycle)	(%)	(%)
No. of Embryo Transfers (ET)		
No. of oocytes (/recovery)	±	±
No. of transferred embryos (/ET)	±	±
Fertilization rate	%	%
No. of clinical pregnancies	cases	cases
Clinical preg. rate (/cycle started)	%	%
Clinical preg. rate (/recovery)	%	%
Clinical preg. rate (/ET)	%	%
No. of ongoing pregnancies	cases	cases
Ongoing preg. rate (/cycle started)	%	%
Ongoing preg. rate (/recovery)	%	%
Ongoing preg. rate (/ET)	%	%
Spont. Abortion (/clinical preg.)	cases (%)	cases (%)
Ectopic preg. (/clinical preg.)	cases (%)	cases (%)
Heterotopic preg. (/clinical preg.)	cases (%)	cases (%)
Termination (/clinical preg.)	cases (%)	cases (%)
Still birth (/clinical preg.)	cases (%)	cases (%)
Neonatal death (/clinical preg.)	cases (%)	cases (%)
Lost to follow up (/clinical preg.)	cases (%)	cases (%)

AS Form 1(2)

Multiple preg. (/clinical preg.)	(cases %)	(cases %)
Embryo reduction (/clinical preg.)	(cases %)	(cases %)
Malformation (/newborn)	(cases %)	(cases %)
No. of delivered or ongoing preg. (/clinical preg.)	(cases %)	(cases %)
Delivery plus ongoing pregnancy rate (/cycle started)	(/cycle)	(/cycle)

**Annual Statistics on Reproductive Technology Treatment
for Submission to the Council on Human Reproductive Technology**

Please complete the form in block letter

Name of centre :

Licence no. :

For Official Use
No.
Form received on
____/____/____
Day Month Year

Period covered : Day Month Year [1] [1] [] [] [] to Day Month Year [3] [1] [1] [2] [] [] [] [] []

2. Frozen-thawed ET (Embryo Transfer)

Patients' Characteristics			
No. of patients	[]	Age, women	[±]
Infertility duration (yr)	[±]	Age, men	[±]
Endometrial Preparation Protocol			
Natural	[]	cycles]	
Artificial	[]	cycles]	
Clinical Results			
	Natural cycle	Artificial cycle	
No. of cycles			
No. of Embryo Transfers (ET)			
Survival rate of frozen-thawed embryos	(/ %)	(/ %)	
Duration of storage (month)	±	±	
No. of transferred embryos (/ET)	±	±	
No. of clinical pregnancies	cases	cases	
Clinical preg. rate (/ET)	%	%	
No. of ongoing pregnancies	cases	cases	
Ongoing preg. rate (/ET)	%	%	
Spont. abortion (/clinical preg.)	(cases %)	(cases %)	
Ectopic preg. (/clinical preg.)	(cases %)	(cases %)	
Heterotopic preg. (/clinical preg.)	(cases %)	(cases %)	
Termination (/clinical preg.)	(cases %)	(cases %)	
Still birth (/clinical preg.)	(cases %)	(cases %)	
Neonatal death (/clinical preg.)	(cases %)	(cases %)	
Lost to follow up (/clinical preg.)	(cases %)	(cases %)	
Multiple preg. (/clinical preg.)	(cases %)	(cases %)	
Embryo reduction (/clinical preg.)	(cases %)	(cases %)	
Malformation (/newborn)	(cases %)	(cases %)	
No. of delivered or ongoing preg. (/clinical preg.)	(cases %)	(cases %)	
Delivery plus ongoing pregnancy rate (/FET cycle)	(/cycle)	(/cycle)	

AS Form 3

**Annual Statistics on Reproductive Technology Treatment
for Submission to the Council on Human Reproductive Technology**

Please complete the form in block letter

For Official Use
No.
Form received on
____/____/____
Day Month Year

Name of centre : _____
Licence no. : _____
Period covered : Day Month Year to Day Month Year
 1 1 to 3 1 1 2

3. ICSI (Intra-Cytoplasmic Sperm Injection)

Patients' Characteristics			
No. of patients	[]	Age, women	[±]
Infertility duration (yr)	[±]	Age, men	[±]
Treatment Method			
ICSI with IVF	cycles	ICSI with PROST	cycles
ICSI with MIFT	cycles		
Clinical Results			
	ICSI with IVF	ICSI with PROST	ICSI with MIFT
No. of cycles			
No. of oocyte recoveries (/cycle)	(%)	(%)	(%)
No. of embryo transfer			
No. of oocytes (/recovery)	±	±	±
No. of transferred embryos (/transfer)	±	±	±
Fertilization rate	%	%	%
No. of clinical pregnancies	cases	cases	cases
Clinical preg. rate (/cycle started)	%	%	%
Clinical preg. rate (/recovery)	%	%	%
Clinical preg. rate (/transfer)	%	%	%
No. of ongoing pregnancies	cases	cases	cases
Ongoing preg. rate (/cycle started)	%	%	%
Ongoing preg. rate (/recovery)	%	%	%
Ongoing preg. rate (/transfer)	%	%	%
Spont. abortion	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Ectopic preg.	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Heterotopic preg.	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Termination	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Still birth	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Neonatal death	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Lost to follow up	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Multiple preg.	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Embryo reduction	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Malformation	cases	cases	cases
(/newborn)	(%)	(%)	(%)
No. of delivered or ongoing preg.	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Delivery plus ongoing pregnancy rate			
(/cycle started)	(/cycle)	(/cycle)	(/cycle)

Annual Statistics on Reproductive Technology Treatment for Submission to the Council on Human Reproductive Technology

Please complete the form in block letter

Name of centre :

Licence no. :

For Official Use No. Form received on ____/____/____ Day Month Year
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Period covered : Day Month Year to Day Month Year
 [1] [1] [][][][] to [3][1] [1][2] [][][][]

4. Use of Reproductive Technology for Surrogacy Arrangement

Patients' Characteristics

No. of patients	[]	Age, women	[±]
Infertility duration (yr)	[±]	Age, men	[±]

Infertility Diagnosis	Stimulation Protocol
Hysterectomy [cases]	Natural [cycles]
Absent/Abnormal uterus and/or ducts [cases]	Stimulated [cycles]
Others (please specify): (cases)	Cycles ending up with ovarian hyperstimulation [cycles]

Surrogate Mothers' Characteristics

No. of surrogate mothers	[]	Single but previously	[case]
Age	[±]	married and had one or	
Married	[case]	more than one pregnancy	
Unmarried	[case]		

Treatment Method

IVF-ET	[cycles]	Frozen-thawed ET	[cycles]
PROST	[cycles]	Others (please specify):	
		()	[cycles]

Clinical Results

	Natural cycle	Stimulated cycle
No. of cycles		
No. of oocyte recoveries (/cycle)	(%)	(%)
No. of embryos transfer		
No. of oocytes (/recovery)	±	±
No. of transferred embryos (/transfer)	±	±
Fertilization rate	%	%
No. of clinical pregnancies	cases	cases
Clinical preg. rate (/cycle started)	%	%
Clinical preg. rate (/recovery)	%	%
Clinical preg. rate (/transfer)	%	%
No. of ongoing pregnancies	cases	cases
Ongoing preg. rate (/cycle started)	%	%
Ongoing preg. rate (/recovery)	%	%
Ongoing preg. rate (/transfer)	%	%
Spont. abortion (/clinical preg.)	cases (%)	cases (%)
Ectopic preg. (/clinical preg.)	cases (%)	cases (%)
Heterotopic preg. (/clinical preg.)	cases (%)	cases (%)
Termination (/clinical preg.)	cases (%)	cases (%)
Still birth (/clinical preg.)	cases (%)	cases (%)

Neonatal death (/clinical preg.)	(cases %)	(cases %)
Lost to follow up (/clinical preg.)	(cases %)	(cases %)
Multiple preg. (/clinical preg.)	(cases %)	(cases %)
Embryo reduction (/clinical preg.)	(cases %)	(cases %)
Malformation (/newborn)	(cases %)	(cases %)
No. of delivered or ongoing preg. (/clinical preg.)	(cases %)	(cases %)
Delivery plus ongoing pregnancy rate (/cycle started)	(/cycle)	(/cycle)

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5. Use of Reproductive Technology for Gender Selection to Avoid Sex-linked Diseases

No. of couples	[]	Affected genes	
Male lethal sex-linked genetic diseases	[cases]	carried by :	Husband [cases]
Female lethal sex-linked genetic diseases	[cases]		Wife [cases]
Male non-lethal sex-linked genetic diseases	[cases]		Both [cases]
Female non-lethal sex-linked genetic diseases	[cases]	Types of sex-linked diseases	[]

Gender Selection Methods Used

Sex-selective abortion [cases] Others (please specify):
() [cases]

	Natural cycle	Stimulated cycle
No. of cycles		
No. of oocyte recoveries (/cycle)	(%)	(%)
No. of male embryo transfer	cases	
No. of female embryo transfer	cases	
No. of oocytes (/recovery)	$\pm$	$\pm$
No. of transferred embryos (/transfer)	$\pm$	$\pm$
Fertilization rate	%	%
No. of clinical pregnancies	cases	cases
Clinical preg. rate (/cycle started)	%	%
Clinical preg. rate (/recovery)	%	%
Clinical preg. rate (/transfer)	%	%
No. of ongoing pregnancies	cases	cases
Ongoing preg. rate (/cycle started)	%	%
Ongoing preg. rate (/recovery)	%	%
Ongoing preg. rate (/transfer)	%	%
Spont. abortion (/clinical preg.)	cases (%)	cases (%)
Ectopic preg. (/clinical preg.)	cases (%)	cases (%)
Heterotopic preg. (/clinical preg.)	cases (%)	cases (%)
Termination (/clinical preg.)	cases (%)	cases (%)

AS Form 5(2)

Still birth (/clinical preg.)	(	cases %)	(	cases %)
Neonatal death (/clinical preg.)	(	cases %)	(	cases %)
Lost to follow up (/clinical preg.)	(	cases %)	(	cases %)
Multiple preg. (/clinical preg.)	(	cases %)	(	cases %)
Embryo reduction (/clinical preg.)	(	cases %)	(	cases %)
Malformation (/newborn)	(	cases %)	(	cases %)
No. of delivered or ongoing preg. (/clinical preg.)	(	cases %)	(	cases %)
Delivery plus ongoing pregnancy rate (/cycle started)	(	/cycle)	(	/cycle)
No. of fetuses aborted for sex selective abortion : [total cases]	male (	)	female (	)
	[	cases]	[	cases]

AS Form 6

**Annual Statistics on Reproductive Technology Treatment
for Submission to the Council on Human Reproductive Technology**

Please complete the form in block letter

Name of centre : _____
Licence no. : _____

For Official Use
No.
Form received on
____/____/____
Day Month Year

Period covered : Day Month Year to Day Month Year
 [1] [1] [] [] [] to [3] [1] [1] [2] [] [] []

6. Others* (_____)

Patients' Characteristics			
No. of patients	[]	Age, women	[±]
Infertility duration (yr)	[±]	Age, men	[±]

Infertility Diagnosis	Stimulation Protocol
Male [cycles]	Natural [cycles]
Male plus tubal [cycles]	Stimulated [cycles]
Endometriosis [cycles]	Cycles ending up with
Male plus endometriosis [cycles]	ovarian hyperstimulation [cycles]
Immunologic [cycles]	
Tubo-peritoneal [cycles]	
Ovulatory [cycles]	
Male plus ovulatory [cycles]	
Tubal plus ovulatory [cycles]	
Unexplained [cycles]	
Others (please specify): [cycles]	Donor semen [patients]
()	Donor oocyte [patients]

Clinical Results		
	Natural cycle	Stimulated cycle
No. of cycles		
No. of oocyte recoveries (/cycle)	(%)	(%)
No. of Embryo Transfers (ET)		
No. of oocytes (/recovery)	±	±
No. of transferred embryos (/ET)	±	±
Fertilization rate	%	%
No. of clinical pregnancies	cases	cases
Clinical preg. rate (/cycle started)	%	%
Clinical preg. rate (/recovery)	%	%
Clinical preg. rate (/ET)	%	%
No. of ongoing pregnancies	cases	cases
Ongoing preg. rate (/cycle started)	%	%
Ongoing preg. rate (/recovery)	%	%
Ongoing preg. rate (/ET)	%	%
Spont. abortion	cases	cases
(/clinical preg.)	(%)	(%)
Ectopic preg.	cases	cases
(/clinical preg.)	(%)	(%)
Heterotopic preg.	cases	cases
(/clinical preg.)	(%)	(%)
Termination	cases	cases
(/clinical preg.)	(%)	(%)
Still birth	cases	cases
(/clinical preg.)	(%)	(%)
Neonatal death	cases	cases
(/clinical preg.)	(%)	(%)
Lost to follow up	cases	cases
(/clinical preg.)	(%)	(%)

Multiple preg. (/clinical preg.)	(	cases %)	(	cases %)
Embryo reduction (/clinical preg.)	(	cases %)	(	cases %)
Malformation (/newborn)	(	cases %)	(	cases %)
No. of delivered or ongoing preg. (/clinical preg.)	(	cases %)	(	cases %)
Delivery plus ongoing pregnancy rate (/cycle started)	(	/cycle)	(	/cycle)

*In the case of micromanipulations, please specify the type of methods (eg. Partial Zona Dissection, Subzonal Sperm Insertion, etc)

Annual Statistics on Reproductive Technology Treatment AS Form 7 for Submission to the Council on Human Reproductive Technology

Please complete the form in block letter

Name of centre : _____
Licence no. : _____

For Official Use		
No. Form received on		
____/____/____	____/____/____	____/____/____
Day	Month	Year

Period covered : Day Month Year to Day Month Year
 [1] [1] [][][][] to [3][1] [1][2] [][][]

7. AIH (Artificial Insemination by Husband)

Patients' Characteristics			
No. of patients	[]	Age, women	[±]
Infertility duration (yr)	[±]	Age, men	[±]

Infertility Diagnosis		Stimulation Protocol	
Male	[cycles]	Natural	[cycles]
Endometriosis	[cycles]	Stimulated	[cycles]
Male plus endometriosis	[cycles]	Cycles ending up with	
Ovulatory	[cycles]	ovarian hyperstimulation	[cycles]
Male plus ovulatory	[cycles]		
Unexplained	[cycles]		
Others (please specify):	[cycles]		
()			

Clinical Results					
		Natural cycle		Stimulated cycle	
No. of cycles started Note 1	IVI and ICI		cases		cases
	IUI		cases		cases
No. of cycle which proceeded to IUI Note 2			cases		cases
IVI and ICI	No. of clinical pregnancies		cases		cases
	Clinical preg. rate (/cycle started)		%		%
	No. of ongoing pregnancies		cases		cases
	Ongoing preg. rate (/cycle started)		%		%
IUI	No. of clinical pregnancies		cases		cases
	Clinical preg. rate (/cycle started)		%		%
	No. of ongoing pregnancies		cases		cases
	Ongoing preg. rate (/cycle started)		%		%
Spont. abortion			cases		cases
(/clinical preg.)			%		%
Ectopic preg.			cases		cases
(/clinical preg.)			%		%
Heterotopic preg.			cases		cases
(/clinical preg.)			%		%
Termination			cases		cases
(/clinical preg.)			%		%
Still birth			cases		cases
(/clinical preg.)			%		%
Neonatal death			cases		cases
(/clinical preg.)			%		%
Lost to follow up			cases		cases
(/clinical preg.)			%		%
Multiple preg.			cases		cases
(/clinical preg.)			%		%
Embryo reduction			cases		cases
(/clinical preg.)			%		%
Malformation			cases		cases
(/newborn)			%		%

No. of delivered or ongoing preg. (/clinical preg.)		cases %		cases %
Delivery plus ongoing pregnancy rate (/cycle started)		/cycle		/cycle

Notes : (1) “No. of cycles started” means the “Total no. of treatment cycles started during the reporting period, including cycles which finally lead to insemination and the cancelled cycles”.

(2) “No. of cycles which proceeded to IUI” means cycles started which finally lead to the intrauterine insemination.

AS Form 8

**Annual Statistics on Reproductive Technology Treatment
for Submission to the Council on Human Reproductive Technology**

Please complete the form in Block Letters

Name of centre : _____

Licence no. : _____

For Official Use
No.
Form received on
____/____/____
Day Month Year

Period covered : Day Month Year to Day Month Year
1 1 to 3 1 1 2

8. Storage of Gametes / Embryos

A. Total number of gametes / embryos stored at the centre (as at end of the above period)

Total number of embryos stored	
Total number of eggs (oocytes) stored	
Total number of semen samples stored	

B. Information on Donors and Donated Materials (for the period covered)

Donated materials	Number of Donors Note 1	Number of donations made	Number of embryos donated
Semen Samples			N.A.
Eggs (Oocytes)			N.A.
Embryos			

C. Age Distribution of Donors

Age Note 2	No. of Female Donors		
	Eggs (Oocytes)	Embryos Note 1	Total
18-20			
21-25			
26-30			
31-35			
36-40			
41-45			
46-50			
51-55			
56 or above			

Age Note 2	No. of Male Donors		
	Semen samples	Embryos Note 1	Total
18-20			
21-25			
26-30			
31-35			
36-40			
41-45			
46-50			
51-55			
56 or above			

D. Storage of Donated Materials ^{Note 3} (No. of sample stored as at the end of the period)

<i>Sources</i> <i>Purposes of storage</i>	<u>Anonymous</u>				<u>Designated</u>			
	<i>Local</i>		<i>Import</i>		<i>Local</i>		<i>Import</i>	
	<i>Treatment</i>	<i>Research</i>	<i>Treatment</i>	<i>Research</i>	<i>Treatment</i>	<i>Research</i>	<i>Treatment</i>	<i>Research</i>
No. of donated semen samples stored								
No. of donated eggs (oocytes) stored								
No. of donated embryos stored								

E. Donated embryos used for research project

Research project licence no. No. of embryos used Dates when embryos were used

		Day	Month	Year
R				
R				
R				
R				
R				
R				
R				
R				
R				
R				
R				

Notes : (1) Same donor giving donation at different time would be counted as 1 donor. For embryos donated from a couple, the number of donors should be 2 as both husband and wife are counted as donors.

(2) For embryo donation, the age of couple donor should be calculated based on the time when the embryos were frozen. In case the donor belongs to different age groups during different cycles, the date of the first cycle should be used.

(3) The number should exclude the gametes/embryos stored for own treatment.

**Annual Statistics on Reproductive Technology Treatment
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Please complete the form in Block Letters

Name of centre :

Licence no. :

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____/____/____
Day Month Year

Period covered : Day Month Year to Day Month Year
 1 1 3 1 1 2

9. Number of patients who stored gametes / embryos for own use

Part 1) Statistics as at the end of the reporting period

For patients who are last known to be married at the end of the reporting period

A. Age^{Note 1} and year of storage^{Note 2} of semen samples for own use at the centre (as at end of the above period)

Age Group Year of storage	25 or below	26 - 30	31 - 35	36 - 40	41 - 45	46 - 50	51 or above	Total
0 - < 5 year								
5 - < 10 years								
10 - < 15 years								
15 - < 20 years								
20 years or above								
Total								

B. Age^{Note 1} and year of storage^{Note 2} of eggs (oocytes) for own use at the centre (as at end of the above period)

Age Group Year of storage	25 or below	26 - 30	31 - 35	36 - 40	41 - 45	46 - 50	51 or above	Total
0 - < 5 year								
5 - < 10 years								
10 - < 15 years								
15 - < 20 years								
20 years or above								
Total								

C. Age^{Note 1} and year of storage^{Note 2} of embryos for own use at the centre (as at end of the above period)

Age Group Year of storage	25 or below	26 - 30	31 - 35	36 - 40	41 - 45	46 - 50	51 or above	Total
0 - < 5 year								
5 - < 10 years								
10 - < 15 years								
15 - < 20 years								
20 years or above								
Total								

For patients who are last known to be unmarried at the end of the reporting period**D. Age^{Note 1} and year of storage^{Note 2} of semen samples for own use at the centre (as at end of the above period)**

Age Group Year of storage	25 or below	26 - 30	31 - 35	36 - 40	41 - 45	46 - 50	51 or above	Total
0 - < 5 year								
5 - < 10 years								
10 - < 15 years								
15 - < 20 years								
20 years or above								
Total								

E. Age^{Note 1} and year of storage^{Note 2} of eggs (oocytes) for own use at the centre (as at end of the above period)

Age Group Year of storage	25 or below	26 - 30	31 - 35	36 - 40	41 - 45	46 - 50	51 or above	Total
0 - < 5 year								
5 - < 10 years								
10 - < 15 years								
15 - < 20 years								
20 years or above								
Total								

Part 2) Statistics during the reporting period**F. Locality^{Note 3}**

	Local ^{Note 4}		Non-local ^{Note 4}	
Material stored for own use	Number of married patients ^{Note 5}	Number of unmarried patients	Number of married patients ^{Note 5}	Number of unmarried patients
Semen samples				
Eggs (oocytes)				
Embryos ^{Note 6}		/		/
Total				

G. Reasons for individuals to seek gametes storage services^{Note 3}

Reason	Number of married patients ^{Note 5}		Number of unmarried patients		Total
	Male	Female	Male	Female	
(i) Medical reasons					
(ii) Non-medical reasons					
Total					

H. Reasons for married patients to seek embryos storage services

Reason	Number of pairs of married patients
(i) Medical reasons	
(ii) Non-medical reasons	
Total	

I. Reasons for individuals to stop gametes storage services ^{Note 3}

Reason	Number of married patients ^{Note 5}		Number of unmarried patients		Total
	Male	Female	Male	Female	
(i) Live-birth event achieved					
(ii) Local transfer					
(iii) Exportation					
(iv) No definite treatment plan					
(v) Others					
Total					

J. Reasons for married patients to stop embryos storage services

Reason	Number of pairs of married patients
(i) Live-birth event achieved	
(ii) Local transfer	
(iii) Exportation	
(iv) No definite treatment plan	
(v) Others	
Total	

For patients who are last known to be married when they stop storage services**K. Age** ^{Note 7} **and year of storage** ^{Note 2} **of semen samples for own use at the centre (when patients stop storage services)**

Age Group \ Year of storage	25 or below	26 - 30	31 - 35	36 - 40	41 - 45	46 - 50	51 or above	Total
0 - < 5 year								
5 - < 10 years								
10 - < 15 years								
15 - < 20 years								
20 years or above								
Total								

L. Age ^{Note 7} **and year of storage** ^{Note 2} **of eggs (oocytes) for own use at the centre (when patients stop storage services)**

Age Group \ Year of storage	25 or below	26 - 30	31 - 35	36 - 40	41 - 45	46 - 50	51 or above	Total
0 - < 5 year								
5 - < 10 years								
10 - < 15 years								
15 - < 20 years								
20 years or above								
Total								

M. Age^{Note 7} and year of storage^{Note 2} of embryos for own use at the centre (when patients stop storage services)

Age Group \ Year of storage	25 or below	26 - 30	31 - 35	36 - 40	41 - 45	46 - 50	51 or above	Total
0 - < 5 year								
5 - < 10 years								
10 - < 15 years								
15 - < 20 years								
20 years or above								
Total								

For patients who are last known to be unmarried when they stop storage services**N. Age^{Note 7} and year of storage^{Note 2} of semen samples for own use at the centre (when patients stop storage services)**

Age Group \ Year of storage	25 or below	26 - 30	31 - 35	36 - 40	41 - 45	46 - 50	51 or above	Total
0 - < 5 year								
5 - < 10 years								
10 - < 15 years								
15 - < 20 years								
20 years or above								
Total								

O. Age^{Note 7} and year of storage^{Note 2} of eggs (oocytes) for own use at the centre (when patients stop storage services)

Age Group \ Year of storage	25 or below	26 - 30	31 - 35	36 - 40	41 - 45	46 - 50	51 or above	Total
0 - < 5 year								
5 - < 10 years								
10 - < 15 years								
15 - < 20 years								
20 years or above								
Total								

- Notes:**
- (1) Age refers to the age of the patients when he / she **started** to store his / her gametes or embryos. The **age of wife** should be used in calculating the age of married patient who stored **embryos** for own use. For patients who stored gametes / embryos repeatedly at different ages, enter data in applicable categories separately.
 - (2) Year of storage refers to the day on which the gamete or embryos begins to be stored, irrespective of the premises in which it is stored.
 - (3) Please adopt the last known marital status of patients **at the end of the reporting period**.
 - (4) Local patients refer to HKID card holders, while non-local patients refer to patients holding identity documents other than HKID card (such as passport, other travel documents, etc).
 - (5) Please count the married patients who sought gamete storage services as individuals. For example, if the husband and the wife respectively store their semen sample and egg, two individuals should be counted. If only one party of the married couple stored his / her gametes, only that one individual should be counted.
 - (6) The locality of wife should be referred to for the purpose of counting the locality of a pair of married patients who stored embryos for their own use.
 - (7) Age refers to the age of the patients when he / she stopped gametes / embryo storage services. The **age of wife** should be used in calculating the age of married patient who stored **embryos** for own use. For patients who stored gametes / embryos and stop storage services repeatedly at different ages, enter data in applicable categories separately.

**Explanatory Notes on the Requirement
in relation to the Use of Donor Gametes/Embryos**

1. Treatment centres duly licensed for the purpose are required to obtain clearance from the Council before the commencement of any reproductive technology (RT) treatment involving the use of donor gametes/embryos, by submitting to the Council the AF Form 1 (for donor gametes) or AF Form 2 (for donor embryos) as appropriate, with Part I of the form duly filled in. The Council Secretariat will normally be able to complete processing an application within two weeks of receipt of the application form.
2. The Council Secretariat will reply, by completing and sending to the licensed centre concerned, Part II of the application form, advising the applicant either that –
 - a) Approval has been granted for the gametes/embryos of the donor(s) specified in the application form to be used for the treatment of the recipient specified in the same form **to achieve one live birth event only**. An approval number will be provided with the approval. You must quote this number in future submissions of DC Forms and in all future communications with the Council in relation to the same matter; or
 - b) The application for the use of the gametes/embryos of the donor(s) specified in the application form for the treatment of the recipient specified in the form is **NOT** approved.

What should be done under scenario 2(a) above

3. Upon approval, and after the donor gametes/embryos concerned have actually been used for the treatment of the recipient specified in the application, the licensed centre concerned shall complete and submit a DC Form 5 or 6 in relation to the treatment within 1 week of treatment to report the use, and also submit other subsequent DC Forms in strict accordance with the time specified in the Code of Practice on Reproductive Technology and Embryo Research. Please quote the corresponding approval number in all subsequent DC Forms submitted to the Council.
4. The approval is granted for the gametes/embryos of the donor(s) named in the application form to be used for the treatment of the recipient specified in the form to achieve **one live birth event** only (please see para. 5.5; and please also see para. 10.7 for use of remaining embryos after one live birth event has been achieved). Unless the Council is otherwise informed, a live birth event will be assumed once approval is granted; and no application for extension of storage period for donated gametes or embryos or embryos produced from a designated recipient is required before one live birth event has been achieved. If the treatment approved by the Council is for any reason no longer proceeded with, the licensed centre concerned is required to inform the Council Secretariat as soon as practicable by completing and submitting Part III of the application form; and whereupon the approval granted will be revoked. The licensed centre concerned is also required to inform the Council Secretariat in writing as soon as practicable if the gametes/embryos of the donor(s) named in Part I of the application form have for any reason not been used within 6 months since the date of approval.
5. The approval granted is not transferrable to other recipients.

What should be done under scenario 2(b) above

6. Since the application has not been approved, the gametes/embryos of the donor(s) specified in the application form **must not** be used for the treatment of any patient.

Handling of Personal Data

7. Licensed centres are reminded to comply with the restrictions, rules, regulations and principles stipulated in:
 - (a) Section 34 of the Human Reproductive Technology Ordinance Cap. 561, on restrictions against disclosure of information;
 - (b) The Personal Data (Privacy) Ordinance Cap. 486, on the collection, retention, use, disposal, access to and correction of the personal data; and
 - (c) Paragraphs 14.15 and 14.16, as well as Appendices X and XI, of the Code of Practice on Reproductive Technology and Embryo Research, on the handling of personal data.

Application for Use of Embryos Produced from a Designated Recipient after Achievement of One Live Birth Event

8. Application for use of remaining embryos produced from a designated recipient after one live birth event has been achieved **must be made in writing before the expiry of the maximum storage period of 2 years**. The Council may allow such application only if the following conditions are satisfied -
 - (a) there are special circumstances justifying the use of the remaining embryos beyond the normal storage period of two years;
 - (b) the recipient couple and the donor concerned should have been properly and adequately counselled about the possible social and psychological consequences of use of the remaining embryos for achieving a further live birth event. The counsellor responsible for such counselling should be an independent person who must have no relationship with the licensed centre concerned. Also, the independent counsellor should have made an assessment on the suitability of the parties concerned for undergoing the RT treatments which involved the use of the remaining embryos gametes; and such treatments should only be carried out with the support of the independent counsellor after the assessment;
 - (c) the donor concerned should have given his or her written consent to the recipient couple concerned for their use of the remaining embryos for achieving a further live birth event clearly and unambiguously after counselling by the independent counsellor; and
 - (d) the licensed centre concerned should submit to the Council the assessment report by the independent counsellor on the recipient couple and the donor concerned together with the corresponding report for designated donation within 3 months after completion of the procedure for each treatment cycle (please see paras. 14.9 and 14.10).

CONFIDENTIAL**Application form for use of donor gametes***To be completed by Council*

Date of receipt: _____

Serial no.: _____

Note:

- (1) If your centre intends to use any donor gametes for the treatment of any recipient patient, as part and parcel of your obligations under section 13(f) of the Human Reproductive Technology (Licensing) Regulation ("the Regulation") and para. 9.6 of the Code of Practice on Reproductive Technology and Embryo Research ("the Code"), you are required to apply to the Council for such intended use, and obtain clearance in relation thereto, before commencement of any treatment, including donor insemination, IVF and embryo transfer.
- (2) Please complete one form for each recipient couple.
- (3) For the avoidance of doubt, we would like to draw your attention to the fact that the sole purpose of the application in AF Form 1 or 2 is to facilitate your centre's fulfillment of its obligations under section 13(f) of the Regulation and para. 9.6 of the Code, viz., that a Person Responsible (PR) must ensure that gametes or embryos from a single donor should not be used to produce more than three "live birth events". The granting of approval herein by no means exonerates a PR from his/her other obligations or responsibilities under the Human Reproductive Technology Ordinance Cap. 561, the Regulation, or the Code.

Part I – to be filled in by the licensed centre

1. Name of licensed centre : _____
 2. Licence no. : _____
 3. Full name of donor : _____
(Surname) (Given name) (Alias, if any)
 4. Sex : M / F *
 5. HKID Card/Passport/ other travel document number*
(Please specify travel document) : _____
 6. Name of sperm bank/donor centre (if any): _____
 7. Donor number assigned by sperm bank/donor centre (if any): _____
 8. Clinic record no. of the recipient : _____
- Signature : _____
- Name : _____ Contact tel. no.: _____
- Position : _____ Date of submission : _____

(* Please delete where inappropriate.)

Part II – to be filled in by the Council Secretariat

- ☐ Approval is hereby given for the gametes of the above-named donor to be used for the treatment of the recipient specified in this application form **to achieve one live birth event only**.
(Approval no. _____) (Please quote this approval no. in future submissions of DC forms.)
- ☐ Application for the use of the gametes of the above-named donor for the treatment of the recipient specified in this form is **NOT** approved.

Signature: _____ Contact tel. no.: _____

Name: _____ Date: _____

Part III – to be filled in by the licensed centre when the treatment approved vide this application form is no longer proceeded with

I hereby inform the Council that the treatment approved vide this application form is no longer proceeded with.

Signature : _____

Name : _____ Contact tel. no. : _____

Position : _____ Date of submission : _____

CONFIDENTIAL**Application form for use of donor embryos**

Note:

To be completed by Council

Date of receipt: _____

Serial no.: _____

(1) If your centre intends to use any donor embryos for the treatment of any recipient patient, as part and parcel of your obligations under section 13(f) of the Human Reproductive Technology (Licensing) Regulation ("the Regulation") and para. 9.6 of the Code of Practice on Reproductive Technology and Embryo Research ("the Code"), you are required to apply to the Council for such intended use, and obtain clearance in relation thereto, before commencement of any treatment, including IVF and embryo transfer.

(2) Please complete one form for each recipient couple.

(3) For the avoidance of doubt, we would like to draw your attention to the fact that the sole purpose of the application in AF Form 1 or 2 is to facilitate your centre's fulfillment of its obligations under section 13 (f) of the Regulation and para. 9.6 of the Code, viz., that a Person Responsible (PR) must ensure that gametes or embryos from a single donor should not be used to produce more than three "live birth events". The granting of approval herein by no means exonerates a PR from his/her other obligations or responsibilities under the Human Reproductive Technology Ordinance Cap. 561, the Regulation, or the Code.

Part I – to be filled in by the licensed centre

1. Name of licensed centre: _____

2. Licence no.: _____

Female donorMale donor

3. Surname	:	_____	_____
4. Given name	:	_____	_____
5. Alias (if any)	:	_____	_____
6. HKID Card/Passport/other travel document number* (Please specify travel document)	:	_____	_____
7. Name of donor centre (if any)	:	_____	_____
8. Donor number assigned by donor centre (if any)	:	_____	_____
9. Clinic record no. of the recipient	:	_____	

Signature : _____

Name : _____

Position : _____

Contact tel. no.: _____

Date of submission : _____

(* Please delete where inappropriate.)

Part II – to be filled in by the Council Secretariat

☐ Approval is hereby given for the embryos of the above-named donors to be used for the treatment of the recipient specified in this application form **to achieve one live birth event only**.

(Approval no. _____) (Please quote this approval no. in future submissions of DC forms.)

☐ Application for the use of the embryos of the above-named donors for the treatment of the recipient specified in this form is **NOT** approved.

Signature: _____

Contact tel. no.: _____

Name: _____

Date: _____

Part III – to be filled in by the licensed centre when the treatment approved vide this application form is no longer proceeded with

I hereby inform the Council that the treatment approved vide this application form is no longer proceeded with.

Signature : _____

Name : _____

Position : _____

Contact tel. no.: _____

Date of submission : _____

INFORMATION SHEET FOR CLIENTS

**Information to be included in the Statutory Declaration
to be made by the Client before Exportation of Gametes/Embryos**

WARNING

Pursuant to section 36 of the Crimes Ordinance (Cap. 200 of the Laws of Hong Kong), any person who knowingly and wilfully makes (otherwise than on oath) a statement false in a material particular, such statement being made in a statutory declaration, shall be guilty of an offence and shall be liable on conviction upon indictment to imprisonment for 2 years and to a fine.

The written record documenting the statutory declaration made by a client regarding his/her request for an exportation of gametes/embryos should include the following information –

1. Name of Client;
2. Hong Kong Identity Card or Passport number of Client;
3. Address of Client;
4. Name of the licensed centre from which gametes/embryos are to be transferred;
5. Name of the overseas receiving centre to which gametes/embryos are to be transferred;
6. A declaration, (please see sample) duly signed by the client (the Declarant) and the oath taking party, stating that the client will not use any of the gametes/embryos that are being transferred for any purpose in contravention with any of the prohibitions under sections 15, 16 and 17 of the Human Reproductive Technology Ordinance (Cap. 561) as reproduced in the detachment sheet (2 pages to be printed double-sided) below; and
7. The detachable sheet mentioned in item 6 above should form an attachment to the statutory declaration.

SAMPLE

DECLARATION

I, (Name) of (Address) _____, holder of Hong Kong Identity Card/(Issuing Country) Passport Number _____, solemnly and sincerely declare that –

1. Before making this declaration, I have read and understood the prohibitions set out in sections 15, 16 and 17 of the Human Reproductive Technology Ordinance, Chapter 561, Laws of Hong Kong. A copy of which is attached to this declaration.
2. I confirm that I do not have the intention to use any of the gametes and/or embryos to be transferred on my behalf from (Name of Licensed Centre in Hong Kong) to (Name of the Overseas Receiving Centre) for any purpose in contravention with any of the said prohibitions.

And I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Ordinance, Chapter 11, Laws of Hong Kong.

[Signed by the Declarant]

Declared at (Place in Hong Kong where the declaration is made)
in Hong Kong this _____ day of _____ 20xx

Before me,

[Signature and designation, i.e. Justice of the Peace/Notary Public/Commissioner for Oaths]

HUMAN REPRODUCTIVE TECHNOLOGY ORDINANCE
(CAP. 561, LAWS OF HONG KONG)

15. Prohibitions in connection with embryos, against sex selection and against the provision of reproductive technology procedures to unmarried persons

- (1) No person shall—
 - (a) for the purposes of embryo research—
 - (i) bring about the creation of an embryo; or
 - (ii) combine human and non-human gametes or embryos or any part thereof such as to give rise to a 2 cell zygote;
 - (b) keep or use an embryo after the appearance of the primitive streak;
 - (c) place any non-human gametes or embryos or any part thereof in any human;
 - (d) place any human gametes or embryo or any part thereof in any animal;
 - (e) replace the nucleus of a cell of an embryo with a nucleus taken from any other cells; of
 - (f) clone any embryo.
- (2) No person shall, for the purposes of a reproductive technology procedure, keep or use any fetal ovarian, or fetal testicular, tissue.
- (3) No person shall, by means of a reproductive technology procedure, cause the sex of an embryo to be selected, whether directly or indirectly (including by the implantation of an embryo of a particular sex in the body of a woman), except where—
 - (a) the purpose of such selection is to avoid a sex-linked genetic disease specified in Schedule 2 which may prejudice the health of the embryo (including any foetus, child or adult which may arise from the embryo); and
 - (b) not less than 2 registered medical practitioners each state in writing that such selection is for that purpose and such disease would be sufficiently severe to a person suffering it to justify such selection.
- (4) For the purposes of subsection (1)(b), the primitive streak shall be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored.
- (5) Subject to subsections (6), (7) and (8), no person shall provide a reproductive technology procedure to persons who are not the parties to a marriage.
- (6) Without prejudice to the operation of section 14, subsection (5) shall not apply in the case of a reproductive technology procedure provided to a person who is to be a surrogate mother where the procedure is provided pursuant to the surrogacy arrangement under which she is to be the surrogate mother.
- (7) It is hereby declared that—
 - (a) subject to paragraph (b), subsection (5) shall not operate to prohibit the continuation of a reproductive technology procedure provided to persons who were the parties to a marriage when gametes were, or an embryo was, placed in the body of a woman pursuant to the procedure;
 - (b) paragraph (a) shall not operate to permit any further gametes or further embryo to be placed in the body of that woman pursuant to that procedure.
- (8) Subsection (5) shall not apply in the case of the reproductive technology procedure referred to in paragraph (c) of the definition of “reproductive technology procedure” in section 2(1).

16. Prohibitions against commercial dealings in prescribed substance

- (1) No person shall—
 - (a) whether in Hong Kong or elsewhere, make or receive any payment for the supply of, or for an offer to supply, a prescribed substance intended to be used for the purposes of any reproductive technology procedure, embryo research or surrogacy arrangement;
 - (b) seek to find a person willing to supply for payment a prescribed substance referred to in paragraph (a);
 - (c) initiate or negotiate any arrangement involving the making of any payment for the supply of, or for an offer to supply, a prescribed substance referred to in paragraph (a); or
 - (d) take part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include the initiation or negotiation of any arrangement referred to in paragraph (c).
- (2) Without prejudice to the generality of subsection (1)(b), no person shall cause to be published or distributed, or knowingly publish or distribute, an advertisement—
 - (a) inviting persons to supply for payment a prescribed substance referred to in subsection (1)(a) or offering to supply any such prescribed substance for payment; or
 - (b) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in subsection (1)(c).
- (3) In this section, “prescribed substance” (訂明物質) means—
 - (a) a gamete or embryo; or
 - (b) fetal ovarian, or fetal testicular, tissue.

17. Prohibition against surrogacy arrangements on commercial basis, etc.

- (1) No person shall—
 - (a) whether in Hong Kong or elsewhere, make or receive any payment for—
 - (i) initiating or taking part in any negotiations with a view to the making of a surrogacy arrangement;
 - (ii) offering or agreeing to negotiate the making of a surrogacy arrangement; or
 - (iii) compiling any information with a view to its use in making, or negotiating the making of, surrogacy arrangements;
 - (b) seek to find a person willing to do any act which contravenes paragraph (a);
 - (c) take part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include any act which contravenes paragraph (a); or
 - (d) carry out or participate in any act in furtherance of any surrogacy arrangement where he knows, or ought reasonably to know, that the arrangement is the subject of any act which contravenes paragraph (a).
- (2) Without prejudice to the generality of subsection (1)(b), no person shall cause to be published or distributed, or knowingly publish or distribute, an advertisement relating to surrogacy arrangements, and whether or not the advertisement invites persons to do any act which contravenes subsection (1)(a).