

# **Code of Practice on Reproductive Technology and Embryo Research**

Council on Human Reproductive Technology

~~January 2013-2023~~

(Comments to this first Draft of the Code are welcome by 13 April 2023)

**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 1<sup>st</sup> August 2007.<sup>1</sup> The Code will be reviewed and updated as necessary to keep up with developments in RT.<sup>2</sup> 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.<sup>3</sup> 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

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<sup>1</sup> s.8(6) of the Human Reproductive Technology Ordinance (the Ordinance)

<sup>2</sup> s.8(3) of the Ordinance

<sup>3</sup> 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.

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## 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.<sup>4</sup>

### 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.<sup>5</sup>

2.3 It shall be the duty of the person responsible to ensure that -<sup>6</sup>

- (a) the other persons to whom the licence applies<sup>7</sup> 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 reproductive technology 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.<sup>8</sup>

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.<sup>9</sup>

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<sup>4</sup> s.13 of the Ordinance

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

<sup>6</sup> s.24(1) of the Ordinance

<sup>7</sup> s.24(3) of the Ordinance

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

<sup>9</sup> 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 practitioner<sup>10</sup> 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) of the Medical Council of Hong Kong. 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 RT-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

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

to guidance laid down by the Medical Council of Hong Kong on fitness to practise.

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Note:

Satellite centres or associated doctors of a reproductive technology centre are those centres, clinics or medical practitioners, not being part and parcel of the organization of the reproductive technology 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.

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### **Chapter III — Facilities and Equipment**

#### General Standard of Clinical and Laboratory Facilities in **RT-Licensed** Centres

3.1 The person responsible must secure that proper facilities and equipment are used and maintained.<sup>11</sup> Licensed centres should promptly report to the Council any change(s) involving critical equipment related to RT procedures.

3.2 Backup and/or emergency support facilities should be arranged and made available for each technique practised in the **RT-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 **RT-Licensed** Centres Offering IVF Services

3.4 The minimum facilities and equipment required for **RT-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 RT**-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 RT**-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 required if general anaesthesia is used for oocyte collection.

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<sup>11</sup> s.24(1)(b) of the Ordinance

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 ~~RT-Licensed~~ centres should ensure a continuous supply of electricity.

3.7 In ~~RT-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 RT~~ 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 marriage<sup>12</sup>, except where the RT procedure is<sup>13</sup>

- (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~~~~sperm/eggs~~/embryos, RT-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

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<sup>12</sup> 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).

<sup>13</sup> s.15(5), 15(6), 15(7) & 15(8) of the Ordinance

- any child born as a result of treatment;
- (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/sperm/eggs/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; ~~and~~
- (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, as a good practice, 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).

### 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, as a good practice, 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. 7.5-7.8)

### Assessment of Donors of Gametes and Embryos

4.6 RT-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, RT-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. 7.9)

#### Persons Considered Unsuitable as Donors or to Undergo RT Treatments

4.14 If the licensed RT-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.

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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 RT-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. RT-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

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- (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 pregnancy and indications for embryonic reduction;
- (c) limitations and possible outcomes of the treatment;
- (d) any other options available; and
- (e) charges for services.

5.3 RT-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 parents<sup>14</sup>;
- (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 16<sup>15</sup>; and
- (c) the legal obligation of licensed RT—centres to report information to the Council in accordance with the Ordinance and its subsidiary legislation.<sup>16</sup>

### Information to Donors of Gametes or Embryos

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

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- (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

<sup>14</sup> s.9 – s.12 of the Parent and Child Ordinance

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

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

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 RT 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 treatment<sup>17</sup>;
- (b) the fact that, under the Laws of Hong Kong<sup>18</sup>, 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 legislation<sup>19</sup>, licensed RT 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 Ordinance<sup>20</sup> (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 -<sup>21</sup>

- (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 RT centres shall follow the guidelines strictly such that gamete donors shall not be paid more than the maximum daily payment level.

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<sup>17</sup> s.34 of the Ordinance

<sup>18</sup> s.9 – s.12 of the Parent and Child Ordinance

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

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

<sup>21</sup> 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 RT 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 must -

- (a) specify the maximum period of storage if this is to be less than the maximum storage period recommended by the Code (details on maximum storage period are described in **Chapter X**); 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 RT-centre every 2 years. In the absence of such notice, licensed RT-centres may dispose of the stored gametes or embryos, donate them for treatment of other infertile couple(s), donate for research or donate for quality control and/or training in accordance with the instruction given by the clients at the start of the storage.

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.

#### Consent Forms

6.10 Licensed RT-centres are required to make use of the appropriate sample consent forms 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 RT-centres may use a simplified consent form (Consent Form (18)) instead of the full consent form.

## 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/fetal 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.<sup>22</sup> They should also be informed that a child born

<sup>22</sup> s.33(1) and s.33(2), s.45(2)(c) and s.45(2)(d) of the Ordinance

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.<sup>23</sup>

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

7.6 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 RT-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

7.7 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.

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

### Counselling for Potential Donors of Gametes or Embryos

7.9 Counsellors should ask potential donors of gametes or embryos to 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

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<sup>23</sup> s.33(3), s.33(4) and s.33(5) of the Ordinance

Council in accordance with the Ordinance and its subsidiary legislation.<sup>24</sup> 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.<sup>25</sup>

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<sup>24</sup> s.33(1) and s.33(2), s.45(2)(c) and s.45(2)(d) of the Ordinance

<sup>25</sup> 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/Fetal Reduction**

8.6 Whenever possible, RT practitioners must take measures to prevent high multiple pregnancies. This is to avoid the known risks of fetal 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 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 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.

8.9 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.

Pre-implantation Genetic ~~Diagnosis~~ 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 arrangement (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 within 3 months after the completion of the procedure detailing –

- (a) the clinical indication(s);
- (b) the likely impact(s) on the embryo(s); and
- (c) 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 pre-implantation genetic ~~diagnosis (PGD)–testing for monogenic defects/chromosomal structural arrangement (PGT-M/SR)~~ is used to combine ~~with IVF and genetic testing~~ 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 ~~PGD-PGT-M/SR~~ 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 RT-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 RT** 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 RT~~ 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 Embryos<sup>26</sup>

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

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<sup>26</sup> s.45(2)(g) of the Ordinance

events in Hong Kong should not be exported for treatment of infertile patients overseas.

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 will not 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 RT-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.

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## Chapter X — Storage and Disposal of Gametes and Embryos<sup>26a</sup>

### 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 RT-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 RT-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.

### Maximum Storage Period for Gametes or Embryos

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 embryos begins to be stored, 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 their patients 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 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. 10.11 (d)).

10.7 Subject to para. 10.8, the maximum storage period for gametes or

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<sup>26a</sup> 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.

embryos stored for patients' own use in a RT procedure should not exceed 10 years. 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. RT Licensed centres may formulate their own policy for a maximum storage period less than 10 years. 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; and
- (b) the licensed centres' responsibility to dispose of 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. 10.11 (d)).

10.8 Notwithstanding the provision in para. 10.7, the maximum storage period of gametes for cancer or other patients who may be rendered infertile as a result of chemotherapy, radiotherapy, surgery or other medical treatment is 10 years, or until the time when the patient is 55 years old, whichever occurs later in time. The maximum storage period of embryos for the said patients is 10 years. 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. The patient may however specify an age limit lower than 55 or a maximum period shorter than 10 years. 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; and
- (b) the licensed centres' responsibility to dispose of 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. 10.11 (d)).

10.9 Designated donations of ~~sperm/eggs/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 begins to be stored, irrespective of the premises in which it is stored. Application for use of remaining embryos produced from a designated recipient after one live birth 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 allowed.

#### Storage of Embryos for Married Persons Only

10.10 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.<sup>27</sup>

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

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

- (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) anyone consenting to store his/her gametes or embryos must specify the maximum storage period (if this is less than the periods specified in paras. 10.6-10.9). 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. Licensed centres should ensure that the stored gametes or embryos are promptly disposed of or handled in accordance with the instructions indicated in the consent forms upon expiry of the maximum storage period. In cases where gametes or embryos are stored for their own use, 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

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<sup>27</sup> s.15(5) of the Ordinance



RT-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.

10.12 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.

10.13 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.<sup>28</sup> 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

10.14 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.<sup>29</sup>

10.15 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.

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<sup>28</sup> s.45(3) of the Ordinance

<sup>29</sup> 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.<sup>30</sup>

11.3 All researches which involve the development, storage, manipulation and usage of human embryos outside human body must be licensed by the Council.<sup>31</sup>

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 -<sup>32</sup>

- (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);

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<sup>30</sup> s.15(1)(a)(i) of the Ordinance

<sup>31</sup> s.2(1) (definition of "relevant activities" and "reproductive technology procedure") and s.13 of the Ordinance

<sup>32</sup> s15(1)(a) to (f) of the Ordinance

- (c) to keep or use an embryo after the appearance of the primitive streak;
- (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 payment<sup>33</sup> 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.<sup>34</sup>

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 Fetal Ovarian or Testicular Tissue

11.14 The use of fetal ovarian or testicular tissue for infertility treatment is prohibited under the Ordinance.<sup>35</sup>

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<sup>33</sup> s.2(1) (see interpretation of the term “payment”) and s.16(1)(a) of the Ordinance

<sup>34</sup> s.20(1) of the Ordinance

<sup>35</sup> s.15(2) of the Ordinance

11.15 In the case of embryo research, the use of fetal ovarian or testicular 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 fetus;
- (d) written consent should be obtained from the spouse or sex partner (if unmarried) of the mother of the fetus where practicable; and
- (e) there should be no financial reward for donating fetal tissue.

11.16 The decision to carry out an abortion must be reached without consideration of the benefits of subsequent use of the aborted fetal 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 fetal 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 fetal ovarian or testicular tissues are prohibited under the Ordinance.<sup>36</sup>

#### 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 fetal tissues as provided in the Code should be followed.

11.23 An institution performing embryo research should have a research

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<sup>36</sup> s.16 of the Ordinance

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 -

- (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~~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.<sup>37</sup>

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 marriage<sup>38</sup>; 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 practitioner<sup>39</sup>, 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.<sup>40</sup>

12.7 Counselling must be provided by a multi-disciplinary team of the licensed RT-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.

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<sup>37</sup> s.17 of the Ordinance

<sup>38</sup> s.14 of the Ordinance

<sup>39</sup> a medical practitioner registered in accordance with s.14 of the Medical Registration Ordinance (Cap. 161)

<sup>40</sup> 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 RT-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 fetal 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.<sup>41</sup>

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.<sup>42</sup>

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**<sup>43</sup> 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.

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 ~~PGD-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. ~~PGD-PGT~~ technique applied to determine normality of the embryo shall not be used for the purpose of sex selection.

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.

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<sup>41</sup> s.15(3)(b) of the Ordinance

<sup>42</sup> s.15(3)(b) of the Ordinance

<sup>43</sup> s.15(3)(a) and Schedule 2 of the Ordinance



13.9 Licensed RT-centres should report to the Council on cases of sex selection achieved through RT (e.g. using sperm treatment with sex-selective insemination or PGD-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.<sup>44</sup>

13.10 Licensed RT-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.

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<sup>44</sup> s.45(2)(d) of the Ordinance

## Chapter XIV — Record Keeping and Information Management

### Accuracy and Confidentiality of Information

14.1 Licensed RT-centres must ensure personal records with identifying information are kept in confidence with controlled access and disclosed only in circumstances permitted by the Ordinance.<sup>45</sup> 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 RT-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 RT-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 submit to the Council information of protocol on how they can be quickly accessed in emergency situation(s).

14.3 General medical record kept and maintained under a treatment licence should be retained by the licensed RT-centres for at least 6 years after the patient ceases to be a client of the licensed RT-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 RT-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 RT-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 A<sup>46</sup>, which shall contain any information obtained by the Council that -

- (a) relates to the provision of a RT procedure where a child born or intended to be born in consequence of the procedure was not

<sup>45</sup> s.34, s.35 and s.36 of the Ordinance

<sup>46</sup> s.33(1) and s.33(2) of the Ordinance and Human Reproductive Technology (Licensing) Regulation (Cap 561 sub. leg. A)

- (b) created from the gametes solely of the parents of the child; and 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 RT~~ 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/sperm/eggs/embryos~~ should not be permitted unless under special circumstances. ~~Licensed RT~~ 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 RT~~ 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 ~~diagnosis~~ testing for monogenic defects/chromosomal structural arrangement (PGT-M/SR~~D~~) (para. 6 of Appendix III);

- (f) ~~Tissue-tissue~~ typing in conjunction with ~~PGD-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**.<sup>47</sup>

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.<sup>48</sup>

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 RT~~ 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 RT~~ 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

<sup>47</sup> s.33, s.34, s.35 and s.36 of the Ordinance

<sup>48</sup> s.33(3) of the Ordinance

records for inspection.

14.17 If a ~~RT~~-licensed centre engages the service of another laboratory licensed by the Council for the purpose to carry out sperm washing or PGT~~D~~ 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.

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## Chapter XV — Handling of Complaints

### Complaints against Licensed RT-Centres

15.1 Licensed RT-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 RT-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.<sup>49</sup> 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.

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<sup>49</sup> 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, 4<sup>th</sup> 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 :**  
The process of transferring a fertilized egg in the course of IVF procedures, where following development in vitro for 2 or 3 days, or after flushing from a woman's uterus by lavage (at 5 days), an early embryo is placed in the uterus of an infertile woman in order to try to achieve implantation and pregnancy.
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), Intra Cytoplasmic Sperm Injection (ICSI), and Epididymal Sperm Aspiration (ESA).

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. **Pronuclear stage tubal transfer (PROST) :**  
A technique which eggs fertilized in vitro are transferred to the fallopian tube before cell division occurs.
33. **Sperm :**  
A mature male germ cell, produced in the testicles.
34. **Sperm-washing :**  
A process in which spermatozoa are separated from seminal plasma.
35. **Superovulation :**  
The medical stimulation of the ovary with hormones so that a woman produces more eggs than usual in a monthly cycle.
36. **Uterus :**  
The womb; the female organ in which the foetus grows during pregnancy.
37. **Zygote :**  
The cell formed by the union of sperm and egg.

**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 at 6-month intervals;
- (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.

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**Guidelines for Payment to Donors**

1. This appendix provides guidance to ~~RT~~-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 defraying<sup>50</sup>-
  - (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\$380630~~. ~~RT~~ ~~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\$300450~~ to cover the travelling expenses incurred in getting to the RT ~~center~~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\$300450~~.

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<sup>50</sup>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 RT-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\$240360**. 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\$380630**.

### 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 RT-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 RT-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 RT-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\$1,060,710**. Such amount may be increased to **HK\$1,360,160** 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.

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**Ethical Guidelines on Pre-implantation Genetic ~~Diagnosis (PGD)~~ Testing for Monogenic Defects/Chromosomal Structural Arrangement (PGT-M/SR)**

**General Principles**

1. Pre-implantation genetics ~~diagnosis (PGD)~~ testing for monogenic defects/chromosomal structural arrangement (PGT-M/SR) is a technique that may be used to combine with IVF and genetic testing as a means of avoiding the transmission of a genetic abnormality or a disease. ~~PGD~~ PGT-M/SR 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-M/SRPGD~~**

2. ~~PGT-M/SRPGD~~ 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-M/SRPGD~~ 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-M/SRPGD~~ Procedures**

4. The use of ~~PGT-M/SRPGD~~ should be a matter of discussion between those seeking ~~PGT-M/SRPGD~~ (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. The clinical team should consist of 2 doctors, one of whom should have proper training in clinical genetics and/or genetic counselling.

6. The clinical team, having discussed with the persons seeking ~~PGT-M/SRPGD~~ and determined the condition to be sufficiently serious to warrant ~~PGT-M/SRPGD~~, need to provide the Council with a report within 3 months after completion of the procedure, detailing -

- (a) the nature of the genetic condition/abnormality;
- (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-M/SR analysis report by the genetic diagnostic laboratory.

7. The clinical team 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-M/SRPGD with appropriate counselling and adequate information on the other genetic testing options.

#### **Tissue Typing in Conjunction with PGT-M/SRPGD**

9. In addition to using PGT-M/SRPGD for genetic ~~diagnosis-testing~~ to avoid serious genetic diseases, PGT-M/SRPGD 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/SRPGD 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/SRPGD 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.

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**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 <sup>51</sup>-

- (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~~ Patients 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 will not 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.

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<sup>51</sup> 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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**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

**A. INTRODUCTION**

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. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.
3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
4. 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."
5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.
6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.
7. 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.

8. In medical practice and in medical research, most interventions involve risks and burdens.
9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.
10. Physicians should 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.

**B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH**

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.
12. 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.
13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.
14. 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 provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.
15. The research protocol must be submitted for consideration, comment, guidance and approval to a 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 change to the protocol may be made without consideration and approval by the committee.
16. Medical research involving human subjects must be conducted only by

individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. 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.

17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.
18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.
19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.
20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.
21. 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.
22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.
23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.
24. In medical research involving competent human subjects, 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, 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.

25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.
26. 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.
27. For a potential research subject who is incompetent, 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 competent persons, and the research entails only minimal risk and minimal burden.
28. When a potential research subject who is deemed incompetent 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.
29. 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 population. 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.
30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors 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. They 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.

**C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE**

31. The physician may combine medical research with medical care 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.
32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
  - The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
  - Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.
33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.
34. The physician must fully inform the patient which aspects of the 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 interfere with the patient-physician relationship.
35. In the treatment of a patient, where proven interventions do not exist or 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. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

22.10.2008

**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.

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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.



**Sex-linked Genetic Diseases** <sup>52</sup>

- 
1. Addison's disease with cerebral sclerosis
  2. Adrenoleucodystrophy
  3. Adrenal hypoplasia
  4. Agammaglobulinaemia, Bruton type
  5. Agammaglobulinaemia, Swiss type
  6. Albinism, ocular
  7. Albinism-deafness syndrome
  8. Aldrich syndrome
  9. Alport syndrome
  10. Amelogenesis imperfecta, hypomaturation type
  11. Amelogenesis imperfecta, hypoplastic type
  12. Anaemia, hereditary hypochromic
  13. Angiokeratoma (Fabry's disease)
  14. Cataract, congenital
  15. Cerebellar ataxia
  16. Cerebral sclerosis, diffuse
  17. Charcot-Marie-Tooth peroneal muscular atrophy
  18. Choroideraemia
  19. Choroidoretinal degeneration
  20. Coffin-Lowry syndrome
  21. Colour blindness, Deutan type
  22. Colour blindness, Protan type
  23. Diabetes insipidus, nephrogenic
  24. Diabetes insipidus, neurohypophyseal
  25. Dyskeratosis congenita
  26. Ectodermal dysplasia, anhidrotic
  27. Ehlers-Danlos syndrome, type V
  28. Faciogenital dysplasia, (Aarskog syndrome)
  29. Focal dermal hypoplasia (x-linked dominant, male lethal)
  30. Glucose 6-phosphate dehydrogenase deficiency
  31. Glycogen storage disease, type VIII
  32. Gonadal dysgenesis (XY female type)
  33. Granulomatous disease (chronic)
  34. Haemophilia A
  35. Haemophilia B
  36. Hydrocephalus (aqueduct stenosis)
  37. Hypophosphataemic rickets
  38. Ichthyosis (~~steriod~~steroid sulphatase deficiency)
  39. Incontinentia pigmenti (x-linked dominant, male lethal)
  40. Kallmann syndrome
  41. Keratosis follicularis spinulosa
  42. Lesch-Nyhan syndrome (hypoxanthine-guanine-phosphoribosyl transferase deficiency)
  43. Lowe (oculocerebrorenal) syndrome
  44. Macular dystrophy of the retina
  45. Menkes syndrome
  46. Mental retardation, FMRI type
  47. Mental retardation, FRAXE type
  48. Mental retardation, MRXI type
  49. Microphthalmia with multiple anomalies (Lenz syndrome)
  50. Mucopolysaccharidosis II (Hunter syndrome)
  51. Muscular dystrophy, Becker type
  52. Muscular dystrophy, Duchenne type
  53. Muscular dystrophy, Emery-Dreifuss type
  54. Myotubular myopathy
  55. Night blindness, congenital stationary
  56. Norrie's disease (pseudoglioma)
  57. Nystagmus, oculomotor or 'jerky'
  58. Ornithine transcarbamylase deficiency (type I hyperammonaemia)
  59. Orofaciodigital syndrome (type I, x-linked dominant, male lethal)
  60. Perceptive deafness, with ataxia and loss of vision
  61. Perceptive deafness, DNFZ type
  62. Phosphoglycerate kinase deficiency
  63. Phosphoribosylpyrophosphate (PRPP) synthetase deficiency
  64. Reifenstein syndrome
  65. Retinitis pigmentosa
  66. Retinoschisis
  67. Spastic paraplegia
  68. Spinal muscular atrophy
  69. Spondyloepiphyseal dysplasia tarda
  70. Testicular feminization syndrome
  71. Thrombocytopenia, hereditary
  72. Thyroxine-binding globulin, absence or variants of
  73. Xg blood group system
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<sup>52</sup> 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 –

- (a) First name and surname of the bride and groom;
- (b) Date of marriage;
- (c) Name and location of the registration office of the marriage; and
- (d) 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.

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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 ~~diagnosis testing~~ (PGDPGT)
- (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 contain<sup>53</sup>-
  - (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 Food and 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 the

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<sup>53</sup> s.33(2) of the Ordinance

information contained in Register A shows that<sup>54</sup> -

- (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.

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<sup>54</sup> 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 RT-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 RT-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 arrangement (PGT-M/SR) ~~diagnosis (PGD)~~ 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 RT-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 RT-centre as it may require is obligatory. If the client fails or refuses to supply the data, the licensed RT 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 RT-centre, including access thereto and correction thereof, should be provided to the parties providing the data.

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**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 1<sup>st</sup> August 2007.<sup>1</sup> It will be reviewed and updated as necessary to keep up with developments in RT.<sup>2</sup> 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.<sup>3</sup>

#### **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.

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<sup>1</sup> s.8(6) of the Human Reproductive Technology Ordinance (the Ordinance)

<sup>2</sup> s.8(3) of the Ordinance

<sup>3</sup> 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.<sup>4</sup>

### 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.<sup>5</sup>

3.3 It shall be the duty of the person responsible to ensure that -<sup>6</sup>

- (a) the other persons to whom the licence applies<sup>7</sup> 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 reproductive technology 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

<sup>4</sup> s.13 of the Ordinance

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

<sup>6</sup> s.24(1) of the Ordinance

<sup>7</sup> 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.<sup>8</sup>

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.<sup>9</sup>

#### 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 ~~RT-licensed~~ centres<sup>10</sup> 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

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

<sup>9</sup> s.23(3) and s.24(2) of the Ordinance

<sup>10</sup> ~~Licensed RT~~ 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.<sup>11</sup> Hormonal assay facilities should be available if needed.

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

- (a) ultrasound equipment, which should be readily available in the licensed RT-centre for monitoring ovarian stimulation; and
- (b) sperm washing facilities, which should be readily available either at the licensed RT-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 RT-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 marriage<sup>12</sup>.

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.

#### **VI. Information to Clients**

6.1 Licensed RT-centres should devise a mechanism to ensure that relevant information is given to persons seeking AIH treatment. Licensed RT-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;

<sup>11</sup> s.24(1)(b) of the Ordinance

<sup>12</sup> 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).

- (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 RT-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 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 **RT-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 RT** centre and is transferred to another **licensed RT** centre where AIH is to be performed, the guidelines as contained in **Appendix IV** regarding the local transfer of stored gametes between **licensed RT** 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 RT-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 RT-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.<sup>13</sup>

### Keeping of Record

11.2 Licensed RT-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 RT-centres are listed at **Appendix IX**.

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

### Submission of Information to Council

11.4 Licensed RT-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

<sup>13</sup> s.34, s.35 and s.36 of the 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 RT~~ 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 RT~~ centres should ensure that clients understand and consent to such disclosures.

11.8 If a ~~licensed RT~~ 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 ~~RT~~Licensed Centres

12.1 ~~Licensed RT~~ 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 RT~~ 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.<sup>14</sup> Failure to co-operate with the Investigation Committee will be taken into account by the Council in assessing whether

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<sup>14</sup> Schedule 1 s.6(c) of the Ordinance

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.

**DRAFT**

Consent Form (1) (Revised in ~~2012~~2023)

**Consent to Freezing and Storage of Gametes**  
**(for own subsequent use)**

1. I \_\_\_\_\_  
(Surname, Given Names) (ID No.)  
(Single/Married\*) of \_\_\_\_\_  
\_\_\_\_\_ (address) DO HEREBY  
AUTHORISE \_\_\_\_\_ (name of the  
reproductive technology 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  
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 an initial period of 2 years from  
the date of freezing of the sperm/eggs(oocytes)\* and that, subject to para. 5 below, 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 current period of storage\* *(please delete this clause if the  
storage period indicated in para. 5 below is shorter than 2 years).*
4. I consent that in the absence of a written notice of extension, the Centre may handle my  
sperm/eggs(oocytes)\* in accordance with my instructions set out in para. 5 below.
5. I understand that, subject to the giving of proper notice(s) of extension as mentioned in  
para. 3 above, my sperm/eggs(oocytes)\* will be frozen and stored for (complete either (a)  
or (b)) –
- (a)\* a maximum of \_\_\_\_\_ years <sup>Note1</sup> from the date of freezing of the sperm/eggs  
(oocytes)\* ; or
- (b)\* until I am \_\_\_\_\_ years old <sup>Note2</sup>, i.e. up to \_\_\_\_\_,  
(dd/mm/yy)
- and upon expiry of the maximum storage period specified above, or upon my death,  
whichever occurs sooner, 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 reproductive technology centre;
  - (b) exported to an overseas centre; or
  - (c) handled 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 handle 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.
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)\* do not produce a higher incidence of carrying abnormal children as compared with a normal pregnancy. Any child conceived or born from the use of such sperm/eggs(oocytes)\* may however suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary or other reasons;
  - (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 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 \_\_\_\_\_  
(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.

- Notes: (1) A maximum storage period for sperm/eggs(oocytes) of up to 10 years may be specified by the patient for own treatment.
- (2) The maximum storage period for sperm/eggs(oocytes) stored for medical reasons is 10 years, or until the patient reaches the age of 55, whichever is the later.

DRAFT



**Consent to Freezing and Storage of Embryos**  
**(for married couples' own use)**

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 reproductive technology 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 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 from the date of freezing of the embryos and that, subject to para. 6 below, 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 current period of storage\* (*please delete this clause if the storage period indicated in para. 6 below is shorter than 2 years*).
5. We consent that in the absence of a written notice of extension, the Centre may handle our embryos in accordance with our instructions set out in para. 6 below.
6. We understand that, subject to the giving of proper notice(s) of extension as mentioned in para. 4 above, our embryos will be frozen and stored for a maximum of \_\_\_\_\_ years<sup>Note</sup> from the date of freezing of the embryos and, upon expiry of the maximum storage period specified above, 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, 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 reproductive technology centre;
  - (b) exported to an overseas centre; or
  - (c) handled 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 handle the stored embryos in accordance with our instructions as set out in para. 6 above.
9. We understand that we are required to inform the Centre of any change of our address 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 do not produce a higher incidence of carrying abnormal children as compared with a normal pregnancy. Any child conceived or born from the use of such embryos may however suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary or other reasons;
  - (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 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 whenever is inapplicable

Note: A maximum period of storage for embryos of up to 10 years may be specified by the patients.

DRAFT

**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 reproductive technology centre) (hereinafter called "the Centre") with the understanding that my sperm 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 my sperm 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 my sperm 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 the 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 my donated sperm. 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 my donated sperm 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 -

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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 my sperm to be exported out of Hong Kong.

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)

Signed \_\_\_\_\_  
(Signature of Witness)

the nature & implications)

Name \_\_\_\_\_  
(in Block Letters)

Name \_\_\_\_\_  
(in Block Letters)

Position \_\_\_\_\_

Position \_\_\_\_\_

\* Delete whichever is inapplicable.

DRAFT

**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 reproductive technology centre) (hereinafter called “the Centre”), with the understanding that my eggs (oocytes) 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 my eggs (oocytes) 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 my eggs (oocytes) 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 the 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 my donated eggs (oocytes). 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 my donated egg(s) [oocyte(s)] 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 -

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

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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 my egg (oocytes) to be exported out of Hong Kong.

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 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  
reproductive technology centre) (hereinafter called "the Centre"), with the  
understanding that our embryos 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 our embryos 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 our embryos 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 the treatment.
6. We understand that under the Parent & Child Ordinance (Cap. 429), we shall not be the  
legal parents of the child(ren) born from our donated embryo(s). 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 our donated embryos 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 -

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

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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 our embryos to be exported out of Hong Kong.

Dated the \_\_\_\_\_ day of \_\_\_\_\_ (Month) \_\_\_\_\_ (Year)

Signed \_\_\_\_\_ (Husband's Signature)      Signed \_\_\_\_\_ (Wife's Signature)

Name \_\_\_\_\_ 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.

DRAFT

**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 reproductive technology 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) any child conceived or born as a result of the procedures, may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary or other reasons, similar to the situation of a normal pregnancy.
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 \_\_\_\_\_  
(Signature of Attending Doctor)

Signed \_\_\_\_\_  
(Signature of Witness)

Name \_\_\_\_\_  
(in Block Letters)

Name \_\_\_\_\_  
(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 ~~2012~~2023)

**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 reproductive technology  
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;  
 pronuclear stage tubal 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.<sup>Note</sup> 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 have been explained to me by \_\_\_\_\_

Consent Form (7) (Revised in ~~2012~~2023)

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) any child conceived or born as a result of the procedures, may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary or other reasons, similar to the situation of a normal pregnancy.
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) (in Chinese)

Signed \_\_\_\_\_  
(Signature of Attending Doctor)

Signed \_\_\_\_\_  
(Signature of Witness)

Name \_\_\_\_\_  
(in Block Letters)

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 handled 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.

DRAFT

**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 my sperm 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 the donation.
3. I understand that my sperm will be stored for a maximum period of 2 years from the date of freezing the sperm. 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 the sperm obtained from me 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 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 my sperm 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 handled in accordance with the Recipients' instructions, as set out in para. 12 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 my donated sperm. 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 -

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

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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 my sperm to be exported out of Hong Kong.

Dated the \_\_\_\_\_ day of \_\_\_\_\_  
(Month) (Year)

Signed \_\_\_\_\_  
(Donor's Signature)

Name \_\_\_\_\_  
(in Block Letters) (in Chinese)

Date of Birth \_\_\_\_\_  
(dd/mm/yy)

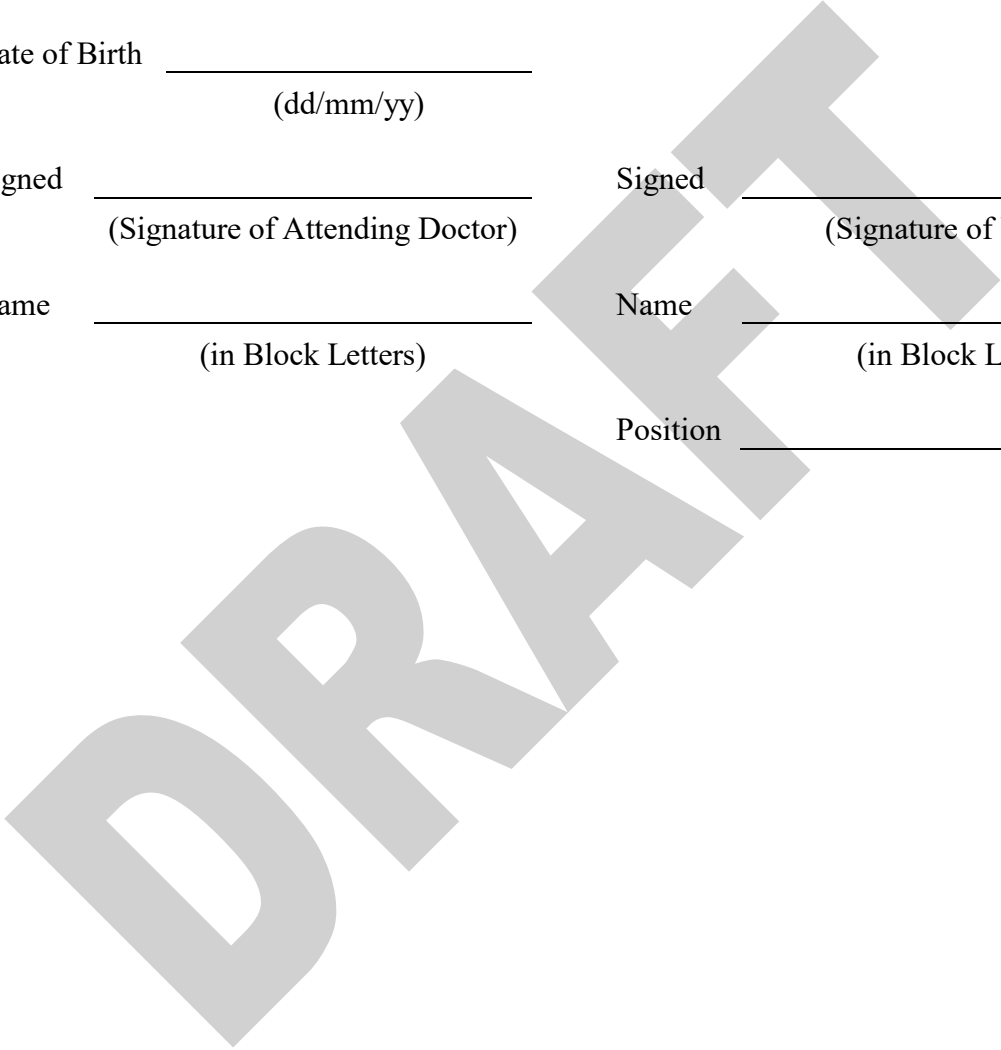
Signed \_\_\_\_\_  
(Signature of Attending Doctor)

Signed \_\_\_\_\_  
(Signature of Witness)

Name \_\_\_\_\_  
(in Block Letters)

Name \_\_\_\_\_  
(in Block Letters)

Position \_\_\_\_\_





Part II RECIPIENTS' CONSENT

~~9~~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.

~~10~~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.

~~11~~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) any child conceived or born as a result of the procedures may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary or other reasons, similar to the situation of a normal pregnancy.

~~12~~13.# We understand that the embryo(s) produced from the fertilization of the gametes of

\_\_\_\_\_  
*(please specify names of persons who are the origins of the gametes)*

will be used for the aforesaid infertility treatment and stored for such purpose for a maximum period of 2 years from the date of freezing the embryos, 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<sup>Note</sup>, including the event of the designated donation, if successful (failing which the Centre may dispose of the embryo(s) in accordance with the Guidelines).

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

~~13~~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.

1415. 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.

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**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.) (husband's name), and  
\_\_\_\_\_  
(Surname, Given Names) (ID No.) (wife's name), with  
the understanding that my eggs (oocytes) 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 the donation.
4. I understand that my eggs (oocytes) will be stored for a maximum period of 2 years from the date of freezing the eggs (oocytes). 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 eggs (oocytes) obtained from me 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 eggs (oocytes) 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 my egg(s) [oocyte(s)] 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 handled in accordance with the Recipients' instructions, as set out in para. 13 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 my donated egg(s) [oocyte(s)]. 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 my eggs (oocytes) to be exported out of Hong Kong.

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~~11. 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 eggs (oocytes) donated by \_\_\_\_\_  
(Surname, Given Names)  
\_\_\_\_\_ (the Donor) for infertility treatment.  
(ID No.)

~~11~~12. 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~~13. 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) any child conceived or born as a result of the procedures may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary or other reasons, similar to the situation of a normal pregnancy.

~~13~~14.# We understand that the embryo(s) produced from the fertilization of the gametes of \_\_\_\_\_ will be used for  
*(please specify names of persons who are the origins of the gametes)*

the aforesaid infertility treatment and stored for such purpose for a maximum period of 2 years from the date of freezing the embryos, 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<sup>Note</sup>, including the event of the designated donation, if successful (failing

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

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

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

~~14~~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.

~~15~~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 \_\_\_\_\_

Signed \_\_\_\_\_



(Signature of Attending Doctor)

(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.

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**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 our embryos 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 the  
donation.
3. We understand that our embryo(s) will be stored for a maximum period of 2 years from the  
date of freezing the embryo(s). 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 the embryo(s) obtained from 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  
our embryos 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 our donated embryo(s). 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 our embryos to be exported out of Hong Kong.

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 \_\_\_\_\_

DRAFT

PART II RECIPIENTS' CONSENT

~~89~~. 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  
receive the embryo(s) donated by the Donors,  
(husband's name),  
\_\_\_\_\_  
(Surname, Given Names) (ID No.)  
and \_\_\_\_\_ (wife's name),  
(Surname, Given Names) (ID No.)  
for infertility treatment.

~~910~~. 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 treatment.

~~1011~~. 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) any child conceived or born as a result of the procedures may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary or other reasons, similar to the situation of a normal pregnancy.

~~1112~~. We understand that the embryo(s) donated to us will be stored for a maximum period of 2 years from the date of freezing of the embryo(s). If the aforesaid infertility 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) donated to us may be handled in accordance with the donors' instructions, as set out in para. 3 hereof.

~~1213~~. 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.

~~1314~~. 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).

DRAFT

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 to Disposal of Stored Embryos**

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 dispose of the stored embryos produced with our  
gametes for which a consent form on embryo storage was previously signed by us on  
\_\_\_\_\_  
(dd/mm/yy)

2. We acknowledge that the nature and the implications of the disposal 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  
disposal.

(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).

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

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 \_\_\_\_\_  
(in Block Letters)

Name \_\_\_\_\_  
(in Block Letters)

Position \_\_\_\_\_

DRAFT

**Consent to Surrogacy Arrangement**

**PART I COMMISSIONING COUPLE’S CONSENT**

1. We (hereinafter called “the Commissioning Couple”) \_\_\_\_\_ (husband’s name),  
(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) any child conceived or born as a result of the procedures, may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary or other reasons, similar to the situation of a normal pregnancy.

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 \_\_\_\_\_ 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 \_\_\_\_\_

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),  
and \_\_\_\_\_ (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;
- pronuclear stage tubal 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/pronuclear stage tubal transfer or other reproductive technology procedures; and
- (d) any child conceived or born as a result of the procedures, may suffer from defect(s) of health or mental or physical impairment(s) as a result of congenital, hereditary or other reasons, similar to the situation of a normal pregnancy.

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 \_\_\_\_\_ Signed \_\_\_\_\_

(Signature of Attending Doctor)

(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.

DRAFT



**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
  - ( ) sperm treatment with pronuclear stage tubal transfer
  - ( ) in-vitro fertilization
  - ( ) preimplantation genetic diagnosis 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) any child conceived or born as a result of the procedures may suffer from defect(s) of  
health or any mental or physical impairment(s) as a result of congenital, hereditary or  
other reasons similar to the situation of a normal pregnancy; 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 \_\_\_\_\_  
(Signature of Attending Doctor)

Signed \_\_\_\_\_  
(Signature of Witness)

Name \_\_\_\_\_  
(in Block Letters)

Name \_\_\_\_\_  
(in Block Letters)

Position \_\_\_\_\_

\* Delete whichever is inapplicable.

DRAFT

**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 <sup>Note</sup>.
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) any child conceived or born as a result of the procedure, may suffer from defect(s) of  
health or mental or physical impairment(s) as a result of congenital, hereditary or  
other reasons, similar to the situation of a normal pregnancy.
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)

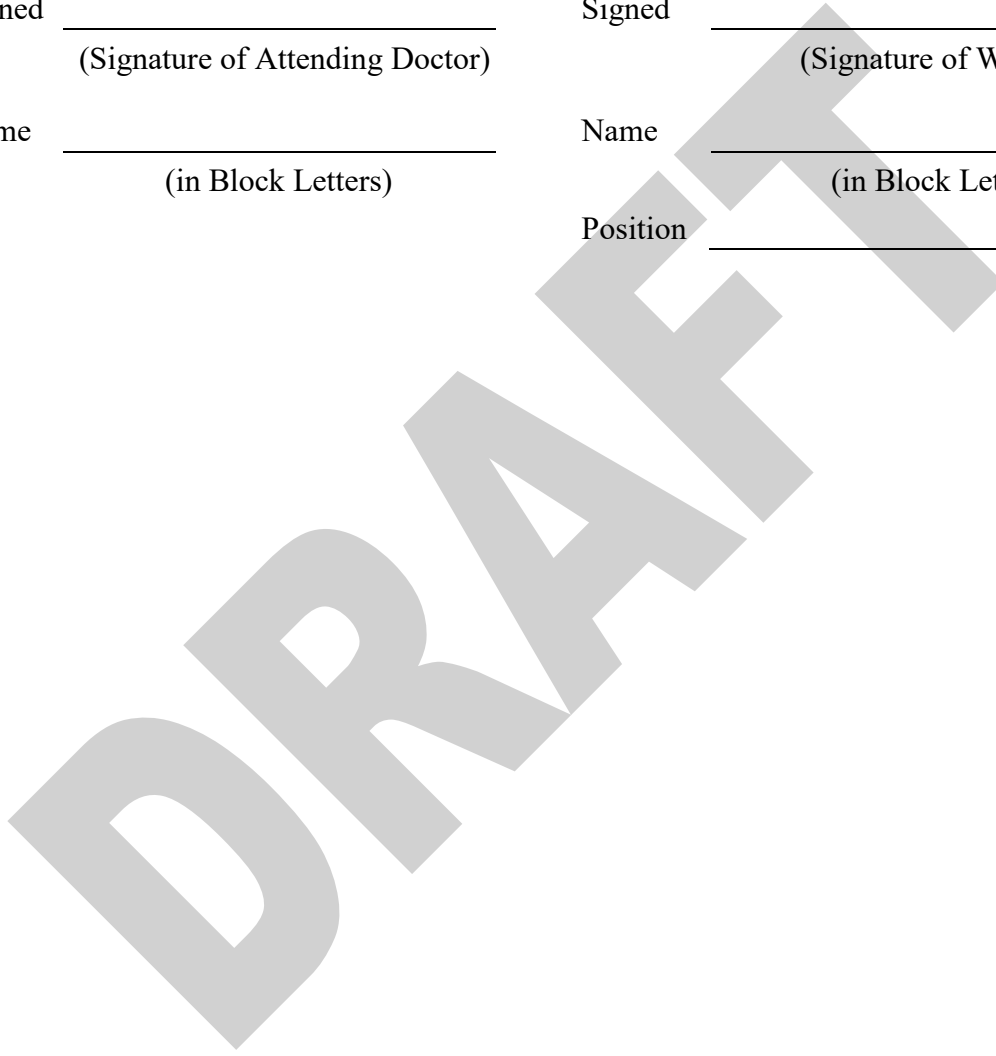
Signed \_\_\_\_\_  
(Signature of Attending Doctor)

Name \_\_\_\_\_  
(in Block Letters)

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.

DRAFT

# 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;

- (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)*

2012

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\* or the one who explained the nature & implications of the RT procedure / donation\*) (Signature of Witness)

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 \_\_\_\_\_  
(Donor's Signature)

# OBSOLETE

Name \_\_\_\_\_  
(in Block Letters)

\_\_\_\_\_  
(in Chinese)

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

Signed \_\_\_\_\_  
(Signature of Witness)

# IN

Name \_\_\_\_\_  
(in Block Letters)

Name \_\_\_\_\_  
(in Block Letters)

Position \_\_\_\_\_

Note: \* Delete whichever is inapplicable.

# 2012

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

# OBSOLETE

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 Form (18) (20122023)

**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 I WIFE'S CONSENT (to be signed in the presence of the attending doctor and witness)

1. I \_\_\_\_\_, of  
(Surname, Given Names) (ID No.)  
\_\_\_\_\_ (address),  
being lawfully married to \_\_\_\_\_,  
(Surname, Given Names of the husband) (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 I am about to receive.

2. 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 \_\_\_\_\_  
(Wife's Signature)

Name \_\_\_\_\_  
(Name of Wife in Block Letters) (Name of Wife in Chinese)

Signed \_\_\_\_\_  
(Signature of Attending Doctor)

Signed \_\_\_\_\_  
(Signature of Witness)

Name \_\_\_\_\_

Name \_\_\_\_\_

(Name of Attending Doctor in  
Block Letters)

(Name of Witness in Block  
Letters)

Position  
of  
Witness \_\_\_\_\_

DRAFT



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

23. 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. \_\_\_\_\_

**REPRODUCTIVE TECHNOLOGY TREATMENT FORM**

**(For treatment NOT involving donor gametes/embryos)** <sup>Note 1</sup>

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 <sup>Note 2</sup>: .....
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 <sup>st</sup> /2 <sup>nd</sup> /3 <sup>rd</sup> 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 <sup>Note 3</sup>				
	Cycle abandonment <sup>Note 3</sup>				
(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 <sup>Note 4</sup>				
	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 <sup>Note 5</sup>				
	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 <sup>Note 6</sup>				
	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".

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**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 : ..... 8. \*HKID Card / Passport / Other Entry Permit Number Note 3:  
Day Month Year .....

9. FULL NAME of husband : .....  
(Surname first)

10. Date of birth : ..... 11. \*HKID Card / Passport / Other Entry Permit Number Note 3:  
Day Month Year .....

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 <sup>st</sup> /2 <sup>nd</sup> /3 <sup>rd</sup> cycle for this couple)
18. Type of treatment :	IVF <input type="checkbox"/> ICSI with IVF <input type="checkbox"/> ICSI with MIFT <input type="checkbox"/> ICSI with PROST <input type="checkbox"/> Other Micromanipulation (please specify) ..... Frozen-thawed ET <input type="checkbox"/> Others (please specify) .....
19. Ovarian stimulation :	Yes <input type="checkbox"/> No <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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 <sup>Note 4</sup> or *Date when cycle was abandoned <sup>Note 4</sup> :	..... 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 <sup>Note 5</sup> ..... Number donated for quality control/training .....
26. Outcome of treatment :	No pregnancy <input type="checkbox"/> Miscarriage <input type="checkbox"/> Ectopic pregnancy <input type="checkbox"/> Heterotopic pregnancy <sup>Note 6</sup> <input type="checkbox"/> Pregnancy terminated <input type="checkbox"/> Ongoing pregnancy <input type="checkbox"/> Hydatidiform mole <input type="checkbox"/> Lost to follow up <input type="checkbox"/>
27. No. of embryos/fetuses involved in the pregnancy:	.....
28. Embryonic/fetal reduction	Embryonic/fetal reduction carried out: Yes <input type="checkbox"/> No <input type="checkbox"/> 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”.

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**DC Form 3**

**DONOR INSEMINATION TREATMENT FORM** <sup>Note 1</sup>

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 <sup>Note 2</sup>: .....
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 <sup>Note 3</sup>: .....  
 Day Month Year

9. FULL NAME of husband : .....  
 (Surname first)

10. Date of birth : ..... 11. \*HKID Card / Passport / Other Entry Permit Number <sup>Note 3</sup>: .....  
 Day Month Year

12. Reasons for treatment :
- |   |     |                          |    |                          |
|---|-----|--------------------------|----|--------------------------|
| Obstructive azoospermia   | YES | <input type="checkbox"/> | NO | <input type="checkbox"/> |
| Nonobstructive azoospermia  | YES | <input type="checkbox"/> | NO | <input type="checkbox"/> |
| Severe deficits in semen quality in couples who do not wish to undergo intracytoplasmic sperm injection | YES | <input type="checkbox"/> | NO | <input type="checkbox"/> |
| Genetic   | YES | <input type="checkbox"/> | NO | <input type="checkbox"/> |
| Infectious disease in the male partner (such as HIV)  | YES | <input type="checkbox"/> | NO | <input type="checkbox"/> |
| Severe rhesus isoimmunisation   | YES | <input type="checkbox"/> | NO | <input type="checkbox"/> |
| Others (please specify) .....   |     |                          |    |                          |

- |  |       |
|--|-------|
| 13. Donor's clinic record number :                               | ..... |
| 14. Donor centre licence number if different from item 2 above : | ..... |

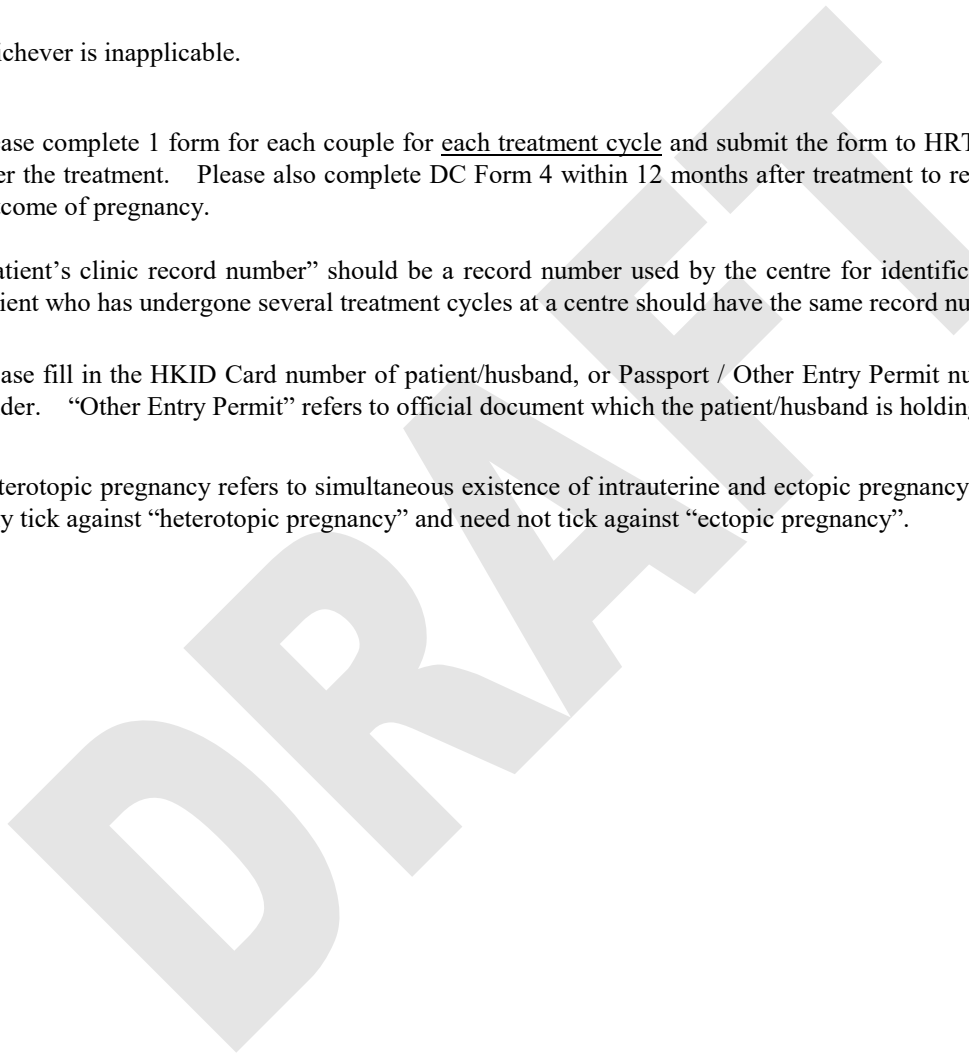
15. The donation is \*anonymous/designated. (If the donation is designated, please refer to para. 14.9 of the Code of Practice on Reproductive Technology and Embryo Research and report the case with detailed information including detailed justifications to the HRT Council within 3 months after the treatment.)

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

17. Ovarian stimulation :	Yes <input type="checkbox"/>	No <input type="checkbox"/>		
18. Outcome of treatment :	No pregnancy	<input type="checkbox"/>	Miscarriage	<input type="checkbox"/>
	Ectopic pregnancy	<input type="checkbox"/>	Heterotopic pregnancy <sup>Note 4</sup>	<input type="checkbox"/>
	Pregnancy terminated	<input type="checkbox"/>	Ongoing pregnancy	<input type="checkbox"/>
	Hydatidiform mole	<input type="checkbox"/>	Lost to follow up	<input type="checkbox"/>
19. No. of embryos/fetuses involved in the pregnancy :	.....			
20. Embryonic/fetal reduction :	Embryonic/fetal reduction carried out: Yes <input type="checkbox"/>		No <input type="checkbox"/>	
	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".





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**DC Form 4**

**PREGNANCY OUTCOME FORM** <sup>Note 1</sup>

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

Please complete the form in block letters

- Name of centre : .....
  - Licence number : ..... 3. Patient's clinic record number <sup>Note 2</sup>: .....
  - 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ectopic pregnancy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
pregnancy terminated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
reason for termination	.....	.....	.....	.....	.....
hydatidiform mole	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
embryo reduction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
still birth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
live birth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
neonatal death	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
lost to follow up	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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 <input type="checkbox"/> F <input type="checkbox"/>	M <input type="checkbox"/> F <input type="checkbox"/>	M <input type="checkbox"/> F <input type="checkbox"/>	M <input type="checkbox"/> F <input type="checkbox"/>	M <input type="checkbox"/> F <input type="checkbox"/>
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.

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**DC Form 5**

**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<sup>Note 1</sup> : .....

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<sup>Note 2</sup>, 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<sup>Note 1</sup> : .....

Relationship with donor: .....

FULL NAME of husband : .....

\*HKID Card / Passport / Other Entry Permit Number<sup>Note 1</sup> : .....

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 <sup>Note 1</sup>:  
Day Month Year

8. FULL NAME of male donor : .....  
(Surname first)
9. Date of birth : ..... 10. \*HKID Card / Passport / Other Entry Permit Number <sup>Note 1</sup>:  
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 <sup>Note 2</sup>, 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 <sup>Note 1</sup>: .....

Relationship with donor: .....

FULL NAME of husband : .....

\*HKID Card / Passport / Other Entry Permit Number <sup>Note 1</sup>: .....

Relationship with donor: .....

**CONFIDENTIAL****DC Form 6(2)****Particulars of female donor :**

14. Height (cm) : .....	15. Weight (kgs) : .....
16. Ethnic group : Chinese <input type="checkbox"/>	Other, describe .....
17. Eye Colour : Brown <input type="checkbox"/>	Other, describe .....
18. Hair Colour : Black <input type="checkbox"/>	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 <input type="checkbox"/>	Other, describe .....
24. Eye Colour : Brown	Other, describe .....
25. Hair Colour : Black <input type="checkbox"/>	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 <small>Note 3</small> (please tick in the appropriate box)				
	Intravaginal (IVI)				
	Intracervical (ICI)				
	Intrauterine (IUI)				
(iii)	Treatment cycle (i.e. 1 <sup>st</sup> /2 <sup>nd</sup> /3 <sup>rd</sup> 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 <small>Note 4</small>				
	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".

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**DC Form 8**

**REPORTING FORM ON THE  
DISPOSAL OF EXCESS EMBRYOS AFTER  
END OF REPRODUCTIVE TECHNOLOGY TREATMENT**

<p><i>For Official Use</i> No. Form received on ____/____/____ Day Month Year</p>
---

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 <sup>Note</sup> : .....

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:	<p>Total number of excess embryos stored at the end of RT treatment: - .....</p> <p><u>Manner of disposal of excess embryos</u></p> <p>Number donated for treatment of others : .....</p> <p>Number donated for research : .....</p> <p>Number donated for quality control or training: .....</p> <p>Number discarded : .....</p>
--	---

\* 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.



**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 8 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
- 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 1-8) 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.

### **~~Spontaneous abortion (miscarriage)~~ Miscarriage**

Loss of ~~an intrauterine pregnancy embryos or foetuses~~ detected clinically or by ultrasound, ~~and less than 20 before 24~~ weeks' gestation (as estimated with reference to by the day of embryo transfer or day of ovulation-).

### **Stillbirth**

~~The birth of an infant after 24 or more weeks of gestation that shows no signs of life~~  
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**

**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  
     to

**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
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)

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**Annual Statistics on Reproductive Technology Treatment  
for Submission to the Council on Human Reproductive Technology**

*Please complete the form in block letter*

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

Period covered : Day Month Year to Day Month Year  
     to

**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.)	( _____ %)	( _____ %)
Ectopic preg. (/clinical preg.)	( _____ %)	( _____ %)
Heterotopic preg. (/clinical preg.)	( _____ %)	( _____ %)
Termination (/clinical preg.)	( _____ %)	( _____ %)
Still birth (/clinical preg.)	( _____ %)	( _____ %)
Neonatal death (/clinical preg.)	( _____ %)	( _____ %)
Lost to follow up (/clinical preg.)	( _____ %)	( _____ %)
Multiple preg. (/clinical preg.)	( _____ %)	( _____ %)
Embryo reduction (/clinical preg.)	( _____ %)	( _____ %)
Malformation (/newborn)	( _____ %)	( _____ %)
No. of delivered or ongoing preg. (/clinical preg.)	( _____ %)	( _____ %)
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                      Day    Month    Year  
                                           to   

**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 (/clinical preg.)	(                      cases %)	(                      cases %)	(                      cases %)
Ectopic preg. (/clinical preg.)	(                      cases %)	(                      cases %)	(                      cases %)
Heterotopic preg. (/clinical preg.)	(                      cases %)	(                      cases %)	(                      cases %)
Termination (/clinical preg.)	(                      cases %)	(                      cases %)	(                      cases %)
Still birth (/clinical preg.)	(                      cases %)	(                      cases %)	(                      cases %)
Neonatal death (/clinical preg.)	(                      cases %)	(                      cases %)	(                      cases %)
Lost to follow up (/clinical preg.)	(                      cases %)	(                      cases %)	(                      cases %)
Multiple preg. (/clinical preg.)	(                      cases %)	(                      cases %)	(                      cases %)
Embryo reduction (/clinical preg.)	(                      cases %)	(                      cases %)	(                      cases %)
Malformation (/newborn)	(                      cases %)	(                      cases %)	(                      cases %)
No. of delivered or ongoing preg. (/clinical preg.)	(                      cases %)	(                      cases %)	(                      cases %)
Delivery plus ongoing pregnancy rate (/cycle started)	(                      /cycle)	(                      /cycle)	(                      /cycle)

**Annual Statistics on Reproductive Technology Treatment  
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*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 ] [ ] [ ] [ ]

**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 married and had one or more than one pregnancy	[ ] case
Age	[ ] ± [ ]		
Married	[ ] case		
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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**AS Form 5**

**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 ] [ ] [ ] [ ]

**5. Use of Reproductive Technology for Gender Selection to Avoid Sex-linked Diseases**

Patients' Characteristics			
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	[ ]

Infertility Diagnosis	Stimulation Protocol
With infertility problems [ ] cases	Natural [ ] cycles
Without infertility problems [ ] cases	Stimulated [ ] cycles
	Cycles ending up with ovarian hyperstimulation [ ] cycles

Gender Selection Methods Used			
Sperm treatment with [ ] cases	<del>PGT-M/SRPGD</del>	with sex-selective embryo transfer	[ ] cases
IVF-ET			
Sex-selective abortion [ ] cases	Others (please specify):	( )	[ ] cases

Clinical Results		
	Natural cycle	Stimulated cycle
No. of cycles	( )	( )
No. of oocyte recoveries (/cycle)	( ) %	( ) %
No. of male embryo transfer	cases	cases
No. of female embryo transfer	cases	cases
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)
No. of fetuses aborted for sex selective abortion : [total cases]	male	( )	female	( )
		[ cases]		[ cases]

**AS Form 6**

**Annual Statistics on Reproductive Technology Treatment  
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*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][ ] [ ] [ ] [ ]

**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)

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Name of centre : \_\_\_\_\_  
Licence no. : \_\_\_\_\_

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 <sup>Note 1</sup>	IVI and ICI	cases	cases
	IUI	cases	cases
No. of cycle which proceeded to IUI <sup>Note 2</sup>		cases	cases
IVI and ICI	No. of clinical pregnancies	cases	cases
	Clinical preg. rate (/cycle started)	%	%
IUI	No. of ongoing pregnancies	cases	cases
	Ongoing preg. rate (/cycle started)	%	%
Spont. abortion (/clinical preg.)	No. of clinical pregnancies	cases	cases
	Clinical preg. rate (/cycle started)	%	%
Ectopic preg. (/clinical preg.)	No. of ongoing pregnancies	cases	cases
	Ongoing preg. rate (/cycle started)	%	%
Heterotopic preg. (/clinical preg.)	No. of clinical pregnancies	cases	cases
	Clinical preg. rate (/cycle started)	%	%
Termination (/clinical preg.)	No. of ongoing pregnancies	cases	cases
	Ongoing preg. rate (/cycle started)	%	%
Still birth (/clinical preg.)	No. of clinical pregnancies	cases	cases
	Clinical preg. rate (/cycle started)	%	%
Neonatal death (/clinical preg.)	No. of ongoing pregnancies	cases	cases
	Ongoing preg. rate (/cycle started)	%	%
Lost to follow up (/clinical preg.)	No. of clinical pregnancies	cases	cases
	Clinical preg. rate (/cycle started)	%	%
Multiple preg. (/clinical preg.)	No. of ongoing pregnancies	cases	cases
	Ongoing preg. rate (/cycle started)	%	%
Embryo reduction (/clinical preg.)	No. of clinical pregnancies	cases	cases
	Clinical preg. rate (/cycle started)	%	%
Malformation (/newborn)	No. of ongoing pregnancies	cases	cases
	Ongoing preg. rate (/cycle started)	%	%

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.

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**Annual Statistics on Reproductive Technology Treatment  
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For Official Use No. Form received on ____/____/____ Day Month Year
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Name of centre : \_\_\_\_\_

Licence no. : \_\_\_\_\_

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 <small>Note 1</small>	Number of donations made	Number of embryos donated
Semen Samples			N.A.
Eggs (Oocytes)			N.A.
Embryos			

**C. Age Distribution of Donors**

Age <small>Note 2</small>	No. of Female Donors		
	Eggs (Oocytes)	Embryos <small>Note 1</small>	Total
18-20			
21-25			
26-30			
31-35			
36-40			
41-45			
46-50			
51-55			
56 or above			

Age <small>Note 2</small>	No. of Male Donors		
	Semen samples	Embryos <small>Note 1</small>	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** <sup>Note 3</sup> (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**

<u>Research project licence no.</u>	<u>No. of embryos used</u>	<u>Dates when embryos were used</u>		
		<u>Day</u>	<u>Month</u>	<u>Year</u>
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.

**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. 10.9 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.
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;
  - (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 afresh 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).

DRAFT

**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**

To be completed by Council

Date of receipt: \_\_\_\_\_

Serial no.: \_\_\_\_\_

Note:

(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.: \_\_\_\_\_

	<u>Female donor</u>	<u>Male donor</u>
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; and
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.
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 will not 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 \_\_\_\_\_ 202x

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).