Code of Practice on Reproductive Technology & Embryo Research

Council on Human Reproductive Technology
December 2002

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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, Laws of Hong Kong) (the Ordinance) in May 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 research.

1.3 The Code sets minimum standards, as described in subsequent chapters, which aim to support best clinical and scientific practice, 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 will come into effect on a date to be published by notice in Gazette.[1] The Code will be reviewed and updated as necessary to keep up with developments in RT.[2] Although the Code is not legally binding, the Council, which is the licensing authority for RT services and embryo research, shall take into account any observance of or failure to observe the provisions of the Code when considering granting, renewal, variation, revocation or suspension of licences.[3]

1.5 In the interim period before the Code comes into force, the Working Group on Code of Practice under the Council will liaise with service providers for voluntary compliance with the Code.

[1] s.8(6) of the Human Reproductive Technology Ordinance (the Ordinance)
[2] s.8(3) of the Ordinance
[3] s.9 of the Ordinance

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

1.6 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.

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

II. Staff

General

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

Person Responsible

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

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

(a) that the other persons to whom the licence applies[7] 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;

(b) that proper equipment is used;

(c) that 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) that proper practices are used in the course of that activity; and

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

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

Licensee

2.5 The "licensee", in relation to a licence, is the holder of the licence as defined in the Ordinance.[8]

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

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[4] s.13 of the Ordinance
[5] s.2(1) of the Ordinance - interpretation of the term "person responsible"
[6] s.24(1) of the Ordinance
[7] s.24(3) of the Ordinance
[8] s.2(1) of the Ordinance - interpretation of the term "licensee"
[9] s.23(3) and s.24(2) of the Ordinance

Medical Practitioners

2.7 RT procedures should be administered and/or supervised by a registered medical practitioner[10].

2.8 The overall clinical responsibility for RT procedures should be held by such registered medical practitioner 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 under the Specialist Register of the Medical Council of Hong Kong. Centres performing artificial insemination (AI) only are exempted from this requirement.

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

Nursing Staff

2.10 All nursing staff employed by RT 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.

Staff Engaged in Scientific/Laboratory Services

2.11 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.

2.12 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 procedure.

Counsellors

2.13 Counselling may be provided by doctors, nurses, social workers or clinical psychologists as appropriate. Please refer to Chapter VII for details on counselling services.

Fitness to Practise

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

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

III. Facilities and Equipment

General Standard of Clinical and Laboratory Facilities in RT centres

3.1 The person responsible must secure that proper facilities and equipment are used and maintained.[11]

3.2 Backup and emergency support facilities for each technique practised should be available at RT centres, equivalent to those which are standard practice in other specialties and appropriate to the degree of risk involved.

3.3 A laboratory manual and logbook must be properly kept and maintained and be available for inspection by persons authorised by the Council.

Minimum Requirements for RT centres offering IVF services

3.4 The minimum facilities and equipment required for RT centres offering 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 a stereomicroscope, a laminar air-flow bench, an incubator and disposable plastic vessels and glassware for cell culture.

(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 either be available at the RT centre or provided if required by another laboratory closely linked to it.

(e) Ultrasound equipment, which should be readily available in the RT centre for monitoring ovarian function and may include a probe attachment to be used for ultrasonically guided retrieval of ova through the vagina.

[11] s.24(1)(b) of the Ordinance

(f) A properly equipped operating theatre is required when general anaesthesia is used. A proper laboratory is required for oocyte collection, vacuum aspiration of the follicles, and embryo transfer. Easy access to facilities for resuscitation and emergency laparotomy must be readily available.

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

3.6 RT centres should ensure a continuous supply of electricity.

3.7 Centres performing embryo transfer should have cryopreservation facilities**.** If cryopreservation is among the activities carried out by the RT centre, the appropriate equipment, including a controlled biological freezer and properly maintained liquid nitrogen facilities, will be required. In RT centres undertaking research as well as providing services, additional and more sophisticated equipment will 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 RT centre, there should be a designated place with privacy and comfort for counselling, where discussion can take place undisturbed.

IV. Assessment of Clients, Donors and Welfare of the Children

4.1 Under the Ordinance, RT treatment should only be provided to persons who are parties to a marriage, except a RT procedure is [12] -

(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; or
(c) for obtaining gametes.

Assessment of Clients

4.2 Clients should be offered fair and unprejudiced assessment. Clients' medical condition should be fully assessed to determine the most appropriate treatment option.

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

(a) their commitment to having and bringing up a child or children;

(b) their ability to provide a stable and supportive environment for any child born as a result of treatment;

(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 inherited disorders, problems during pregnancy and of neglect or abuse;

[12] s.15(5), 15(6), 15(7) & 15(8) of the Ordinance

(g) in cases where donated gametes are used, the possible attitudes of other members of the family towards the child.

Proper Counselling

4.4 Proper counselling should be provided to the commissioning couple and concerned parties before RT treatment is provided. (also see paras. 7.5 to 7.8)

Assessment of Donors (Gametes and Embryos)

4.5 RT 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.

4.6 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.

4.7 Guidelines for screening are at **Appendix I**. Gamete or embryo donors must be tested free of HIV antibody six months after donation before their donated gametes or embryos could be considered safe for use.

4.8 As a matter of good clinical practice, RT 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.

4.9 # Female donors should be below the age of 35 and male donors should be under 55. These age limits may be exceeded in appropriate circumstances or where the gametes are to be used for their own or their spouse's treatment. 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. (see Note 1)

4.10 # 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)

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

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 as set at para. 4.9.

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.

4.12 Proper counselling should also be provided to potential donors of gametes or embryos. (also see para. 7.9)

Persons considered unsuitable as donors

4.13 If the RT centre decides that a person is unsuitable as a donor, 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.

Payment to Donors

4.14 Under the Ordinance, donors should not be paid for the supply of gametes or embryos, except for reimbursing or defraying -[13]

(a) the cost of removing, transporting or storing gametes or an embryo to be supplied; and

(b) any expenses or loss of earnings incurred by the donor.

4.15 Guideline for payment to donors is set out at **Appendix II**. RT centres shall follow the guideline strictly such that gamete donors shall not be paid more than the maximum daily payment level.

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

V. Information to Clients and Donors

General

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

Information to Clients

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

(a) explanation of the procedure,

(b) possible discomfort, side effects and complications of treatment to the woman and the resulting pregnancy including, where relevant, risk of ovarian hyperstimulation syndrome or multiple 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 centres should also advise their clients on any information disseminated by the Council on matters related to legal provisions under the Human Reproductive Technology Ordinance (Cap. 561) and the Parent and Child (Cap. 429) Ordinance such as -

(a) the legal status of the child and parents,[14]

(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 16,[15] and

(c) the legal obligation of RT centres to report information to the Council in accordance with the Human Reproductive Technology Ordinance.[16]

[14] ss.9 - 12 of the Parent and Child Ordinance
[15] s.33(3)(a), s.33(4), s.33(5) and s.33(7) of the Ordinance
[16] s.33(1) and s.33(2), s.45(2)(c) and s.45(2)(d) of the Ordinance

Information to Donors of Gametes or Embryos

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

(a) the procedures involved and the associated discomfort, pain and risks, including the risk of ovarian hyperstimulation syndrome for oocyte donors;

(b) the screening tests to be performed and the implications of having the HIV antibody test (also see para. 4.7 and **Appendix I**);

(c) purpose for which their gametes or embryos may be used;

(d) a child may be born disabled as a result of the donor's failure to disclose defects, about which he or she knows or should reasonably have known; and

(e) a donor's gametes may not be allowed to bring about more than three pregnancies to minimise risk of inadvertent incest in the offspring.

5.5 RT centres should also advise donors on any information disseminated by the Council such as -

(a) protection under the Ordinance regarding donor's anonymity and confidentiality of patients seeking infertility treatment,[17]

(b) whether or not they will be regarded as the parents of any child born as a result under the Laws of Hong Kong,[18]

(c) RT centres are required to register information on the donors with the Council under the Ordinance,[19] and

(d) reimbursement may only be given in accordance with the provision in the Ordinance[20] (please see para. 4.14, para. 4.15 and **Appendix II** for details).

[17] s.34 of the Ordinance
[18] ss.9 - 12 of the Parent and Child Ordinance
[19] s.33(1) and s.33(2), s.45(2)(c) and s.45(2)(d) of the Ordinance
[20] s.2(1) of the Ordinance - interpretation of the term "payment" and s.16(1)(a)

VI. Consent

Informed Consent

6.1 Informed consent with respect to receiving RT treatment, and to donating gametes or embryos must be obtained in writing.

6.2 RT practitioners are advised to refer to the *Professional Code and 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 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 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 donate to a pool kept by the RT centre for treating other infertile patients, or

(c) for research.

Consent to Storage of Gametes and Embryos
(this section is not applicable to anonymous donors and designated donors)

6.7 Donors 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 of Practice (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 post-humous arrangement are described in Chapter X).

6.8 Donors should be informed that they are required to give a written notice of renewal of consent to the RT centre every two years. RT centres may dispose of the stored gametes or embryos in the absence of a renewal notice.

6.9 Donors 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 Sample consent forms are at **Annex I.**

VII. Counselling

General

7.1 Counselling must be provided to all clients and donors by doctors, nurses, social workers or clinical psychologists of the RT centre as appropriate. Counselling services should be provided by someone other than the clinician responsible for the treatment or donation. Such counselling should be independent of the clinical decision-making process. In the course of therapy, counselling should be provided to address the consequences of treatment and to cope with the emotional stress and social adjustment. It should be available to service users after the baby is born if this is needed.

7.2 Non-directional counselling on the implications of the RT procedures and consideration of other options (including adoption) must be offered to clients and donors before they consent to RT procedures. Couples seeking treatment should be given adequate time to consider the issue and offered counselling again 3 to 4 weeks after the initial counselling.

7.3 Information obtained during counselling must be kept in confidence.

7.4 Proper records should be kept of the counselling service offered.

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 treatment (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 treatment may change as personal circumstance changes;

(h) all the terms and conditions set out in the consent form;

(i) their consent is needed so that information on their particulars will be submitted to the register kept by the Council in accordance with the Ordinance.[21] The resulting children may apply to the Council when they reach the age of 16 to check whether they were born in consequence of RT involving donated gametes or donated embryos although no identifying information about the donor would be released.[22]

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 be advised to consider -

(a) their own feelings about not being the genetic parent of the child;

(b) their spouse's feelings about not being the genetic parent of the child;

(c) the desirability of revealing the history of gamete/embryo donation to their future child and the possible reaction of the child;

(d) the desirability of informing their future child of the right to check information in Register A before marriage (see para. 7.5(i) above) to avoid incest; and

(e) the importance of reporting to the RT centres any successful births so that donated gametes or embryos will not be used to bring about more than three pregnancies to avoid the possibility of incest (also see para. 9.5).

[21] s.33(1) and s.33(2), s.45(2)(c) and s.45(2)(d) of the Ordinance
[22] s.33(3) and s.33(5) of the Ordinance

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 treatment or those whose treatment has failed to allow them to adjust their expectation and to accept the situation.

7.8 When indicated by the clients, they 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) their perception of the needs of any resulting children;

(f) the feelings of their spouse or sex partner;

(g) their attitudes to allowing embryos which have been produced from their gametes to be used for research;

(h) their consent is needed so that information on their particulars will be submitted to the Register kept by the Council in accordance with the Ordinance.[23] The resulting children may apply to the Council when they reach the age of 16 to check whether they were born in consequence of RT involving donated gametes or donated embryos although no identifying information about the donor would be released.[24]

[23] s.33(1) and s.33(2), s.45(2)(c) and s.45(2)(d) of the Ordinance
[24] s.33(3) and s.33(5) of the Ordinance

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.

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 in-vitro fertilisation (IVF) techniques, no more than three embryos should be replaced at a time. For Gamete Intra-Fallopian Transfer (GIFT), the number of oocytes replaced should not normally be more than three. However, as the fertilisation/implantation rate is dependent on a woman's age and her medical condition, under special circumstances with medical justification, the limit of three oocytes or embryos may be relaxed for women above the age of 34 so that a maximum of four or five oocytes/embryos could be replaced in the first and subsequent treatment cycles respectively. Such justifications must be recorded in the medical record. The Council will request additional information from clinics reporting high rates of multiple pregnancies.

8.8 If a pregnancy involving more than three 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.

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 RT centre.

Screening and Selection of Gametes or Embryos

9.2 Only banked 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 banked 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.

Importation of Gametes or Embryos[25]

9.4 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 Form) 5 and 6 of **Annex II** has to be submitted to the Council (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;

(f) The supplier and RT practitioner concerned ensure that the

[25] s.45(2)(g) of the Ordinance

safety and quality of the gametes or embryos are protected during the transport process -

- A reputable courier should be employed.
- The container must be securely sealed to avoid contamination and prevent tampering.
- Suitable cold storage to preserve the gametes or embryos should be ensured.
- A specified person should be assigned to collect the gametes or embryos upon arrival.

Limitation on the number of times donated gametes or embryos may be used

9.5 Gametes or embryos from any single donor should not be used to produce more than three **"**successful pregnancies". The person responsible must try his/her best to ensure that this is observed through close liaison with the recipient couple(s) and by reporting each successful pregnancy and birth resulting from donor gametes or embryos to the Council.

9.6 RT centres are required to inform the Council within one week of the date when a donor's gametes are used (data collection forms (DC Form) 5 and 6 at **Annex II** are relevant). If it is reported that a donor's gametes have been used for treatment for 3 times, centres will be informed to freeze using the gametes of this particular donor for any further treatment. A successful pregnancy or live birth will be assumed after use of a donor's gametes for treatment has been reported unless the Council is informed otherwise.

9.7 In the case of imported gametes or embryos, even if the exporting country allows a higher limit on the number of pregnancies, the local limit of three pregnancies must be observed.[26]

9.8 If the donor has specified a limit lower than three pregnancies, this must be observed if practicable.

Limitation on the number and source of eggs or embryos that may be placed in a woman

9.9 Normally, no more than three oocytes or embryos should be placed in a woman in any one cycle. As the fertilisation or implantation rate is dependent on a woman's age and her medical condition, under special circumstances with medical justifications, the limit of three oocytes or embryos may be relaxed for patients above the age of 34 so that a maximum of four or five oocytes or embryos could be replaced in the first and subsequent treatment cycles respectively. Such justifications must be

[26] s.45(2)(g) of the Ordinance

recorded in the medical record.

9.10 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

9.11 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[27]

9.12 No embryo beyond 14 days old may be exported.

9.13 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.

9.14 A donor's gametes which have produced three successful pregnancies in Hong Kong should not be exported for treatment of infertile patients overseas.

9.15 RT centres should report to the Council within three months after they have exported any gametes or embryos. Information should include the personal particulars of the client/couple exporting the gamete(s)/embryo(s), destinations, date of export, etc. and the reason for export.

[27] s.45(2)(g) of the Ordinance

X. Storage and Disposal of Gametes and Embryos

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 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 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. If gametes or embryos are intended to be stored or used for research, written consent of the donor or client must be obtained.

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 three successful pregnancies, whichever is earlier.

10.7 Subject to para. 10.13, the maximum storage period for gametes or embryos stored for patients' own treatment should not exceed 10 years. RT centres may formulate their own policy for a maximum storage period less than 10 years.

10.8 Only under special circumstances may a designated recipient be permitted (also see para. 14.8 for reporting information to the Council on such cases). The maximum storage period for donated sperm or embryos for a designated recipient should not exceed two years.

Storage of Embryos for Married Persons Only

10.9 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.[28]

Storage of Gametes or Embryos for Cancer Patients or Other Patients

10.10 Cancer patients or other patients may be rendered infertile as a result of chemotherapy, radiotherapy or surgery. Service may be provided for these patients, either single or married, who wish to store their gametes or embryos for their own or their spouse's future use. Only married patients are allowed to store embryos (see para. 10.9 above).

10.11 In determining whether RT services should be provided to a patient, the clinician must take into account the welfare of the potential child born to this person and the patient's fitness for parenting. In order to protect the welfare of the child, gametes or embryos stored for cancer patients should only be used after the patient is "cured". The appropriate timing for insemination or gamete/embryo transfer is a matter for clinical judgement between the oncologists and gynaecologists. The arrangement for a post-humous child shall not be allowed.[29] The same principles apply to other patients whose fertility is compromised as a result of other diseases or treatment process.

10.12 Stored gametes or embryos should not be used by "cured" patients unless the patients are married.[30]

10.13 Notwithstanding the provision in para. 10.7, the maximum storage period for gametes for cancer patients or other types of patients for medical reasons is until that patient is 55 years old or for 10 years, whichever is later. The maximum storage period for embryos for cancer patients or other types of patients for medical reasons is 10 years. The patient can specify an age limit lower than 55 or a maximum period shorter than 10 years.

10.14 The following should be observed when considering to provide gamete or embryo storage for patients who may be rendered infertile as a result of disease or treatment -

(a) The welfare of the child is of paramount importance.

(b) Fitness for parenting should be assessed.

(c) The gamete or embryo storage facility is for patients who have not completed their families and whose fertility is

[28] s.15(5) of the Ordinance
[29] s.45(3) of the Ordinance
[30] s.15(5) of the Ordinance

compromised as a result of disease. The stored gametes or embryos are to be used by the patient or the patient's spouse only.

(d) Appropriate counselling on all the implications must be provided by service providers before patients make the decision to store their gametes or embryos.

(e) Consent of the patient to store the gametes or embryos must be obtained in writing. The patient should specify the maximum storage period (if this is less than the period set in para. 10.13) and state what is to be done with the gametes or embryos if they die or become incapable of revoking their consent (i.e. whether to donate them to other infertile couples or for research or to let them perish). The patient should also state in the consent form that the service provider would be allowed to dispose of the stored embryos if the patient divorces or becomes legally separated. The patient's consent for insemination or gamete/embryo transfer should also be obtained in writing.

(f) A couple should have joint authority to determine what is to be done to the embryos created from their gametes. Their conjoint decision in this regard should be obtained in writing before gametes collection and fertilisation.

(g) Upon death of the patient, gametes or embryos stored for the patient's or spouse's own use shall not be used by the surviving spouse to bring about a post-humous child.[31]

Post-humous Arrangement

10.15 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.[32]

10.16 Given the complexities and potential consequences of post-humous use of gametes or embryos, stored sperm or embryos should not be used to bring about a post-humous 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 the husband or wife, 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 have given conjoint written

[31] s.45(3) of the Ordinance
[32] s.10(7)(a) and s.10(7)(b) of the Parent and Child Ordinance

consent, the stored gametes or embryos can be donated for research or for treatment of other infertile couples.

General Principles for Storing Gametes and Embryos

10.17 In general, the following guiding principles for storing gametes and embryos should be observed -

(a) The welfare of the child is of paramount importance.

(b) All 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 donate to a pool kept by the RT centre for the purpose of treating other infertile patients;
(iii) for research.

(c) Anyone consenting to store his/her gametes or embryos must specify the maximum storage period (if this is less than the periods set in paras. 10.6 - 10.8 and 10.13). 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) if they die or become incapable of revoking their consent.

(d) 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 fertilisation.

(e) Gametes or embryos stored for the donor's or commissioning couple's own use should not be stored beyond the death of donor/either the husband or wife, except that the gametes of the surviving spouse may still be retained for storage. If it is the wish of the donor 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. Such donated gametes or embryos for treatment of other infertile couples have to be properly screened to ensure that no genetic or infectious disease would be transmitted before the stored gametes or embryos could be used. (see paras. 4.5 to 4.8 on screening of donors)

XI. Research

Basic Principles

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

11.2 No person shall bring about the creation of a human embryo for the purpose of research.[33]

11.3 All researches which involve the development, storage, manipulation and usage of human embryos outside human body must be licensed by the Council.[34]

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**.**

11.5 The Council may grant licences for embryo research projects for the following purposes only -

(a) to promote advances in the treatment of infertility;

(b) to increase knowledge about the causes or treatment of congenital disease;

(c) to increase knowledge about the causes or treatment of miscarriages;

(d) to develop more effective techniques of contraception; and

(e) to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

Prohibitions in Connection with Embryos

11.6 The following activities in relation to human embryos are prohibited under the Ordinance -[35]

(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 two-cell zygote for

[33] s.15(1)(a)(i) of the Ordinance
[34] s.2(1) of the Ordinance - interpretation of the term "relevant activities" and s.13
[35] s15(1)(a) to (f) of the Ordinance

the purpose of research (under such restriction, the Hamster Test may be performed under licence);

(c) to keep or use an embryo after the appearance of the primitive streak;

(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 may be offered to potential donors to influence their decision.

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

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

(a) on the validity of the research;

(b) that the objectives of the proposed research cannot be achieved in any other way; and

(c) that the researchers have the necessary facilities and skills.

11.12 The institutional Research Ethics Committee has the duty to monitor the progress of the research.

[36] s.20(1) of the Ordinance

Use of Fetal Ovarian or Testicular Tissue

11.13 The use of fetal ovarian or testicular tissue for infertility treatment is prohibited under the Ordinance.[37]

11.14 In the case of research where no embryo is to be created, 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;

(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 of the mother of the fetus where practicable; and

(e) there should be no financial reward for donating fetal tissue.

11.15 The decision to carry out an abortion must be reached without consideration of the benefits of subsequent use of the aborted fetal tissue.

11.16 The management of the pregnancy of any mother should not be influenced by any potential use of the fetal tissue.

Genetic Manipulation

11.17 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.

11.18 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.

11.19 Germ-line gene therapy should not be performed.

11.20 As with all innovative therapies, somatic cell gene therapy

[37] s.15(2) of the Ordinance

should be subject to rigorous ethical appraisal and be used only when there is no alternative available or when it offers genuine advantages, such as safety or efficacy, over other types of treatment.

11.21 Somatic cell gene therapy may hold great potential benefit for some patients; but it may also carry risks. To ensure that the benefits are assessed and the risks are identified as expeditiously as possible, somatic cell gene therapy should be conducted in accordance with the principles for biomedical research involving human subjects of the Declaration of Helsinki.

11.22 The first candidates for somatic cell gene therapy should be patients who are suffering from a disorder which is life-threatening, or causes serious handicap, and for which treatment is unavailable or unsatisfactory, but which has not already progressed so far as to reduce significantly the potential for benefit.

Prohibition Against Commercial Dealings

11.23 Commercial dealings in gametes, embryos or fetal ovarian or testicular tissues are prohibited under the Ordinance.[38]

Terms of Reference and Membership of Institutional Research Ethics Committee

11.24 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.

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

(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

[38] s.16 of the Ordinance

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.

11.26 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. Cooption of members should be allowed where appropriate. Members should be required to declare any interest for each proposal submitted.

XII. Surrogacy

12.1 Commercial surrogacy is prohibited under the Ordinance; its arrangement or advertising is a criminal offence.[39]

12.2 Under the Ordinance, no person shall use gametes other than the gametes of the commissioning couple who are the parties to a marriage for the purposes of a surrogacy arrangement.[40]

12.3 Genetic surrogacy should only be performed for infertile married couples where no other treatment is possible.

12.4 The suitability of a woman to be a surrogate mother should be assessed by a registered medical practitioner[41], who is not responsible for the RT procedures regarding the surrogacy, by taking into account the following considerations -

- marital status;
- history of pregnancy; and
- physical & 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.

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

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

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

12.8 Counselling must be provided by a multi-disciplinary team of the 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

[39] s.17 of the Ordinance
[40] s.14 of the Ordinance
[41] a medical practitioner registered in accordance with s.14 of the Medical Registration Ordinance (Cap. 161)
[42] s.18 of the Ordinance

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.

12.9 In assessing surrogate mother (and her husband if any), the welfare of the child is of paramount importance. The assessment should take into account her (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;

(g) the possible attitudes of other members of the family towards the child.

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

12.11 RT centres should report to the Council on cases of surrogacy within three months after completion of the procedure for each treatment cycle. It is advisable to submit this report together with data collection form (DC Form) 1 at **Annex II** as required in para. 14.7. 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.

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 that purpose and such disease would be sufficiently severe to a person suffering it to justify such selection.[43]

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

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

13.4 Sex selection should only be conducted to avoid a sex-linked genetic disease specified in Schedule 2[45] of the Ordinance which may prejudice the health of the embryo. Each disease in the schedule by itself is not an indication for sex selection. The schedule is attached as **Appendix IV** 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 -

- the probability of having an affected child;
- the chance of the child being physically or mentally handicapped;
- the natural history of the disease;
- the life expectancy of an affected child;
- whether the affected child needs to go through life long and/or invasive medical procedures/treatment;
- the perception of the parents of having an affected child;
- the ability of the parents to cope with an affected child; and
- 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 Preimplantation genetic diagnosis (PGD) with sex-selective zygote transfer should only be carried out on medical grounds and in compliance with the requirement laid down in this part. PGD technique applied to determine normality of the embryo shall not be used for the

[43] s.15(3)(b) of the Ordinance
[44] s.15(3)(b) of the Ordinance
[45] s.15(3)(a) and Schedule 2 of the Ordinance

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.

13.9 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 preimplantation genetic diagnosis with sex-selective zygote transfer) within three months after the procedure has taken place. Information should include the personal particulars of the commissioning couple, the indication, the choice of technique and the outcome of sex selection procedure. The Council may make regulation specifying any other information to be submitted to the Council.[46]

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

[46] s.45(2)(d) of the Ordinance

XIV. Record Keeping and Information Management

Accuracy and Confidentiality of Information

14.1 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.

14.2 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.[47]

Submission of Information

14.3 RT centres are required to submit to the Council any information as required by it.

(A) The Central Register (Register A)

14.4 The Council shall keep a register as Register A containing any such information, if -[48]

(a) it related to the provision of a RT procedure where a child born or intended to be born in consequence of the procedure was not created from the gametes solely of the parents of the child; and

(b) the child, any of the parties to the marriage, or any individual whose gametes have been used, or any combination thereof, can be identified from the information.

14.5 The information required in para. 14.4 above should be submitted in the prescribed format using the data collection forms (DC Form) 2, 3, 4, 5 and 6 at **Annex II**.

(B) RT procedures not involving use of donated gametes or embryos

14.6 For RT procedures not involving use of donated gametes or donated embryos, RT centres are required to submit non-identifying information on such cases to the Council.

14.7 The information required in para. 14.6 above should be submitted in the prescribed format using the data collection forms (DC

[47] s.34, s.35 and s.36 of the Ordinance
[48] s.33(1) and s.33(2), s.45(2)(c) and s.45(2)(d) of the Ordinance

Form) 1 and 4 at **Annex II**.

(C) Designated Donation

14.8 Designated donations of sperm/oocytes/embryos should not be permitted unless under special circumstances. RT centres should report to the Council on such cases in writing within three months after completion of the procedure for each treatment cycle. It is advisable to submit this report together with the appropriate data collection forms (DC Forms) (as in **Annex II**), as required in paras. 14.5 and 14.7. Information should include personal particulars of the donor(s) and the recipient couple, their relationship and detailed justifications as to why the donation has to be designated.

(D) Others

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

(a) exportation of gametes and embryos (para. 9.15)
(b) surrogacy (para. 12.11)
(c) sex selection (paras. 13.9 and 13.10)

(E) Annual Statistics

14.10 Other non-identifying data in the prescribed format at **Annex III** should be submitted on an annual basis to the Council. 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

14.11 Under section 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:-[49]

(a) Disclosure to a member of the Council, a member of its Committees or a designated public officer designated by the Secretary for Health, Welfare and Food (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 (Licence), which permits the licensee to carry out activities which consist of or involve provision of a reproductive technology

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

procedure, conducting of embryo research or handling, storing or disposing of a gamete or embryo used or intended to be used in the reproductive technology 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 is allowed when no identifying information in Register A is given;

(d) Any adult (age 16 or above) may request the Council to state whether or not the information contained in Register A shows that

(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 embryo shall be given, if such information is provided at a time that the Council could not be required to give such information);

(e) Disclosure is allowed when it is done 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 order may not require the Council to disclose any information which may identify the donors of gametes;

(f) Disclosure to the Registrar of Births and Deaths or any deputy registrar of births and deaths is allowed if it is made pursuant to their notice of request. Such notice requests 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 that information;

(g) Disclosure is allowed when an individual, who undergoes a reproductive technology procedure, consents in writing before the provision of the procedure to disclose his/ her information

as specified in the permission;

(h) Disclosure is allowed when an individual, who undergoes a reproductive technology procedure, 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 consents to disclose information relating to the provision of the procedure to him/ her, either generally or in circumstances specified in the permission. Subsequently, the individual is so contacted and he/ she consents in writing after the provision of the procedure to disclose his/ her information;

(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

(a) the child has been carried by a surrogate mother, or

(b) the gametes of either or both the parties to the marriage were used to bring about the creation of the embryo.

Access to Information

14.12 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 reproductive technology procedure involving donated gametes or donated embryos.[50] However, in accordance with the provisions in the Ordinance, no identifying information regarding the gamete or embryo donor is to be released.[51]

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

14.13 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.

[50] s.33(3) of the Ordinance
[51] s.33(5) of the Ordinance

XV. Handling of Complaints

Complaints against RT centres

15.1 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 centre, he/she should be advised of the appeal channel including, if appropriate, the Investigation Committee of the Council or the Medical Council of Hong Kong for matters relating to professional misconduct.

Breach of Code of Practice

15.3 Any allegations of breach of the Code will be investigated by the Investigation Committee of the Council.[52] Failure to co-operate with an Investigation Committee will be taken into account by the Council in assessing whether there is a ground for revocation and suspension of licence.

15.4 Professionals concerned are reminded that they are also under Codes of Practice or Ethics of their respective professional disciplines.

[52] 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 Fertilisation & Embryology Authority, United Kingdom.

3. Code of Practice for Units Using In Vitro Fertilisation 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. Professional Code and Conduct for the Guidance of Registered Medical Practitioners by the Medical Council of Hong Kong.

6. Guidelines for the Use of Semen Donor Insemination. American Fertility Society 1990.

7. World Medical Association Statement on Ethical Aspects of Embryonic Reduction, adopted by the 47th WMA General Assembly, Bali, Indonesia, September 1995.

8. World Health Organisation. WHO Technical Report Series 820. Recent Advances in Medically Assisted Conception. Report of a WHO Scientific Group. Geneva 1992.

9. Review of the Guidance on the Research Use of Fetuses and Fetal Materials (The Polkinghorne Report), July 1989. Her Majesty's Stationery Office. ISBN 0 10 107622 3.

10. Report of the Committee on the Ethics of Gene Therapy (The Clothier Report), January 1992. Her Majesty's Stationery Office. ISBN 0 10 117882 4.

11. Peter S Harper, Practical Genetic Counselling, 4th Edition. Butterworth Heinmann, 1993.

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 sperms inside a woman's vagina or uterus (ie 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), sperms 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 one 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 fertilised in vitro with the semen of the partner of a woman who no longer produces eggs.

11. **Embryo :**
The product of human conception, often understood to cover the period from fertilisation 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 fourteen days' development after fertilisation. Around this point the "primitive streak" develops.

12. **Embryo (or ovum) transfer :**
The process of transferring a fertilised egg in the course of IVF or GIFT procedures, where following development in vitro for two or three 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 and 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 epididymus).

14. **Fallopian tubes :**
The organs which carry 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. **Fertilisation :**
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 (eight weeks after fertilisation) 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 male partner has a low sperm count or poor quality sperm to use the partner'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 fertilising 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. **Gamete intra-fallopian transfer (GIFT) :**
A process by which an egg or eggs are transferred with sperm into the woman's fallopian tubes so that fertilisation can take place in vivo.

21. **Germ-line Gene Therapy**
A kind of gene therapy which would entail "foreign" genes into fertilised 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.

22. **Implantation :**
The process whereby the embryo becomes burrowed in the lining of the uterus.

23. **Intra Cytoplasmic Sperm Injection (ICSI) :**
A method of gamete micromanipulation where a single sperm is injected into the inner cellular structure of the egg. This technique is used for couples in which the male partner has severely impaired or few sperm.

24. **In vitro :**
Literally, in glass. More commonly to describe a biological event that occurs in a laboratory or in an artificial environment.

25. **In vivo :**
Describing a biological event that occurs in an intact animal or in the natural environment.

26. **In-vitro fertilisation (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 fertilisation can occur. Once the fertilised 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.

27. **Laparoscopy :**
Examination of the pelvic or other abdominal organs with a fibreoptic 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.

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 fertilisation. This is the rudimentary nervous tissue of the embryo.

32. **Pronuclear stage tubal transfer (PROST) :**
A variant of ZIFT.

33. **Sperm :**
A mature male germ cell, produced in the testicles.

34. **Superovulation :**
The medical stimulation of the ovary with hormones so that a woman produces more eggs than usual in a monthly cycle.

35. **Uterus :**
The womb; the female organ in which the foetus grows during pregnancy.

36. **Zygote :**

The cell formed by the union of sperm and egg.

37. **Zygote intra-fallopian transfer (ZIFT) :**
Where eggs fertilised in vitro are transferred to the fallopian tubes at the zygote (pronuclear) stage (1 day).

Appendix I

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

The following guidelines for screening potential gamete/embryo donors aim to decrease the potential hazards for transmitting infectious diseases through gamete/embryo donation. It is modified from the "Guidelines for Gamete Donation: 1993" issued by the American Fertility Society. Local conditions differ and may call for approaches different from those provided in the guidelines.

A. 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.

3. Medical History -

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

(b) 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.

4. Physical Examination -

(a) 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.

(b) 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.

5. Laboratory Screening -

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 antigen (HBsAg) and hepatitis C antibody should be obtained initially and at 6- month intervals.

(c) Semen 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 (immunoglobulin G) for CMV should be obtained.

(i) If the antibody tests are positive, it is suggested that the donor should only be used with recipients who are CMV-positive.

(ii) 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.

(iii) 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.

(f) Haematological tests on MCV screening for thalassanemia should be performed initially. Patients with low MCV should be subject to Haemoglobin pattern test.

B. Guidelines for Screening Potential Egg Donors

6. In general, the screening of egg donors should follow the guidelines for screening potential semen donors described above. The donor must have been screened negative for HIV status before the donation.

7. If the use of donor eggs creates the potential of an Rh incompatibility, couples should be informed about the obstetrical significance of this condition.

8. Freezing and Quarantining of Eggs or Embryos -

(a) Guidelines require that donor semen be quarantined for 180 days before being released for use. As no practical procedure exists, eggs cannot be frozen and quarantined prior to use.

(b) Couples entering an egg donor programme should be given the following choices:

(i) Whether they wish to assume the low risk of acquiring HIV by using fresh embryos.

(ii) Whether they wish to have the donated eggs fertilised, the embryos frozen and quarantined, the donor recalled and retested for HIV 6 months later, and only then to undergo embryo transfer.

C. Guidelines for Screening Embryo Donors

9. The respective donors of the sperm and the egg in embryo donation should undergo screening according to the guidelines described in A and B above.

Appendix II

Guideline for Payment to Donors

This guideline provides guidance to RT 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 -

(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 three categories:

(a) Loss of Earnings

(b) Other Accountable Expenses

(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$380.** RT 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$300 to cover the travelling expenses incurred in getting to the RT center 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$300.

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 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$240**. 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$380**.

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 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 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 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 each Donation

21. Subject to the limit specified for each item, total **daily** amount that can be claimed for each donation cannot exceed **HK$1,060 and HK$1,360 for egg donor on the date of egg collection**. i.e. the total sum for loss of earnings and other accountable expenses (excluding medical expenses where no upper limit is levied).

Appendix III

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
and the
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002

A. INTRODUCTION

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.

2. It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.

3. The Declaration of Geneva of the World Medical Association 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 only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

4. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.

6. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.

7. In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.

8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.

9. Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.

11. 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 on adequate laboratory and, where appropriate, animal experimentation.

12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

13. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.

15. Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.

16. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.

17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

18. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and

burdens to the subject. This is especially important when the human subjects are healthy volunteers.

19. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.

20. The subjects must be volunteers and informed participants in the research project.

21. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

22. In any research on human beings, 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. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

24. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this

research cannot instead be performed on legally competent persons.

25. When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.

26. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.

27. Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

28. The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.

29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.

30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

31. The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.

32. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

FOOTNOTE:

Note of Clarification on Paragraph 29 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or

- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

Appendix IV

Sex-linked Genetic Diseases[53]

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 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

[53] Schedule 2 of the Ordinance

Appendix V

Fact Sheet on Disclosure of Information Related to Provision of Reproductive Technology Procedure (For Reference Only)

Keeping of Register A

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, Register A.

Information contained in Register A shall be kept for 80 years.

Information contained in Register A

The register shall contain:

(1) information related to the provision of a reproductive technology procedure where a child born or intended to be born in consequence of the procedure involving donated gametes or donated embryos.

(2) 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

Under section 34(2) & (3) of the Ordinance, disclosure of any information contained or required to be contained in Register A is allowed in the following circumstances: -

(a) Disclosure to a member of the Council, a member of its Committees or a designated public officer designated by the Secretary for Health, Welfare and Food (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 (Licence), which permits the licensee to carry out activities which consist of or involve provision of a reproductive technology procedure, conducting of embryo research or handling,

storing or disposing of a gamete or embryo used or intended to be used in the reproductive technology 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 is allowed when no identifying information in Register A is given;

(d) Any adult (age 16 or above) may request the Council to state whether or not the information contained in Register A shows that

(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 embryo shall be given, if such information is provided at a time that the Council could not be required to give such information);

(e) Disclosure is allowed when it is done 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 order may not require the Council to disclose any information which may identify the donors of gametes;

(f) Disclosure to the Registrar of Births and Deaths or any deputy registrar of births and deaths is allowed if it is made pursuant to their notice of request. Such notice requests 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 that information;

(g) Disclosure is allowed when an individual, who undergoes a

reproductive technology procedure, consents in writing before the provision of the procedure to disclose his/ her information as specified in the permission;

(h) Disclosure is allowed when an individual, who undergoes a reproductive technology procedure, 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 consents to disclose information relating to the provision of the procedure to him/ her, either generally or in circumstances specified in the permission. Subsequently, the individual is so contacted and he/ she consents in writing after the provision of the procedure to disclose his/ her information;

(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

  (a) the child has been carried by a surrogate mother, or
  (b) the gametes of either or both the parties to the marriage were used to bring about the creation of the embryo.

Annex I

Consent Form (1)

SAMPLE

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

1. I _____
(Surname, Given Names) (ID No.)
(Single/Married*) of _____
_____ (address) DO HEREBY CONSENT AND AUTHORISE the medical staff of _____ (centre), hereinafter called "the centre", to freeze and store my sperm ("the programme").

2. I acknowledge that the nature, procedures and possible complications have been explained to me by _____ and I have been given the opportunity to ask any questions 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 will be stored for a period of two years, up to _____, and subject to para 5 below, storage will be renewed by that date
(dd/mm/yr)
and thereafter every two years only if I give a written notice of renewal. I understand that notice of renewal in writing must reach the centre one month before the date of renewal. * (delete this clause if storage period indicated in clause 5 below is shorter than two years)

4. I consent that in the absence of written notice of renewal, the centre may dispose of my stored sperm.

5. I understand that my sperm will be frozen and stored for (complete either (a) or (b)) -
(a)* a maximum of _____ days/months/years[@(a)] , i.e. up to _____ ; or
(dd/mm/yr)
(b)* until I am _____ years old[@(b)], i.e. up to _____,
(dd/mm/yr)
and upon expiry of the storage period specified above, the centre may dispose of my stored sperm.

6. I understand that my stored sperm can be used for insemination or other reproductive technology procedures only when I am married except in circumstances as specified by the law or by the Code of Practice. Also, upon my death, my stored sperm cannot be used by my spouse to bring about a posthumous child(ren) .

7. I understand that I can withdraw from the programme at any time by giving a written notice to the centre stating the intention to withdraw and whether the sperm will be reclaimed in person, or disposed of, or donated for the treatment of other infertile couples or for research. In the event that I withdraw from the programme and no indication is given as to how the sperm is to be dealt with, the centre will be allowed to dispose of the stored sperm.

8. I consent that upon my death, (tick one)
   [ ] the centre may dispose of my stored sperm.
   [ ] my stored sperm may be donated for the treatment of other infertile couples.
   [ ] my stored sperm may be donated for research.

9. I understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on my particulars to the Council on Human Reproductive Technology if my sperm is donated for the treatment of other infertile couples with my consent.

10. I understand that I am required to inform the centre of any change of my address.

11. I fully understand and accept that -

    (a) My sperm stored may not produce a pregnancy ;

    (b) The procedures of freezing, thawing and storage do not produce higher incidence of carrying abnormal children as compared with normal pregnancy. Any child conceived or born as a result of the procedures may suffer any defect of health or any mental or physical impairment whether congenital, hereditary or otherwise;

    (c) The quality of the sperm depends to a large extent on the quality of the specimen when first submitted for storage;

    (d) The quality of the sperm 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 held responsible for damage or deterioration from whatever cause which is beyond its control or due to unforeseen circumstances.

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

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

Position _____

Notes : * Delete whichever is inapplicable

@ (a) The storage period for sperm can be specified by the patient, subject to a maximum of 10 years.
(b) The maximum storage period for storing sperm for medical reasons is until the patient reaches the age of 55 or for 10 years, whichever is later.

To be completed if the patient is married .

Consent Form (2)

SAMPLE

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 CONSENT AND AUTHORISE the medical staff of _____
_____ (centre), hereinafter called "the centre", to freeze and store the embryos produced with our gametes ("the programme").

2. We acknowledge that the nature, procedures and possible complications have been explained to us by _____ and we have been given the opportunity to ask any questions 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 for the purpose of giving notices under the programme, a notice is only valid with our conjoint signatures.

4. We consent that our embryos will be stored for an initial period of two years, up to _____, and subject to para 6 below, storage will be renewed by that date
(dd/mm/yr)
and thereafter every two years only if we give a written notice of renewal. We understand that notice of renewal in writing must reach the centre one month before the date of renewal.

5. We consent that in the absence of written notice of renewal, the centre may dispose of the stored embryos.

6. We understand that our embryos will be frozen and stored for a maximum of _____ years[@], i.e. up to _____, and upon expiry of the storage
(dd/mm/yr)
period specified above, the centre may dispose of our stored embryos.

7. We understand that our stored embryos can only be used for reproductive technology procedures when we are the parties to a marriage except in circumstances as specified by the law or by the Code of Practice. Also, upon death of either of us, our stored embryos cannot be used by the surviving spouse to bring about a posthumous child(ren) .

8. We understand that we can withdraw from the programme at any time by giving a written notice to the centre stating the intention to withdraw and whether the embryos will be reclaimed by either of us or only both of us in person, or disposed of, or donated for the treatment of other infertile couples or for research. In the event that we withdraw from the programme and no indication is given as to how the embryos are to be dealt with, the centre will be allowed to dispose of the stored embryos.

9. We consent that upon death of either of us or in the event of divorce or legal separation or one partner is incapable of revoking his or her consent, (tick one)
   [ ] the centre may dispose of our stored embryos.
   [ ] our stored embryos may be donated for the treatment of other infertile couples.
   [ ] our stored embryos may be donated for research.

10. We understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on our particulars to the Council on Human Reproductive Technology if our embryos are donated for the treatment of other infertile couples with our joint consent.

11. We understand that we are required to inform the centre of any change of our address or our marital relationship.

12. We fully understand and accept that -

    (a) The embryos stored may not produce a pregnancy;

    (b) The procedures of freezing, thawing and storage do not produce higher incidence of carrying abnormal children as compared with normal pregnancy. Any child conceived or born as a result of the procedures may suffer any defect of health or any mental or physical impairment whether congenital, hereditary or otherwise.

    (c) The quality of the embryos 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.

    (e) The centre will not be held responsible for damage or deterioration from whatever cause which is beyond its control or due to unforeseen circumstances.

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 _____

Notes : @ The storage period for embryos can be specified by the patients, subject to a maximum of 10 years.

Consent Form (3)

SAMPLE

Consent to Anonymous Donation of Sperm

1. I _____
(Surname, Given Names) (ID No.)
(Single/Married*), DO HEREBY CONSENT to donate my sperm anonymously to _____ (centre), hereinafter called "the centre", with the understanding that my sperm will be used for the treatment of infertile couples.

2. I consent that my sperm can be stored and disposed of by the centre as the centre deems appropriate.

3. I consent that my sperm should only be used to produce one / two / three* pregnancies.

4. I acknowledge that the nature and implications have been explained to me by _____ and I have been given the opportunity to ask any questions I wish. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the donation.

5. I understand that under the Parent & Child Ordinance (Cap. 429), I shall not be the legal father of the resulting child(ren). I also agree never to seek to make any claim of any such child(ren) in any circumstance whatsoever.

6. I understand and agree that the identity of any recipient and of any child(ren) that may be born by the recipient after using my sperm shall not be disclosed to me, nor shall my identity be revealed to the recipient couple or to any child(ren) born as a result.

7. I understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on my particulars to the Council on Human Reproductive Technology.

8. I understand that under section 34(2) and 34(3) of the Human Reproductive Technology Ordinance (Cap. 561), as explained in the "Fact Sheet on Disclosure of Information Related to Provision of Reproductive Technology Procedure", any information relating to provision of the RT procedures to me may be disclosed.

[#]9. I consent that -

[ ] under circumstances specified by Human Reproductive Technology Ordinance, information relating to provision of the RT procedures to me can be disclosed.

[ ] under circumstances specified by Human Reproductive Technology Ordinance, I could be approached by the Council on Human Reproductive Technology to consider disclosing information relating to provision of the RT procedures to me.

[#] s.34(2)(e), (f), (g), s.35 and s.36 of the Human Reproductive Technology Ordinance

[ ] I should never be approached under any circumstances.

10. To the best of my knowledge and belief -

(a) I am in good health and have no communicable disease nor hereditary disorders, except as follows -

_____

_____

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

_____

_____

11. For the purpose of determining whether I am suitable as a donor of sperm, I consent to undergo a routine physical examination and several blood tests (including HIV test) designated by the centre.

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

Signed _____
(Donor's Signature)

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

Date of Birth _____
(dd/mm/yr)

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

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

Position _____ Position _____

Signed _____
(Signature of Counsellor)

Name _____
(in Block Letters)

* Delete whichever is inapplicable.

Consent Form (4)

SAMPLE

Consent to Anonymous Donation of Eggs

1. I _____
(Surname, Given Names) (ID No.)
(Single/Married*), DO HEREBY CONSENT to donate my eggs anonymously to _____ (centre), hereinafter called "the centre", with the understanding that my eggs will be used for the treatment of infertile couples.

2. I consent to -
   (a) be prepared for egg retrieval including the use of drugs for hyperstimulation;
   (b) the removal of eggs from my ovaries with the aid of laparoscopy/ultrasound;
   (c) the administration of any drugs and/or anaesthetics on me which may be found necessary in the course of the procedure(s).

3. I consent that my eggs should only be used to produce one / two / three* pregnancies.

4. I acknowledge that the nature, procedures and possible complications have been explained to me by _____ and I have been given the opportunity to ask any questions I wish. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the treatment.

5. I understand that under the Parent & Child Ordinance (Cap. 429), I shall not be the legal mother of the resulting child(ren). I also agree never to seek to make any claim of any such child(ren) in any circumstance whatsoever.

6. I understand and agree that the identity of any recipient and of any child(ren) that may be born by the recipient after using my eggs shall not be disclosed to me, nor shall my identity be revealed to the recipient couple or to any child(ren) born as a result.

7. I understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on my particulars to the Council on Human Reproductive Technology.

8. I understand that under section 34(2) and 34(3) of the Human Reproductive Technology Ordinance (Cap. 561), as explained in the "Fact Sheet on Disclosure of Information Related to Provision of Reproductive Technology Procedure", any information relating to provision of the RT procedures to me may be disclosed.

[#]9. I consent that -

[ ] under circumstances specified by Human Reproductive Technology Ordinance, information relating to provision of the RT procedures to me can be disclosed.

[ ] under circumstances specified by Human Reproductive Technology Ordinance, I could be approached by the Council on Human Reproductive Technology to consider disclosing information relating to provision of the RT procedures to me.

[ ] I should never be approached under any circumstances.

10. To the best of my knowledge and belief -

(a) I am in good health and have no communicable disease nor hereditary disorders, except as follows -

_____

_____

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

_____

_____

11. For the purpose of determining whether I am suitable as a donor of eggs, I consent to undergo a routine physical examination and several blood tests (including HIV test) designated by the centre.

[#] s.34(2)(e), (f), (g), s.35 and s.36 of the Human Reproductive Technology Ordinance

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

Signed _____
(Donor's Signature)

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

Date of Birth _____
(dd/mm/yr)

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

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

Position _____

* Delete whichever is inapplicable.

Consent Form (5)

SAMPLE

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 donate our excess frozen embryo(s) anonymously to _____ (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*.

2. We consent that our embryos can be stored and disposed of by the centre as the centre deems appropriate.

3. We consent that our embryos should only be used to produce one / two / three* pregnancies.

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

5. We understand that under the Parent & Child Ordinance (Cap. 429), we shall not be the legal parents of the resulting child(ren). We also agree never to seek to make any claim of any such child(ren) in any circumstance whatsoever.

6. We understand and agree that the identity of any recipient and of any child(ren) that may be born after transfer of our embryos to any recipient shall not be disclosed to us, nor shall our identity be revealed to the recipient couple or to any child(ren) born as a result.

7. We understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on our particulars to the Council on Human Reproductive Technology.

8. We understand that under section 34(2) and 34(3) of the Human Reproductive Technology Ordinance (Cap. 561), as explained in the "Fact Sheet on Disclosure of Information Related to Provision of Reproductive Technology Procedure", any information relating to provision of the RT procedures to us may be disclosed.

[#]9. We consent that -

[ ] under circumstances specified by Human Reproductive Technology Ordinance, information relating to provision of the RT procedures to us can be disclosed.

[ ] under circumstances specified by Human Reproductive Technology Ordinance, we could be approached by the Council on Human Reproductive Technology to consider disclosing information relating to provision of the RT procedures to us.

[ ] We should never be approached under any circumstances.

10. To the best of our knowledge and belief -

(a) We are in good health and have no communicable disease nor hereditary disorders, except as follows -

_____

_____

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

_____

_____

11. For the purpose of determining whether we are suitable as donors of embryos, we consent to undergo a routine physical examination and several blood tests (including HIV test) designated by the centre.

[#] s.34(2)(e), (f), (g), s.35 and s.36 of the Human Reproductive Technology Ordinance

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

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

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

_____ _____
(in Chinese) (in Chinese)

Marriage Certificate No. _____

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

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

Position _____

* Delete whichever is inapplicable.

Consent Form (6)

SAMPLE

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 CONSENT AND AUTHORISE the medical staff of _____ (centre), hereinafter called "the centre", to perform the treatment of donor insemination.

2. I understand that drugs would be administered to me if necessary in the course of the treatment.

3. I understand that the donor shall be unidentified* (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 resulting child(ren).

4. I acknowledge that the nature, procedures and possible complications have been explained to me by _____ and I have been given the opportunity to ask any questions I wish. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the treatment.

5. I fully understand and accept that -

   (a) I may not become pregnant;

   (b) I may not be able to carry the pregnancy to term;

   (c) I may suffer any illness arising out of or consequent upon a pregnancy resulting from the donor insemination;

   (d) The procedures of donor insemination do not produce higher incidence of carrying abnormal children as compared with normal pregnancy. Any child conceived or born as a result of the procedures may suffer any defect of health or any mental or physical impairment whether congenital, hereditary or otherwise.

6. I understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on my particulars to the Council on Human Reproductive Technology and the resulting

child(ren) will have the right to have access to certain information (including non-identifying information about the donor) as stipulated under the Ordinance.

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

Signed _____
(Patient's Signature)

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

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

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

Position _____

PART II HUSBAND'S CONSENT

7. 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 resulting child(ren).

8. I understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on my particulars to the Council on Human Reproductive Technology and the resulting child(ren) will have the right to have access to certain information (including non-identifying information about the donor) as stipulated under the Ordinance.

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)

SAMPLE

Consent to In-Vitro Fertilisation/Gamete Intra-Fallopian Transfer/ Embryo Transfer (including frozen/thawed embryo) (IVF/GIFT/ET)

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 CONSENT AND AUTHORISE the medical staff of _____ (centre), hereinafter called "the centre", to perform the treatment of in-vitro fertilisation/gamete intra-fallopian transfer/embryo transfer.

2. I also hereby consent that the medical staff of the centre may proceed with the following RT procedures -
   (a) in-vitro fertilisation & embryo transfer
   (b) gamete intra-fallopian transfer
   (c) pronuclear stage tubal transfer
   (d) others (please specify)_____

3. I consent to -

   (a)* be prepared for egg retrieval including the use of drugs for hyperstimulation ;

   (b) the removal of eggs from my ovaries with the aid of laparoscopy/ultrasound;

   (c) the administration of any drugs and/or anaesthetics on me which may be found necessary in the course of the procedure(s);

   (d) the transfer of gametes/embryos to me.

4.# I consent to the mixing of gametes of _____.
*(*please specify the reference no. of man who provides sperm and woman who provides egg, if applicable)

5. I understand that the donor(s) shall be unidentified***** (delete this sentence if the donation is designated). Under the Parent & Child Ordinance (Cap. 429), he/she shall not be the legal parent of any resulting child(ren). * (delete this clause if no donated gametes/embryos are involved)

6. I acknowledge that the nature, procedures and possible complications have been explained to me by _____ and I have been given the opportunity to ask any questions I wish. I have also been offered a suitable opportunity to take part in counselling with _____about the implications of the treatment.

7. I fully understand and accept that -

   (a) I may not become pregnant;

   (b) I may not be able to carry the pregnancy to term;

   (c) I may suffer any illness arising out of or consequent upon a pregnancy resulting from the in-vitro fertilisation/gamete intra-fallopian transfer/embryo transfer;

   (d) The procedures of in-vitro fertilisation/gamete intra-fallopian transfer/embryo transfer/embryo freezing and storage do not produce higher incidence of carrying abnormal children as compared with normal pregnancy. Any child conceived or born as a result of the procedures may suffer any defect of health or any mental or physical impairment whether congenital, hereditary or otherwise.

8. I consent that the unfertilised eggs or surplus embryos could be
   [ ] disposed of.
   [ ] donated anonymously for the treatment of other infertile couples.
   [ ] donated for research.

9. I understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on my particulars to the Council on Human Reproductive Technology if donor gametes/embryos have been used in the treatment and the resulting child(ren) will have the right to have access to certain information (including non-identifying information about the donor) as stipulated under the Ordinance.

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

Signed _____
(Patient's Signature)

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

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

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

Position _____

PART II HUSBAND'S CONSENT

10. 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 resulting child(ren).

11. I understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on my particulars to the Council on Human Reproductive Technology if donor gametes/embryos have been used in the treatment and the resulting child(ren) will have the right to have access to certain information (including non-identifying information about the donor) as stipulated under the Ordinance.

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

Signed _____
(Husband's Signature)

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

Marriage Certificate No. _____

* Delete whichever is inapplicable

\# Under normal circumstances, gametes from the husband and wife should be used. The use of donated gametes would be subject to proof of difficulties in obtaining normal gametes from either the husband or the wife.

Consent Form (8)

SAMPLE

Consent to Designated Donation of Sperm

Part I DONOR'S CONSENT

1. I _____ (the donor), hereinafter called "the donor",
(Surname, Given Names) (ID No.)
DO HEREBY CONSENT to donate my stored sperm designated 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.

2. I consent that my sperm should only be used to produce one / two / three* pregnancies .

3. I acknowledge that the nature and implications have been explained to me by _____ and I have been given the opportunity to ask any questions I wish. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the donation.

4. I consent that my sperm will be stored for a period of two years, up to _____ , upon expiry of the storage period specified above, the centre
(dd/mm/yr)
can dispose the stored sperm.

5. I understand that under the Parent & Child Ordinance (Cap. 429), I shall not be the legal father of the resulting child(ren). I also agree never to seek to make any claim of any such child(ren) in any circumstance whatsoever.

6. To the best of my knowledge and belief -

   (a) I am in good health and have no communicable disease nor hereditary disorders, except as follows -

   _____

   _____

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

   _____

7. For the purpose of determining whether I am suitable as a donor of sperm, I consent to undergo a routine physical examination and several blood tests (including HIV test) designated by the centre.

8. I understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on my particulars to the Council on Human Reproductive Technology and the resulting child(ren) will have the right to have access to certain information (including non-identifying information about the donor) as stipulated under the Ordinance.

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

Signed _____
(Donor's Signature)

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

Date of Birth _____
(dd/mm/yr)

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

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

Position _____

Part II RECIPIENTS' CONSENT

9. 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 stored sperm donated by _____
(Surname, Given Names) (ID No.)
(the donor) for infertility treatment.

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

11. We consent that the sperm donated to us will be stored for a period of two years, up to _____ , upon expiry of the storage period specified above, the centre
(dd/mm/yr)
may dispose of the stored sperm.

12. We understand that under the Parent & Child Ordinance (Cap. 429), we shall be the legal parents of the resulting child(ren).

13. We understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on our particulars to the Council on Human Reproductive Technology and the resulting child(ren) will have the right to have access to certain information (including non-identifying information about the donor) as stipulated under the Ordinance.

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

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

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

_____ _____
(in Chinese) (in Chinese)

Marriage Certificate No. _____

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

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

Position _____

* Delete whichever is inapplicable.

Consent Form (9)

SAMPLE

Consent to Designated Donation of Eggs

Part I DONOR'S CONSENT

1. I _____ (the donor), hereinafter called "the donor",
   (Surname, Given Names) (ID No.)
   DO HEREBY CONSENT to donate my eggs designated 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 eggs will be used for the treatment of the recipients.

2. I consent to -
   (a) be prepared for egg retrieval including the use of drugs for hyperstimulation;
   (b) the removal of eggs from my ovaries with the aid of laparoscopy/ultrasound;
   (c) the administration of any drugs and/or anaesthetics on me which may be found necessary in the course of the procedure(s).

3. I consent that my eggs should only be used to produce one / two / three* pregnancies.

4. I acknowledge that the nature and implications have been explained to me by _____ and I have been given the opportunity to ask any questions I wish. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the donation.

5. I understand that under the Parent & Child Ordinance (Cap. 429), I shall not be the legal mother of the resulting child(ren). I also agree never to seek to make any claim of any such child(ren) in any circumstance whatsoever.

6. To the best of my knowledge and belief -

   (a) I am in good health and have no communicable disease nor hereditary disorders, except as follows -

   _____

   _____

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

_____

_____

7. For the purpose of determining whether I am suitable as a donor of eggs, I consent to undergo a routine physical examination and several blood tests (including HIV test) designated by the centre.

8. I understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on my particulars to the Council on Human Reproductive Technology and the resulting child(ren) will have the right to have access to certain information (including non-identifying information about the donor) as stipulated under the Ordinance.

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

Signed _____
(Donor's Signature)

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

Date of Birth _____
(dd/mm/yr)

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

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

Position _____

Part II RECIPIENTS' CONSENT

9. 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 eggs donated by _____
(Surname, Given Names) (ID No.)
(the donor) for infertility treatment.

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

11.* We consent that the stored embryos produced with _____
(please specify names of persons who are the origins of gametes)
will be stored for a period of two years, up to _____ , upon
(dd/mm/yr)
expiry of the storage period specified above, the centre may dispose of the stored embryos.

12. We understand that under the Parent & Child Ordinance (Cap. 429), we shall be the legal parents of the resulting child(ren).

13. We understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on our particulars to the Council on Human Reproductive Technology and the resulting child(ren) will have the right to have access to certain information (including non-identifying information about the donor) as stipulated under the Ordinance.

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 _____

* To be completed only if the donated eggs were fertilised with the husband's sperm and stored.

Consent Form (10)

SAMPLE

Consent to Designated Donation of Embryos

PART I DONORS' CONSENT

1. We (the donors), hereinafter called "the donors" _____
_____ (husband's name),
(Surname, Given Names) (ID No.)
and _____ (wife's name),
(Surname, Given Names) (ID No.)
DO HEREBY CONSENT to donate the stored embryos produced with our gametes to the following couple, hereinafter called "the recipients",
_____ (husband's name),
(Surname, Given Names) (ID No.)
and _____ (wife's name),
(Surname, Given Names) (ID No.)
with the understanding that our stored embryos will be used for the treatment of the recipients.

2. We consent that our embryos should only be used to produce one / two / three* pregnancies.

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

4. We consent that our embryos will be stored for a period of two years, up to _____ , upon expiry of the storage period specified above, the centre
(dd/mm/yr)
can dispose the stored embryos.

5. We understand that under the Parent & Child Ordinance (Cap. 429), we shall not be the legal parents of the resulting child(ren). We also agree never to seek to make any claim of any such child(ren) in any circumstance whatsoever.

6. To the best of our knowledge and belief -

   (a) We are in good health and have no communicable disease nor hereditary disorders, except as follows -

   _____

   _____

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

_____

_____

7. For the purpose of determining whether we are suitable as donors of embryos, we consent to undergo a routine physical examination and several blood tests (including HIV test) designated by the centre.

8. We understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on our particulars to the Council on Human Reproductive Technology and the resulting child(ren) will have the right to have access to certain information (including non-identifying information about the donor) as stipulated under the Ordinance.

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 RECIPIENTS' CONSENT

9. 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 stored embryos donated by the donors, _____ (husband's name),
(Surname, Given Names) (ID No.)
and _____ (wife's name),
(Surname, Given Names) (ID No.)
for infertility treatment.

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

11. We consent that the embryos donated to us will be stored for a period of two years, up to _____ , upon expiry of the storage period specified above, the centre
(dd/mm/yr)
may dispose of the stored embryos.

12. We understand that under the Parent & Child Ordinance (Cap. 429), we shall be the legal parents of the resulting child(ren).

13. We understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on our particulars to the Council on Human Reproductive Technology and the resulting child(ren) will have the right to have access to certain information (including non-identifying information about the donor) as stipulated under the Ordinance.

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 _____

Consent Form (11)

SAMPLE

Consent to Disposal of Stored Embryos

1. We _____ (husband's name), and
(Surname, Given Names) (ID No.)
_____ (wife's name), of
(Surname, Given Names) (ID No.)
_____
(address), DO HEREBY CONSENT AND AUTHORISE the medical staff of _____ (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/yr)

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 questions we wish. We have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the disposal.

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

Position _____

Complete if applicable

Consent Form (12)

SAMPLE

Consent to Surrogacy Arrangement

PART I COMMISSIONING COUPLE'S CONSENT

1. We (the commissioning couple), 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 commission _____
   (Surname, Given Names)
   _____ (surrogate mother's name), hereinafter called "the surrogate mother",
   (ID No.)
   to act as the surrogate mother, with the understanding that only our own gametes and embryos will be used for the surrogacy arrangement.

2. We acknowledge that the nature and implication of the arrangement and procedures have been explained to us by _____ and we have been given the opportunity to ask any questions 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 to assist us in having a baby of our own, after discussing with us our clinical conditions and confirming 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 resulting child(ren) unless the court made an parental order in favour of us upon our application within 6 months of the birth of the child(ren).

5. We understand that under the Human Reproductive Technology Ordinance (Cap. 561) -
   (a) no surrogacy arrangements on commercial basis should be allowed; and
   (b) no surrogacy arrangement is enforceable by or against any of the persons making it.

6. We understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on our particulars to the Council on Human Reproductive Technology.

7. For the purpose of determining whether we have communicable disease that could be transmitted through our gametes/embryos, we consent to undergo a routine physical examination and several blood tests (including HIV test) designated by the centre.

8. We fully understand and accept that -
   (a) the surrogate mother may not become pregnant;
   (b) the surrogate mother may not be able to carry the pregnancy to term;
   (c) the procedures of in-vitro fertilisation/gamete intra-fallopian transfer/embryo transfer/embryo freezing and storage do not produce higher incidence of carrying abnormal children as compared with normal pregnancy. Any child conceived or born as a result of the procedures may suffer any defect of health or any mental or physical impairment whether congenital, hereditary or otherwise.

9. I _____ (the wife's name), consent to -
   (Surname, Given Names) (ID No.)
   (a)* be prepared for egg retrieval including the use of drugs for hyperstimulation ;
   (b) the removal of eggs from my ovaries with the aid of laparoscopy/ultrasound; and
   (c) the administration of any drugs and/or anaesthetics on me which may be found necessary in the course of the procedure(s);

10. I _____ (the wife's name), acknowledge
    (Surname, Given Names) (ID No.)
    that the nature, procedures and possible complications for egg collection procedures as mentioned above have been explained to me by _____ and I have been given the opportunity to ask any questions I wish. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the procedures.

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.)
(the surrogate mother), hereinafter called "the surrogate mother", DO HEREBY CONSENT to act as the surrogate mother for the commissioning couple, _____ (husband's name),
(Surname, Given Names) (ID No.)
and _____ (wife's name),
(Surname, Given Names) (ID No.)
with the understanding that gametes/embryos* of the commissioning couple would be used for the surrogacy arrangement.

12. I acknowledge that the nature and implications of surrogacy arrangement have been explained to me by _____ and I have been given the opportunity to ask any questions I wish. I have also been offered a suitable opportunity to take part in counselling with a multi-disciplinary team about the implications of surrogacy arrangement.

13. I understand that under the Parent & Child Ordinance (Cap. 429), I shall be the legal mother of the resulting child(ren) unless the court made an parental order in favour of the commissioning couple upon their application within 6 months of the birth of the child(ren).

14. I understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on my particulars to the Council on Human Reproductive Technology.

15. I consent that the medical staff of the centre may transfer gametes/embryos* of the commissioning couple to me by the following RT procedures* -
    (a) embryo transfer
    (b) gamete intra-fallopian transfer
    (c) pronuclear stage tubal transfer
    (d) others (please specify)_____

16. I acknowledge that the nature, procedures and possible complications for the above RT procedures have been explained to me by _____ and I have been given the opportunity to ask any questions I wish. I have also been offered a suitable opportunity to take part in counselling with _____about the implications of the treatment.

17. I fully understand and accept that -
    (a) I may not become pregnant;
    (b) I may not be able to carry the pregnancy to term;
    (c) I may suffer any illness arising out of or consequent upon a pregnancy resulting from the embryo transfer/gamete intra-fallopian transfer/pronuclear stage tubal transfer or other RT procedures.

(d) The procedures of in-vitro fertilisation/gamete intra-fallopian transfer/embryo transfer/embryo freezing and storage do not produce higher incidence of carrying abnormal children as compared with normal pregnancy. Any child conceived or born as a result of the procedures may suffer any defect of health or any mental or physical impairment whether congenital, hereditary or otherwise.

18. For the purpose of determining whether I am physically fit to act as a surrogate mother and whether I have communicable disease that could be transmitted to the possible resulting child(ren), I consent to undergo a routine physical examination and several blood tests (including HIV test) designated by the centre.

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

Signed _____
(Surrogate Mother's Signature)

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

Marriage Certificate No. _____

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

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

Position _____

PART III# HUSBAND OF THE SURROGATE MOTHER'S CONSENT

19. I _____ am
(Surname, Given Names) (ID No.)
the husband of _____ (the surrogate mother)
(Surname, Given Names) (ID No.)
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 resulting child(ren) unless the court made an parental order in favour of the commissioning couple upon their application within 6 months of the birth of the child(ren).

20. I acknowledge that the nature and implications of surrogacy have been explained to me by _____ and I have been given the opportunity to ask any questions I wish. I have also been offered a suitable opportunity to take part in counselling with a multi-disciplinary team about the implications of surrogacy.

21. I understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on my particulars to the Council on Human Reproductive Technology.

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

Position _____

* Delete whichever is inapplicable

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

Consent Form (13)

SAMPLE

Consent to the 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 the medical staff of _____
_____(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 medical staff of the centre may proceed with the following RT procedures - *
   (a) sperm treatment with sex-selective insemination
   (b) sperm treatment with gamete intra-fallopian transfer
   (c) sperm treatment with pronuclear stage tubal transfer
   (d) in-vitro fertilisation
   (e) Preimplantation genetic diagnosis with sex-selective zygote transfer
   (f) Prenatal diagnosis with sex-selective abortion
   (g) 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 of Human Reproductive Technology Ordinance, 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 questions we wish. We have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the treatment.

5. We understand that the centre is subject to the Code of Practice published by the Council on Human Reproductive Technology from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap. 561)] which requires or will require, amongst other things, the supply of information on our particulars to the Council on Human Reproductive Technology.

6. 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 any illness arising out of or consequent upon a pregnancy resulting from the in-vitro fertilisation/gamete intra-fallopian transfer/embryo transfer;
   (d) The procedures of in-vitro fertilisation/gamete intra-fallopian transfer/embryo transfer/embryo freezing and storage do not produce higher incidence of carrying abnormal children as compared with normal pregnancy. Any child conceived or born as a result of the procedures may suffer any defect of health or any mental or physical impairment whether congenital, hereditary or otherwise; 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 chosen.

7. I _____ (the wife's name), consent to -
   (Surname, Given Names) (ID No.)
   (a)* be prepared for egg retrieval including the use of drugs for hyperstimulation ;
   (b) the removal of eggs from my ovaries with the aid of laparoscopy/ultrasound; and
   (c) the administration of any drugs and/or anaesthetics on me which may be found necessary in the course of the procedure(s).

8. I _____ (the wife's name), acknowledge
   (Surname, Given Names) (ID No.)
   that the nature, procedures and possible complications for egg collection procedures as mentioned above have been explained to me by _____ and I have been given the opportunity to ask any questions I wish. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the procedures.

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

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

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

_____ _____
(in Chinese) (in Chinese)

Marriage Certificate No. _____

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

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

Position _____

* Delete whichever is inapplicable

Annex II

Council on Human Reproductive Technology

CONFIDENTIAL **DC Form 1**

REPRODUCTIVE TECHNOLOGY TREATMENT FORM

(For treatment NOT involving donor gametes/embryos)

For Official Use
No.

1. Name of centre : .....

2. HRT Council centre licence number : ☐☐☐☐ 3. Patient's clinic record number : ☐☐☐☐☐☐☐☐

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

Treatment cycle : ……. (eg 1st/2nd/3rd cycle for this couple)

6. Type of treatment :
   - IVF ☐ ICSI with IVF ☐
   - GIFT ☐ ICSI with PROST ☐
   - ZIFT/PROST ☐ ICSI with MIFT ☐
   - Other Micromanipulation (please specify) ……
   - Surrogacy @ ☐ Frozen-thawed ET ☐
   - Other (please specify) ……

7. Ovarian stimulation — Yes ☐ No ☐

8. Number of embryos developed in this cycle : ☐☐

9. *Date of *gamete transfer/ embryo replacement or *date when cycle was abandoned : Day ☐☐ Month ☐☐ Year ☐☐☐☐

10. Embryos transferred : Number of embryos transferred : ☐ Developed from :
    - Fresh embryos ☐
    - Frozen/thawed embryos ☐

11. Number of oocytes transferred ☐

12. Spare embryos after replacement : Cumulative total number of spare embryos since first treatment cycle : ☐☐
    - Number stored for treatment of patient ☐
    - Number stored for treatment of others ☐
    - Number used for research ☐
    - (Research project licence number and no. of embryos used :
      - R ☐☐☐☐ ☐
      - R ☐☐☐☐ ☐
      - R ☐☐☐☐ ☐)
    - Number stored for research ☐
    - Number discarded ☐

13. Outcome of treatment :
    - No pregnancy ☐ Miscarriage ☐
    - Ectopic pregnancy ☐ Heterotopic pregnancy ☐
    - Pregnancy terminated ☐ Ongoing pregnancy ☐
    - Hydatidiform mole ☐ Lost to follow up ☐

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

(b) * Delete where inapplicable

(c) @ For surrogacy cases, please refer to para 12.11 of the Code of Practice and report on the case with detailed information including detailed justifications to the HRT Council within three months after the treatment.

(d) For item 13, 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"

Council on Human Reproductive Technology

CONFIDENTIAL **DC Form 2**

For Official Use
No.

REPRODUCTIVE TECHNOLOGY TREATMENT FORM

(For RT treatment involving donor gametes/embryos [other than donor insemination])

1. Name of centre : ..……………………………………………………………………………………….…
2. HRT Council centre licence number : |__|__|__|__| 3. Patient's clinic record number : |__|__|__|__|__|__|__|__|
4. Name of centre where treatment started, if different: ………………………………………………………….....

---

5. FULL NAME of patient : |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
(Surname first)
6. Date of birth : Day |__|__| Month |__|__| Year |__|__|__|__| 7. HKID / Passport No. : |__|__|__|__|__|__|__|__|__|__|__|__|__|__|

---

8. FULL NAME of husband : |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
(Surname first)
9. Date of birth : Day |__|__| Month |__|__| Year |__|__|__|__| 10. HKID / Passport No. : |__|__|__|__|__|__|__|__|__|__|__|__|__|__|

---

11. Does the treatment involve donated sperm : YES |__| NO |__| donor's clinic record no.: |__|__|__|__|__|__|__|__|
12. Does the treatment involve donated eggs : YES |__| NO |__| donor's clinic record no.: |__|__|__|__|__|__|__|__|
13. Does the treatment involve donated embryos :YES |__| NO |__| donor's clinic record no.: |__|__|__|__|__|__|__|__|
14. Donor(s) centre licence number(s) (if gamete/embryo is obtained from another licensed centre) :
sperm donor |__|__|__|__| egg donor |__|__|__|__| embryo donor |__|__|__|__|

---

15. The donation is *anonymous/designated. (If the donation is designated, please refer to para 14.8 of the Code of Practice and report the case with detailed information including detailed justifications to the HRT Council within three months after the treatment.)

	Treatment cycle : ……. (eg 1st/2nd/3rd cycle for this couple)
16. Type of treatment :	IVF |__| ICSI with IVF |__| GIFT |__| ICSI with PROST |__| ZIFT/PROST |__| ICSI with MIFT |__| Other Micromanipulation (please specify) ………………………………………… Frozen-thawed ET |__| Other (please specify) …………………………………………………………
17. Ovarian stimulation :	Yes |__| No |__|
18. Number of embryos developed in this cycle :	|__|__|
19. *Date of *gamete transfer/ embryo replacement or *date when cycle was abandoned :	Day |__|__| Month |__|__| Year |__|__|__|__|
20. Embryos transferred :	Number of embryos transferred : |__| Developed from : Fresh embryos |__| Frozen/thawed embryos |__|
21. Number of oocytes transferred	|__|

22. Spare embryos after replacement :	Cumulative total number of spare embryos since first treatment cycle : ☐☐ Number stored for treatment of patient ☐ Number stored for treatment of others ☐ Number used for research ☐ (Research project licence number and no. of embryos used : R ☐☐☐☐ ☐ R ☐☐☐☐ ☐ R ☐☐☐☐ ☐) Number stored for research ☐ Number discarded ☐
23. Outcome of treatment :	No pregnancy ☐ Miscarriage ☐ Ectopic pregnancy ☐ Heterotopic pregnancy ☐ Pregnancy terminated ☐ Ongoing pregnancy ☐ Hydatidiform mole ☐ Lost to follow up ☐

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

(b) For items 7 and 10, please fill in the HKID card no. of patient/husband, or passport no. for non-HKID card holder.

(c) * Delete where inapplicable.

(d) For item 23, 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”

Council on Human Reproductive Technology

CONFIDENTIAL **DC Form 3**

DONOR INSEMINATION TREATMENT FORM

For Official Use
No.

1. Name of centre : ....

2. HRT Council centre licence number : |_|_|_|_| 3. Patient's clinic record number : |_|_|_|_|_|_|_|_|

4. FULL NAME of patient : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|
(Surname first)

5. Date of birth : Day |_|_| Month |_|_| Year |_|_|_|_| 6. HKID / Passport No. : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|

7. FULL NAME of husband : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|
(Surname first)

8. Date of birth : Day |_|_| Month |_|_| Year |_|_|_|_| 9. HKID / Passport No. : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|

10. Reasons for treatment : Male Factor YES |_| |_|
Genetic YES |_| |_|
Others (please specify) ....

11. The donation is *anonymous/designated. (If the donation is designated, please refer to para 14.8 of the Code of Practice and report the case with detailed information including detailed justifications to the HRT Council within three months after the treatment.)

	Treatment cycle : ……. (eg 1st/2nd/3rd cycle for this couple)
12. Donor clinic record number :	|_|_|_|_|_|_|_|_|
13. Donor's centre licence no. if different from 2. above :	|_|_|_|_|
14. Dates of treatment(s) (if more than one insemination per treatment cycle, give all dates) :	Day |_|_| Month |_|_| Year |_|_|_|_| |_|_| |_|_| |_|_|_|_| |_|_| |_|_| |_|_|_|_|
15. Ovarian stimulation :	Yes |_| No |_|
16. Outcome of treatment :	No pregnancy |_| Miscarriage |_| Ectopic pregnancy |_| Heterotopic pregnancy |_| Pregnancy terminated |_| Ongoing pregnancy |_| Hydatidiform mole |_| Lost to follow up |_|

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

(b) For items 6 and 9, please fill in the HKID card no. of patient/husband, or passport no. for non-HKID card holder.

(c) * Delete where inapplicable.

(d) For item 16, 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"

Council on Human Reproductive Technology

CONFIDENTIAL

DC Form 4

PREGNANCY OUTCOME FORM

For Official Use
No.

1. Name of centre : .....
2. HRT Council centre licence number : ☐☐☐☐
3. Patient's clinic record number : ☐☐☐☐☐☐☐☐

---

4. Date of *gamete transfer / embryo replacement / insemination resulting in pregnancy: Day ☐☐ Month ☐☐ Year ☐☐☐☐

5. Pregnancy outcome :	Fetal heart 1	Fetal heart 2	Fetal heart 3	Fetal heart 4	Fetal heart 5
no pregnancy	☐	☐	☐	☐	☐
miscarriage	☐	☐	☐	☐	☐
ectopic pregnancy	☐	☐	☐	☐	☐
heterotopic pregnancy	☐	☐	☐	☐	☐
pregnancy terminated	☐	☐	☐	☐	☐
reason for termination	.....	.....	.....	.....	.....
hydatidiform mole	☐	☐	☐	☐	☐
embryo reduction	☐	☐	☐	☐	☐
still birth	☐	☐	☐	☐	☐
live birth	☐	☐	☐	☐	☐
neonatal death	☐	☐	☐	☐	☐
lost to follow up	☐	☐	☐	☐	☐
others (describe)	.....	.....	.....	.....	.....
(Please complete item 6. if outcome is live birth)					

6. Baby born :	Baby 1	Baby 2	Baby 3	Baby 4	Baby 5
gestation (weeks)	☐☐	☐☐	☐☐	☐☐	☐☐
weight (grammes)	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐
sex	M☐ F☐	M☐ F☐	M☐ F☐	M☐ F☐	M☐ F☐
date of delivery	Day ☐☐ Month ☐☐ Year ☐☐☐☐	Day ☐☐ Month ☐☐ Year ☐☐☐☐	Day ☐☐ Month ☐☐ Year ☐☐☐☐	Day ☐☐ Month ☐☐ Year ☐☐☐☐	Day ☐☐ Month ☐☐ Year ☐☐☐☐
method of delivery	.....	.....	.....	.....	.....
7. Congenital abnormalities if present please describe :	.....	.....	.....	.....	.....

Note : (a) * Delete where inapplicable

(b) For item 5, heterotopic pregnancy refers to simultaneous existence of intrauterine and ectopic pregnancy. For such a case, please only tick against "heterotopic pregnancy" and need not tick against "ectopic pregnancy"

CONFIDENTIAL **DC Form 5**

(Set of 3 carbon copies. Top & second copy to be submitted to HRT Council when the donor's gametes are used and the third copy for the centre's record)

For Official Use
No.

DONOR INFORMATION FORM
(For Gamete Donor)

Top copy should be returned to the Council within one week of the date when a donor's gametes are used by a licensed centre. The second copy should be returned to the Council within three weeks of the date this donor's gametes are used with item 10 completed as appropriate. If it is reported that a donor's gametes have been used for treatment for 3 times, centres will be informed to freeze using the gametes of this particular donor for any further treatment. A successful pregnancy or live birth will be assumed after use of a donor's gametes for treatment has been reported unless the Council is informed otherwise. In such circumstances, centres will be informed if the gametes of this donor could be used again. Therefore, apart from reporting on item 10 of this form and reporting pregnancy information in DC Form 2 or 3 and 4, centres are encouraged to inform this Council if at any stage it is known that the treatment ends up with unsuccessful pregnancy.

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. HRT Council centre licence number : ☐☐☐☐ 3. Donor's clinic record number : ☐☐☐☐☐☐☐☐

---

4. FULL NAME of donor : ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ (Surname first)

5. Sex : Male ☐ Female ☐

6. Date of Birth : Day ☐☐ Month ☐☐ Year ☐☐☐☐. HKID / Passport No. : ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

---

8. Full Correspondence Address and Contact Telephone No.:

Room/Flat: ☐☐☐☐☐ Floor: ☐☐ Block: ☐☐☐☐☐

Name of Building: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

No. & Name of Street: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

District: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐ HK ☐ KLN ☐ NT

Tel. No. (Home): ☐☐☐☐☐☐☐☐ Tel. No. (Mobile): ☐☐☐☐☐☐☐☐

---

9. Date when gametes of this donor are used:

Day ☐☐ Month ☐☐ Year ☐☐☐☐

This is the ....(e.g. 1st/2nd/3rd/...) time of use in this centre.

10. Outcome of treatment :
- Clinical pregnancy ☐
- No pregnancy ☐
- Lost to follow up ☐

---

11. If this is for designated recipients, give names of the couple and their HKID/passport no :

FULL NAME of wife : ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

HKID / Passport No. : ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

FULL NAME of husband : ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

HKID / Passport No. : ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

---

12. Any donation at other centres : YES ☐ NO ☐

If yes, name of centre(s) : ....

13. Height (m) : |__|.__|__| 14. Weight (kgs) : |__|__|.__|__|

15. Ethnic group : Chinese |__| Other, describe |__|__|__|__|__|__|__|__|__|

16. Eye Colour : Brown |__| Other, describe |__|__|__|__|__|__|__|__|__|

17. Hair Colour : Black |__| Other, describe |__|__|__|__|__|__|__|__|__|

18. Occupation : |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|

Notes : (a) For items 7 and 11, please fill in the HKID card no. of donor/recipients, or passport no. for non-HKID card holder.

(b) Please leave item 8 blank if the donor does not want to be contacted after donation.

(c) Please also complete DC Form 2 or 3 and 4 as appropriate.

CONFIDENTIAL **DC Form 6**

(Set of 3 carbon copies. Top & second copy to be submitted to HRT Council when the donors' embryos are used and the third copy for the centre's record)

For Official Use
No.

DONOR INFORMATION FORM
(For Embryo Donors)

Top copy should be returned to the Council within one week of the date when a donor's embryos are used by a licensed centre. The second copy should be returned to the Council within three weeks of the date this donor's embryos are used with item 12 completed as appropriate. If it is reported that a donor's embryos have been used for treatment for 3 times, centres will be informed to freeze using the embryos of this particular donor for any further treatment. A successful pregnancy or live birth will be assumed after use of a donor's embryos for treatment has been reported unless the Council is informed otherwise. In such circumstances, centres will be informed if the embryos of this donor could be used again. Therefore, apart from reporting on item 12 of this form and reporting pregnancy information in DC Form 2 and 4, centres are encouraged to inform this Council if at any stage it is known that the treatment ends up with unsuccessful pregnancy.

A new DC Form 6 should be completed and returned to the Council each time when a donor's embryos are used.

---

1. Name of centre : ....

2. HRT Council centre licence number : |_|_|_|_| 3. Donor's clinic record number : |_|_|_|_|_|_|_|_|

---

4. FULL NAME of female donor : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|
(Surname first)

5. Date of Birth : Day |_|_| Month |_|_| Year |_|_|_|_| 6. HKID / Passport No. : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|

---

7. FULL NAME of male donor : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|
(Surname first)

8. Date of Birth : Day |_|_| Month |_|_| Year |_|_|_|_| 9. HKID / Passport No. : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|

---

10. Full Correspondence Address and Contact Telephone No.:

Room/Flat: |_|_|_|_|_| Floor: |_|_| Block: |_|_|_|_|_|

Name of Building: |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

No. & Name of Street: |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

District: |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_| |_| HK |_| KLN |_| NT

Tel. No. (Home): |_|_|_|_|_|_|_|_| Tel. No. (Mobile): |_|_|_|_|_|_|_|_|

---

11. Date when embryos of this donor are used:

Day |_|_| Month |_|_| Year |_|_|_|_|

This is the ………(e.g. 1st/2nd/3rd/…) time of use in this centre.

12. Outcome of treatment :
- Clinical pregnancy |_|
- No pregnancy |_|
- Lost to follow up |_|

---

13. If this is for designated recipients, give names of the couple and their HKID/passport no :

FULL NAME of wife : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

HKID / Passport No. : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|

FULL NAME of husband : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

HKID / Passport No. : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|

14. Any donation of embryos at other centres : YES ☐ NO ☐
If yes, name of centre(s) : ……..……

Any donation of eggs at other centres by the female donor: YES ☐ NO ☐
If yes, name of centre(s) : ……..……

Any donation of sperm at other centres by the male donor : YES ☐ NO ☐
If yes, name of centre(s) : ……..……

Particulars of female donor

15. Height (m) : ☐☐.☐☐	16. Weight (kgs) : ☐☐☐.☐☐
17. Ethnic group : Chinese ☐	Other, describe ……..…….
18. Eye Colour : Brown ☐	Other, describe ……..…….
19. Hair Colour : Black ☐	Other, describe ……..…….
20. Occupation : ……..	

Particulars of male donor

21. Height (m) : ☐☐.☐☐	22. Weight (kgs) : ☐☐☐.☐☐
23. Ethnic group : Chinese ☐	Other, describe ……..…….
24. Eye Colour : Brown ☐	Other, describe ……..…….
25. Hair Colour : Black ☐	Other, describe ……..…….
26. Occupation : ……..	

Notes : (a) For items 6, 9 and 13, please fill in the HKID card no. of donors/recipients, or passport no. for non-HKID card holder.

(b) Please leave item 10 blank if the donors do not want to be contacted after donation.

(c) Please also complete DC Form 2 and 4.

Annex III

Explanatory Notes for completing the forms
on annual statistics on reproductive technology treatment
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 eight individual forms numbered as follows -
  1. IVF-ET
  2. GIFT
  3. ZIFT/PROST
  4. Frozen-thawed ET
  5. ICSI
  6. Use of Reproductive Technology for Surrogacy Arrangement
  7. Use of Reproductive Technology for Gender Selection to Avoid Sex-linked Diseases
  8. Others [for any other programmes outside those numbered from 1 to 5. Please give the name of the programme in the bracket.]

- For the brackets or spaces with '±' sign on each form, please provide mean '±' SD (standard deviation) value.

- In the cases where diagnosis(es) is (are) not mentioned under the block-heading of "Infertility Diagnosis" in the forms, use the "Others" bracket to specify the diagnosis if singular and if multiple, use any adjacent available space within the block for their specification. For the multiple diagnoses cases, please take heed to individualise the diagnoses, and separately compute to provide values for all pertinent items.

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

Name of centre : _____

HRT Council centre licence no. : _____

Period covered : 1/1/20XX to 31/12/20XX

1. IVF-ET (In-Vitro Fertilisation & Embryo Transfer)

Patients' Characteristics

No. of patients	[ ]	Age, women	[±]
Infertility duration (yr)	[±]	Age, men	[±]

Infertility Diagnosis		Stimulation Protocol	
Male	[cycles]	Natural	[cycles]
Male plus tubal	[cycles]	Stimulated	[cycles]
Endometriosis	[cycles]	Cycles ending up with ovarian hyperstimulation	[cycles]
Male plus endometriosis	[cycles]		
Immunologic	[cycles]		
Tubo-peritoneal	[cycles]		
Unexplained	[cycles]		
Others ( )	[cycles]		
Donor semen	[patients]		
Donor oocyte	[patients]		

Clinical Results

	Natural cycle	Stimulated cycle
No. of cycles		
No. of oocyte recoveries (/cycle)	(%)	(%)
No. of ET		
No. of oocytes (/recovery)	±	±
No. of transferred embryos (/ET)	±	±
Fertilisation rate	%	%
No. of clinical pregnancies	cases	cases
Preg. rate (/recovery)	%	%
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.	cases	cases
(/clinical preg.)	(%)	(%)
Embryo reduction	cases	cases
(/clinical preg.)	(%)	(%)
Malformation	cases	cases
(/newborn)	(%)	(%)
No. of delivered or ongoing preg.	cases	cases
(/clinical preg.)	(%)	(%)
Delivery plus ongoing pregnancy rate		
(/cycle initiated)	(/cycle)	(/cycle)

No. of embryos stored as at end of the year : ( )

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

Name of centre : _____
HRT Council centre licence no. : _____
Period covered : 1/1/20XX to 31/12/20XX

2. GIFT (Gamete Intra-Fallopian Transfer)

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 ovarian hyperstimulation	[cycles]
Immunologic	[cycles]		
Peritoneal	cycles]		
Ovulatory	[cycles]		
Unexplained	[cycles]		
Others	[cycles]		
( )			
Donor semen	[patients]		
Donor oocyte	[patients]		

Clinical Results

	Natural cycle	Stimulated cycle
No. of cycles No. of oocyte recoveries (/cycle) No. of gamete transfer	(%)	(%)
No. of oocytes (/recovery) No. of transferred oocytes (/transfer)	± ±	± ±
No. of clinical pregnancies Preg. rate (/transfer)	cases %	cases %
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 initiated)	(/cycle)	(/cycle)

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

Name of centre : _____
HRT Council centre licence no. : _____
Period covered : 1/1/20XX to 31/12/20XX

3. ZIFT/PROST (Zygote Intra-Fallopian Transfer/Pronuclear Stage Tubal Transfer)

Patients' Characteristics

No. of patients	[ ]	Age, women	[±]
Infertility duration (yr)	[±]	Age, men	[±]

Infertility Diagnosis		Stimulation Protocol	
Male	[cycles]	Natural	[cycles]
Male plus tubal	[cycles]	Stimulated	[cycles]
Endometriosis	[cycles]	Cycles ending up with ovarian hyperstimulation	[cycles]
Male plus endometriosis	[cycles]		
Immunologic	[cycles]		
Tubo-peritoneal	[cycles]		
Ovulatory	[cycles]		
Unexplained	[cycles]		
Others ( )	[cycles]		
Donor semen	[patients]		
Donor oocyte	[patients]		

Clinical Results

	Natural cycle	Stimulated cycle
No. of cycles		
No. of oocyte recoveries (/cycle)	(%)	(%)
No. of zygote transfer		
No. of oocytes (/recovery)	±	±
No. of transferred zygotes (/transfer)	±	±
No. of clinical pregnancies	cases	cases
Preg. rate (/transfer)	%	%
Spont. abortion	cases	cases
(/clinical preg.)	(%)	(%)
Ectopic preg.	cases	cases
(/clinical preg.)	(%)	(%)
Heterotopic preg.	cases	cases
(/clinical preg.)	(%)	(%)
Termination	cases	cases
(/clinical preg.)	(%)	(%)
Still birth	cases	cases
(/clinical preg.)	(%)	(%)
Neonatal death	cases	cases
(/clinical preg.)	(%)	(%)
Lost to follow up	cases	cases
(/clinical preg.)	(%)	(%)
Multiple preg.	cases	cases
(/clinical preg.)	(%)	(%)
Embryo reduction	cases	cases
(/clinical preg.)	(%)	(%)
Malformation	cases	cases
(/newborn)	(%)	(%)
No. of delivered or ongoing preg.	cases	cases
(/clinical preg.)	(%)	(%)
Delivery plus ongoing pregnancy rate		
(/cycle initiated)	(/cycle)	(/cycle)

No. of embryos stored as at end of the year : ( )

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

Name of centre : _____

HRT Council centre licence no. : _____

Period covered : 1/1/20XX to 31/12/20XX

4. 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 ET		
Survival rate of frozen-thawed embryos	/ (%)	/ (%)
Duration of storage (month)	±	±
No. of transferred embryos (/ET)	±	±
No. of clinical pregnancies	cases	cases
Preg. rate (/ET)	%	%
Spont. abortion (/clinical preg.)	cases (%)	cases (%)
Ectopic preg. (/clinical preg.)	cases (%)	cases (%)
Heterotopic preg. (/clinical preg.)	cases (%)	cases (%)
Termination (/clinical preg.)	cases (%)	cases (%)
Still birth (/clinical preg.)	cases (%)	cases (%)
Neonatal death (/clinical preg.)	cases (%)	cases (%)
Lost to follow up (/clinical preg.)	cases (%)	cases (%)
Multiple preg. (/clinical preg.)	cases (%)	cases (%)
Embryo reduction (/clinical preg.)	cases (%)	cases (%)
Malformation (/newborn)	cases (%)	cases (%)
No. of delivered or ongoing preg. (/clinical preg.)	cases (%)	cases (%)
Delivery plus ongoing pregnancy rate (/cycle initiated)	(/cycle)	(/cycle)

No. of embryos stored as at end of the year : ( )

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

Name of centre : _____

HRT Council centre licence no. : _____

Period covered : 1/1/20XX to 31/12/20XX

5. 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 zygote transfer			
No. of oocytes (/recovery)	±	±	±
No. of transferred zygotes(/transfer)	±	±	±
Fertilisation rate	%	%	%
No. of clinical pregnancies	cases	cases	cases
Preg. rate (/recovery)	%	%	%
Preg. rate (/transfer)	%	%	%
Spont. abortion	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Ectopic preg.	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Heterotopic preg.	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Termination	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Still birth	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Neonatal death	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Lost to follow up	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Multiple preg.	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Embryo reduction	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Malformation	cases	cases	cases
(/newborn)	(%)	(%)	(%)
No. of delivered or ongoing preg.	cases	cases	cases
(/clinical preg.)	(%)	(%)	(%)
Delivery plus ongoing pregnancy rate			
(/cycle initiated)	(/cycle)	(/cycle)	(/cycle)

No. of embryos stored as at end of the year : ( )

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

Name of centre : _____

HRT Council centre licence no. : _____

Period covered : 1/1/20XX to 31/12/20XX

6. Use of Reproductive Technology for Surrogacy Arrangement

Patients' Characteristics

No. of patients	[ ]	Age, women	[±]
Infertility duration (yr)	[±]	Age, men	[±]

Infertility Diagnosis		Stimulation Protocol	
Hysterectomy	[case]	Natural	[cycles]
Absent/Abnormal uterus and/or ducts	[case]	Stimulated	[cycles]
		Cycles ending up with ovarian hyperstimulation	[cycles]
Others ( )	[case]		

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]
ZIFT/PROST	[cycles]	Others ( )	[cycles]

Clinical Results

	Natural cycle	Stimulated cycle
No. of cycles		
No. of oocyte recoveries (/cycle)	(%)	(%)
No. of embryos/zygotes transfer		
No. of oocytes (/recovery)	±	±
No. of transferred embryos/zygotes (/transfer)	±	±
Fertilisation rate	%	%
No. of clinical pregnancies	cases	cases
Preg. rate (/recovery)	%	%
Preg. rate (/transfer)	%	%
Spont. abortion	cases	cases
(/clinical preg.)	(%)	(%)
Ectopic preg.	cases	cases
(/clinical preg.)	(%)	(%)
Heterotopic preg.	cases	cases
(/clinical preg.)	(%)	(%)
Termination	cases	cases
(/clinical preg.)	(%)	(%)
Still birth	cases	cases
(/clinical preg.)	(%)	(%)
Neonatal death	cases	cases
(/clinical preg.)	(%)	(%)
Lost to follow up	cases	cases
(/clinical preg.)	(%)	(%)
Multiple preg.	cases	cases
(/clinical preg.)	(%)	(%)
Embryo reduction	cases	cases
(/clinical preg.)	(%)	(%)

Malformation (/newborn)	cases (%)	cases (%)
No. of delivered or ongoing preg. (/clinical preg.)	cases (%)	cases (%)
Delivery plus ongoing pregnancy rate (/cycle initiated)	(/cycle)	(/cycle)

No. of embryos stored as at end of the year : ( )

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

Name of centre : _____
HRT Council centre licence no. : _____
Period covered : 1/1/20XX to 31/12/20XX

7. 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 IVF-ET	[cases]	PGD with sex-selective zygote transfer	[	cases]
Sex-selective abortion	[cases]	Others ( )	[	cases]

Clinical Results

	Natural cycle	Stimulated cycle
No. of cycles		
No. of oocyte recoveries (/cycle)	(%)	(%)
No. of male embryo/zygote transfer	cases	
No. of female embryo/zygote transfer	cases	
No. of oocytes (/recovery)	±	±
No. of transferred embryos/zygotes (/transfer)	±	±
Fertilisation rate	%	%
No. of clinical pregnancies	cases	cases
Preg. rate (/recovery)	%	%
Preg. rate (/transfer)	%	%
Spont. abortion	cases	cases
(/clinical preg.)	(%)	(%)
Ectopic preg.	cases	cases
(/clinical preg.)	(%)	(%)
Heterotopic preg.	cases	cases
(/clinical preg.)	(%)	(%)
Termination	cases	cases
(/clinical preg.)	(%)	(%)
Still birth	cases	cases
(/clinical preg.)	(%)	(%)
Neonatal death	cases	cases
(/clinical preg.)	(%)	(%)
Lost to follow up	cases	cases
(/clinical preg.)	(%)	(%)
Multiple preg.	cases	cases
(/clinical preg.)	(%)	(%)
Embryo reduction	cases	cases
(/clinical preg.)	(%)	(%)
Malformation	cases	cases
(/newborn)	(%)	(%)
No. of delivered or ongoing preg.	cases	cases
(/clinical preg.)	(%)	(%)
Delivery plus ongoing pregnancy rate (/cycle initiated)	(/cycle)	(/cycle)

No. of fetuses aborted for sex selective abortion : male ( ) female ( )
[total cases] [cases] [cases]

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

Name of centre : _____

HRT Council centre licence no. : _____

Period covered : 1/1/20XX to 31/12/20XX

8. 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 ovarian hyperstimulation	[cycles]
Male plus endometriosis	[cycles]		
Immunologic	[cycles]		
Tubo-peritoneal	[cycles]		
Ovulatory	[cycles]		
Unexplained	[cycles]		
Others ( )	[cycles]		
Donor semen	[patients]		
Donor oocyte	[patients]		

Clinical Results

	Natural cycle	Stimulated cycle
No. of cycles		
No. of oocyte recoveries (/cycle)	(%)	(%)
No. of ET		
No. of oocytes (/recovery)	±	±
No. of transferred embryos (/ET)	±	±
Fertilisation rate	%	%
No. of clinical pregnancies	cases	cases
Preg. rate (/recovery)	%	%
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.	cases	cases
(/clinical preg.)	(%)	(%)
Embryo reduction	cases	cases
(/clinical preg.)	(%)	(%)
Malformation	cases	cases
(/newborn)	(%)	(%)
No. of delivered or ongoing preg.	cases	cases
(/clinical preg.)	(%)	(%)
Delivery plus ongoing pregnancy rate		
(/cycle initiated)	(/cycle)	(/cycle)

No. of embryos stored as at end of the year : ( )

*In the case of micromanipulations, please specify the type of methods (eg. Partial Zona Dissection, Subzonal Sperm Insertion, etc)