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From : Clerk to Bills Committee

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Bills Committee on Human Reproductive Technology Bill

Meeting on 9 February 1999

I attach a copy of the draft Code of Practice for discussion at the next meeting to be held on 9 February 1999.

(Mrs Eleanor CHOW)
for Clerk to Bills Committee

Encl.

c.c. Hon LAU Chin-shek, JP
SALA

Draft as at January 1999
To be finalised before it is issued for consultation

(DRAFT)

CODE OF PRACTICE ON REPRODUCTIVE TECHNOLOGY AND EMBRYO RESEARCH

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donors)

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CODE OF PRACTICE ON REPRODUCTIVE TECHNOLOGY AND EMBRYO RESEARCH

I. Introduction

Preamble

1.1 The Provisional Council on Reproductive Technology (the Provisional Council) was appointed by the Secretary for Health & Welfare in 1996 to advise Government on the drafting of legislation and a Code of Practice on reproductive technology (RT) and embryo research. The Provisional Council takes a multidisciplinary approach in formulating proposals to ensure the safe and informed practice of 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 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 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. The Code will be reviewed and updated as necessary to keep up with developments in RT. Although the Code is not legally binding, the Council on Human Reproductive Technology (the Council), which is the licensing authority for RT services and embryo research, may 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.

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

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 familiarise themselves with the Human Reproductive Technology Ordinance (the Ordinance) (Chapter _____, Law of Hong Kong). Reference should be made to the Interpretation Section of 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.

The 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.

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

(a) that the other persons to whom the licence applies 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 suitable 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.

2.6 It is the duty of the licensee to ensure that the person responsible discharges his/her duty.

Medical Practitioners

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

2.8 The overall clinical responsibility for RT procedures should be held by someone with relevant training and experience and with postgraduate 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. Medical staff in a training capacity shall only carry out such procedures under supervision.

Nursing Staff

2.9 All nursing staff employed by RT centres must be effectively registered under the Nurses Registration Ordinance (Cap 164) and be appropriately trained for the duties they carry out.

Staff Engaged in Scientific/Laboratory Services

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

2.11 Scientific or laboratory staff should have a degree or higher qualification in a relevant discipline, plus a period of experience sufficient to qualify them to perform the duties of the respective RT procedure.

Counsellors

2.12 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

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

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.

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 person 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 upto the specifications laid down in the World Health Organisation (WHO) laboratory manual for examination of human semen and semen-cervical mucus interaction, 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. All culture media currently in use require incubation with 5% carbon dioxide.

(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.

(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 If cryopreservation is among the activities carried out by the RT centre, the appropriate equipment, including a controlled biological freezer and liquid nitrogen facilities maintained by automatic filling, 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, contamination or confusion relating to the donor's identification.

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 the Welfare of Children

4.1 Under the Ordinance, RT treatment should only be provided to persons who are parties to a marriage, except in circumstances to be specified in the Human Reproductive Technology Regulation (the Regulation).

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, consideration should be given to the physical, mental and social wellbeing. The impact on the spouse, children and family as well as the welfare of the child who may be born should also be taken into account. The following factors should be considered -

(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;

(g) the effect of any new baby or babies upon any existing child of the family; and

(h) in cases where donated gametes are used, the possible

attitudes of other members of the family towards the child.

Welfare of the Child

4.4 Proper counselling should be provided to the commissioning couple and concerned parties before RT treatment is provided. In particular, the welfare of any child who may be born as a result of the treatment, and of any child who may be affected by the birth must be taken into account.

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 for 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 exceptional cases or where the gametes are to be used for their own or their partner's treatment. 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 partner'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.

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.

Persons considered unsuitable as donors

4.12 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

4.13 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 gametes or an embryo to be supplied; and

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

V. Information to Clients and Donors

General

5.1 RT centres should devise a mechanism to ensure that relevant information is given to people 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 Ordinance such as -

(a) the legal status of the child and parents,

(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, and

(c) the legal obligation of RT centres to report information to the Council in accordance with 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 HIV antibody test;

(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 incest.

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,

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

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

(d) reimbursement may only be given in accordance with the provision in the Ordinance (please see para 4.13 for details).

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 the 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 the Storage and Use of Gametes and Embryos
(this section is not applicable to anonymous donors)

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.

6.7 Designated donations of sperm/oocytes/embryos should not be permitted unless under very exceptional 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 Register A Form 2 or 3, as applicable, as required in para 14.4. 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.

6.8 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).

6.9 Donors should be informed that they are required to give 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 renewal notice.

6.10 Donors may vary or withdraw their consent at any time in writing provided that the genetic material has not already been used (ie the point before the gametes or embryos have been used in treatment or research).

6.11 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 (eg, 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 possibility 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. The resulting children may apply to the Council when they reach the age of 16 to check that they were born in consequence of RT involving donated gametes or donated embryos although no identifying information about the donor would be released.

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).

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, clients should be referred for specialist counselling or support group counselling as appropriate.

Counselling for Potential Donors of Gametes or Embryos

7.9 Counsellors should ask potential donors of gametes or embryos to consider all possible implications such as -

(a) their reasons for wanting to donate gametes or embryos;

(b) implications of the procedure for themselves, their spouse, their family and relatives, their social circle and any resulting child;

(c) their feelings about manipulation of their gametes or embryos outside the human body and the possible storage and disposal of gametes or embryos;

(d) their willingness to forego knowledge of and responsibility for the resulting children;

(e) 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. The resulting children may apply to the Council when they reach the age of 16 to check that they were born in consequence of RT involving donated gametes or donated embryos although no identifying information about the donor would be released.

VIII. Treatment Methods

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 implanted 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, for special circumstances with medical justification, the limit of three oocytes or embryos may be relaxed for women above the age of 35 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 that in order to improve the survival of the embryos, a procedure of fetal reduction may be necessary. However because of the uncertainties as to whether selective reduction and reduction of multiple pregnancy in utero are authorised under s.47A of the Offences against the Person Ordinance, Cap 212, such fetal reduction procedure should not be carried out unless it is authorised by the court. 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 done 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.

The Use of Gonadotrophins

8.10 Please refer to **Appendix II** for the guidelines provided by the Hong Kong College of Obstetricians & Gynaecologists on the use of gonadotrophins.

IX. Use of Gametes and Embryos

Collection of Gametes or Embryos

9.1 Collection of sperm 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 AIH, either banked or fresh semen can be used.

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

Importation of Gametes or Embryos

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, eg no embryo that is created for research should be imported;

(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 agree to ensure that the 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 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 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.

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

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

9.8 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, for special circumstances with medical justifications, the limit of three oocytes or embryos may be relaxed for patients above the age of 35 so that a maximum of four or five oocytes or embryos could be replaced in the first and subsequent treatment cycles respectively. Such justification must be recorded in the medical record.

9.9 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

9.10 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

9.11 No embryo beyond 14 days old may be exported.

9.12 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.

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

9.14 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.

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. Periodic review of the status of the stored materials should be performed at least once a year.

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 The maximum storage period for gametes or embryos stored for patients' own infertility 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 very exceptional circumstances may a designated recipient other than the spouse be permitted (also see para 6.7 for reporting

information to the Council on such cases). The maximum storage period for donated sperm or embryos for a designated recipient other than the spouse should not exceed one year.

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.

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 should not be allowed. 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.

10.13 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. 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 guiding principles 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 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 (ie 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 gametes or 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 should not be used by the surviving spouse to bring about a post-humous child.

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.

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. However, if the patient has given written consent, or the commissioning couple have given conjoint written 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 para 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 (ie 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. 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. 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.

XI. Research

Basic Principles

11.1 The basic principles of the Declaration of Helsinki 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.

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

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 approval.

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 -

(a) to bring about the creation of a human embryo for the purpose of 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 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.

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

(a) on the validity of the research;

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

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

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

Use of Fetal Ovarian or Testicular Tissue

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

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 approval.

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 should be subject to rigorious 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.

Terms of Reference and Membership of Institutional (Research) Ethics Committee

11.24 The terms of reference of existing research ethics committees of local professional and academic bodies are generally in line with the principles of the Declaration of Helsinki. The Committees should be responsible for scrutinising 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 Where an institution performing embryo research does not have a research ethics committee, such committee should be formed in accordance with the principles of the Declaration of Helsinki. As a general guideline, the following terms of reference could be considered -

(a) to advise the appointing institution on the ethics of the methodology involved in research involving human gametes or embryos;

(b) to keep under review such guidelines on the ethical requirements in research involving human gametes or embryos;

(c) to consider individual research protocols submitted to the committee, to advise the investigators and other bodies in the light of approved guidelines and where appropriate to certify that ethical requirements have been fulfilled, to enable researchers to state in their publications that ethical problems have received independent consideration; and

(d) to seek advice as appropriate from specialist advisers.

11.26 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.

12.2 Under the Ordinance, only genetic surrogacy is allowed, i.e. where the commissioning couple contributes both the sperm and egg to be fertilised outside or inside the body of the surrogate mother.

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

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

12.7 Counselling must be provided by a multidisciplinary 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.

12.8 A minor should not act as a surrogate mother.

12.9 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 Register A Form 2 as required in para 14.4. 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 should only be offered in cases where 2 registered medical practitioners have certified that it is necessary for the purpose of avoiding or preventing the birth of a child with a severe sex-linked genetic disease.

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

13.3 A list of examples of sex-linked genetic disorders is provided at **Appendix IV**. The list is, however, by no means exhaustive.

13.4 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
- the family and social support available for the parents

13.5 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.

13.6 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.

13.7 Preimplantation genetic diagnosis (PGD) with sex-selective zygote transfer should only be carried out on medical grounds. PGD should not include a X or Y probe if the screening is only to determine normality of the embryo.

13.8 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.

13.9 RT centres should report to the Council on cases of sex selection achieved through RT (eg using sperm treatment with sex-selective insemination or preimplantation 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 Regulation will specify any other information to be submitted to the Council.

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.

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 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 law. Such records must allow contact to be made with any relevant parties in the event of later medical complications.

Submission of Information

(A) The Central Register (Register A)

14.3 RT centres are required under the Ordinance to submit to the Register kept by the Council information related to the provision of a RT procedure for an identifiable individual (including identity of his/her spouse) where the procedure involves the use of-

(a) the gametes donated by another identifiable individual who is not the first-mentioned individual's spouse; and

(b) an embryo donated by another identifiable couple or an embryo formed with gametes donated by two other identifiable individuals.

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

14.4 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.

14.5 The information required in (A) and (B) above should be submitted in the prescribed format using the data collection forms at **Annex II**.

(C) Others

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

(a) designated donation (para 6.7)
(b) exportation of gametes and embryos (para 9.14)
(c) surrogacy (para 12.9)
(d) sex selection (paras 13.9 and 13.10)

(D) Annual Statistics

14.7 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).

Access to Information

14.8 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. However, in accordance with the provisions in the Ordinance, no identifying information regarding the gamete or embryo donor is to be released.

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

14.9 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.

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 be 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.

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

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.

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 or partner's sperm is used. In artificial insemination by donor (AID or DI), sperms collected from a man who is not the woman's husband or partner 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℃, in order to store them for subsequent use.

6. **DNA:**
Deoxyribonucleic acid, the major constituent of the chromosomes, and the hereditary material of most living organisms.

7. **Ectogenesis:**
The complete development of an embryo outside the body.

8. **Ectopic pregnancy**
A pregnancy in which implantation has taken place outside the uterine cavity.

9. **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.

10. **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.

11. **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 flusing 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.

12. **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).

13. **Fallopian tubes:**
The organs which carry an egg from the ovary to the womb.

14. **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.

15. **Fertilisation:**
The fusing together of the maternal and paternal genetic material from the sperm and the egg.

16. **Foetus:**
The product of conception from end of embryonic stage (eight weeks after fertilisation) until birth.

17. **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.

18. **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).

19. **Gamete intra-fallopian transfer (GIFT):**
A process by which an egg or eggs are tranferred with sperm into the woman's fallopian tubes so that fertilisation can in vivo.

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

21. **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 techniques is used for couples in which the male partner has severely impaired or few sperm.

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

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

24. **In-vitro fertilisation (IVF):**
This techniques 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.

25. **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.

26. **Ovary:**
The female reproductive organ in which oocytes are produced from pre-existing germ cells.

27. **Ovulation:**
The release of an egg from a follicle in the ovary.

28. **Ovum:**
Egg; female gamete.

29. **Primitive Streak:**
A groove which develops in the embryo about 14-15 days after fertilisation. This is the rudimentary nervous tissue of the embryo.

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

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

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

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

34. **Zygote:**
The cell formed by the union of sperm and egg.

35. **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 Donors Against Infectious Diseases

The following guidelines for screening potential gamete donors aim to decrease the potential hazards for transmitting infectious diseases through gamete 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

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

Medical History

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

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

Physical Examination

1. 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.

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

Laboratory Screening

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:

1. Serologic tests for syphilis should be obtained initially on blood serum and need not be repeated unless clinically indicated.

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

3. 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.

4. Serum antibody tests (immunoglobulin G) for CMV should be obtained.

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

   (b) 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.

   (c) The donor should also be monitored for any development of heterophil-negative mononucleosis-type illness.

5. An initial serum screening for HIV antibodies should be performed.

   (a) A positive assay should be verified with a Western Blot test before notifying the potential donor.

   (b) If the test is negative, semen samples may be collected and prepared for cryopreservation.

   (c) 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.

B. Guidelines for Screening Potential Oocyte Donors

In general, the screening of oocyte 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.

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

Freezing and Quarantining of Oocytes or Embryos

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

2. Couples entering an oocyte donor programme should be given the following choice:

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

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

Appendix II

Guidelines by the Hong Kong College of Obstetricians and Gynaecologists for the Use of Gonadotrophins

1. Introduction

Recent changes in infertility practice have meant that gonadotrophic hormones are now used in a far wider group of infertile patients than merely those with anovulation.

The use of gonadotrophic hormone preparations to induce multiple follicular growth for in vitro fertilisation (IVF) falls within the remit of the Provisional Council on Reproductive Technology and the future Council on Reproductive technology, who will issue their own Code of Practice in relation to treatments covered by the Human Reproductive Technology Bill (1997) recently tabled at the Legislative Council, so are not discussed here.

2. Current Use of Gonadotrophins

2.1 Anovulation

There is good evidence that medical treatments are highly effective in ovulatory infertility where a specific problem in the hypothalamic pituitary axis has been identified. For hyperprolactinaemia, bromocryptine or another dopamine agonist are appropriate first time treatments. Pulsatile administration of GnRH has proven efficacy in selected patients with hypogonadotrophic amenorrhoea and in the remainder of clomiphene resistant patients the use of gonadotrophins is indicated with reported excellent results.

2.2 Polycystic Ovary Syndrome

Treatment of ovulatory dysfunction caused by the more complex hormonal dysfunctions in patients with polycystic ovary syndrome are less effective but the use of gonadotrophins is commonly tried with successful conception. The polycystic ovary may be more sensitive to such treatment regimens and requires particular vigilance or use of GnRH analogue and gonadotrophin regimens.

2.3 Superovulation with Intrauterine Insemination (IUI) or Donor Inseminaiton (DI)

Many "unexplained" infertile women with normal ovulatory cycles are now receiving gonadotrophin therapy to induce multiple ovarian follicles in an effort to try to improve the chances of conception in any given cycle. Used in conjunction with IUI this may be an effective therapy, although only for the first few cycles. IUI without ovarian stimulation does not appear to be an effective treatment when compared to an untreated control group. Many clinics are now using gonadotrophic treatment in donor insemination cycles using the same logic of hopefully improving per cycle fecundity rates from the induction of multiple ovulations.

3. Concerns with Gonadotrophin Therapy

Induction of ovulation in anovulatory women, or hyperstimulation of ovulatory women, results in unpredictable numbers of follicles and hence oocytes. Patients with polycystic ovaries may be particularly at risk. Multiple pregnancy occurs in approximately 15 - 20% of cases following gonadotrophin induced ovulations. Measures should be taken to avoid these multiple pregnancies whenever possible because of the increased likelihood of pre-term deliveries and the higher perinatal morbidity and mortality associated with delivery of small pre-term infants.

The aim should also be to avoid selective fetal reduction being contemplated because infertility treatment has caused a higher order multiple pregnancy.

Ovarian hyperstimulation syndorme with its resultant discomfort and pain, fluid-balance alterations and risk of thrombosis can be a fatal condition and is to be avoided wherever possible. Whilst appropriate selection of patients, treatment protocols, effective gonadotrophin (hCG) injections can reduce its rate, the risk cannot be entirely removed in any cycle in which gonadotrophins are administered.

There is no convincing evidence at the present moment that gonadotrophic hormone preparations can cause ovarian cancer. Patients undergoing ovulation induction may be advised that we are aware of this particular concern but the current available evidence is insufficient to implicate or otherwise gonadotrophins.

4. **Recommendations**

4.1 **Selection of patients** - Treatment with gonadotrophins should be restricted to appropriately investigated couples with a diagnosis in whom such treatment has been shown to be beneficial in view of its costs and risks. Results in relation to patients' age and diagnosis should be considered.

4.2 **Welfare of child** - As with all types of "assisted conception", the welfare of any resulting child from the treatment and of other existing children, must be considered.

4.3 **Counselling** - Prior to treatment couples must be made aware of the problem of multiple pregnancy and the potential risks this carries during the antenatal, intrapartum and neonatal period as well as subsequently. The risk of ovarian hyperstimulation syndrome and its symptoms during development need highlighting.

4.4. **Treatment Centre** - Stimulation of ovarian function with gonadotrophins should be restricted to specialist practice with access to intensive monitoring by plasma or serum estradiol and pelvic ultrasound. Careful monitoring is especially important to allow adjustment of dosage and to avoid hyperstimulation. Such specialist practice centres should also have trained gynaecologists with specialist knowledge and facilities to monitor and treat patients with hyperstimulation should it develop.

4.5 **Multiple Pregnancy** - In the management of induction of ovulation it is extremely important to prevent multiple pregnancy. In general regimens which minimise or avoid the risk of multiple pregnancy, even at the expense of lower pregnancy rates are recommended. No further gonadotrophins should be given and the ovulatory dose of hCG should be withheld if there are more than three follicles with maximum diameter of 16-18 mm. *When hCG is withheld because of the risk of ovaian hyperstimulation and/or multiple pregnancy, the couple should be warned of such risk and to avoid sexual intercourse*. The number and size of the secondary cohort of follicles need also to be considered in the timing or advisability to administer further gonadotrophins or hCG (this does not apply to IVF or GIFT cycles).

5. These guidelines do not define a standard of care, nor is it intended to dictate an exclusive course of management. It presents recognised methods and techniques of clinical practice for consideration by

obstetricians/gynaecologists for incorporation into their practices. Variation of practice taking into account the needs of the individual patient, resources and limitations unique to the institution or type of practice may be appropriate.

Appendix III

World Medical Association Declaration of Helsinki

Recommendations guiding physicians in biomedical research involving human subjects

Adopted by the 18th World Medical Assembly
Helsinki, Finland, June 1964

and amended by the
29th World Medical Assembly, Tokyo, Japan, October 1975
35th World Medical Assembly, Venice, Italy, October 1983
41st World Medical Assembly, Hong Kong, September 1989
and the
48th General Assembly,
Somerset West, Republic of South Africa, October 1996

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

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."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

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

In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic

or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special 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.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. Basic Principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical 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 his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison

with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimise the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.

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

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

Whenever the minor child is in fact able to give a consent, the minor's

consent must be obtained in addition to the consent of the minor's legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. Medical Research combined with Professional Care (Clinicla Research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, reestablishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method. This does not exclude the use of inert placebo in studies where no proven diagnostic or therapeutic method exists.

4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.

5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (1, 2).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-Therapeutic Biomedical Research Involving Human Subjects (Non-Clinical Biomedical Research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subject should be volunteers - either healthy persons or patients for whom the experimental design is not related to the patient’s illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well being of the subject.

Appendix IV

Mendelian Disorders Following X-Linked Inheritance

Addison's disease with cerebral sclerosis
Adrenoleucodystrophy
Adrenal hypoplasia (one type)
Agammagloblinaemia, Bruton type (sometimes also Swiss type)
Albinism, ocular
Albinism-deafness syndrome
Aldrich syndrome
Alport syndrome (some kindreds)
Amelogenesis imperfecta (two types)
Anaemia, hereditary hypochromic
Angiokeratoma (Fabry's disease)
Cataract, congenital (one type)
Cerebellar ataxia (one type)
Cerebral sclerosis, diffuse
Charcot-Marie-Tooth peroneal muscular atrophy (one type)
Choroideraemia
Choroidoretinal degeneration (one rare type)
Coffin-Lowry syndrome
Colour blindness (several types)
Deafness, perceptive (several types)
Diabetes insipidus, nephrogenic
Diabetes insipidus, neurohypophyseal (some families)
Dyskeratosis congenita
Ectodermal dysplasia, anhidrotic
Ehlers-Danlos syndrome, type V
Faciogenital dysplasia, (Aarskog syndrome)
Focal dermal hypoplasia*
Glucose 6-phosphate dehydrogenase deficiency
Glycogen storage disease, type VIII
Gonadal dysgenesis (XY female type)
Granulomatous disease (chronic)
Haemophilia A
Haemophilia B
Hydrocephalus (aqueduct stenosis, one type)
Hypophosphataemic rickets
Ichthyosis (steriod sulphatase deficiency)
Incontinentia pigmenti*
Kallmann syndrome
Keratosis follicularis spinulosa
Lesch-Nyhan syndrome (hypoxanthine-guanine-phosph transferase deficiency)
Lowe (oculocerebrorenal) syndrome
Macular dystrophy of the retina (one type)
Menkes syndrome
Mental retardation, with or without fragile site (several specific types)
Microphthalmia with multiple anomalies (Lenz syndrome)
Mucopolysaccharidosis II (Hunter syndrome)
Muscular dystrophy (Becker, Duchenne and Emery-Dreifuss types)
Myotubular myopathy (one type)
Night blindness, congenital stationary
Norrie's disease (pseudoglioma)
Nystagmus, oculomotor or 'jerky'
Ornithine transcarbamylase deficiency (type I hyperammonaemia)
Orofaciodigital syndrome (type 1)*
Phosphoglycerate kinase deficiency
Phosphoribosylpyrophosphat (PRPP) synthetase deficiency
Reifenstein syndrome
Retinitis pigmentosa (one type)
Retinoschisis
Spastic paraplegia (one type)
Spinal muscular atrophy (one type)
Spondyloepiphyseal dysplasia tarda
Testicular feminization syndrome
Thrombocytopenia, hereditary (one type)
Thyroxine-binding globulin, absence or variants of
Xg blood group system

*X-linked dominant, male lethal.

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. upto _____ ; or
(dd/mm/yr)
(b)* until I am _____ years old[@(b)], i.e. upto _____,
(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 _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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)* My wife may not become pregnant or in the event of conception, she may not be able to carry the pregnancy to term;

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

    (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.

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 _____
(please specify names of persons who are the origins of 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. upto _____,
(dd/mm/yr)
and upon expiry of the storage 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, (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 - _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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 wife may not become pregnant or in the event of conception, she 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 embryo transfer;

    (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 stored and used for the treatment of infertile couples.

2. 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.

3. 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.

4. 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.

5. I understand that the centre is subject to the Code of Practice published by the _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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.

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.

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

Signed _____
(Donor's Signature)

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

Date of Birth _____
(dd/mm/yr)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Position _____

* 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 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.

4. 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.

5. 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.

6. I understand that the centre is subject to the Code of Practice published by the _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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.

7. 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 -

_____

_____

8. 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.

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

Signed _____
(Donor's Signature)

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

Date of Birth _____
(dd/mm/yr)

Signed _____
(Signature of Witness)

Name _____
(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 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. I have also been offered a suitable opportunity to take part in counselling with _____ about the implications of the treatment.

3. 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.

4. 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.

5. We understand that the centre is subject to the Code of Practice published by the _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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.

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.

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 _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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 _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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 (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 names of persons who are the origins of gametes)

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 understand that the centre is subject to the Code of Practice published by the _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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

9. 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).

10. I understand that the centre is subject to the Code of Practice published by the _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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 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.

3. 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.

4. 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 -

   _____

   _____

5. 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.

6. I understand that the centre is subject to the Code of Practice published by the _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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

7. 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.

8. 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.

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

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

11. We understand that the centre is subject to the Code of Practice published by the _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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 (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 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 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.

5. 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 -

   _____

   _____

6. 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.

7. I understand that the centre is subject to the Code of Practice published by the _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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 _____
(Signature of Attending Doctor)

Signed _____
(Signature of Witness)

Name _____
(in Block Letters)

Name _____
(in Block Letters)

Position _____

Part II RECIPIENTS' CONSENT

8. 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.

9. 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.

10.* 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 one year, up to _____, upon expiry of
(dd/mm/yr)
the storage period specified above, the centre may dispose of the stored embryos.

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

12. We understand that the centre is subject to the Code of Practice published by the _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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 _____ 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 sperm and eggs 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 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.

3. 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.

4. 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 -

   _____

   _____

5. 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.

6. We understand that the centre is subject to the Code of Practice published by the _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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 _____ 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

7. 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.

8. 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.

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

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

11. We understand that the centre is subject to the Code of Practice published by the _____ from time to time and to all laws which are or will be in force [including the Human Reproductive Technology Ordinance (Cap ?)] 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 _____ 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 _____, and
(Surname, Given Names) (ID No.)
_____, 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 _____ on which a consent form on
(please specify names of persons who are the origins of gametes)
embryo storage has previously been 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 _____
(Signature) (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

Annex II

Council on Human Reproductive Technology

'ONFIDENTIAL

Register A 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 HRT Council Register A Form 4 to report on details concerning outcome of pregnancy.

(b) * Delete where inapplicable

(c) @ For surrogacy cases, please refer to para 12.9 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.

CONFIDENTIAL

Register A 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 6.9 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 $1^{st}/2^{nd}/3^{rd}$ 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	|_|

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

otes : (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 Register A 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

CONFIDENTIAL

Register A Form 3

For Official Use
No.

DONOR INSEMINATION TREATMENT FORM

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 |_| NO |_|
Genetic YES |_| NO |_|
Others (please specify) ....

11. The donation is *anonymous/designated. (If the donation is designated, please refer to para 6.9 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 HRT Council Register A 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

CONFIDENTIAL

Council on Human Reproductive Technology

Register A Form 4

PREGNANCY OUTCOME FORM

For Official Use
No.

Name of centre : .....

HRT Council centre licence number : ☐☐☐

Patient's clinic record number : ☐☐☐☐☐☐☐

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

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)					

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	.....	.....	.....	.....	.....
Congenital abnormalities if present please describe :	.....	.....	.....	.....	.....

te : * Delete where inapplicable

Council on Human Reproductive Technology

Register A Form 5

CONFIDENTIAL

(Set of 4 carbon copies. One copy to be submitted to HRT Council each time when the donor's gametes are used and the fourth copy for the centre's record)

For Official Use
No.

DONOR INFORMATION FORM
(For Gamete Donor)

Top copy should be returned to the HRT Council within one week of the date this donor's gametes are first supplied for use in treatment by a licensed centre. Similarly the second and third copy should be returned to the Council within one week of the date this donor's gametes are used for the second and third time with item 8 completed as appropriate.

---

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 |_|_| 7. HKID / Passport No. : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|

---

8. Date when gametes of this donor are first supplied for use in treatment :

	Day	Month	Year
For the first time :	|_|_|	|_|_|	|_|_|
For the second time :	|_|_|	|_|_|	|_|_|
For the third time :	|_|_|	|_|_|	|_|_|

---

9. 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. : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|

---

10. Any donation at other centres : YES |_| NO |_|
If yes, name of centre(s) : ....

---

11. Height (m) : |_|.|_|_| 12. Weight (kgs) : |_|_|.|_|_|

---

13. Ethnic group : Chinese |_| Other, describe |_|_|_|_|_|_|_|_|_|

---

14. Eye Colour : Brown |_| Other, describe |_|_|_|_|_|_|_|_|_|

---

15. Hair Colour : Black |_| Other, describe |_|_|_|_|_|_|_|_|_|

---

16. Occupation : |_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

<u>Note</u> : For items 7 and 9, please fill in the HKID card no. of donor/recipients, or passport no. for non-HKID card holder.

(Form 5/97)

Council on Human Reproductive Technology

:ONFIDENTIAL

Register A Form 6

(Set of 4 carbon copies. One copy to be submitted to HRT Council each time when the donors' embryos are used and the fourth copy for the centre's record)

For Official Use No.

DONOR INFORMATION FORM
(For Embryo Donors)

Top copy should be returned to the HRT Council within one week of the date these donors' embryos are first supplied for use in treatment by a licensed centre. Similarly the second and third copy should be returned to the Council within one week of the date these donors' embryos are used for the second and third time with item 10 completed as appropriate.

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. Date when embryos of these donors are first supplied for use in treatment :

	Day	Month	Year
For the first time :	|_|_|	|_|_|	|_|_|
For the second time :	|_|_|	|_|_|	|_|_|
For the third time :	|_|_|	|_|_|	|_|_|

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 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) : ....

'articulars of female donor

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 : ....

CONFIDENTIAL

Register A Form 6(2)

Particulars of male donor

19. Height (m) :	☐.☐☐	20. Weight (kgs) :	☐☐.☐☐
21. Ethnic group : Chinese	☐	Other, describe	
22. Eye Colour : Brown	☐	Other, describe	
23. Hair Colour : Black	☐	Other, describe	
24. Occupation :			

Note : For items 6, 9 and 11, please fill in the HKID card no. of donors/recipients, or passport no. for non-HKID card holder.

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 (ie from January 1 to December 31 of the year) should be included.

- There are six individual forms numbered as follows -
  1. IVF-ET
  2. GIFT
  3. ZIFT/PROST
  4. Frozen-thawed ET
  5. ICSI
  6. 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 : 1/1/19XX to 31/12/19XX

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 (/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 : 1/1/19XX to 31/12/19XX

2. GIFT (Gamete Intra-Fallopian Transfer)

Patients' Characteristics

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

Infertility Diagnosis

Male	[cycles]
Endometriosis	[cycles]
Male plus endometriosis	[cycles]
Immunologic	[cycles]
Peritoneal	cycles]
Ovulatory	[cycles]
Unexplained	[cycles]
Others	[cycles]
( )	
Donor semen	[patients]
Donor oocyte	[patients]

Stimulation Protocol

Natural	[cycles]
Stimulated	[cycles]
Cycles ending up with ovarian hyperstimulation	[cycles]

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	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)

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 : 1/1/19XX to 31/12/19XX

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 : 1/1/19XX to 31/12/19XX

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 : 1/1/19XX to 31/12/19XX

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)	± ±	± ±	± ±
No. of clinical pregnancies Preg. rate (/recovery) Preg. rate (/transfer)	cases % %	cases % %	cases % %
Spont. abortion (/clinical preg.)	cases (%)	cases (%)	cases (%)
Ectopic preg. (/clinical preg.)	cases (%)	cases (%)	cases (%)
Heterotopic preg. (/clinical preg.)	cases (%)	cases (%)	cases (%)
Termination (/clinical preg.)	cases (%)	cases (%)	cases (%)
Still birth (/clinical preg.)	cases (%)	cases (%)	cases (%)
Neonatal death (/clinical preg.)	cases (%)	cases (%)	cases (%)
Lost to follow up (/clinical preg.)	cases (%)	cases (%)	cases (%)
Multiple preg. (/clinical preg.)	cases (%)	cases (%)	cases (%)
Embryo reduction (/clinical preg.)	cases (%)	cases (%)	cases (%)
Malformation (/newborn)	cases (%)	cases (%)	cases (%)
No. of delivered or ongoing preg. (/clinical preg.)	cases (%)	cases (%)	cases (%)
Delivery plus ongoing pregnancy rate (/cycle 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 : 1/1/19XX to 31/12/19XX

6. Others* (**)**

Patients' Characteristics

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

Infertility Diagnosis		Stimulation Protocol	
Male	[cycles]	Natural	[cycles]
Male plus tubal	[cycles]	Stimulated	[cycles]
Endometriosis	[cycles]	Cycles ending up with	
Male plus endometriosis	[cycles]	ovarian hyperstimulation	[cycles]
Immunologic	[cycles]		
Tubo-peritoneal	[cycles]		
Ovulatory	[cycles]		
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)**