Licensing Manual for Reproductive Technology Centres

Council on Human Reproductive Technology

April 2025

CONTENTS **Page**

CONTENTS **Page**

ANNEXES

SECTION 1 – LICENSING SYSTEM

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1. Introduction

1.1 This "Licensing Manual" is published by the Council on Human Reproductive Technology to provide guidance to persons who intend to apply for a licence or for renewal of a licence to carry on relevant activities under the Human Reproductive Technology Ordinance (Cap. 561) ("the Ordinance"). It is recommended that an intended applicant read and follow the instructions contained in this manual. Although this manual is based on the licensing system as stipulated under the Ordinance and the Human Reproductive Technology (Licensing) Regulation ("the Regulation"), in case of any discrepancy, the Ordinance and the Regulation prevail and intended applicants are advised to familiarize themselves with the Ordinance and the Regulation as well.

1.2 In this manual, unless the context otherwise requires —

"the Council" refers to the Council on Human Reproductive Technology

"the Ordinance" refers to the Human Reproductive Technology Ordinance (Cap. 561)

"the HRT (Licensing) Regulation" refers to the Human Reproductive Technology (Licensing) Regulation (Cap. 561 sub. Leg. A)

"the HRT (Fees) Regulation" refers to the Human Reproductive Technology (Fees) Regulation (Cap. 561 sub. Leg. B)

"the Code" refers to the Code of Practice on Reproductive Technology and Embryo Research issued by the Council on Human Reproductive Technology

"the Supplementary Code" refers to the Supplementary Code of Practice on Reproductive Technology – Artificial Insemination by Husband (AIH) annexed to the Code

"the Secretariat" refers to the Secretariat for the Council on Human Reproductive Technology

2. The Human Reproductive Technology Ordinance (Cap. 561)

2.1 Before a person carries out any relevant activity governed by the Ordinance, a licence for that activity must be obtained from the Council.

2.2 The objective of the Ordinance and its subsidiary regulations is, amongst other matters, to regulate, by means of licensing, the provision of reproductive technology (RT) procedures; the conducting of embryo research; and the handling, storing or disposing of gametes or embryos used or intended to be used in connection with a RT procedure or embryo research. They set out the statutory framework within which persons carrying out such activities must operate. The Council expects persons properly licensed for such activities to carry out their activities in compliance with the Code and the Supplementary Code as appropriate.

2.3 Relevant activities which are governed by the Ordinance, and which is illegal for any person to carry out except pursuant to a licence, are —

(a) the provision of a RT procedure,
where RT procedure means a medical, surgical, obstetric or other procedure (whether or not it is provided to the public or a section of the public) assisting or otherwise bringing about human reproduction by artificial means, and includes —
(i) in vitro fertilization;
(ii) artificial insemination;
(iii) the obtaining of gametes;
(iv) manipulation of embryos or gametes outside the body;
(v) a procedure specified by the Secretary for Health by notice in the Gazette to be a RT procedure; and
(vi) a gender selection achieved or intended to be achieved by means of a procedure which falls within this definition,
but excludes a procedure specified by the Secretary for Health by notice in the Gazette not to be a RT procedure;

(b) the conducting of embryo research; and

(c) the handling, storing or disposing of a gamete or embryo used or intended to be used in connection with a RT procedure or embryo research.

3. Classes of Licences

3.1 Under the HRT (Licensing) Regulation, the Council may issue four classes of licences, namely artificial insemination by husband (AIH) licence, treatment licence, research licence and storage licence. The Council has specified in the HRT (Licensing) Regulation details such as the scopes of activities permitted under each class of licence and the conditions subject to which the licence is granted.

3.2 The Council may, from time to time, review the classes of licences, the scopes of activities permitted under each class of licence and the conditions subject to which the licence is granted.

AIH Licence

3.3 An AIH licence authorizes —

(a) a procedure under which a man's sperm are introduced into the vagina or uterus of his wife otherwise than by sexual intercourse; and

(b) if necessary for and incidental to such procedure, the storage of sperm used or intended to be used in the procedure.

3.4 AIH is broadly categorized into three types, namely intravaginal, intracervical and intrauterine. Institutions/ private practitioners performing AIH only (and not other RT procedures) may refer to the Supplementary Code for details.

Treatment Licence

3.5 A treatment licence authorizes —

(a) the carrying on of one or more than one type of RT procedure; and

(b) the storage of gametes or embryos used or intended to be used in such procedure.

3.6 A person who wants to apply for a treatment licence shall specify in the application the relevant activities intended to be carried on in the premises that the licence applies. These may include —

(a) in vitro fertilization (IVF);

(b) artificial insemination (AI), which includes —

  (i) artificial insemination by husband (AIH)[1];

  (ii) artificial insemination by donor (AID)/ donor insemination (DI);

(c) obtaining of gametes, which includes —

  (i) removal of oocytes from ovaries with the aid of laparoscopy, ultrasound or other techniques;

  (ii) retrieval of sperm from testis;

  (iii) retrieval of sperm from epididymis;

(d) manipulation of embryos or gametes outside the body, which includes —

  (i) frozen-thawed/ fresh embryo transfer (ET);

  (ii) microinjection intra-fallopian transfer (MIFT);

  (iii) fallopian replacement of eggs with delayed insemination (FREDI);

  (iv) intra cytoplasmic sperm injection (ICSI);

  (v) pre-implantation genetic testing (PGT)[2];

  (vi) sperm sorting technique[3];

  (vii) sperm washing;

  (viii) in vitro maturation of oocytes;

  (ix) storage of semen/ sperm;

  (x) storage of oocyte;

  (xi) storage of embryo;

  (xii) storage of testicular tissue;

  (xiii) storage of ovarian tissue;

  (xiv) embryo donation;

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[1] Institutions/ private practitioners performing AIH only should apply for an AIH licence.

[2] A treatment licence may grant a general permission for a RT centre to carry out PGT. A RT centre licensed to carry out PGT, and which intends to carry out tissue typing in conjunction with PGT, is required to submit an application (vide the form at Annex 9) together with a clinical report to the Council to seek prior approval on a case-by-case basis for each treatment involving tissue typing in conjunction with PGT. The principles set out in the "Ethical Guidelines on Pre-implantation Genetic Testing" appended to the Code should also be followed. The Council will make every effort to ensure that applications are considered and responded to within 30 days of receipt of the application subject to all required information being adequately provided at the time of the application.

[3] Sperm sorting technique means a technique intended to separate sperm carrying a Y chromosome (which would create a male embryo) from sperm carrying X chromosome (which would create a female embryo).

(xv) sperm donation;
(xvi) oocyte donation;
(xvii) assisted hatching;
(xviii) embryo micromanipulation (other than assisted hatching);
(xix) sex selection;
(xx) surrogacy arrangement;
(xxi) other micromanipulation as specified;
(xxii) others as specified.

3.7 The Secretary for Health may, by notice in the Gazette, specify a procedure to be, or not to be, a RT procedure subject to the terms and conditions as specified in the notice. *(Section 2(2) of the Ordinance)*

Research Licence

3.8 Under section 2(1) of the Ordinance, "embryo research" —

(a) means any research involving the creation, use or manipulation of an embryo, whether or not the embryo is to be implanted into the body of a woman;
(b) includes a procedure specified by the Secretary for Health in a Gazette notice to be embryo research;
(c) excludes a procedure specified by the Secretary for Health in a Gazette notice not to be embryo research.

3.9 A research licence authorizes —

(a) the conduct of one project of embryo research; and
(b) the storage of gametes or embryos used or intended to be used in such research.

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

(a) to promote advances in the treatment of infertility;
(b) to increase knowledge about the causes or treatment of congenital disease;
(c) to increase knowledge about the causes or treatment of

miscarriages;

(d) to develop more effective techniques of contraception;

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

(f) to increase knowledge about the development of embryos;

(g) to increase knowledge about serious diseases; and

(h) to enable such knowledge to be applied in the development of treatments to combat serious diseases.

(the Code, paragraph 11.5)

3.11 The Secretary for Health may, by notice in the Gazette, specify a procedure to be, or not to be, an embryo research subject to the terms and conditions as specified in the notice. *(Section 2(2) of the Ordinance)*

Storage Licence

3.12 A storage licence authorizes the storage of gametes or embryos used or intended to be used in a RT procedure or embryo research.

3.13 Licence applicants should also note the following points —

(a) an AIH licence, treatment licence or research licence may also permit storage of gametes or embryos used or intended to be used in the relevant activity authorized by the licence. Persons who have already obtained or applied for a licence for the carrying out AIH, providing treatment or undertaking research may not therefore have to apply for a separate storage licence;

(b) persons intending to carry out both in vitro fertilization (IVF) and other types of assisted conception treatment using donor gametes require only one licence. Such persons should state clearly under section 6 of their application form all types of treatment intended to be carried out;

(c) persons who intend to carry out treatment as well as undertaking research need separate licences for treatment and for research;

(d) each research project requires a separate licence; separate application forms should therefore be submitted for each project;

(e) persons who intend to carry out storage only should apply for a storage licence; and

(f) separate licences are required for separate premises even if they are for the same purpose and managed or owned by the same

institution; separate application forms should therefore be submitted for each separate premises.

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4. Licence Conditions

4.1 General Conditions of Every Licence

4.1.1 The following are the general conditions applicable to every licence —

(a) only the relevant activity specified in the licence may be carried on pursuant to the licence;

(b) any such activity shall not be carried on in contravention of any provision of the Ordinance or any other enactment;

(c) any such activity may be carried on only in the licensed premises and under the supervision of the person responsible;

(d) without prejudice to other conditions applicable to the licence, the proper conduct of any such activity, and the proper discharge of the functions of any person to whom the licence applies, shall at all time be secured, taking account of any relevant provision of the Code;

(e) any such activity may be carried on for a person only if a consent form has been signed in relation to that person in accordance with the Code;

(f) the registers and records in relation to any consent or information as required by the Code to be obtained and kept shall be properly maintained in, or readily accessible from, the licensed premises;

(g) the licensee shall provide to the Council the information required to be contained in Register A in such form as specified in the Code; and

(h) a notice of a change in any information provided in relation to the licence, or the application for the licence, shall be given to the Council within 28 days after the occurrence of the change.

(Section 11 of the HRT (Licensing) Regulation)

4.2 Specific Conditions of AIH Licence

4.2.1 Apart from the general conditions as set out in paragraph 4.1 above, the following are the specific conditions applicable to every AIH licence —

(a) any RT procedure specified in the licence may be provided only to

persons who are the parties to a marriage, except where the procedure is continued to be provided to persons who were the parties to a marriage when sperm were placed in the body of the wife pursuant to the procedure;

(b) proper practices and procedures shall be adopted to identify and record —

(i) the identity of each individual who undergoes a RT procedure in the licensed premises; and

(ii) any sperm used at the time of insemination in each case; and

(c) a Patients Register and a Children Register shall be properly kept and maintained in, or readily accessible from, the licensed premises.

(Section 12 of the HRT (Licensing) Regulation)

4.3 Specific Conditions of Treatment Licence

4.3.1 Apart from the general conditions as set out in paragraph 4.1 above, the following are the specific conditions applicable to every treatment licence —

(a) any RT procedure specified in the licence may be provided only to persons who are the parties to a marriage, except where the procedure is —

(i) provided to a surrogate mother pursuant to a surrogacy arrangement;

(ii) continued to be provided to persons who were the parties to a marriage when gametes were, or an embryo was, placed in the body of a woman pursuant to the procedure; or

(iii) for obtaining gametes;

(b) a RT procedure shall not be provided to a person unless account has been taken of the welfare of any child who may be born in consequence of the procedure;

(c) if any surrogacy arrangement is authorized by the licence —

(i) a RT procedure may be provided pursuant to such arrangement only if —

(A) the gametes used in the procedure are those of the parties to a marriage; and

(B) the wife in that marriage is unable to carry a pregnancy to term and no other treatment option is practicable for her; and

(ii) the arrangement shall be reported to the Council within 3

months after the completion of the procedure for each treatment cycle;

(d) if sex selection is authorized by the licence —

(i) it may be conducted only for the purpose of avoiding a sex-linked genetic disease specified in Schedule 2 to the Ordinance which may prejudice the health of the embryo; and

(ii) each case of sex selection achieved through a RT procedure shall be reported to the Council within 3 months after the procedure has taken place;

(e) prior approval of the Council shall be obtained for carrying on any RT procedure involving tissue typing in conjunction with preimplantation genetic testing in the licensed premises;

(f) close liaison with —

(i) any donor of gametes or embryos stored in the licensed premises;

(ii) any recipient of the donated gametes or embryos and her husband;

(iii) if other gametes or embryos of the donor are stored in the licensed premises under another licence, a person to whom that licence applies; and

(iv) if other gametes or embryos of the donor are donated in any other premises, the person in charge of those premises,

shall be established for the purpose of ensuring that no more than 3 live birth events are brought about by the gametes or embryos donated by any single donor;

(g) a system shall be established and maintained so as to ensure that proper practices and procedures are adopted and followed in the licensed premises;

(h) proper practices and procedures shall be adopted to identify and record —

(i) the identity of each individual who undergoes a RT procedure in the licensed premises;

(ii) any sperm and egg used in each RT procedure;

(iii) any embryo used in each case and the patient undergoing the RT procedure at the time of embryo transfer; and

(iv) any gamete or embryo involved at the time of cryopreservation and thawing; and

(i) a Patients Register and a Children Register shall be properly kept and maintained in, or readily accessible from, the licensed

premises.

(Section 13 of the HRT (Licensing) Regulation)

4.4 Specific Conditions of Research Licence

4.4.1 Apart from the general conditions as set out in paragraph 4.1 above, the following are the specific conditions applicable to every research licence —

(a) a person shall not do any of the following in the licensed premises —

(i) for the purposes of embryo research —

(A) bring about the creation of an embryo; or

(B) combine human and non-human gametes or embryos or any part of them such as to give rise to a 2 cell zygote;

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

(iii) place any non-human gamete or embryo or any part of it in any human;

(iv) place any human gamete or embryo or any part of it in any animal;

(v) replace the nucleus of a cell of an embryo with a nucleus taken from any other cell; or

(vi) clone any embryo;

(b) an embryo the creation of which was brought about in vitro may be stored in the licensed premises only if acquired from a person to whom another licence applies or imported in accordance with the Code; and

(c) a notice with a copy of the report of the outcome of the research project authorized by the licence attached to it shall be given to the Council within 3 months after the completion of the project.

(Section14 of the HRT (Licensing) Regulation)

4.5 Specific Conditions relating to Storage

4.5.1 Apart from the general conditions as set out in paragraph 4.1 above, the following are the specific conditions applicable to every treatment licence or storage licence —

(a) embryos may be stored in the licensed premises only for and on behalf of the parties to a marriage;

(b) in the case of a treatment licence, an embryo the creation of which was brought about in vitro otherwise than pursuant to the licence may be stored in the licensed premises only if acquired from a person to whom another licence applies or imported in accordance with the Code;

(c) in the case of a storage licence, an embryo the creation of which was brought about in vitro may be stored in the licensed premises only if acquired from a person to whom another licence applies or imported in accordance with the Code;

(d) a person shall not be allowed to collect his or her own gametes or embryos from the licensed premises except in circumstances specified in the Code;

(e) except as provided in paragraph 4.5.3 —

(i) a gamete or embryo shall not be stored in the licensed premises beyond the period as provided in paragraph 4.5.2; and

(ii) the gamete or embryo shall, upon the expiry of that period, be disposed of according to the instructions given in the consent form required by the Code to be signed by the person entitled to the gamete or embryo; and

(f) a Donors Register shall be properly kept and maintained in, or readily accessible from, the licensed premises.

4.5.2 For the purposes of paragraph 4.5.1(e), regardless of whether any gamete or embryo has been stored in any premises before or since the commencement of section 15 of the HRT (Licensing) Regulation, it shall not be stored in the licensed premises beyond the following period starting from the day on which the gamete or embryo begins to be stored —

(a) in the case of an anonymous donation, the shorter of the following —

(i) 10 years; or

(ii) the period up to the time when the donated gametes or embryos have brought about 3 live birth events, or such other number of live birth events as specified by the donor, whichever is smaller;

(b) in the case of a person whose gametes or embryos are stored for use in a RT procedure to be provided to the person, 10 years;

(c) except as otherwise provided by the Code, in the case of a donation made by the donor to a recipient designated by the donor in the

circumstances permitted under the Code, 2 years;

(d) in the case of a cancer patient, or any other patient, who may be rendered infertile as a result of chemotherapy, radiotherapy, surgery or other medical treatment —

(i) for gametes, the longer of the following —

(A) 10 years; or

(B) the period up to the time when the patient reaches the age of 55 years; and

(ii) for embryos, 10 years.

4.5.3 Subject to paragraphs 4.5.4 and 4.5.5, paragraph 4.5.1(e) does not apply to any gamete or embryo if —

(a) it has been stored in any premises before the commencement of section 15 of the HRT (Licensing) Regulation; and

(b) the Council is satisfied that the person responsible under the licence has used his best endeavours but failed to obtain the consent of the person entitled to the gamete or embryo to dispose of it.

4.5.4 If the gametes or embryos donated by any single donor fall within the description in paragraph 4.5.3 and no proper record is kept of any live birth event brought about by them, those gametes or embryos shall not be used in any RT procedure —

(a) after they have brought about 3 live birth events since the commencement of section 15 of the HRT (Licensing) Regulation; or

(b) after the expiry of 2 years from the commencement of section 15 of the HRT (Licensing) Regulation,

whichever is earlier.

4.5.5 If the gametes or embryos donated by any single donor fall within the description in paragraph 4.5.3 and proper record is kept of any live birth event brought about by them, but there is no proper record of the day from which they have been stored, those gametes or embryos shall not be used in any RT procedure —

(a) after they have brought about 3 live birth events, or such other number of live birth events as specified by the donor, whichever is smaller; or

(b) after the expiry of 2 years from the commencement of section 15 of the HRT (Licensing) Regulation,

whichever is earlier.

(Section 15 of the HRT (Licensing) Regulation)

4.6 Special Conditions

4.6.1 Apart from the general conditions and the specific conditions mentioned above, the Council may also impose conditions (hereinafter called "special conditions") applicable to a particular licensee only.

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5. Person Responsible and Licensee

5.1 For the purposes of section 23(2)(c) of the Ordinance, an individual designated in an application for a licence to be a person responsible is considered to possess the prescribed qualifications if —

(a) he is a registered medical practitioner;
(b) he is a registered nurse within the meaning of the Nurses Registration Ordinance (Cap. 164);
(c) he is a medical laboratory technologist registered under the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations (Cap. 359 sub. leg. A);
(d) he holds a bachelor degree or above in a field of science that is considered by the Council as relevant to human reproductive technology; or
(e) he holds other qualification in the medical, nursing, scientific or management field that is considered by the Council as acceptable for the purposes of supervising the relevant activity specified in the application.

5.2 It is the duty of the person responsible under a licence to secure that —

(a) 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 authorized by the licence; for reproductive technology centres with satellite centres / associated doctors, the person responsible of the centre is fully responsible for the acts of his / her satellite centres / associated doctors. Therefore, person responsible must play a supervisory and proactive role to ensure that his / her satellite centres /

associated doctors[4] provide the relevant reproductive technology services authorized by the licence in compliance with the Ordinance and its subsidiary legislation, the Code, the Licensing Manual, and the terms and conditions to which the licence is subject;

(b) proper equipment is used;

(c) proper arrangements are made for the keeping of gametes and embryos and for the disposal of gametes or embryos that have been allowed to perish;

(d) in all the circumstances, proper practices are used in the course of that activity; and

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

(Section 24(1) of the Ordinance)

5.3 It is the duty of the licensee under a licence to secure that the person responsible under the licence discharges his/ her duty under paragraph 5.2 above. *(Section 24(2) of the Ordinance)*

5.4 In case of the death or incapacity of the incumbent person responsible to discharge his/ her duty, the licensee should make a report to the Council about the event, and provide a temporary appointment of a person who will act as a deputy during the absence of the PR to discharge the duty prescribed in section 24(1) of the Ordinance **within six calendar days of the event**. A curriculum vitae of the proposed deputy should be included in the report. If the Council is satisfied with the proposed temporary appointment, the Council will acknowledge the report and further request the licensee to submit an application for a variation of licence **within 28 calendar days** to propose a new person responsible. Upon receipt of an application for variation of the licence from the licensee, the Council shall process the application according to the prevailing procedures. In case the Council is not satisfied with the proposed temporary appointment, or the centre is not submitting an application for a variation of licence according to the stipulated timeframe, or the centre is not providing any temporary appointment of a deputy at all within the timeframe, the Council shall

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

consider revoking the licence of the centre in accordance with the sections 27(1) or 27(2) of the Ordinance.

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6. Information to be furnished to Council

6.1 An applicant for a licence shall furnish to the Council such information as the Council requires for determining whether the licence should be granted or refused. *(Section 22(1) of the Ordinance)*

General Information

6.2 General information to be submitted in relation to an application for a licence shall include —

(a) centre information e.g. name, address, telephone and fax numbers;
(b) corporate information e.g. whether sole proprietor, partnership, or limited company;
(c) personal particulars of the proposed person responsible and proposed licensee e.g. name and position held (with CVs as supporting documents). An applicant for a licence under the Ordinance and the proposed person responsible in relation to a licence must, regardless of whether the matter is under appeal, inform the Council of any conviction in Hong Kong or elsewhere of offences punishable with imprisonment; and/or he has been found guilty of misconduct in a professional respect, in Hong Kong or elsewhere. This requirement is also applicable to the licensee and the person responsible for a licensed centre; and they should report to the Council within 28 calendar days from the date of conviction and/or finding of misconduct in a professional respect, even if the matter is under appeal. In case of doubt, the matter should be reported;
(d) personal particulars of staff e.g. that of the accredited specialist, embryologist in charge, nurse co-ordinator, counsellor in charge, etc. (with CVs as supporting documents);
(e) information leaflets/booklets, price list, newsletters, etc.;
(f) one complete set of all consent forms to be used by the centre;
(g) one complete set of all treatment record forms to be used by the centre (for treatment and AIH licences only);
(h) clinical and laboratory protocols to be used by the centre; and

(i) a contingency plan to be adopted by the centre. The contingency plan should include —
   (i) risk assessment (personnel, finance, operation, etc.); and
   (ii) prior arrangements with other centres/ actions to be taken in case of emergency or contingency.

Specific Information

Treatment Licence

6.3 For treatment licences, applicants should also state what kinds of RT procedures the centre intends to carry on.

6.4 If other centres, clinics or practitioners will be allowed to use the centre's facilities or services, the applicant should identify clearly all such centres, clinics or practitioners in the licence application form and specify the part(s) of the treatment procedure or services that will be carried out by each of the centres, clinics or practitioners so identified. The applicant should also submit a set of written agreement(s) and/or other documents clearly specifying the respective duties and responsibilities of each party to the arrangement, including provisions as to how the following matters are to be dealt with —

(a) the various elements of treatment including monitoring of patients;
(b) the assessment of the welfare of the child;
(c) the offer and provision of counselling;
(d) the provision of relevant information to patients;
(e) the filling in of consent forms; and
(f) the filling in and submission of data collection forms and annual statistics forms.

6.5 For RT centres licensed to carry out PGT, and which intends to carry out tissue typing in conjunction with PGT, an application form (Annex 9) together with a clinical report should be submitted to the Council for prior approval on a case-by-case basis for each treatment involving tissue typing in conjunction with PGT. The applicant should also observe the "Ethical Guidelines on Pre-implantation Genetic Testing" appended to the Code.

Research Licence

6.6 For research licences, applicants should also supply the following

information or documents —

(a) research title, background and objective;
(b) research commencement date and proposed research duration;
(c) methodology to be used/ experiments to be carried out;
(d) estimated number of oocytes/ embryos expected to be used;
(e) source of gametes/ embryos;
(f) details concerning the research ethics committee of the applicant, as stipulated in paragraph 11.11 of the Code, including its role and memberships;
(g) source of funding;
(h) protocol for research approved by the research ethics committee of the applicant;
(i) consent forms to be filled in by donors of gametes/ embryos; and
(j) recent publications by the centre on similar research(es).

Storage Licence

6.7 For storage licences, applicants should also specify the material(s) intended to be stored in the centre, as well as the persons to whom the storage service is intended to be provided.

Change of Information

6.8 For changes involving the following types of information, the changes should be reported to the Council within 28 days after the occurrence of the change —

(a) medical practitioner, or staff occupying the roles of "accredited specialist", "embryologist in charge", "nurse co-ordinator" and "counsellor in charge";
(b) critical equipment related to reproductive technology procedures;
(c) contingency plan to be adopted by the centre; and
(d) clinical, laboratory and research protocols to be used by the centre.

The Council may refuse to grant a licence, or, if a licence has already been granted by the Council in ignorance of the said change, vary or revoke or temporarily suspend a licence should the centre fail to report such change within the said period.

6.9 A person who, for the purposes of the grant of a licence, knowingly or

recklessly provides any information which is false or misleading in a material particular commits an offence under section 39(2) of the Ordinance.

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7. Grant of Licence

7.1 The Council may grant a licence to an applicant if it is satisfied that —

(a) the application concerned is —
  (i) for a licence designating an individual, not being the applicant, as the person under whose supervision the relevant activity to be authorized by the licence is to be carried on; and
  (ii) made with the consent of the individual;

(b) the applicant is a suitable person to hold the licence and that the applicant will discharge the duty under section 24(2) of the Ordinance;

(c) the individual referred to in paragraph (a)(i) above has the prescribed qualifications under section 5 of the HRT (Licensing) Regulation, the character and experience of the individual are such as are required for the supervision of that activity and the individual will discharge the duty under section 24(1) of the Ordinance;

(d) the premises in respect of which the licence is to be granted are suitable for that activity;

(e) all other requirements of the Ordinance in relation to the granting of the licence are satisfied; and

(f) in all circumstances, the applicant and the individual referred to in paragraph (a)(i), if the licence is granted, would be capable of complying with the requirements under the Ordinance with which it is their respective duty to comply.

(Section 23(2) of the Ordinance)

7.2 The Council may also grant a licence to an applicant notwithstanding that the licensee and the person responsible are the same person if the Council is satisfied that it will not prejudice the discharge of the duty under section 24(1) of the Ordinance by the person responsible. *(Section 23(3) of the Ordinance)*

7.3 The Council shall not grant a licence where 2 or more individuals are to be the person responsible unless it specifies in the licence which of the functions and powers imposed or conferred on a person responsible under the Ordinance

shall be performed or exercised, in relation to that licence, by —

(a) any such individual alone;
(b) any such individuals jointly;
(c) each such individual,

and, in any such case, the provisions of the Ordinance shall be read and have effect with such modifications as are necessary to take into account any such licence. *(Section 23(5) of the Ordinance)*

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8. Revocation and Variation of Licence

8.1 The Council may revoke a licence if it is satisfied that —

(a) any information furnished for licence application was false or misleading;
(b) the premises to which the licence relates are no longer suitable for the relevant activity authorized by the licence;
(c) the person responsible has failed to discharge, or is unable because of incapacity to discharge his/ her duty under section 24(1) of the Ordinance;
(d) there has been any other material change of circumstances since the licence was last granted;

(Section 27(1) of the Ordinance)

(e) the character of the person responsible is no longer suitable as required for the supervision of the relevant activity authorized by the licence;
(f) the licensee is no longer a suitable person to hold a licence;
(g) the person responsible dies or the person responsible or the licensee is convicted of an offence against the Ordinance;

(Section 27(2) of the Ordinance)

8.2 Where the Council has power to revoke a licence under section 27(1) of the Ordinance, it may instead vary any terms of the licence. *(Section 27(3) of the Ordinance)*

8.3 Where the Council proposes to vary or revoke a licence, the Council shall give notice of the proposal, the reasons for it, and the effect of section 28(3) of the Ordinance to the person responsible and the licensee (but not to any person who has applied for the variation or revocation). *(Section 28(2) of the Ordinance)*

8.4 If, within the period of 28 days beginning with the day on which notice of the proposal is given, any person to whom notice was given under section 28(2) of the Ordinance gives notice to the Council of a wish to make to the Council representations about the proposal in any way referred to in section 28(4) of the Ordinance, the Council shall, before making its determination, give the person an opportunity to make representations. *(Section 28(3) of the Ordinance)*

8.5 Such representations may be —

(a) oral representations made by the person, or another person acting on behalf of the person at a meeting of the Council;

(b) written representations made by the person.

(Section 28(4) of the Ordinance)

8.6 The Council shall, in the case of a determination to vary or revoke a licence, give notice of the determination to the licensee and the person responsible. The Council shall also give in the notice the reasons for its decision. *(Section 28(5)(c)& (6)(e) of the Ordinance)*

8.7 The revocation of a licence may be subject to the conditions specified in the notice effecting the revocation. A person who contravenes any such condition commits an offence under section 39(1) of the Ordinance.

8.8 A person aggrieved by the Council's decision may appeal to the Administrative Appeals Board. *(Section 41 of the Ordinance)*

8.9 The Council may also vary or revoke a licence on an application by the person responsible or the licensee. *(Section 27(4) of the Ordinance)*

8.10 The Council may, on application by the licensee, designate another individual in place of the person responsible if —

(a) the Council is satisfied that the other individual has the qualifications prescribed under section 5 of the HRT (Licensing) Regulation, the character and experience of the individual are such as are required for the supervision of the relevant activity authorized by the licence, and the individual will discharge the duty under section 24(1) of the Ordinance; and

(b) the application is made with the consent of the other individual.

(Section 27(5) of the Ordinance)

8.11 A licence may also be varied if the variation relates to —

(a) the relevant activity authorized by the licence, the manner in which it is conducted or the conditions to which the licence is subject by virtue of section 23(1)(a)(ii) of the Ordinance; or

(b) extension or restriction of the premises to which the licence relates.

(Section 27(6) of the Ordinance)

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9. Suspension of Licence

9.1 For the purposes of performing any function delegated to it by the Council pursuant to section 10(1) of the Ordinance in relation to the suspension of a licence related to a complaint, the Investigation Committee may by notice suspend a licence for a period not exceeding three months if it —

(a) has reasonable grounds to suspect that there are grounds for the Council to revoke a licence under section 27 of the Ordinance; and

(b) is of the opinion that the licence should immediately be suspended.

(Section 29(1) of the Ordinance)

9.2 The notice shall be given to the licensee and the person responsible under the licence and the Investigation Committee may, by a further notice, renew or further renew the notice for a period not exceeding three months as may be specified in the renewal notice. *(Section 29(2) of the Ordinance)*

9.3 While suspended under section 29 of the Ordinance, a licence shall be of no effect except as specified in any conditions to which the suspension is subject, but application may be made to the Council under section 27(5) of the Ordinance by the licensee to vary the licence so as to designate another individual as the person responsible. *(Section 29(3) of the Ordinance)*

9.4 The Investigation Committee may include in the notice any conditions that it thinks fit, including conditions in relation to all or any of the following matters —

(a) the appointment of an administrator to carry out the functions of the licensee/ person responsible in relation to any activities affected by the suspension;

(b) the transfer of gametes, zygotes or embryos stored in the centre;

(c) the transfer of research or treatment procedures affected by the

suspension to another licensed RT centre which has agreed to accept the transfer;

(d) the keeping and transfer of records;

(e) any other matter that the Investigation Committee considers necessary.

9.5 The Council may at any time revoke a notice of licence suspension under section 29 of the Ordinance. The person responsible under a licence or the licensee who has received a notice under paragraph 9.1 above may at any time make a written representation to the Council for the purposes of —

(a) raising his objection to the suspension of the licence; and

(b) setting out any ground on which he seeks a revocation of that notice.

9.6 On receipt of any representation made under paragraph 9.5, the Chairperson of the Council shall direct the Secretary to the Council to —

(a) fix the date, time and place for the purpose of determining whether the notice of suspension should be revoked under section 29(4) of the Ordinance; and

(b) invite the person responsible or the licensee concerned to make oral representations at the hearing, whether by himself or by a person acting on his behalf.

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10. Voluntary Surrender of Licence

10.1 Without prejudice to the generality of section 27(4) of the Ordinance regarding the application to vary or revoke a licence, a licensee may surrender his licence by lodging it at the office of the Council. *(Section 32(1) of the Ordinance)*

10.2 The licensee shall return the licence to the Council, together with a letter and proposal, stating the reason(s) for the surrender, the proposed closing date of the centre, and arrangements proposed to be made in relation to relevant activities in progress at the centre at the time of closure. The detailed conditions and procedures for voluntary surrender of licence are attached at Annex 13.

10.3 The surrender of a licence shall not have effect until the licensee is served with a notice by the Council stating that the Council accepts the surrender of the licence subject to such conditions, if any, as the Council thinks fit specified

in the notice. *(Section 32(2) of the Ordinance)*

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11. Representation to Council and Appeal to Administrative Appeals Board

11.1 If a centre is dissatisfied with a decision of the Council, the centre may always contact the Council and try to resolve the matter by discussions. In the case of an application for a licence, the Ordinance provides applicants with a right to make representations to the Council where the Council proposes to refuse to grant a licence, or to grant a licence in respect of part only of the premises or relevant activity specified in the application concerned, or to grant a licence subject to special conditions, or to refuse to vary a licence so as to designate another individual in place of the person responsible. The procedures for making such representations to the Council are set out in section 2, under Licence Application Procedures, of this Manual.

11.2 Any person aggrieved by a decision made in respect of him by the Council may, where the decision is a determination concerning licensing referred to in section 28(5) of the Ordinance to which section 28(6) applies, or the suspension of a licence under section 29 of the Ordinance, also appeal to the Administrative Appeals Board against the said decisions of the Council within 28 days after receiving notice of the decisions. *(Section 41 of the Ordinance)*

11.3 Any appeal to the Administrative Appeals Board should be made in accordance with section 9 of the Administrative Appeals Board Ordinance (Cap. 442).

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12. Validity of Licence

12.1 Normally, a licence is valid for a period of three years, or such lesser period as specified in the licence. *(Section 25(a) of the Ordinance)*

12.2 A licence becomes invalid if the licence —

(a) expires under section 25(a) of the Ordinance;
(b) is revoked under section 27 of the Ordinance;
(c) is suspended under section 29(1) of the Ordinance; or
(d) is surrendered (and the surrender is accepted by the Council) under section 32 of the Ordinance.

13. Renewal of Licence

13.1 In applications for renewal of a licence, the licence application procedures under Section 2 of this Manual should be followed.

13.2 Centres must submit their renewal applications 6 months before the expiration of the licence.

13.3 Late applications may result in the centre concerned not being able to continue with the relevant activity upon expiry of licence.

14. Display of Licence

14.1 The person responsible under a licence shall display the licence or an exact copy of the licence at all times in a conspicuous position in the premises to which the licence relates. *(Section 30 of the Ordinance)*

15. Loss of Licence

15.1 Where a licence has been lost, defaced or destroyed, the Council may issue to the holder another licence in like terms subject to payment of the prescribed fee under the HRT (Fees) Regulation. *(Section 3(3)(c) of the HRT (Licensing) Regulation)*

SECTION 2 – LICENCE APPLICATION PROCEDURES

The following procedures apply to all applications for the grant, renewal, variation or revocation of a licence.

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1. Application for Licence and Licence Renewal

1.1 Subject to section 4 of the HRT (Licensing) Regulation, a person may make an application to the Council for the grant or renewal of a licence to carry on a relevant activity in premises specified in the application. *(Section 21 of the Ordinance)*

1.2 Under normal circumstances, the Council will make a decision to grant a licence; a proposal to refuse to grant a licence; or a proposal to grant a licence subject to special conditions (including the grant of a licence in respect of part only of the premises or relevant activity specified in the application concerned) in approximately 6 months on receipt of all necessary documents and information from the applicant.

1.3 Applications should be made on the Council's standard licence application form, together with a crossed cheque or e-cheque in the amount of the application fee under the HRT (Fees) Regulation (see Section 3) made payable to "the Government of the Hong Kong Special Administrative Region" or "the Government of the HKSAR". The Secretariat of the Council could be contacted if payment of application fee is to be settled by other means. The application should contain all items of information requested in the form, and should be accompanied by such additional information or material as may be specified in the application form or in any notes which accompany the application form.

1.4 The Council's standard licence application forms are available at the Council's website. Applicants are recommended to download the up-to-date forms from the Council's website —

http://www.chrt.org.hk/

1.5 Completed applications should be submitted in person, by post or by email together with the application fee to —

In person or by post
Council on Human Reproductive Technology
Room 58, 17/F, Wu Chung House
213 Queen's Road East
Wanchai, Hong Kong

By email
hrtc@dh.gov.hk

1.6 When a completed licence application form is received by the Council, an acknowledgement will be sent and the Secretariat will conduct an initial check for any omissions. If there are any omissions from the information required for consideration of a licence application by the Council, the Secretariat will request for additional information before the Council commences to consider the application. Despite the said initial check, the Council may ask for further information from time to time in the course of processing the application.

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2. Inspection

2.1 The Secretariat will arrange for an inspection team to visit the premises in which it is proposed that the relevant activity will take place.

2.2 A report of the inspection will be prepared by the inspection team for consideration by the Inspection Committee.

Treatment or Storage Licence

2.3 For the purposes of considering whether to grant a treatment or storage licence, inspection(s) will normally be carried out by an inspection team which is composed of a member of the Council, a registered medical practitioner from the Department of Health, a scientist nominated by the Inspection Committee, a representative from the Hong Kong College of Obstetricians and Gynaecologists (HKCOG) (if the application involves authorization of relevant activities which have to be performed by medical practitioner) and a lay person.

Research Licence

2.4 For the purposes of considering whether to grant a research licence,

inspection(s) will normally be carried out by an inspection team consisting of a member of the Ethics Committee, a registered medical practitioner from the Department of Health, a scientist nominated by the Inspection Committee, and a lay person.

AIH Licence

2.5 For the purposes of considering whether to grant an AIH licence, inspection(s) will normally be carried out by an inspection team consisting of the Chairperson or a member of the Inspection Committee, a registered medical practitioner from the Department of Health or a scientist, and a lay person.

General

2.6 Inspections will normally include the following elements —

(a) general consideration of the application for the licence and how the inspection is to be structured. For this purpose the centre should provide a private room for the inspection team during inspection;

(b) a meeting with the senior members of staff. This will normally include the person responsible, licensee, embryologist in charge, accredited specialist, counsellor in charge and nurse co-ordinator;

(c) a tour of the centre to inspect the premises. During this part of the visit the team may wish to speak to other staff, such as the clinical, laboratory, nursing and counselling staff; and

(d) a meeting with patients nominated by the centre. This will be conducted without the presence of any representative of the centre.

2.7 Inspection will normally last between half a day and a full day depending on the size of the centre and the nature of the activities to be licensed. During the inspection, the inspection team will be looking to ensure that the centre is complying with the requirements of the Ordinance, regulations/ guidelines, and that its practices are in line with the Code and the Supplementary Code. The inspection team will cover the area outlined in the checklist enclosed at Annex 11.

2.8 If other centres, clinics or practitioners are allowed to use the centre's facilities or services, the applicants may be requested to make arrangements for the inspections of these other centres, clinics or premises of these practitioners.

2.9 Inspections will normally be arranged with the centre in advance. The inspection team may, however, make unannounced inspections from time to time.

2.10 The Council, or a person or committee delegated by the Council under section 10(1) of the Ordinance, has powers under sections 27 and 29 of the Ordinance to revoke, vary or suspend a licence irrespective of whether any inspection has been conducted prior to the revocation, variation or suspension. The circumstances and procedures for revocation, variation and suspension are set out in detail in Parts 8 and 9 of Section 1 of this Manual.

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3. Examination by Inspection Committee

3.1 The Inspection Committee is responsible for —

(a) conducting inspections of premises for the purposes of ascertaining whether the premises in respect of which the licence is to be granted are suitable for the relevant activity; and

(b) making recommendations to the Council in respect of —

(i) the grant of licences;

(ii) any conditions to which any licence, or class of licence, may be subject.

(Section 6(b) of Schedule 1 to the Ordinance)

3.2 The Inspection Committee may meet regularly or on ad hoc basis.

3.3 For the purposes of performing its functions as mentioned in paragraph 3.1 above, the Inspection Committee may require an applicant for a licence to provide such information, documents, assistance and facilities as are reasonably necessary to enable the Committee to make recommendations to the Council in respect of the grant of a licence or any condition to which the licence may subject.

3.4 If a complaint is received against an applicant for a licence (other than an applicant for renewal of a licence), the Inspection Committee shall give the applicant under complaint a notice inviting him to submit a written representation in respect of the complaint within 14 days after the date of the notice. An authorized person may enter and inspect any premises to which a licence relates pursuant to section 37 of the Ordinance, and produce a report on

the findings for consideration by the Inspection Committee.

3.5 Where the application is for the renewal of a licence, and there is an outstanding complaint against the licensee, the application will be processed by the Inspection Committee, but without prejudice to the outstanding complaint being handled in accordance with Part 4 of the HRT (Licensing) Regulation.

3.6 For the purposes of facilitating the determination of an application for a licence, the Inspection Committee shall present to the Council —

(a) the Committee's recommendations in respect of the application;
(b) any representation submitted under paragraph 3.4; and
(c) any other information or documents that the Council or the Committee considers relevant to the application.

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4. Consideration by Council

4.1 Upon receipt of the recommendations made by the Inspection Committee and other relevant information as detailed in paragraph 3.6 (b) and (c) above, and subject to the procedure as set out in paragraphs 4.8 to 4.12 hereof, the Council shall, as soon as is practicable, by notice given to the applicant —

(a) grant a licence to the applicant —
    (i) to carry on in the premises specified in the application (or such part of those premises as may be specified in the licence) the relevant activity specified in the application (or such part of that activity as may be specified in the licence); and
    (ii) subject to such conditions, if any, as are specified in the licence; or
(b) refuse to grant a licence to the applicant.

(Section 23(1) of the Ordinance)

4.2 A licence granted by the Council will be subject to the conditions to be attached to —

(a) every licence; or
(b) every licence belonging to a class of licence specified in the HRT (Licensing) Regulation.

(Section 45(2)(a) of the Ordinance)

4.3 For the purposes of determining whether a licence should be granted or refused, the Council may require the attendance before it of an applicant who is an individual or, in the case of an applicant which is company, a representative of the company who is an individual authorized by the company to so attend, and may examine any individual who so attends. *(Section 22(2) of the Ordinance)*

4.4 The Council may ask for such further information or report(s) as it considers desirable or necessary, and may give directions as to the manner in which, and the person(s) by whom such information or report(s) are to be furnished.

4.5 If the Council considers that the information available to it is insufficient for it to be able to determine a licence application, it will inform the applicant through the Secretariat. The Council will not consider the application until the applicant provides such additional information as it may require.

Grant or Renewal of Licence

4.6 The Council shall, in the case of a determination to grant or renew a licence, give notice of the determination to the licensee and the person responsible. *(Sections 28(5)(a))*

4.7 Upon receipt of the prescribed fee in respect of the grant or renewal of a licence under the HRT (Fees) Regulation, the Council shall issue the appropriate licence. Each licence shall specify the relevant activity that may be carried on in the premises specified in the application. Payment of the prescribed fee can be made by a crossed cheque or e-cheque made payable to "the Government of the Hong Kong Special Administrative Region" or "the Government of the HKSAR". The cheque should be submitted in person or by post to —

Council on Human Reproductive Technology
Room 58, 17/F, Wu Chung House
213 Queen's Road East
Wanchai, Hong Kong

The e-cheque should be sent by email to —

hrtc@dh.gov.hk

The Secretariat of the Council could be contacted if payment of application fee is to be settled by other means.

Refusal to Grant a Licence, Grant of Licence subject to Special Conditions, etc.

4.8 Where the Council proposes to —

(a) refuse to grant a licence;

(b) grant a licence in respect of part only of the premises or part only of the relevant activity specified in the application concerned; or

(c) grant a licence subject to special conditions,

the Council shall give notice of the proposal, the reasons for it, and the effect of section 28(3) of the Ordinance to the applicant. *(Section 28(1)(a), (b)&(c) of the Ordinance)*

4.9 If, within the period of 28 days beginning with the day on which notice of the proposal is given, any person to whom notice was given under section 28(1) of the Ordinance gives notice to the Council of a wish to make to the Council representations about the proposal in any way referred to in section 28(4) of the Ordinance, the Council shall, before making its determination, give the person an opportunity to make representations. *(Section 28(3) of the Ordinance)*

4.10 Such representations may be —

(a) oral representations made by the person, or another person acting on behalf of the person, at a meeting of the Council;

(b) written representations made by the person.

(Section 28(4) of the Ordinance)

4.11 The Council shall, in the case of a determination to —

(a) refuse to grant a licence;

(b) grant a licence in respect of part only of the premises or part only of the relevant activity specified in the application concerned; or

(c) grant a licence subject to special conditions,

give notice of the determination to the applicant, and the person responsible as appropriate. The Council shall also give in the notice the reasons for its decision. *(Sections 28(5)(a)&(b) and (6)(a),(b)&(c) of the Ordinance)*

4.12 An applicant who is aggrieved by the Council's decision may appeal to the Administrative Appeals Board. *(Section 41 of the Ordinance)*

5. Application for Revocation and Variation of Licence

5.1 Applications for variation or revocation of licence should be made to the Council in written form, stating the reasons for variation or revocation and any proposed measures or arrangements consequential upon the variation or revocation, and accompanied by the prescribed fee in relation to the application for variation or revocation of a licence under the HRT (Fees) Regulation (see Section 3 and paragraphs 8.9 to 8.11 of Section 1)

5.2 An applicant for variation or revocation of a licence should state in his/her application the address at which any notice, order or other document may be served on him/her.

5.3 When an application is received by the Council, an acknowledgement will be sent by the Secretariat. If the Council considers that the information available to it is insufficient for it to be able to determine the application, it will request for additional information through the Secretariat. The Council will not further process the application until the applicant has provided such additional information as it may require.

Inspection

5.4 Depending on the circumstance of individual applications, the Council may request for an inspection to all relevant premises for the purpose of consideration of the application.

Revocation or Variation of Licence

5.5 The Council shall, in the case of a determination to vary or revoke a licence, give notice of the determination to the licensee and the person responsible. *(Section 28(5)(c) of the Ordinance)*

5.6 The revocation of a licence may be subject to the conditions specified in the notice effecting the revocation. A person who contravenes any such condition commits an offence under section 39(1) of the Ordinance.

5.7 In the case of variation of licence, the original licence before variation should be returned to the Secretariat. Upon receipt of the original licence, the Council shall issue a new licence. The new licence shall incorporate the variation approved by the Council and shall specify the relevant activity that may be carried on in the premises specified in the application.

5.8 The expiry date of the new licence shall remain the same as the original licence.

Refusal to Vary a Licence so as to Designate Another Individual in place of the Person Responsible

5.9 Where the Council proposes to refuse to vary a licence so as to designate another individual in place of the person responsible, the Council shall, in giving notice of the proposal, also give in the notice the reasons for it, and the effect of section 28(3) of the Ordinance, to the applicant. *(Section 28(1)(d) of the Ordinance)*

5.10 If, within the period of 28 days beginning with the day on which notice of the proposal is given, any person to whom notice was given under section 28(1) of the Ordinance gives notice to the Council of a wish to make to the Council representations about the proposal in any way referred to in section 28(4) of the Ordinance, the Council shall, before making its determination, give the person an opportunity to make representations. *(Section 28(3) of the Ordinance)*

5.11 Such representations may be —

(a) oral representations made by the person, or another person acting on behalf of the person at a meeting of the Council;

(b) written representations made by the person.

(Section 28(4) of the Ordinance)

5.12 The Council shall, in the case of a determination to refuse to vary a licence so as to designate another individual in place of the person responsible, give notice of the determination to the applicant. The Council shall also give in the notice the reasons for its decision. *(Sections 28(5)(b) & (6)(d) of the Ordinance)*

5.13 Any person aggrieved by the Council's decision may appeal to the Administrative Appeals Board against that decision made by the Council. *(Section 41 of the Ordinance)*

6. Withdrawal of Application

6.1 Any application for a licence or application for variation or revocation of a licence may be withdrawn at any time by giving notice in writing to the Council.

SECTION 3 – PRESCRIBED FEES

1. Introduction

1.1 Under the Ordinance, the Financial Secretary may make regulations to prescribe the fees to be paid to the Council in respect of any application under the Ordinance; the provision of any service or facility connected with licences; or any other matter to which the Ordinance relates. *(Section 44(1) of the Ordinance)*

1.2 The amount of fees prescribed in the HRT (Fees) Regulation was based on the "user pays" principle. They shall not be limited by reference to the amount of administrative or other costs incurred or likely to be incurred in relation to the application, service or facility, or other matter, to which such fee relates, and different fees may be so prescribed for the same type of application, service or facility, or other matter, in order to provide for particular circumstances or particular cases specified in the Regulation. *(Section 44(2) of the Ordinance)*

1.3 The amount of fees would be reviewed periodically. All fees are non-refundable.

1.4 Six types of fees are prescribed under the HRT (Fees) Regulation, in respect of the following matters —

(a) application for, or application for the renewal of a licence under section 21 of the Ordinance;
(b) grant or renewal of a licence under section 23(1)(a) of the Ordinance;
(c) application for variation of a licence under section 27(4) of the Ordinance;
(d) application for revocation of a licence under section 27(4) of the Ordinance;
(e) issue of an exact copy of a licence for the purposes of section 30 of the Ordinance; and
(f) issue of a licence in like terms as those contained in a lost, defaced or destroyed licence under section 31 of the Ordinance.

2. Application for, or Application for Renewal of, Licence

2.1 The prescribed fee in respect of an application for, or application for the renewal of, a licence is payable on EACH licence application. All applications should therefore be accompanied by the appropriate application fee as set out on the respective licence application forms (including both first time applications and applications for renewal).

3. Grant or Renewal of Licence

3.1 The prescribed fee in respect of the grant or renewal of a licence is payable prior to the issue of a licence.

4. Others

4.1 Other types of fees, i.e. those mentioned in paragraph 1.4 (c) to (e) above, are payable on application for the matter concerned.

5. Rate of Fees

5.1 The rate of different types of fees should refer to the HRT (Fees) Regulation —

https://www.elegislation.gov.hk/hk/cap561B

Annex 1 - 8 are obsolete.
Applicants are recommended to download
the up-to-date forms from the Council's website.

Annex 9

COUNCIL ON HUMAN REPRODUCTIVE TECHNOLOGY
人類生殖科技管理局

APPLICATION FOR PGT WITH TISSUE TYPING
植入前基因檢測與組織分型結合使用申請書

Reference Number: _____ *(For official use only)*
參考編號： *(只供管理局職員填寫)*

This application specifies the information required from a licensed RT centre intending to perform Pre-implantation Genetic Testing (PGT) and Histocompatibility Leukocyte Antigen (HLA) Tissue Typing in accordance with the licence conditions stated in the Licensing Manual for Reproductive Technology Centres and the Ethical Guidelines on PGT in Appendix III of the Code of Practice on RT & Embryo Research (the Code). A reference number will be provided by the Council on Human Reproductive Technology upon receipt of the application. This number should be cited in all future correspondence and enquiry about the application.
本申請書列明擬按《供生殖科技中心參考的發牌手冊》所載明的牌照條件和《生殖科技及胚胎研究實務守則》(《實務守則》)附錄 III 的「植入前基因檢測倫理指引」進行植入前基因檢測和人類白血球抗原組織分型的持牌生殖科技中心所需提供的資料。在收到申請書後，申請機構會獲人類生殖科技管理局提供一個參考編號；日後書信往來及查詢申請事宜時，也應註明該參考編號。

I. Details of Licensed Centre and Doctors 持牌生殖科技中心及醫生的詳細資料

Name of Centre/ Institution : _____
中心/機構名稱

Licence No. : _____
牌照號碼

Contact Phone No. : _____
聯絡電話號碼

Name of Attending Doctor : _____
主診醫生姓名

Name of Doctor with Training in Genetics
曾接受遺傳學訓練的醫生的姓名 : _____

II. Description of Condition 病理情況的說明

Please provide a clinical report, **in lay terms,** from a clinical team consisting 2 doctors, one of whom should have proper training in genetics. The report should include the following:
請**以淺白文字**提供一份由臨牀隊伍擬備的臨牀報告；該隊伍應包括兩名醫生，其中一位須曾接受遺傳學的適當訓練。報告應包括以下各項：

(a) an outline of the genetic condition / abnormality and its likely effect;
有關遺傳病症/異常和可能影響的概要；
(b) the current prognosis for the affected child who has the condition;
目前對有此病理情況的患病孩子所作的預診；

(c) the nature of the procedure proposed in relation to the child who is to be born (cord blood or bone marrow transplantation) and the likely effect on the future prognosis of the affected child;
關乎擬誕孩子的建議程序的性質(臍血或骨髓移植)和對患病孩子日後預診所造成的可能影響；

(d) whether all other possibilities of treatment and existing sources of tissue for the affected child have been explored; and
是否已為患病孩子探討過所有其他治療方法和現有組織來源但發現無一適用；及

(e) confirming that the primary tissue recipient is a sibling and embryos are not to be modified to provide tissue match.
確定第一預定受贈人為捐贈人的兄姊，而且沒有為組織配對而對胚胎進行基因改造。

III. Clinical and Counselling Services Provided To Date
至今所曾提供的臨牀及輔導服務

(a) Have the patients (the couple receiving the treatment) been assessed by two doctors, one of whom has proper training in genetics?
病人(接受治療的夫婦)是否已由兩名醫生(其中一位曾接受遺傳學的適當訓練)進行評估？

Yes 是_____* No 否_____

* If the doctors are different from the ones signing this form, please provide their names:
如該兩名醫生並非於本申請書上簽署的醫生，請提供其姓名：

_____

(b) Has the motivation of the patients in having an additional child been assessed according to the ethical principles laid down in the Ethical Guidelines on PGT issued by the HRT Council?
是否已根據管理局所發出的「植入前基因檢測倫理指引」中載明的倫理原則，就病人希望多誕一名孩子的動機進行評估？

Yes 是_____ No 否_____

(c) Have the patients (in particular the woman undertaking the IVF treatment) been counselled on the implications of the treatment?
是否已向病人(尤其是接受體外受精治療的婦女)提供有關治療影響的輔導？

Yes 是_____* No 否_____

* If the persons providing the counselling are different from the doctors signing this form, please provide their names and relevant qualification in counselling.
如提供輔導者並非在本申請書上簽署的醫生，請提供其姓名及輔導方面的相關資格。

_____

_____

IV. Implications Counselling and Advice to Patient
向病人提供有關治療影響的輔導及意見

Please confirm that the following aspects have been addressed during the implications counselling provided to the patients:
在向病人提供有關治療影響的輔導時，請確定已闡明下列事項：

(a) the woman undertaking the IVF has been informed of the risks associated with the treatment and the likely success rates of achieving pregnancy 接受體外受精的婦女已獲悉治療的相關風險和促成妊娠的成功比率	Yes 是 _____	No 否 _____
(b) the chance of producing an embryo which is unaffected by the genetic condition and with matched tissue type 製造不受遺傳病症影響並在組織類型上相配的胚胎的機會	Yes 是 _____	No 否 _____
(c) the condition of and prognosis for the affected child in relation to all treatment options available 患病孩子的病理情況及就一切可用治療方法對其作出的預診	Yes 是 _____	No 否 _____
(d) the possible consequences of the treatment to the child to be born (such as the risk associated with embryo biopsy, the likely long term emotional and psychological implication) and the surgery required 擬誕孩子可能面對的治療後果(例如進行胚胎活組織檢查所構成的風險、可能引起的長遠情緒和心理影響等)及所需進行的手術	Yes 是 _____	No 否 _____
(e) the family has been informed of the possible consequences of an unsuccessful outcome, the issue which might arise if the birth of a child does not resolve the genetic condition of the existing child 有關家庭已獲悉治療一旦失敗所帶來的後果，以及新生孩子不能解決患病孩子的遺傳病症時可能引起的問題	Yes 是 _____	No 否 _____
(f) the source of further follow up counselling if required 在有需要時尋求進一步輔導的途徑	Yes 是 _____	No 否 _____

V. Declarations 聲明

We hereby declare that the licence conditions stated in the Licensing Manual for Reproductive Technology Centres and the ethical principles as laid down in the Ethical Guidelines on PGT in the Code were observed and followed.
謹此聲明，我們已遵照及遵從《供生殖科技中心參考的發牌手冊》的牌照條件和《實務守則》內「植入前基因檢測倫理指引」所載明的倫理原則。

Attending Doctor:
主診醫生：

Signature **簽署**

( )
Name in block letters
姓名**(以正楷書寫)**

Doctor with Training in Genetics:
曾接受遺傳學訓練的醫生：

Signature **簽署**

( )
Name in block letters
姓名**(以正楷書寫)**

Witness:
見證人：

Signature **簽署**

( )
Name in block letters
姓名**(以正楷書寫)**

Date: _____
(date/month/year)
(日/月/年)

- END 完-

Annex 10

COUNCIL ON HUMAN REPRODUCTIVE TECHNOLOGY
人類生殖科技管理局

CURRICULUM VITAE 履歷表

Name of Centre 中心名稱：_____

Council Reference Number 管理局參考編號：_____
(For official use only) (只供管理局職員填寫)

1. Personal Details 個人資料

Name 姓名：……..	Date of Birth 出生日期：……..…….…
Nationality 國籍：……..….	HKID/ Passport No.* 香港身分證/護照號碼*：……....….
Address 地址：……	Position 職位：……
……	……
……	……

2. Academic Information 學歷資料

Degree/Diploma *學位/文憑*	*Awarding Institution* *頒發機構*	*Date Awarded* *頒發日期*

Membership of professional bodies, including membership number or date of membership:
專業團體會籍，包括會員編號或會籍日期：

_____

_____

* Please delete as appropriate. 請刪去不適用者。

Membership of professional societies and committees:
專業公會及委員會會籍:

3. Employment 受聘資料

Please give details of name and address of present and previous employer(s), positions held with dates: 請填寫現時及前度僱主的名稱和地址、所任職位及受聘日期:

	Employer 僱主	*Position 職位*	*Date 日期*	*Referee(s)諮詢人*
Present 現時				
Previous 前度				

Please give details of experience relevant to this application (use a separate sheet if necessary):
請填寫與本申請相關的經驗 (如有需要，請另頁書寫) :

4. Other 其他

Publications (list most recent relevant publications only):
發表(只需列出最近期所發表的資料)：

Present clinical/research interests:
現時的臨牀/研究興趣：

- END 完-

Annex 11

Standard Inspection Visits

When visiting centres, the Council's inspectors will wish to satisfy themselves that each centre is complying with the Code or the Supplementary Code or will be able to comply with the Code or Supplementary Code. Questions will therefore be asked on all areas of the centre's practice, as detailed in the following paragraphs.

Staff

2. Inspectors will wish to satisfy themselves that all staff have appropriate qualifications and experience. This will include the person responsible (or proposed person responsible), licensee (or proposed licensee), medical practitioners, embryologists, nursing staff, laboratory technicians, counsellors, etc. The person responsible (or proposed person responsible) must ensure that employees have suitable qualifications, experience and character to fulfill their roles effectively. The issue of on-going training for staff will also be addressed.

Facilities

3. During the inspection, the inspection team will tour the centre to inspect the facilities used for storage, treatment, research and AIH. Particular attention will be given to ensuring that the facilities and laboratory conditions are of a sufficiently high standard and that attention has been given to security and to monitoring clinical, counselling and laboratory practice. The inspectors will also wish to ensure that adequate arrangements have been made for the availability of emergency treatment at all times.

Assessing Clients, Donors and Welfare of the Child

4. Centres will need to show that adequate clinical investigations are conducted before a particular treatment is offered to ensure that the treatment to be provided is appropriate. The inspectors will also wish to enquire about other investigations conducted before treatment is offered including the welfare of any child who may be born or affected by the treatment and ways of assessing the involvement of spouse. The number of oocytes or embryos placed in a single cycle and limits on the number of treatment cycles offered to a client will also be addressed. Those involved in deciding whether or not to provide a particular treatment may be asked to discuss the criteria used in making such decisions.

Donors

5. Centres using donated gametes will be asked about their procedures for the recruitment and counselling of donors, and the screening performed before donated material is used. The inspectors will also wish to have information about the criteria used for matching donors and recipients, payments to donors in accordance with the Code and the limits on the number of live birth events from a single donor.

Information and Consent

6. Any information given (or proposed to be given) to patients before, during or after treatment will be considered by the inspection team to ensure that all necessary information are provided in a way which is easily understood. The information will be checked to ensure that any success rates quoted are accurate for that particular centre and that all charges are quoted in full with no hidden extras. The inspectors will wish to be assured that the Council's data collection forms and annual statistics forms are being used. RT centres are required to make use of the appropriate sample consent forms at Annex II of the Code unless there are justifiable reasons why they should not be used or should be departed from or modified.

Counselling

7. Inspectors will wish to ensure that counselling is available and is offered to all clients considering treatment and to all potential donors, and will take account of when, where and how the counselling is offered. The training and experience of the counsellors will be discussed. The inspectors may also enquire about the procedures for counselling on the implications of having a test for HIV antibodies. The inspectors may wish to see a record of counselling offered and received. Patient support groups, if in existence, may also be discussed.

Handling, Use, Storage and Disposal of Gametes and Embryos

8. The inspection team will wish to satisfy itself that proper arrangements have been made for handling gametes and embryos and for their transfer between clinical and laboratory facilities. If the centre has a freezing programme, the protocol will be assessed as well as the procedures for reviewing the storage with patients on a periodic basis. A protocol for the disposal of gametes or embryos should be in place. If any gametes or embryos are transferred to another centre, this will also be discussed.

Records

9. When touring the centre the inspectors will wish to ensure that adequate precautions have been taken for the security of patients' records. Some of the records may be checked by the team to ensure that record-keeping is satisfactory. The inspectors will also ask about the Council's data collection system to check that data collection forms are completed and that arrangements have been made to trace the outcomes of any pregnancies resulting from treatment.

Research

10. In those centres undertaking licensed research, the team may request a copy of the research ethics committee's annual report.

Others

11. Inspectors may also ask questions about the complaints handling procedure including the number, nature and outcome of any complaints, about surrogacy, if offered, and any other activities of interest to the Council, including services which are not themselves licensable.

12. After the inspection, the team will submit a report to the Inspection Committee. The Inspection Committee will make recommendation to the Council for making decision on whether a licence should be granted or renewed.

Annex 12

COUNCIL ON HUMAN REPRODUCTIVE TECHNOLOGY
人類生殖科技管理局

COLLECTION OF PERSONAL DATA FOR LICENCE APPLICATION
收集個人資料以處理牌照申請

Statement of Purposes 目的聲明

1. Purposes of Collection 收集資料的目的

Personal data are provided by applicants to the Council on Human Reproductive Technology for a licence to carry on a relevant activity, as the term is defined under section 2(1) of the Human Reproductive Technology Ordinance (Cap. 561). The personal data provided will be used for the following purposes:
申請人向人類生殖科技管理局申請牌照以進行有關活動(按照《人類生殖科技條例》(第 561 章)第 2(1)條的定義)時會提供個人資料，此資料將作下述用途-

(a) to facilitate the Council on Human Reproductive Technology in carrying out activities relating to the processing of your application via this form;
為利便人類生殖科技管理局為處理你透過本申請書提出的申請所進行的活動；

(b) to facilitate communication or follow up action in relation to the purposes stated in (a) above ;
為上述(a)段所指的目的利便相互溝通和所需的跟進行動；

(c) for statistical and other legitimate purposes;
統計及其他法定用途；

(d) administration and enforcement of relevant legislation and regulations; and
有關法例及附屬法例的執行和執法；及

(e) to handle complaints against licence applicant, licensee and person responsible under a licence.
處理對牌照申請人、持牌人或牌照負責人的申訴。

The provision of personal data asked for in the relevant application form is obligatory by virtue of section 22 of the Human Reproductive Technology Ordinance.
根據《人類生殖科技條例》第 22 條，申請人必須按照有關申請書的要求提供個人資料。

2. Classes of Transferees 獲轉授資料者的類別

The personal data which you have provided is mainly for use within the Council on Human Reproductive Technology but they may also be disclosed to government bureaux, departments and any other agencies or organizations for the purposes mentioned in paragraph 1 above. Apart from that, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance (Cap. 486).
申請人所提供的個人資料，主要供人類生殖科技管理局內部使用，但亦可能向政府政策局、部門及任何其他機構或組織披露以作上文第 1 段所提及的用途。此外，有關資料只會披露給申請人已同意向其披露的相關各方，或用作《個人資料(私隱)條例》(第 486 章)所核准的資料披露。

3. Access to Personal Data 查閱個人資料

You have a right to access and make correction with respect to the personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 to the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data provided by you during the occasions as mentioned in paragraph 1 above. A fee may be imposed for complying with a data access request.
根據《個人資料(私隱)條例》第 18 和 22 條及附表 1 的第 6 原則，申請人有權查閱和更正個人資料。申請人的查閱權力包括索取其在上文第 1 段所述情況下提供的個人資料的副本。查閱資料或須收費。

4. Enquiries 查詢

Enquiries concerning the personal data provided, including requests for access and the making of corrections, should be addressed to:
如對所提供的個人資料有任何查詢(包括要求查閱和更改資料)，請按下列聯絡方法提出-

Council on Human Reproductive Technology
Room 58, 17/F, Wu Chung House
213 Queen's Road East
Wanchai
Hong Kong
Tel. No. : 2961 8955
Fax No. : 2527 9849
香港灣仔
皇后大道東 213 號
胡忠大廈 17 樓 58 室
人類生殖科技管理局
電話號碼：2961 8955
傳真號碼：2527 9849

Annex 13

Conditions and Procedures for Voluntary Surrender of Licence

Conditions

Without prejudice to the generality of section 27(4) of the Ordinance on an application by the person responsible or the licensee to vary or revoke a licence, a licensee may surrender his licence by lodging it at the office of the Council. The surrender shall not have effect until the licensee is served with a notice by the Council stating that the Council accepts the surrender of the licence subject to conditions, if any, as the Council thinks fit specified in the notice.

Procedures

Lodging licence at office of Council

2. The licensee shall return the licence to the Council, together with a letter and proposal, stating the reason(s) for the surrender, the proposed closing date of the centre, and arrangements proposed to be made in relation to relevant activities in progress at the centre at the time of closure.

3. The proposal should normally include proposed arrangements for —

(a) the transfer of gametes, zygotes or embryos stored in the centre;

(b) the transfer of research or treatment procedures affected by the surrender to another licensed RT centre which has agreed to accept the transfer;

(c) advising and obtaining consents from donors and patients in respect of the arrangements in (a) and (b) above; and

(d) the keeping and transfer of records.

Consideration by Council

4. Upon receipt of the licence and the proposal for voluntary surrender, the Council may hold a meeting to determine whether to accept the surrender.

5. The Chairperson of the Council may before or after the beginning of the meeting call for such further information or reports as he/she thinks desirable, and may give directions as to the manner in which, and the persons by whom such material is to be furnished.

6. In determining whether to approve the surrender, the Council will study the proposal and ensure that the interests of donors and patients are well protected, that records will be properly transferred and kept confidential, and that gametes, zygotes or embryos will be properly transferred or disposed of.

Acceptance of surrender

7. The Council may, by notice given to the licensee, determine that the Council accepts the surrender of the licence subject to such conditions as the Council thinks fit and specified in the notice.

8. Immediately upon being served with a notice by the Council as in paragraph 7 above, the licensee shall cease to be licensed but shall remain liable for —

(a) any act or omission done, caused, permitted or made by him prior to the surrender; and

(b) any liability incurred by him under the Ordinance prior to the surrender.

9. The centre whose licence has been surrendered is responsible for making its own arrangements with regard to the transfer of patients, genetic substances, clinical records and so on, in accordance with the conditions imposed by the Council. The Council takes no responsibility in making such arrangements.

Refusal of surrender

10. The Council may refuse to accept the surrender of a licence if —

(a) the licensee has been served with a notice revoking the licence;

(b) the Council has reasons to suspect that there are grounds for revoking the licence; or

(c) the proposal for voluntary surrender fails to meet the Council's requirements.